Sustainable Solutions for Medical Devices and Services

by

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ABSTRACT

In the burgeoning field of sustainability, there is a pressing need for healthcare to understand the increased environmental and economic impact of healthcare products and services. The overall aim of this dissertation is to assess the sustainability of commonly used medical products, devices, and services as well as to identify strategies for making easy, low cost changes that result in environmental and economic savings for healthcare systems. Life cycle environmental assessments (LCAs) and life cycle costing assessments (LCCAs) will be used to quantitatively evaluate life-cycle scenarios for commonly utilized products, devices, and services. This dissertation will focus on several strategic and high impact areas that have potential for significant life-cycle environmental and economic improvements: 1) increased deployment of reprocessed medical devices in favor of disposable medical devices, 2) innovations to expand the use of biopolymers in healthcare materials and devices, and 3) assess the environmental and economic impacts of various medical devices and services in order to give healthcare administrators and employees the ability to make more informed decisions about the sustainability of their utilized materials, devices, and services.

DEDICATION

I dedicate my dissertation to my mom, or the name I used most frequently, “Ma”. My mom, who passed away from lung cancer on August 29, 2014, received her undergraduate degree in architecture, and later received her Master’s degree in Southwestern Native American Art. She was truly a master of academics, where she possessed a rare combination of quantitative, qualitative, communicative, creative, and organizational skills.

To her credit, my mom was not just a librarian for 10 years, but she solely designed and remodeled her school’s library wing. And my mom was not just a teacher for 20 years, but she gave unwavering support to children with learning disabilities and at-risk youth. While my dad was the doctor of the family, my brother and I always knew that “Ma” was the brains of the family.

There are two truths I know to be certain. The first is that my mom endowed me with excellent genes and intellect. The second is that my mom instilled in me a sense of academic excellence that has been an immeasurable asset to my personal and professional success. I was certain of these truths when she was alive. I will continue to know these truths in her absence.

Speaking directly to you, Ma, I will continue to make you proud. And I will make good decisions. I love you.

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I would first like to acknowledge my advisor, Dr. Amy Landis. When I first started working under Dr. Landis I considered myself a student. Now that I am leaving the Landis research team, I consider myself a professional. The direction, support, and countless reviews provided by Dr. Landis have been crucial to my growth as a professional. Thank you so much, Amy.

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I also want to extend thanks to all of my coauthors, which includes Amy, Troy, Nikki, Cassie, and Melissa. Needless to say, this dissertation and its associated publications would not be possible without all of your help and contributions.

Last, but certainly not least, I would like to thank my dad, Andrea, Casey, “Jojo”, Erik, and Sam—or, “The Fam”. Thank you for not only putting up with my shenanigans, but for the being the best family a person could imagine. I love you all.

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CHAPTER 1

INTRODUCTION

1. Moving Towards a Sustainable Healthcare System

The environmental and economic impacts resulting from the healthcare system are becoming increasingly apparent. The World Health Organization (WHO) estimates that healthcare accounts for 17.1% of the United States' Gross Domestic Product (GDP) (WHO, 2015). Direct and total CO_2 emissions attributed to the healthcare system are approximately 253 and 545 million metric tons, respectively, which equates to 4.6% to 9.9% of the total United States' (US) annual CO_2 emissions (Jeanette W. Chung & David O. Meltzer, 2009; EPA, 2009). To support the healthcare system's energy needs, 73 billion kWh is used annually (WHO, 2008). Hospitals alone generate more than 5.9 million tons of waste on annual basis, where a significant proportion of United States (US) hospital waste is either landfilled or incinerated (Practice Greenhealth, 2014). Hospitals also spend anywhere from $44 to $68 per ton on waste disposal, which equates to $259 to $401 million spent by US hospitals on waste on annual basis (Practice Greenhealth, 2014). A significant proportion of hospital waste streams are regulated medical waste (RMW), where RMW undergoes incineration before eventually reaching a landfill. The incineration of RMW has several resulting effects, including significant consumption of energy for incineration, significant expenditures, and the emission of CO_2, dioxins, heavy metals (e.g., mercury and cadmium), hydrochloric gas, and other toxic substances (while also leaving a toxic fly ash residue that must be managed) (Karlsson & Pigretti-Ohman, 2005).

Given the healthcare's significant consumption of goods and services, recent studies are examining the indirect environmental, human health, and economic impacts attributed to the large volumes of materials, devices, and services utilized by the healthcare system (Adler, Scherrer, Rückauer, & Daschner, 2005; Brown, Buettner, Canyon, Crawford, & Judd, 2012; Campion et al., 2015; Overcash, 2012a; J. Sherman, Le, Lamers, & Eckelman, 2012; Sorensen & Wenzel, 2014; Zhao, van der Voet, Huppes, & Zhang, 2009). These studies support a growing recognition in the healthcare community that the rising volumes of produced waste are representative of significant supply chain and service inefficiencies occurring in hospitals. These studies have also pointed to numerous sustainable strategies that can be applied to the healthcare system and to how those strategies can reduce adverse environmental impacts associated with healthcare activities, while still providing the same, if not better patient outcomes. Some of these strategies include: reusing medical devices, increasing recycling, optimizing medical waste incineration processes, and reducing products used in custom packs used in surgical procedures. While these studies have significantly advanced knowledge in the sustainable healthcare field, there are still an array of highly utilized healthcare products and services whose life-cycles have yet to be quantified environmentally or economically.

2. Research Goals and Objectives

In the burgeoning field of sustainability, there is a pressing need for healthcare to understand the increased environmental and economic impact of healthcare products and services. The overall aim of this dissertation is to assess the sustainability of commonly used medical products, devices, and services as well as to identify strategies for making easy, low cost

changes that result in environmental and economic savings for healthcare systems. Life cycle environmental assessments (LCAs) and life cycle costing assessments (LCCAs) will be used to quantitatively evaluate life-cycle scenarios for commonly utilized products, devices, and services. This dissertation will focus on several strategic and high impact areas that have potential for significant life-cycle environmental and economic improvements: 1) increased deployment of reprocessed medical devices in favor of disposable medical devices, 2) innovations to expand the use of biopolymers in healthcare materials and devices, and 3) assess the environmental and economic impacts of various medical devices and services in order to give healthcare administrators and employees the ability to make more informed decisions about the sustainability of their utilized materials, devices, and services. The research questions for this dissertation are to:

1. determine the comparative environmental and economic impacts of single-use devices vs. reprocessed devices in a hospital's supply chain;
2. assess opportunities for using biopolymers in healthcare and the resultant comparative environmental impacts of single use disposable devices with increased biopolymer content vs. typically manufactured devices in hysterectomy procedures; and,
3. synthesize and prioritize the salient conclusions from the first two research questions, as well as from recent studies focusing on the environmental impacts of various medical products and/or services for the use of hospital administrators and employees

The three research questions will be addressed in Chapters 3, 4, and 5 of the dissertation. Chapters 3, 4, and 5 will include a brief introduction and background, proposed methodology,

and where applicable, preliminary results for each research question. Chapter 1 includes the dissertation introduction, goals and objectives and research questions. Chapter 2 covers a detailed literature review. The following sections are organized by anticipated dissertation chapter and the associated research question.

3. Broader Impacts

This research involved collaboration from a diverse team of engineers, healthcare administrators, hospital "green team" members, and service professionals in the healthcare industry (e.g., representatives from Stryker, Inc. and Stericycle, Inc.). A number of sustainable healthcare service strategies were verified by this research, including the reprocessing of medical devices, the utilization of biopolymers in medical devices, and the optimal use of disposable and reusable devices in healthcare supply chains.

This research will address several opportunities for sustainable healthcare development, and will disseminate those results to our partner healthcare institutions: Phoenix Baptist Hospital (PBH) and Magee-Womens Hospital of University of Pittsburgh Medical Center (Magee). The results of this research will reach PBH administrators, and it will enable them to determine the economic viability of their reprocessing device supply chain scaled with various supply chain and reprocessing instance inputs. PBH will also have a greater understanding of the precise GHG emissions and human-health impacts resulting from their reprocessed device supply chain, which can also be scaled with various supply chain and reprocessing instance inputs. From a broader perspective, these results will reach a national audience that will learn of the economic and

environmental benefits associated with reprocessed medical devices; given that the life-cycle processes and materials associated with reprocessing (i.e., ethylene oxide, electricity, and water) are optimally utilized.

Magee administrators will also be able to use this research to determine the environmental impacts associated with increasing biopolymer compositions in products used in their performed hysterectomies. The results will bear significance due to the considerable use of typically-used plastics (i.e., LDPE, HDPE, polypropylene, polyisoprene, nitrile, and neoprene) used in their hysterectomy product supply chain. Similar to the reprocessing research, these results will reach a national audience that will gain a gain an increased understanding of the environmental impacts associated with increased biopolymer composition in various medical devices.

This research will also enable healthcare administrators and employees to prioritize the environmental and economic performance of several medical products and services. Such a prioritization system is novel to the healthcare community, but has increased in need as the environmental and economic magnitude of the healthcare system becomes more apparent.

4. Intellectual Merit

A range of sustainable strategies are being used in healthcare, yet there is still a fundamental lack of understanding of what indirect environmental, economic, and human health impacts occur as a result of decisions made in the name of sustainability. The proposed research

addresses this knowledge gap two-fold. First, the research assesses environmental and economic impacts resulting from either the increased use of reprocessed devices in a hospital's supply chain, or from the increased use of biopolymers in medical devices. Both issues are burgeoning fields in the healthcare system, and merit a greater understanding of their environmental and economic impacts based on either there current utilization or potential utilization. Second, the research aggregates findings from healthcare environmental and economic studies (including those performed in the first elements of the research) and provides a holistic understanding of environmental and economic impacts resulting from how different sustainable strategies are deployed.

CHAPTER 2

BACKGROUND AND LITERATURE REVIEW

There are several definitions that characterize how a medical device is used. When a device is used only one instance prior to disposal, the device is defined as a single-use disposable device (SUD). Devices that are not SUDs can either be reused or reprocessed. Reused medical devices requires the reuser (i.e., hospital, healthcare provider) to possess sterilizing equipment (i.e., autoclaves, ultrasonics). The devices are cleaned onsite by the reuser, and in some instances, can be reused thousands of instances. Reprocessed medical devices are sterilized by third-party reprocessors located offsite from the devices' point-of-use. The third-party reprocessors are responsible for cleaning the devices, such that the devices will meet their original equipment manufacturer (OEM) FDA-regulated requirements. The third-party reprocessors repackage the devices and send them back to their point-of-use. Reprocessing can occur up to five instances, at which time the third-party reprocessor cleans the device an additional instance before the devices are recycled.

1. Disposable and Reusable Medical Products

As early as the late 19th century, hospitals made, processed, and sterilized a number of medical devices in their supply chain. The preparation and re-sterilization of gloves, masks, gowns, and drapes, and a multitude of medical devices was performed by or at least supervised by the onsite healthcare provider. It was not until the 1960s that disposable medical devices became popular in healthcare (V. Greene, 1986). At this time, the healthcare industry learned

how to substitute polyvinyls, polycarbonates, and polystyrenes with materials originally made out of glass, rubber, metal, and woven textiles (V. Greene, 1986). Additionally, device manufacturers learned how to sterilize these devices with ethylene oxide or radiation-technologies, which were not yet available in hospitals. Above all, medical device manufacturing companies learned to make these devices efficiently and cheaply. The result was a medical device marketing revolution. There was an abundance of inexpensive yet reliable needles, syringes, tubing, gloves, catheters, etc; all of which were pre-packaged, pre-sterilized, and pre-labeled as SUDs. The switch to disposable devices was marketed by device manufacturers as a means to decrease risks for pathogenic cross-contamination through device reuse (V. Greene, 1986). However, recent studies are showing that utilizing reusable devices does not correlate with an increased infection risk (Favero, 2001; FDA, 2013a; GAO, 2008b; US Food and Drug Administration (FDA), 2009).

The impacts of medical waste resulting from single-use disposable medical products are becoming more apparent, and recent studies are showing that utilization of single-use medical devices is increasingly considered to be materially and economically wasteful (Hailey, Jacobs, Ries, & Polisena, 2008a; Overcash, 2012a; Rutala & Weber, 2001; Shuman & Chenoweth, 2012; Suter, Yueng, Johnston, & Suter, 2009). A 2014 study that focused on different types of hysterectomies (i.e., abdominal, laparoscopic, vaginal, and robotic) showed that SUDs dominated the life-cycle environmental impacts in OR procedures. Disposables contributed anywhere from 50 to 90% toward a range of environmental impacts for the four OR procedures. The study found that the most commonly disposed items in OR procedures were plastics (or trays, bins, and packaging making up 36-46% of waste stream by weight), spunbound/meltblown

polypropylene textiles (or blue wrap and gowns, which comprised 22-35% of the waste stream), cotton materials (blue towels, laparotomy pads, and gauze), and paper. Eckelman et al. found that reusable LMAs had less adverse environmental impacts than single-use LMAs. Overcash found that reusing surgical drapes and gowns correlates with significant environmental benefits over their disposable counterparts, in categories including: natural resource energy, water, carbon footprint, solid waste, and volatile organics (Overcash, 2012a).

The author's Master's Thesis was published in the International Journal of Life Cycle Assessment, and the focus of the Thesis was a comparative life cycle assessment (LCA) on reusable versus disposable dental burs (Unger, 2013; Unger & Landis, 2014). In dental practice, the dental bur is a commonly used drilling instrument that can either be reused or used one instance and then disposed. The study was performed to evaluate the disparities in environmental impacts of disposable and reusable dental burs. The LCA evaluated a reusable 2.00mm Internal Irrigation Pilot Drill dental bur that was reused 30 instances, versus 30 identical burs used as disposables. The LCA was performed using framework described by the International Organization for Standardization (ISO) 14040 series.

The sensitivity analysis was performed with respect to ultrasonic and autoclave loading. When the autoclave and ultrasonic were loaded to 30 dental burs (i.e., best-case loading scenario), reusable burs were environmentally favorable over single-use dental burs according to all nine environmental and human health impact categories. Reused burs exhibited approximately one-third less impacts in the following categories: ozone depletion, smog, respiratory effects, and ecotoxicity. The global warming impact category was characterized by

kg CO_2eq emissions, which was 1.19 kg CO_2eq and 0.42 kg CO_2eq for disposable and reused burs, respectively. Notably, the dental bur's packaging materials contributed more negative environmental impacts than the processes associated with the dental bur's production. Therefore, the study recommended that less materially-intensive packaging should be utilized.

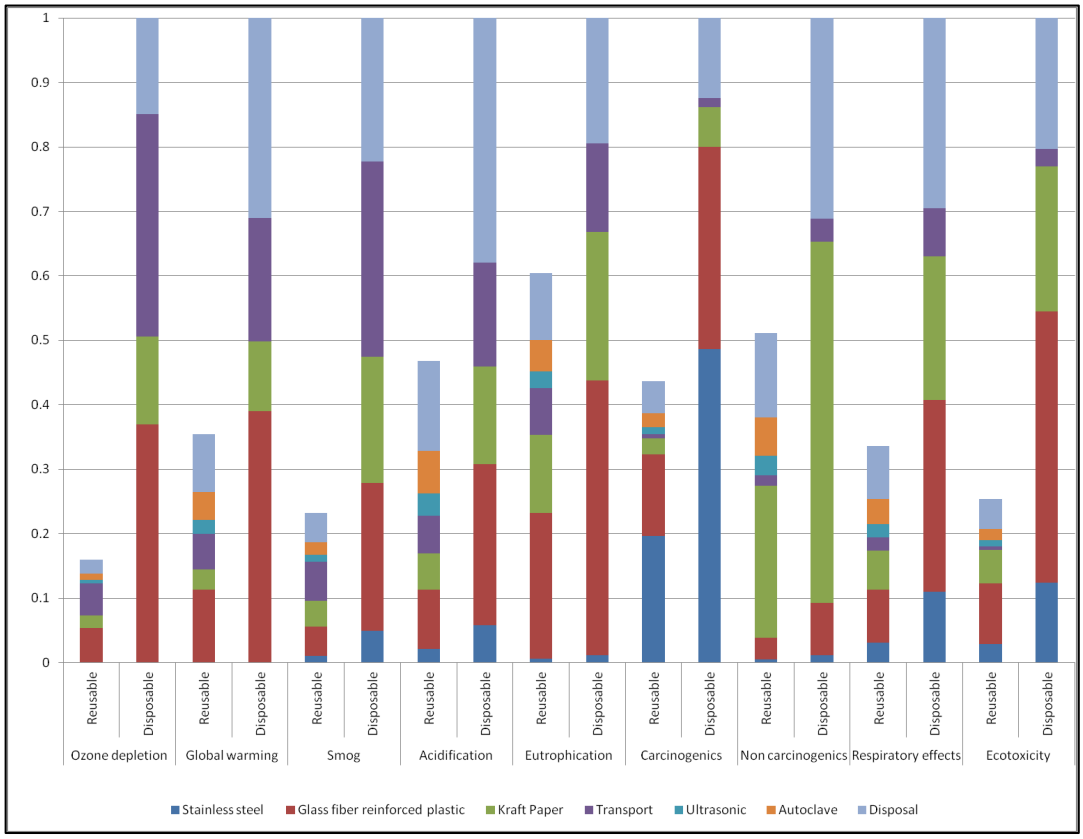


Figure 1. Comparative Environmental and Human Health Impacts for Disposable versus Reusable Dental Burs.

(Caption Text) Figure 1 represents the autoclave and ultrasonic cleaning filled to their highest capacity, which was 30 burs.

Reusing medical devices presents also present an opportunity for healthcare providers to reduce their economic bottom-line. A case study performed by Cohen et al. analyzed the economic impacts of reused papillotomes and baskets (Cohen, Haber, Dorais, Scheider, & Kortan, 1996). Endoscopists were blind to the number of prior reuses, where all reuse instances where characterized by enzymatic, manual, and ethylene oxide sterilization. Twenty-five papillotomes were used with a mean of 9.8 reuses and 15 baskets reused a mean of 12.9 times. The study found that the projected yearly savings was approximately $62,000 for papillotomes and $41,000 for the baskets (Cohen et al., 1996). A different case study performed by Canard et al. evaluated the economic function of double-lumen spincterotomes, where the kits were reused a mean of 3.4 instances (Canard et al., 2000). Their study found that the estimated annual savings at their case study hospital was $66,000 (Canard et al., 2000). Cost savings opportunities are based on a number of factors, including: staff compliance, cost of the reusable devices, devices selected by the hospital, pace of reuse implementation, and number of reuse instances. Some hospitals are also experiencing an unexpected benefit from utilizing reusable medical devices. They are using the lower-cost, reusable devices as leverage when negotiating the price of disposable devices with original equipment manufacturers.

Labor is also an important concept when discussing the economic impacts of reusable medical devices. For example, reusable medical devices require on-site facilitation of the processes related to making a device suitable for procedural use. Therefore, the staff (e.g., nurses, technicians, doctors, etc.) needs to be familiar with the processes for sorting, cleaning, sterilizing, and repackaging certain reusable medical devices. The additional training requiring for the staff related to the previously stated processes, as well as the additional time required for

performing these services should be factored into whether reusable medical devices are financially viable. Few studies have integrated labor into comparative financial analyses regarding reusable medical devices. In 2012, Eckelman et al. found that reusable laryngeal mask airways were economically favorable compared to disposable laryngeal mask airways. Included in their analysis was a labor component, which they found to be negligible from an economic standpoint (M. Eckelman, M. Mosher, A. Gonzalez, & J. Sherman, 2012).

Negative economic outcomes related to the utilization of reusable medical devices should also be considered. For example, medical malpractice resulting from reused medical devices would potentially offset the previously discussed cost savings. Although there are no studies that specifically analyze reusing medical devices and their correlation with offsetting potential medical malpractice costs, there are several conclusions that can be made regarding malpractice and its effect on utilizing reusable medical devices. For example, even if a reused medical device resulted in a nosocomial (i.e., hospital-acquired) infection, it would be difficult to prove that the reused device was solely responsible for the secondary infection. In a trial setting, lawyers would need to research the particular reused medical device that potentially caused the nosocomial infection and determine if the device has been cited for causing previous secondary infections. Additionally, there is no correlation between insurance rates and utilization rates of reused medical devices.

2. Reprocessed Medical Devices

Approximately 3,000 US hospitals actively engage in third-party medical device reprocessing services, and the reprocessing industry is valued at roughly $400 million (AMDR, 2012). The reprocessing industry's current valuation represents considerable growth within the past decade, where in 2000 the reprocessing industry was valued at $20 million (AMDR, 2012). US Government Accountability Office (GAO) and the FDA are the primary agencies responsible for review and regulation of reprocessed devices.

In 2000, the FDA issued a guidance document "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." The document stated that reprocessors must be in compliance with the following requirements: registration and listing, medical device reporting and tracking, medical device corrections and removals, quality system regulation, labeling, and pre-market submission. In 2002, the FDA enacted the Medical Device User Fee and Modernization Act (MDUFMA), which required labeling and identification of third-party reprocessors" (FDA, 2012). MDUFMA also required FDA clearance (i.e. Premarket Notification/ Approval) based on the classification of the medical device.

As of 2013, there were approximately 50 FDA-registered third-party reprocessors of SUDs (FDA, 2013b). In 2007, 11 of these establishments were actively reprocessing or planning to reprocess more than 100 different types of medical devices (GAO, 2008b). The most commonly reprocessed medical devices in the United States include: cardiac stabilization and positioning devices, diagnostic electrophysiology (EP) catheters, blood pressure cuffs/tourniquet

cuffs, electrophysiology cables, pulse oximeters, ultrasonic electrophysiology catheters, arthroscopic burrs, soft tissue ablators, and harmonic scalpels (AMDR, 2013).

One of the most commonly cited reasons for not using reprocessed devices is the fear of increased infection rates (Krüger, 2008); however extensive research has shown this to be not true. The Government Accountability Office (GAO) concluded in 2008 that *reprocessed single-use devices present no elevated health risk when compared their originally manufactured counterparts* (GAO, 2008a). This finding is based on the FDA's review of available adverse health events reported with reprocessed SUDs, and having no identification of a causative link between the adverse health events and use of reprocessed devices. This conclusion is also based on several FDA-conducted reviews, including a 2006 review where the FDA identified 434 adverse health reports submitted from October to July 2006. Of the 434 reports, 65 reports involved a reprocessed device and that the reprocessed device may have been a causal factor in the adverse health effect. However, the FDA found that the events reported to be associated with the use of reprocessed devices were same types and rates of adverse health events reported for new, non-reprocessed devices (GAO, 2008b). Additionally, in 2005 the FDA consulted hospitals in Medical Product Safety Network (MedSun) about their experiences with reprocessing, including adverse health events or safety concerns. None of the MedSun representatives who participated in FDA reprocessing focus groups reported being aware of infections related to use of reprocessed devices (GAO, 2008b).

3. Life Cycle Assessment Background and Methodology

LCA is a method used to assess environmental impacts throughout a product or process' life, which analyzes all stages of the product or process' life, including: raw material extraction and processing, manufacture, distribution, use, maintenance and repair, recycling, and disposal. Established guidelines for performing detailed LCAs are well documented by the Environmental Protection Agency (EPA), Society for Environmental Toxicologists and Chemists (SETAC), and the International Organization of Standardization (ISO) (Fava et al., 1991; ISO, 2006a; UNEP/SETAC, 2005; Vigon et al., 1992). LCAs seek to address a number of environmentally related concerns, including: compilation of material and energy input and outputs; evaluation of potential impacts attributed to the inputs and outputs; and, interpretation of the results to help make a more informed decision (EPA, 2010). According to ISO 14040 standards, an LCA is defined by four steps, as shown in Figure 2 (ISO, 2006c; "Life cycle assessment (ISO 14040)," 1996).

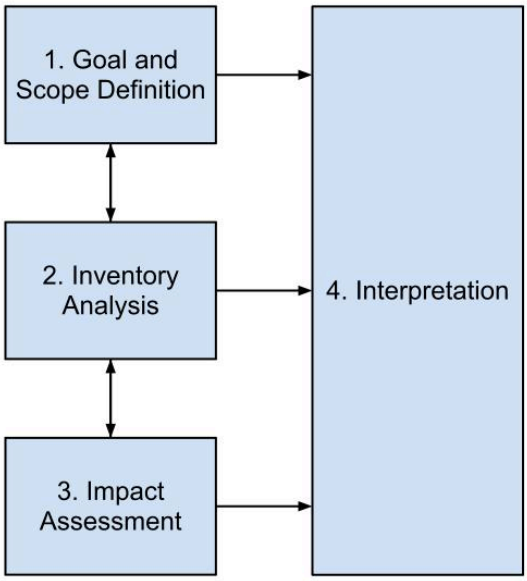


Figure 2. Life Cycle Assessment Steps.

(Caption Text) Adapted from ISO 14040 (ISO, 2006c; "Life cycle assessment (ISO 14040)," 1996)

LCAs begin with the goal and scope definition, which explicitly sets the context of the study and defines the functional unit. The functional unit defines the precise quantities of what product to be analyzed within the system boundary, which provides reference to the product's associated inputs and outputs. The system boundary describes the extent to which a product's life cycle is analyzed. Defining the goal and scope also addresses any limitations or assumptions associated with the study, as well as designate impact categories (e.g., global warming, acidification, eutrophication, carcinogenic impacts, respiratory effects).

The second step of the LCA is to perform an inventory analysis. The life cycle inventory (LCI) analysis documents the inputs and outputs in the product's system boundary. Exact

quantities of emissions, materials and energy to and from the technosphere (i.e., manmade materials/products) are included in the inventory analysis. Development of an inventory analysis is characterized by a process flow model, which illustrates the relevant activities included and not included the LCA's system boundary.

Followed by the inventory analysis is the impact assessment, which aggregates the LCI data into environmental impact categories. The typical process for conducting a Life Cycle Impact Assessment (LCIA) consists of: impact category selection; classification, where the inventory parameters are assigned to designated impact categories; and, impact measurement, where the LCI data is characterized into a common equivalence unit so that it can be aggregated within an LCIA category. Common impact assessment methodologies include the Tool for the Reduction and Assessment of Chemical and Other Environmental Impacts (TRACI), ReCiPe , and Eco-indicator (J. Bare, 2011; Pre, 2013a, 2013b).

The fourth step of a LCA is interpretation, which is performed iteratively throughout each step of the LCA. The iterative nature of LCA is shown in Figure 1, where the interpretation is performed concurrently with the three preceding LCA steps. LCA interpretation identifies, quantifies, and evaluates data and results from the inventory or impact assessment steps. Interpretation will identify significant issues based on results from the inventory and impact assessments.

LCA can aid in identifying the most benign technology among an array of options, and in the case of single-use healthcare products can aid in comparing the environmental impacts of

alternative products by tracking their impacts throughout their manufacture, use and disposal. Through use of LCA, it is possible to observe which process (or processes) drive environmental and human health impacts, and may offer insight into minimizing impacts throughout a product's life. In the case of innovations for new single-use and reprocessed healthcare products, LCA can provide insight into the impacts and tradeoffs of alternatives during the innovation process.

4. Life Cycle Costing Assessment

Determining economic impacts are another critical element of sustainability, and major federally-funded efforts are underway to identify inefficiencies in the health care system and to optimize systems using industrial engineering and life cycle costing tools. Life Cycle Costing (LCC), which is also commonly called Life Cycle Cost Analysis (LCCA), is commonly applied in the building sector as a method for assessing the total cost of facility ownership and/or comparing alternatives (Curran, 1996). Applied to single use versus reusable versus reprocessed medical products, LCC can assess the total cost of the alternatives, taking into account costs of purchasing, operating, maintaining, sanitizing, and disposing of each product. LCC allows decision makers to compare products based on costs and maximized net economic bottom-lines. Unlike LCA, LCC does not take into consideration 'upstream' costs such as raw materials extraction.

5. Life Cycle Assessment Healthcare Applications

In recent years hospitals have employed a number of strategies to decrease environmental and economic costs. The strategies have included increasing a hospital's: energy efficiency, water efficiency, green purchasing, waste diversion strategies, and healthy food purchasing (Janet, 2013; Kaplan et al., 2012; Kwakye, Brat, & Makary, 2011). Practice Greenhealth publishes an annual report which provides a comprehensive analysis of how sustainable strategies were being integrated at their member institutions. When aggregating the 2013 savings of all Practice Greenhealth member institutions, over 100,000 tons of waste was diverted, 275 million gallons of water were saved, and energy use was reduced by 1.85% (PG, 2015a).

While hospitals made reduced environmental and economic costs, many of these strategies still lack scientific validation. To address these research needs, several recent studies have applied life cycle methodologies to better understand the environmental and economic impacts of the healthcare industry at various levels of detail. The publications in this field range in foci and scope; where, a 2007 Economic Input-Output LCA of the entire US healthcare sector found that healthcare activities account for 8% of total US greenhouse gas emissions (J. W. Chung & D. O. Meltzer, 2009). Power, et al. calculated the annual CO_2 emissions of the US's minimally invasive surgeries to be 355,924 metric tons per year, putting the US on par with the 2008 CO_2 emissions of France or Spain (Power, Silberstein, Ghoneim, Guillonneau, & Touijer, 2012; United Nations (UN), 2012). And even smaller-scoped studies, such as a paper that performed a comparative environmental assessment of surgical modalities (i.e., laparotomy, conventional laparoscopy, and robotically-assisted laparoscopy), found that robotically-assisted

surgeries represent a 38% increase of kg CO_2eq over that of conventional laparoscopy, and a 77% of kg CO_2eq increase over laparotomy. There are also several LCAs that compared individual single use and reusable materials in the healthcare industry (Adler et al., 2005; Dettenkofer, Grießhammer, Scherrer, & Daschner, 1999; M. Eckelman et al., 2012; Sorensen & Wenzel, 2014; Unger & Landis, 2014). McGain, et al. found that reusable plastic anesthetic drug trays cost less and emitted less CO_2 than single-use trays (F. McGain, McAlister, McGavin, & Story, 2010). Similarly, a comparative study of the life cycle inventory of reusable and disposable laparotomy pads found the disposable pads had a larger impact on the environment than reusable pads (Kümmerer, Dettenkofer, & Scherrer, 1996).

The following three chapters aim to extend this field of research into novel areas that have not yet been scientifically validated for their environmental and economic impacts.

CHAPTER 3

ASSESSING THE ENVIRONMENTAL AND ECONOMIC IMPACTS OF REPROCESSED MEDICAL DEVICES IN A PHOENIX HOSPITAL'S SUPPLY CHAIN

This chapter was published in the peer reviewed journal The Journal of Cleaner Production and appears exactly as published with the exception of text and figure formatting. The citation for this article is: Unger, S., & Landis, A. (2015). Assessing the environmental, human health, and economic impacts of reprocessed medical devices in a Phoenix hospital's supply chain. *Journal of Cleaner Production*.

This chapter addresses the dissertation research question 1) determine the comparative environmental and economic impacts of single-use devices vs. reprocessed devices in a hospital's supply chain;

1. Introduction

The structure of hospital supply chains and the processes by which they utilize and dispose of medical devices is increasingly considered to be materially and economically wasteful. Practice Greenhealth estimates that hospitals generate more than 5.9 million tons of waste on annual basis, where a significant proportion of United States (US) hospital waste is either landfilled or incinerated (Practice Greenhealth, 2014). Additionally, hospitals spend anywhere from $44 to $68 per ton on waste disposal, which equates to $259 to $401 million spent by US hospitals on waste on annual basis (Practice Greenhealth, 2014). The significant

volume of waste generated by hospitals has incentivized waste reduction strategies in order to decrease the considerable environmental and economic costs associated with hospital waste. Decreasing utilization of single-use devices (SUDs) in favor of suitable reprocessed medical devices is one waste mitigation strategy that can decrease waste created by hospitals, thus decreasing the environmental and economic costs incurred by hospitals.

SUDs became more widely utilized in the 1960s with the advent of polymers and the integration of high-density polyethylene (HDPE) and low-density polyethylene (LDPE) into medical products (V. W. Greene, 1986). The integration of LDPE and HDPE allowed for medical devices to be manufactured at a cost low enough for the devices to be used once and then disposed without being cost prohibitive. Additionally, the use of SUDs in favor or reprocessed alternatives was attributed to concerns about pathogenic cross-contamination through use of reprocessed devices (V. W. Greene, 1986).

However, FDA studies have shown that the use of reprocessed devices does not correlate with an increased infection risk (Favero, 2001; GAO, 2008b). The Government Accountability Office (GAO) concluded in 2008 that "[the] FDA's analysis of reported device-related adverse events does not show that reprocessed SUDs present an elevated health risk" (GAO, 2008b). The GAO found that the events reported to be associated with the use of reprocessed items were the same types and rates of adverse health events reported for new, non-reprocessed devices (GAO, 2008b).

Because there are no cross-contamination risks associated with reprocessed devices, they can be considered as a potential strategy for reducing hospital waste. There are hundreds of devices that either have been reprocessed in the US or have been considered for reprocessing in the US. Reprocessed devices are used in a variety of medical specialties, which includes: cardio, dental, otolaryngology, gastro/urology, neurology, obstetrics/gynecology, ophthalmic, orthopedic, physical medicine, respiratory, and general surgery. While most products are suitable for reprocessing, several characteristics can influence the efficacy of reprocessing for certain devices. These characteristics include either high quantities of polymers or complex design features (Hailey, Jacobs, Ries, & Polisena, 2008b). While polymers allow for limited economic costs, they may not be durable and may deteriorate after undergoing reprocessing. Additionally, complex design features can hinder the ability of reprocessing technicians to fully disassemble a device; where, full disassembly is required to ensure effective reprocessing for a device. Therefore, devices that have stronger materials in favor of polymers and relatively basic assembly/disassembly requirements are typically considered more favorable for reprocessing (Hailey et al., 2008b).

Due to the reduced waste and materials used in a hospital's medical device supply chain, reprocessing presents an opportunity for reducing environmental impacts associated with medical devices used in hospital supply chains. Life cycle assessment (LCA) is a widely accepted methodology for determining and validating environmental impacts associated with a particular product or process. LCAs seek to address a number of environmentally related concerns, including the: compilation of energy and material input and outputs; evaluation of

potential environmental impacts attributed to the inputs and outputs; and, interpretation of the results to help make a more sustainable decision (ISO, 2006b).

With regards to LCAs focused on medical devices, Stripple et al. (2008) performed an environmental evaluation of plastics used in hydrophilic catheters, which found that polyolefin-based elastomers showed better environmental performance than the thermoplastic polyurethane materials (Stripple, Westman, & Holm, 2008). There have also been several other recent LCA studies that have focused their attention on SUDs and other healthcare activities including: ambulance services (Brown et al., 2012), reusable versus single-use bedpans (Sorensen & Wenzel, 2014), incineration vs. non-incineration treatments (Zhao et al., 2009), anesthetic drugs (J. Sherman et al., 2012), disposable custom packs (Campion et al., 2015), and reusable versus single-use scissors (Adler et al., 2005).

There have also been several other recent LCA studies that have focused their attention on various other devices or activities, including: ambulance services (Brown et al., 2012), reusable versus single-use bedpans (Sorensen & Wenzel, 2014), incineration vs. non-incineration treatments (Zhao et al., 2009), anesthetic drugs (J. Sherman et al., 2012), disposable custom packs (Campion et al., 2015), and reusable versus single-use scissors (Adler et al., 2005).

In addition to LCAs, life cycle cost analyses (LCCAs) account for all recurring and one-time economic costs over the full life cycle of a product. With regards to economic impacts of reprocessed medical products quantified through LCCAs, a 2013 literature review performed by

Jacobs et al. was able to show that utilization of reprocessed devices in a hospital's supply chains offers a 49% reduction in direct costs (Jacobs, Polisena, Hailey, & Susan Lafferty, 2008).

Performing a LCA and LCCA on medical devices offers several advantages. First, a LCA characterizes a range of environmental impacts resulting from different medical device supply chains, rather than simply quantifying waste streams. Quantification of waste streams fails to give administrators and healthcare personnel relevant information relating to the procurement, management, use, and disposal of medical devices. Additionally, the use of LCCAs on medical products helps administrators to more effectively understand life-cycle costs of their utilized devices, as opposed to exclusively focusing on procurement costs of devices.

While there are hundreds of items that are suitable for reprocessing, to date there have been no studies that evaluate the potential economic and environmnetal benefits of a reprocessed device. Additionally a system-wide LCA and life LCCA has not yet been performed on an aggregation of reprocessed devices comprising a hospital supply chain. This study fills this knowledge gap by using LCA and LCCA to model the environmental and economic impacts of medical device supply chains when varying levels of reprocessed devices are utilized.

2. Materials and Methods

a. Case Study Description

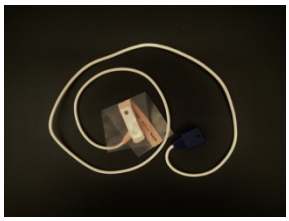
Phoenix Baptist Hospital (PBH) is a general medical and surgical hospital located in what is considered the metropolitan Phoenix area. PBH is equipped with 215 certified hospital beds and employs over 900 healthcare professionals. PBH has admitted roughly 9,000 patients and performed over 900 births (i.e., approximately one patient/bed/day) since its opening in 1963. Under their classification as a general medical and surgical hospital, PBH performs the following types of procedures: cardiovascular, orthopedics, women's services, radiology, and 24-hour emergency services. PBH reprocesses seven devices, including the: deep vein thrombosis (DVT) compression sleeve, pulse oximeter, ligasure, harmonic scalpel, endoscopic trocar, arthroscopic shaver, and scissor tip. Figure 3 shows these devices, and their associated annual utilization rates.

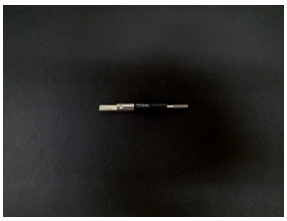
Endoscopic Trocar

DVT Compression Device

Pulse Oximeter

Scissor Tip





Arthroscopic Shaver

Ligasure

Ultrasonic Scalpel

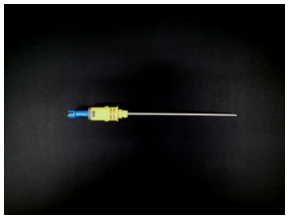


Figure 3. Devices Included in LCA.

b. Life Cycle Assessment

Life cycle assessment (LCA) is a method used to assess potential environmental and human health impacts throughout a product's life, including the product's: raw material extraction and processing, manufacture, distribution, use, maintenance and repair, and disposal. LCAs seek to address a number of environmentally related concerns, including: compilation of energy and material input and outputs; evaluation of potential impacts attributed to the inputs and outputs; and, interpretation of the results to help make a more informed decision (EPA, 2010). According to the International Organization for Standardization (ISO) 14040 and

14044 documents, a LCA is defined by four distinct steps, including: goal and scope definition, inventory analysis, impact assessment, and interpretation (ISO, 2006c).

The first step of a LCA, the goal and scope definition, explicitly sets the context of the study, defines the precise quantities of what product to be analyzed, and characterizes the extent to which a product's life cycle (e.g., manufacturing, use, disposal) is analyzed. After the goal and scope are defined, the second step of the LCA is inventory analysis. Inventory analysis documents exact quantities of emissions, materials and energy to and from the environment. Followed by the inventory analysis is the impact assessment, which aggregates the inventory data into environmental and human health impact categories. The final step of a LCA is interpretation, which is typically performed iteratively throughout each step of the LCA. Interpretation is performed, such that, information from the inventory and impact assessment steps are identified, quantified, and evaluated.

c. Goal and Scope Definition

An LCA was performed to model the environmental impacts of varying levels of reprocessing at Phoenix Baptist Hospital (PBH), located in Phoenix, Arizona. The functional unit (FU) was defined as seven medical devices, which is the number of medical devices needed to fulfill the reprocessed device supply chain requirements of PBH. The seven devices included were: a deep vein thrombosis (DVT) compression sleeve, a pulse oximeter, a ligasure, a harmonic scalpel, an endoscopic trocar, an arthroscopic shaver and a scissor tip. The LCA included all cradle-to-grave processes for the seven medical devices, where the processes are

further detailed in Figure 4. Figure 4 shows that the first five processes in the LCA included the seven devices' fabrication and transport to PBH. Once arriving at PBH, the decision of whether to use any of the seven devices as disposables or as reprocessed devises was established. If used as a reprocessed device, the devices would undergo transport from the hospital to the reprocessing facility, and back from the reprocessing facility to the hospital anywhere from one to five instances. When the devices reached their useful reprocessing lifetime, the devices would then undergo incineration. Disposable devices were incinerated after being used one instance.

Each device was assumed to be interchangeable as either an SUD or a reprocessed device, which assumption is according to the PBH suite of reprocessed devices but it may not be the same for other hospitals. However, this assumption may not be true for other hospitals. This study assumed that the packaging for reprocessing was the same as the packaging for an SUD; the packaging modeled herein was from a new device.

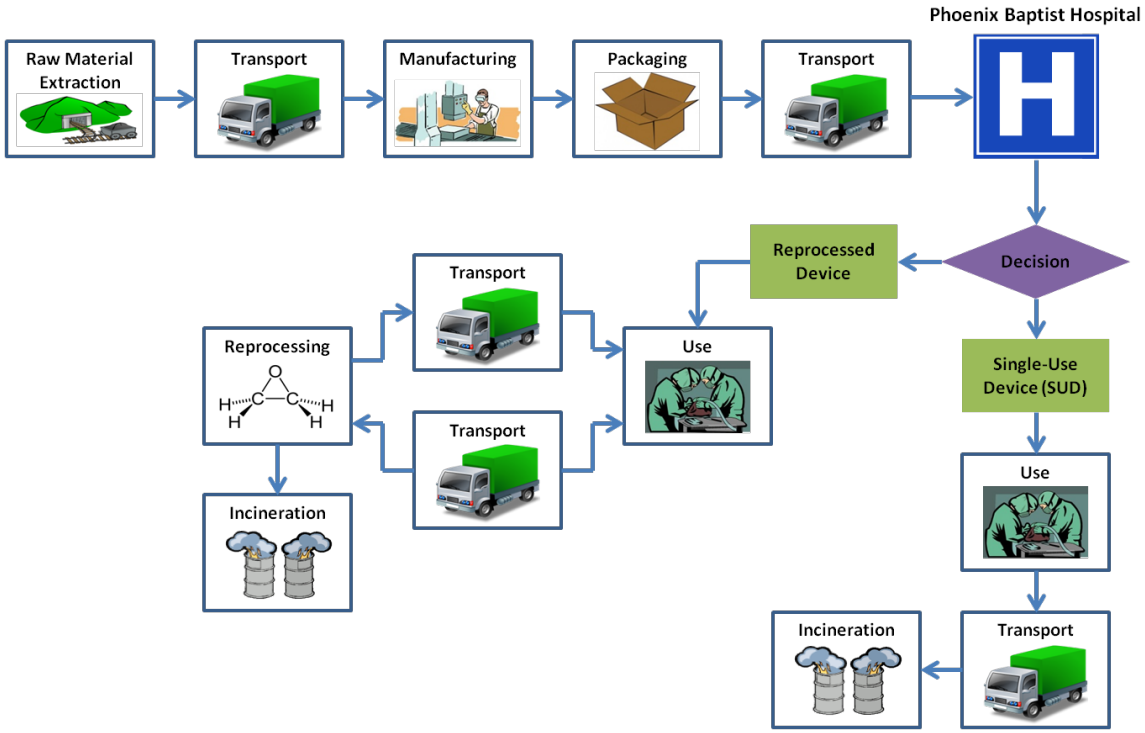


Figure 4. System Boundary Showing Processes Included in the LCA.

(Caption Text) While not shown, the system boundaries include energy, materials, and emissions associated with each process.

d. Inventory Analysis

In order to determine each device's bill of materials, each device was disassembled and de-manufactured. The materials for each device were weighed using an Ohaus Pioneer analytical scale with ma 0.001-gram detection limit. Materials were identified within the corresponding life cycle inventory records from the ELCD (European Reference Life Cycle Database) and ecoinvent v2.2.

Devices that were used more than once underwent reprocessing, where a commercial gas sterilizer was used to reprocess the seven medical devices. The gas sterilization cycle consisted of six phases: pre-sterilization conditioning, sterilization, evacuation, air wash, chamber exhaust, and aeration. The six phases of gas sterilization phases required inputs of electricity and ethylene oxide (ETO). The electricity, ETO, and water were included in the inventory. The inputs related to transporting the medical devices from the hospital to the reprocessing center, and back from reprocessing center to the hospital were also included in the life cycle inventory. At the end of their useful life all devices were treated as regulated medical waste (RMW); where all RMW underwent incineration followed by landfilling. The end-of-life processes were included in the inventory analysis. All LCI inputs and data sources are summarized in Table 1.

Table 1. Utilized Inventory Data.

Material/Process	LCI Database	Process Name
Aluminum	Ecoinvent v. 2.2	Aluminum, secondary, shape casted/RNA
Copper	Ecoinvent v. 2.2	Copper, secondary, shape casted/RNA
Cotton	Ecoinvent v. 2.2	Textile, woven cotton, at plant/GLO U
Electricity	Modified Ecoinvent v. 2.2	Electricity, production mix Arizona/Arizona U
Ethylene oxide	USLCI	Ethylene Oxide, at plant/RNA
High-density polyethylene (HDPE)	Ecoinvent v. 2.2	Polyethylene, HDPE, granulate, at plant/RER U
Incineration	Ecoinvent v. 2.2	Incineration/CH U
Kraft paper	Ecoinvent v. 2.2	Kraft paper, bleached, at plant/RER U
Low-density polyethylene (LDPE)	Ecoinvent v. 2.2	Polyethylene, LDPE, granulate, at plant/RER U
Paperboard	Ecoinvent v. 2.2	Solid bleached board, SBB, at plant/RER U
Stainless steel	Ecoinvent v. 2.2	Stainless steel hot rolled coil, annealed & pickled, elec. arc furnace route, prod. mix, grade 304 RER U
Tap water	Ecoinvent v. 2.2	Tap water, at user/RER U
Van transport	Ecoinvent v. 2.2	Transport, van <3.5t/RER U

(Caption Text:) USLCI: United States Life Cycle Database Inventory

Table 1 summarizes the number of devices that PBH would need to purchase on an annual basis to meet their supply chain requirements. Table 1 shows the number of devices needed to fulfill PBH's reprocessed device supply chain for each reprocessing instance (i.e., none, one, two, three, four, and five). For each of the seven devices, these values were calculated using the following equation:

Equation 1. Number of Devices Needed to Fulfill PBH's Reprocessed Devices Supply Chain Given Each Reprocessing Instance.

$$D_x = \frac{D_0}{x + 1}$$

D_x ≡ Number of devices purchased with x reprocessing instances

D_0 ≡ Number of devices purchased with 0 reprocessing instances

x ≡ Reprocessing instances

M_x ≡ Reprocessing input multiplier for x reprocessing instances

The reprocessing inputs were also varied given the number of devices that were used for each associated reprocessing instance. For example, a number of devices reprocessed with a certain number of reprocessing instances will have differing associated reprocessing inputs (i.e., ethylene oxide, electricity, water) when compared to the same number of devices that are reprocessed more or less instances. The varied inputs for electricity, water, and ethylene oxide each reprocessing instance were calculated with using the following equation and summarized in Equation 2:

Equation 2. Associated Reprocessing Inputs Given Each Reprocessing Instance.

$$M_x = D_x \cdot x$$

Table 2. Number of Devices Needed to Fulfill PBH's Reprocessed Devices Supply Chain for Each Reprocessing Instance.

	Reprocessing Instances					
	0	**1**	**2**	**3**	**4**	**5**
Arthroscopic Shavers / Burs	47	24	16	12	9	8
Compression Device - Pairs	6427	3213	2142	1607	1285	1071
Endoscopic Trocars	5418	2709	1806	1355	1084	903
Ligasures	29	14	10	7	6	5
Pulse Oximeters	2351	1175	784	588	470	392
Scissor Tips	110	55	37	27	22	18
Ultrasonic Scalpels	613	307	204	153	123	102

Results showed that ETO and electricity were the significant contributors to most of the environmental impacts, and as such a sensitivity analysis on ETO, electricity, and water was performed. The sensitivity analysis varied quantities of ETO consumed by the commercial gas sterilizer. The utilized quantities for ETO and carbon dioxide were based on the values described in both the *Sterilisation of Polymer Healthcare Products* and the *Ethylene Oxide Commercial Sterilization and Fumigation Operations NESHAP Implementation Document* (Midwest Research Institute, Environmental Protection Agency, & Office of Air Quality Planning and Standards, 1997; Rogers, 2005). The *Sterilisation of Polymer Healthcare Products* describes the range of ETO concentrations that may be used is healthcare product gas sterilizers. The sensitivity analysis included the range of ETO concentrations described in the *Sterilisation of Polymer Healthcare Products*, which was 400 to 1,500 mg/L. Additionally, the *Ethylene Oxide*

Commercial Sterilization and Fumigation Operations NESHAP Implementation Document describes the range of loading volumes for healthcare product gas sterilizers. The sensitivity analysis also included the range the loading volumes for gas sterilizers shown in the *Ethylene Oxide Commercial Sterilization and Fumigation Operations NESHAP Implementation Document*, which was 2.8m^3 to 28m^3. Table 3 shows the gas sterilizer volumes and concentrations of ETO used to calculate the kilograms ETO consumed by the commercial gas sterilizer.

Table 3. Kilograms of ETO Used by Gas Sterilizer Based on Gas Sterilizer Volume and ETO Concentration for the Sensitivity Analysis.

Gas Sterilizer Volume (m^3)	Concentration ETO (mg/L)	Concentration ETO (kg/m^3)	Kilograms ETO
2.8	400	0.4	1.12
15.4	400	0.4	6.16
28	400	0.4	11.2
2.8	950	0.95	2.66
15.4	950	0.95	14.63
28	950	0.95	26.6
2.8	1500	1.5	4.2
15.4	1500	1.5	23.1
28	1500	1.5	42

(Caption Text) Kilograms of ETO were the product of gas sterilizer volume and the ETO concentration in kg/m^3.

e. Impact Assessment

The Life Cycle Impact Assessment (LCIA) was conducted using the Tool for the Reduction and Assessment of Chemical and Other Environmental Impacts (TRACI) v2.0

developed by the USEPA (2013). TRACI was used to calculate the following environmental and human health impacts: global warming, carcinogenic, non-carcinogenic, and respiratory effects. TRACI utilizes global warming potentials (GWPs) to calculate the potency of greenhouse gases (relative to carbon dioxide) that are emitted during life-cycle phases of a product or process (J. Bare, 2011). These values are used to determine the overall global warming impact of a product or process. For human health impacts (i.e., carcinogenic, non-carcinogenic, respiratory effects), TRACI employs USEtox, which assess the toxicological effects of a chemical emitted into a the environment through the following cause-effect chain: environmental fate, exposure, and resulting effects (Rosenbaum et al., 2008).

The characterization factor, CTU_h (i.e., comparative toxic unit), was used to express human toxicity (i.e., carcinogenic and non-carcinogenic impacts). CTU_h are the estimated increase in morbidity per unit mass of a chemical emitted. CTU_h are determined by calculating the aggregate potential for carcinogenic or non-carcinogenic diseases based on a combination of factors. These factors include a chemical's: fate factor, exposure factor, effect factor, and intake factor.

The reference emission, PM_{10} (i.e.., particulate matter less than 10 micrometers in diameter), was used to determine the human respiratory impacts posed by reprocessed and/or disposable devices. Respiratory effects were calculated by modeling and correlating fate and exposure with intake fractions (i.e., a portion of an emitted substance, which is expected to be inhaled by a human being). The intake fractions were calculated as a function of the amount of PM_{10} emitted into the environment, the resulting increase in PM_{10} atmospheric concentration,

and the breathing rate of the exposed population (J. Bare, 2012). PM_{10} was used as the reference substance because numerous epidemiology studies have shown increased levels of adverse human respiratory impacts with elevated levels of ambient particulate matter (Dominici et al., 2006; Pope III et al., 2002).

f. Life Cycle Cost Analysis

A LCCA was also performed to model the economic impacts of varying levels of reprocessing at PBH. The LCCA modeled the economics costs incurred by PBH when using varying levels of reprocessed devices vs. SUDs, which spanned each of the seven devices' procurement to disposal. The system boundary of the LCCA matches that of the LCA, where both include each device's manufacturing, use, and disposal phases. Several inputs constructed the LCCA, which were the: price of each device (in terms of 2013 US dollars), quantity of each device used on an annual basis, waste disposal costs, and the reprocessing markdown for each device; all data was obtained from PBH.

The reprocessing markdown for devices was 50%, which was the markdown set by PBH's third-party reprocessor, Stryker. Additionally, PBH's waste handler, Stericycle, charged $0.14 per kilogram of waste generated by PBH, where this markdown was used to calculate waste disposal costs for all devices that were not reprocessed by PBH. Because Stryker would incur costs for all reprocessed devices, any instance of reprocessing for PBH would correlate with no waste disposal costs incurred by PBH. Or, any device or any number of devices that were not reprocessed would represent increased waste disposal costs incurred by PBH.

3. Results

a. LCA

Given median/mean reprocessing life-cycle inventory inputs, Figure 5 shows that the reprocessing of the seven analyzed devices slightly reduces global warming impacts, but concurrently exacerbates human health impacts (i.e., carcinogenic, non-carcinogenic, respiratory effects). Irrespective of the number of reprocessing instances, the driving factor in both global warming and human health impacts was the reprocessing life-cycle inventory. This life-cycle inventory data included: the amount of ETO, electricity, and water consumed. The sensitivity anaylsis' results discussed later varies these inputs based on accepted regulatory reprocessing standards.

Whether used as a SUD or a reprocessed device, the use of DVT compression sleeves had the highest contribution of all the devices (excluding disposal and reprocessing impacts) to environmental impacts, while the trocar was second highest. The significant environmental impacts associated with DVT compression sleeves and trocar were driven by the high utilization rates; PBH uses 6,427 of DVT compression sleeves and 5,418 trocars on annual basis. The other devices were used less frequently (summarized in Figure 3). In addition, the compression sleeve was made up of 93% cotton on a weight basis, while all other devices were primarily made of plastic and metal. Cotton production has significant energy, chemical, and water inputs, which result in the environmental impacts in Figure 5. These environmental impacts are due to the

significant direct and indirect agricultural life-cycle inputs involved with manufacturing woven cotton.

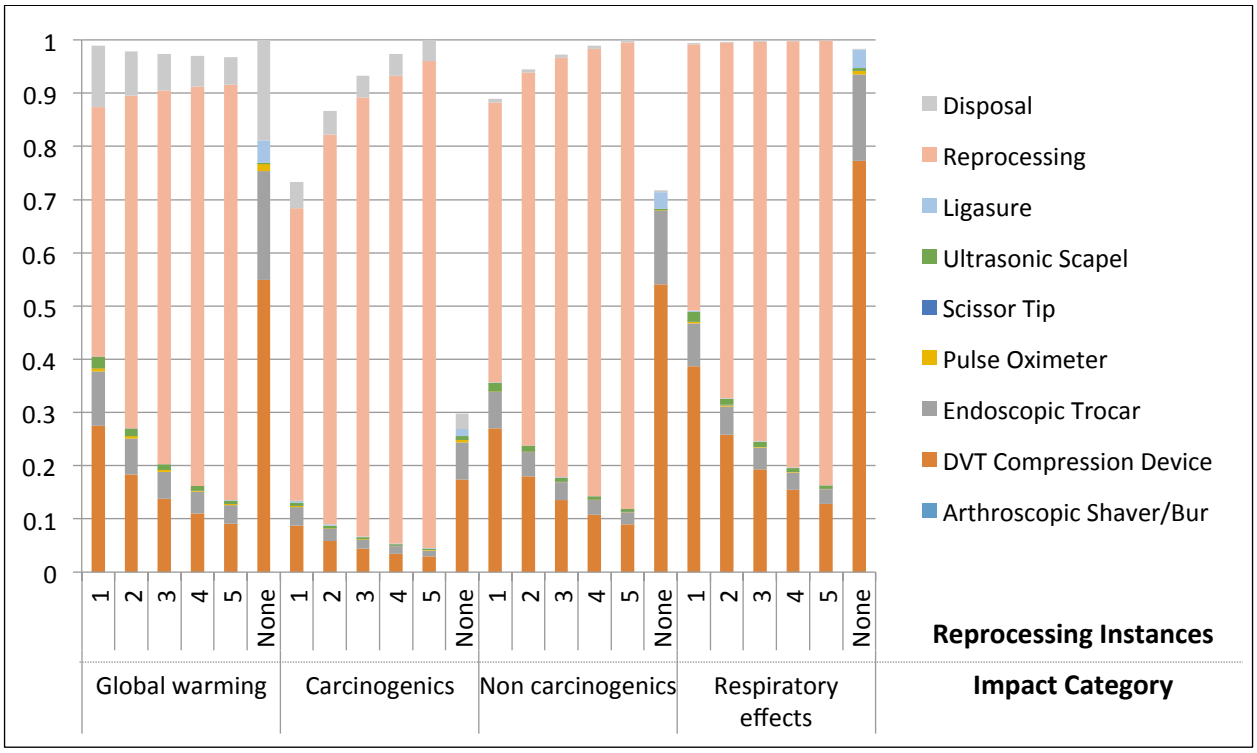


Figure 5. Normalized Global Warming, Carcinogenic, Non-Carcinogenic, and Respiratory Effects for PBH's Reprocessed Device Supply Chain Using Median/Mean Reprocessing Life-Cycle Inventory Inputs.

(Caption Text) Disposal corresponds with incineration and waste-handling processes. The seven devices (i.e., ligasure, ultrasonic scalpel, scissor tip, pulse oximeter, endoscopic trocar, DVT compression device, arthroscopic shaver/bur) include all processes related to raw material extraction, device manufacturing, and device packaging.

The kg CO_2 eq emitted by PBH reprocessed devices on annual basis given varied reprocessing inputs is shown in Figure 6. The reprocessing inputs were based on the values used in the sensitivity analysis, which varied the water and ethylene oxide used during reprocessing. Figure 6 shows that decreased reprocessing inputs were correlated with decreased levels of kg CO_2 eq. Increased instances of reprocessing were also correlated with decreased levels of kg CO_2 eq when the reprocessing life-cycle inputs were approximately less than half of the median reprocessing life-cycle inputs. In terms of a breakeven point when compared to no reprocessing, the most statistically similar data points were that of median reprocessing inputs. Additionally, as reprocessing inputs decreased, the kg CO_2 eq would be further reduced with each additional reprocessing instance.

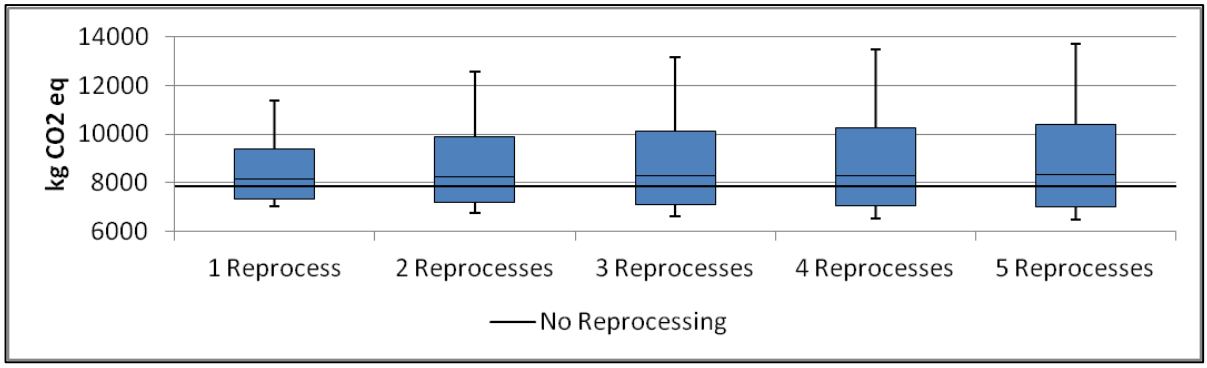


Figure 6. Greenhouse Gas Emissions in kg CO_2eq with Varied Reprocessing Inputs for Devices Reprocessed One, Two, Three, Four, Five, and No Instances for PBH on an Annual Basis.

The carcinogenic, non-carcinogenic, and respiratory effects produced from PBH on an annual basis given varied reprocessing inputs are shown in Figure 7, Figure 8, and Figure 9, respectively. Figure 7 through Figure 9 show that decreased reprocessing inputs were correlated

with decreased magnitudes of human health impacts. When limiting reprocessing life-cycle inputs, increased instances of reprocessing were also correlated with decreased magnitudes of human health impacts.

Carcinogenic impacts required the lowest quantity of reprocessing inputs to reach breakeven with respect to reprocessed and disposable devices. Respiratory effects required the highest amounts of reprocessing inputs to reach breakeven with respect to reprocessed and disposable devices. Therefore, carcinogenic impacts are especially vulnerable to being exacerbated given increased reprocessing inputs; and, vice versa for that of respiratory effects.

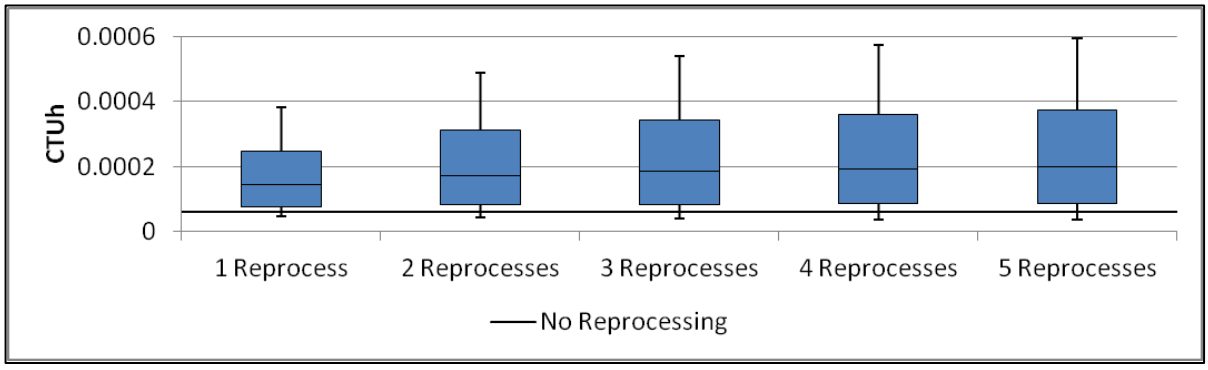


Figure 7. Carcinogenic in Comparative Toxic Units (CTUh) with Varied Reprocessing Inputs for Devices Reprocessed One, Two, Three, Four, Five, and No Instances for PBH on an Annual Basis.

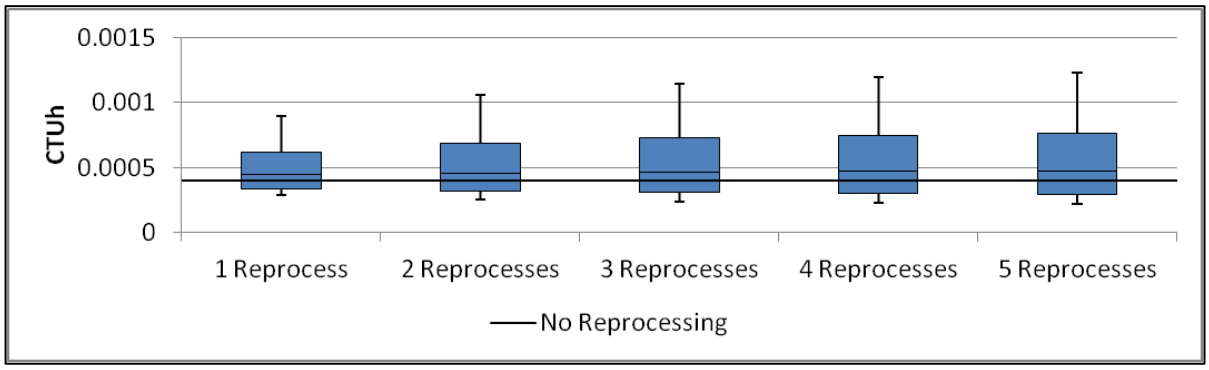


Figure 8. Non-Carcinogenic Impacts in Comparative Toxic Units (CTUh) with Varied Reprocessing Inputs for Devices Reprocessed One, Two, Three, Four, Five, and No Instances for PBH on an Annual Basis.

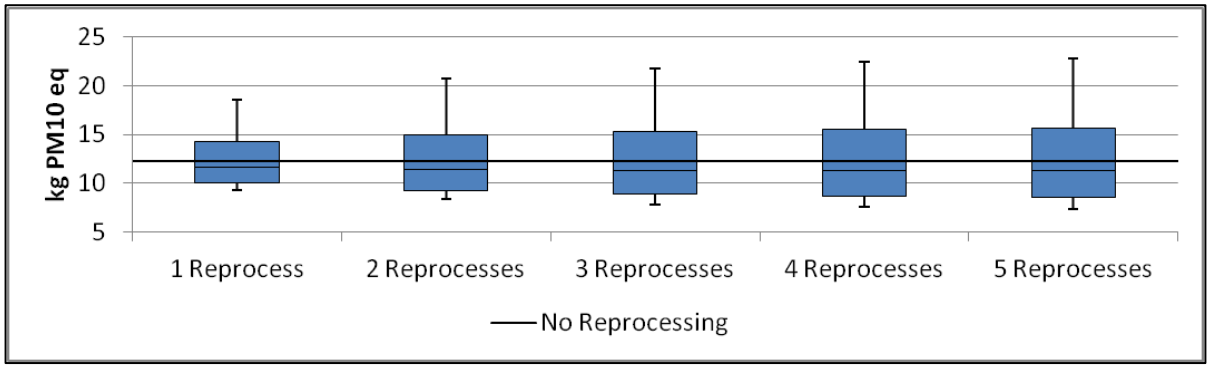


Figure 9. Respiratory Effects kg PM_{10}eq with Varied Reprocessing Inputs for Devices Reprocessed One, Two, Three, Four, Five, and No Instances for PBH on an Annual Basis.

Figure 10 shows the relative global warming and human health impacts for the seven analyzed devices where annual usage is not taken into account (i.e., one-to-one device comparison). The compression device and ligasure are the devices with the highest environmental impacts; while the ultrasonic scalpel is consistently third and the endoscopic

trocar is consistently fourth. The woven cotton textiles drive the environmental impacts of the compression device; textiles contribute over 91% to all four compression device impact categories. Additionally, the high levels of polyethylenes in the Ligasure and its packaging are statistically significant in contributing to environmental impacts. The pulse oximeter, scissor tip, and arthroscopic shaver were not statistically significant; where, these devices had normalized global warming and human health impact values that were all less than 7%.

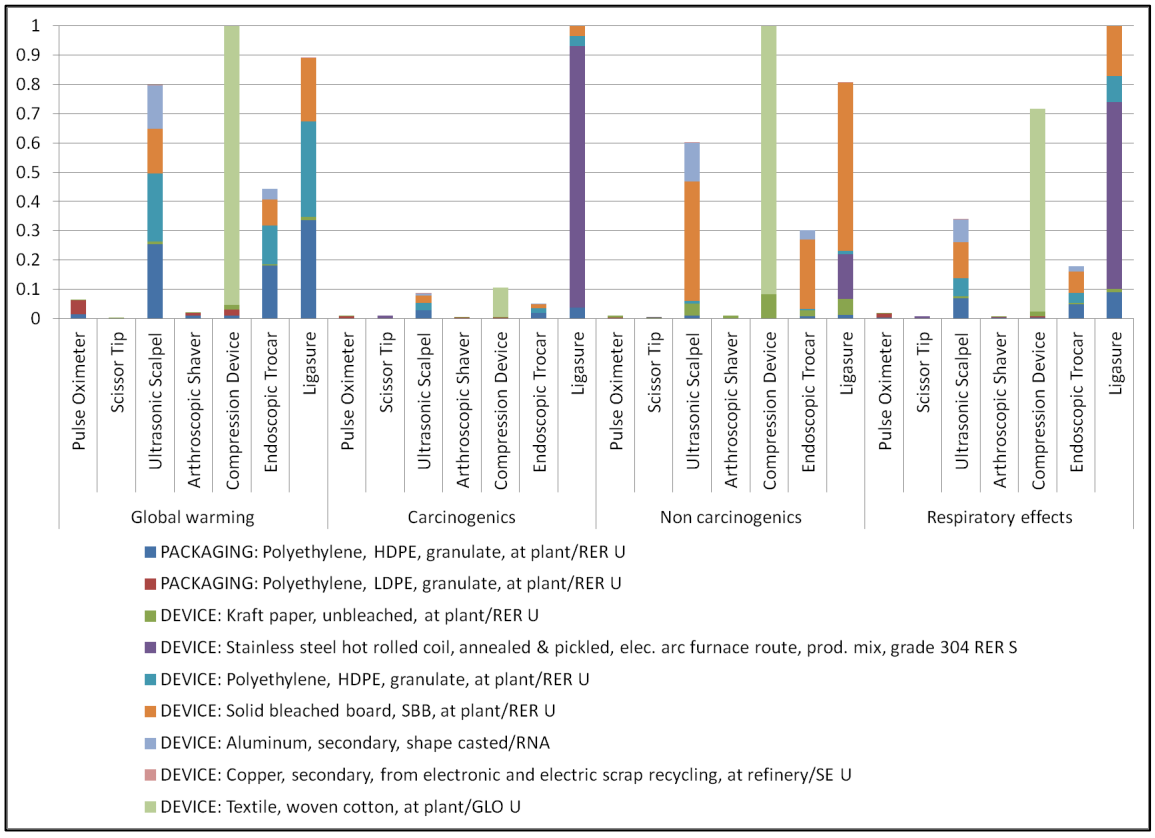


Figure 10. Global Warming and Human Health Impacts for the Seven Analyzed Devices Normalized to the Device with the Highest Impact.

b. LCCA

Increased reprocessing of the seven medical devices utilized by PBH correlated with a decrease in overall economic costs associated with the manufacturing, use, and disposal of those devices. When all seven devices were reprocessed one through five instances, the total savings on an annual basis (versus when no devices were reprocessed) were $182k, $351k, and $520k (in terms of 2013 US dollars), respectively. These results are further detailed in Figure 11.

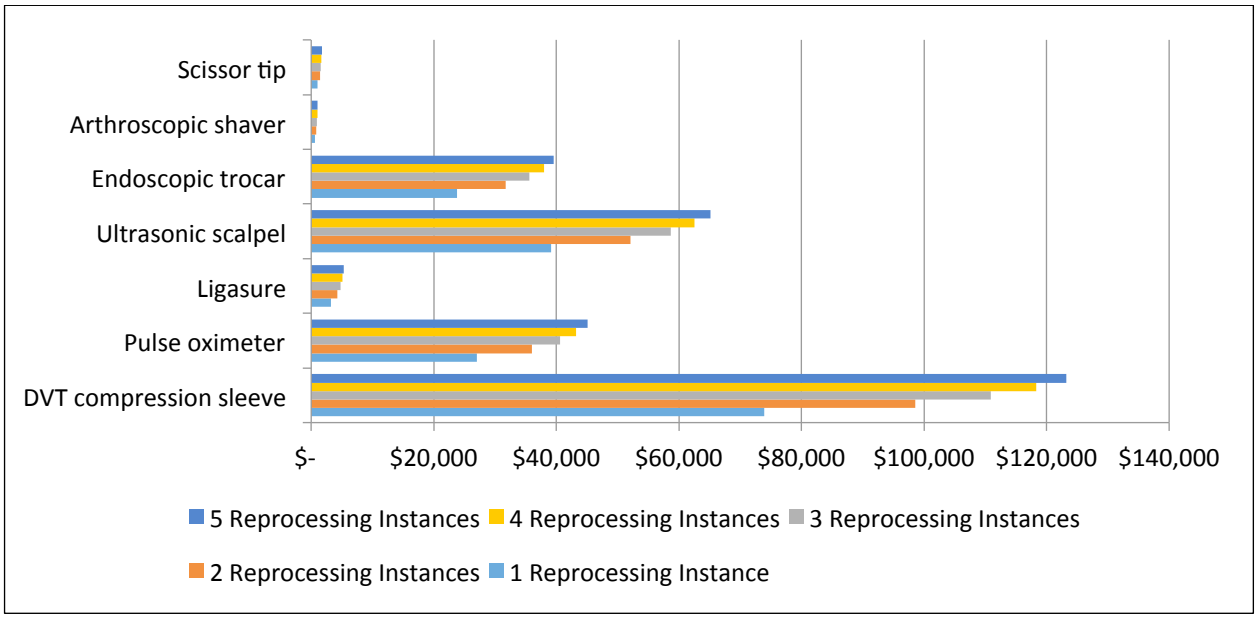


Figure 11. Reductions in Supply Chain Cost for each Device versus Instances Reprocessed.

Additionally, the reprocessing of DVT compression sleeves had the highest potential for cost savings, where the cost savings for DVT compression sleeves represented nearly half of the potential savings realizable to the hypothetical hospital. And because of the high original equipment manufacturer (OEM) costs associated with harmonic scalpels, the reprocessing of

ultrasonic scalpels also represented significant reductions to the economic costs of PBH's supply chain.

4. Conclusions

When employing 'average' reprocessing inputs, the results showed that the global warming impacts were marginally lower in reprocessing scenarios when compared to scenarios that employed no reprocessing. On the other hand, the human health impact results marginally favored that of no reprocessing when compared to reprocessing scenarios when using median values. While these results are pertinent, the overarching result is that if reprocessing inputs are minimized, then employing reprocessing is favorable from both a global warming and human health perspective.

Whether used as a SUD or a reprocessed device, the use of DVT compression sleeves have the highest environmental impacts when devices are compared one-to-one. The significant environmental impacts associated with DVT compression sleeves were driven by the high utilization of DVT compression sleeves on annual basis at PBH, as well as the considerable environmental impacts associated with manufacturing woven cotton. Therefore, substituting woven cotton for a less environmentally intensive material could reduce environmental impacts associated with DVT compression sleeves. It should also be noted that the high quantities of plastics (i.e., HDPE, LDPE) in ligasures correlated with significant environmental and human health impacts when used as either reprocessed or disposable devices

When taking into consideration the economic benefits of reprocessing, the favorability of reprocessing medical devices becomes more apparent. Even in scenarios of high reprocessing inputs, the global warming and human health tradeoffs between reprocessed and disposable supply chains is not sufficiently significant to outweigh the financial benefits of reprocessing.

Hospitals that are comparable in size, services provided, and overall reprocessing profile to PBH can expect similar results. Hospitals that also have increased levels of reprocessing, in terms of instanced reprocessed and devices in reprocessing profile, can expects greater economic benefits; and, reduced global warming and human health impacts, under the assumption that reprocessing inputs are minimized. For all hospitals, if reprocessing inputs are optimized, reprocessing offers global warming, human health, and economic benefits over the same devices used as disposables.

5. Acknowledgements

The authors would like to acknowledge the Phoenix Baptist Hospital Green Team for their provided help, as well as the Ira A. Fulton Schools of Engineering Dean's Fellowship for funding related to this project.

CHAPTER 4

INVESTIGATING INNOVATIVE AND TRADITIONAL MATERIALS SHIFTS IN MEDICAL PRODUCTS TO REDUCE ENVIRONMENTAL IMPACTS: FOCUS ON BIOPOLYMERS AND COTTON REUSE

This chapter addresses the dissertation research question 2) assess opportunities for using biopolymers in healthcare and the resultant comparative environmental impacts of single use disposable devices with increased biopolymer content vs. typically manufactured devices in hysterectomy procedures. Due to the apparent environmental impacts associated with disposable woven-cotton, this study also compares the environmental impacts of reusable woven-cotton medical products versus disposable woven-cotton medical products.

1. Introduction

Over the past half-century, plastics have become a ubiquitous material in the medical device industry. In a study analyzing environmental impact of seven single-use medical devices undergoing reprocessing, all had some form of polyethylene in each of their respective bill of materials (Unger & Landis, 2015). Total polyethylene weight ranged anywhere from 7% to 88% of total weight for individual devices, and made up 52% of total weight for the combined average of the seven devices (Unger & Landis, 2015). In another study of four types of hysterectomy (abdominal, vaginal, laparoscopic, robotic), plastics were again found to be a significant portion of the operating room (OR) waste stream. The study concluded that the plastics used (e.g., thin film packaging wrappers, hard plastic trays) accounted for a minimum of

36% of material solid waste (MSW) by weight for vaginal hysterectomies and a maximum of 46% of MSW by weight for robotic procedures (Thiel et al., 2014).

It was not until the 1960s that plastics became so pervasively used in healthcare (V. Greene, 1986). At this time, the healthcare industry learned how to substitute polyvinyls, polycarbonates, and polystyrenes for materials originally made out of glass, rubber, metal, and woven textiles (V. Greene, 1986). The substitution occurred primarily because medical device manufacturing companies learned to make devices with plastics efficiently and cheaply. These factors led to increases in healthcare plastic use, which consequentially led to fundamental changes in the processes that governed medical device manufacturing, use, and disposal. For example, before the substitution of petroleum-based plastics, medical products made of woven-cotton would undergo cleaning on-site at the hospital once they were used (V. Greene, 1986). Following the substitution of petroleum-based plastics, devices made of plastic that fulfilled the same function would be disposed after being used only one instance; which consequently led to increased quantities of waste created by hospitals. Moreover, while plastics typically have less of an environmental footprint than woven-cotton on a per-weight basis with a single use, woven-cotton has recently been found to be the most favorable environmental option; where, the caveat is that the woven cotton must be reused and not treated as a disposable item (Campion et al., 2015; Thiel et al., 2014). Recent studies suggest that reusing woven-cotton, as opposed to utilizing petroleum-based disposable plastics, could significantly reduce environmental and human health impacts associated with healthcare procedures; however, more LCA data is needed with respect to laundering facilities (Campion et al., 2015; Thiel et al., 2014).

While petroleum-based plastics are extensively used in healthcare settings, bio-plastics for the past several decades have also formed their own niche market in the healthcare industry. As opposed to petroleum-based plastics that obtain their carbon from non-renewable resources (e.g., petroleum), bio-plastics (a.k.a. biopolymers) are plastics in which some or all of the polymer is derived from renewable feedstocks. With regards to healthcare applications, recent developments in biopolymer manufacturing processes have created new avenues and opportunities for increased integration of biopolymers into medical products, devices, and services. One factor that has contributed to these opportunities is that newly developed biopolymers are able to retain similar physical characteristics of synthetic plastics. For example, emerging studies show that guayule-derived latex rubber is a suitable substitute for flexible plastics and traditional rubber products (Cornish, Williams, Hall, & III, 2008; Rasutis, Soratana, McMahan, & Landis, 2015). Another study shows that the biopolymer polylactide (PLA) is a suitable substitute for different forms of plastic (Madhavan Nampoothiri, Nair, & John, 2010). Based on the material and chemical properties of PLA, the study concluded that PLA has many potential applications, including upholstery, disposable garments, awnings, feminine hygiene products, and diapers (Madhavan Nampoothiri et al., 2010). One of the benefits of PLA is that it is compostable, and might allow hospitals to decrease the amount of plastics in their waste stream (Ghorpade, Gennadios, & Hanna, 2001).

Given recent development in the field of biopolymers and their potential to replace commonly used plastics, there is the possibility to use biopolymers in a variety of medical products. Replacing petroleum-based plastics with biopolymers would not only reduce depletion of non-renewable resources, but could also reduce hospital-generated material solid waste

(MSW) and regulated medical waste (RMW) if the biopolymers are composted. Despite these benefits, there are very few medical products manufacturers that currently utilize biopolymers in their products. Additionally, an assessment of the environmental impacts of increased biopolymer use in favor of petroleum-based plastics in medical devices and products has not yet been performed. *This study addresses this knowledge gap by comparing the environmental impacts of medical devices composed of plastics versus the same medical devices made with biopolymers. Due to the apparent environmental impacts associated with disposable woven-cotton, this study also compares the environmental impacts of reusable woven-cotton medical products versus disposable woven-cotton medical products.*

This study utilized an OR material audit data from previous work and will focus on four of the most common types of hysterectomies performed: robotic, abdominal, laparoscopic, and vaginal (Thiel et al., 2014). Studies show that the OR is the most resource-intensive area of a hospital (Goldberg, Vekeman, Torjman, Seltzer, & Kynes, 1996; Lee, Ellenbecker, & Moure-Eraso, 2002). A hysterectomy, the removal of a woman's uterus, is the second most common major surgery performed on women in the US, and is the ninth most performed procedure in ORs (Health & Human, 2013; Whiteman et al., 2008). The methods, products, and devices employed in a hysterectomy are representative of many forms of abdominal surgery. While there is overlap in the devices and products used in each type of hysterectomy, there are noteworthy differences regarding the technologies, materials, and devices used in hysterectomies; which, suggests a need for an increased understanding of how each procedure, and developments within in each procedure, differs in their overall environmental impact. For example, a robotic hysterectomy uses more technologically-advanced products and devices (e.g., circuit boards,

diodes) than that of a vaginal hysterectomy. Therefore, understanding the environmental impacts of procedures performed regularly in the OR (in this case, a hysterectomy), is critical to understanding environmental impacts related to the aggregate healthcare system.

2. Method

The methods section parallels the four major steps of a life cycle assessment (LCA) (i.e., goal and scope definition, inventory analysis, impact assessment, interpretation). LCAs are used to assess environmental impacts throughout a product's life and seek to address a number of environmentally related concerns, including: compilation of energy and material input and outputs; evaluation of potential impacts attributed to the inputs and outputs; and, interpretation of the results to help make a more informed decision (EPA, 2010).

An LCA begins with the goal and scope definition, which explicitly sets the context of the study. Once the goal and scope are defined, the second step of an LCA is inventory analysis. The life-cycle inventory (LCI) analysis documents the inputs and outputs of the studied system, where quantities of emissions, materials and energy are quantified. The third step in an LCA is the impact assessment, which aggregates the LCI data into environmental impact categories. And the final step of a LCA is interpretation, which is typically performed iteratively throughout each step of the LCA. LCA interpretation is systematic, and it identifies, quantifies, and evaluates information from the inventory or impact assessment steps.

In addition to the LCA, a 2^3 factorial experiment was used to demonstrate the environmental and human health impacts resulting from different substitutions biopolymers. An analysis was also performed to determine how the laundering of woven cotton products would affect environmental and human health impacts.

a. Scope and System Boundary

This study presents a comparative life cycle assessment of single-use-disposable medical products containing plastic(s) versus the same single-use medical devices with biopolymers substituted for plastic(s). The context of this LCA was that of Magee-Womens Hospital (Magee) in Pittsburgh, PA, and the products used in four types of hysterectomies performed at Magee that contained plastics potentially suitable for biopolymer substitution. Magee is a 360-bed teaching hospital, which performs approximately 1400 hysterectomies annually. The products and devices evaluated are those used in four types of hysterectomy (i.e., vaginal, abdominal, laparoscopic, robotic) at Magee. Figure 12 shows that plastics are the most significant portion by weight of MSW per procedure for all types of hysterectomies. The high quantity of plastic waste confirms that there is considerable potential for the substitution of biopolymers. When averaging the total waste from the four hysterectomies, polypropylene, polyvinylchloride, and various forms of hard plastic represented the greatest sources of produced waste by mass. On a percent basis by mass, polypropylene, polyvinylchloride, and hard plastic represented 32%, 25%, and 14%, respectively, of the total waste produced by the four hysterectomies (Thiel et al., 2014).

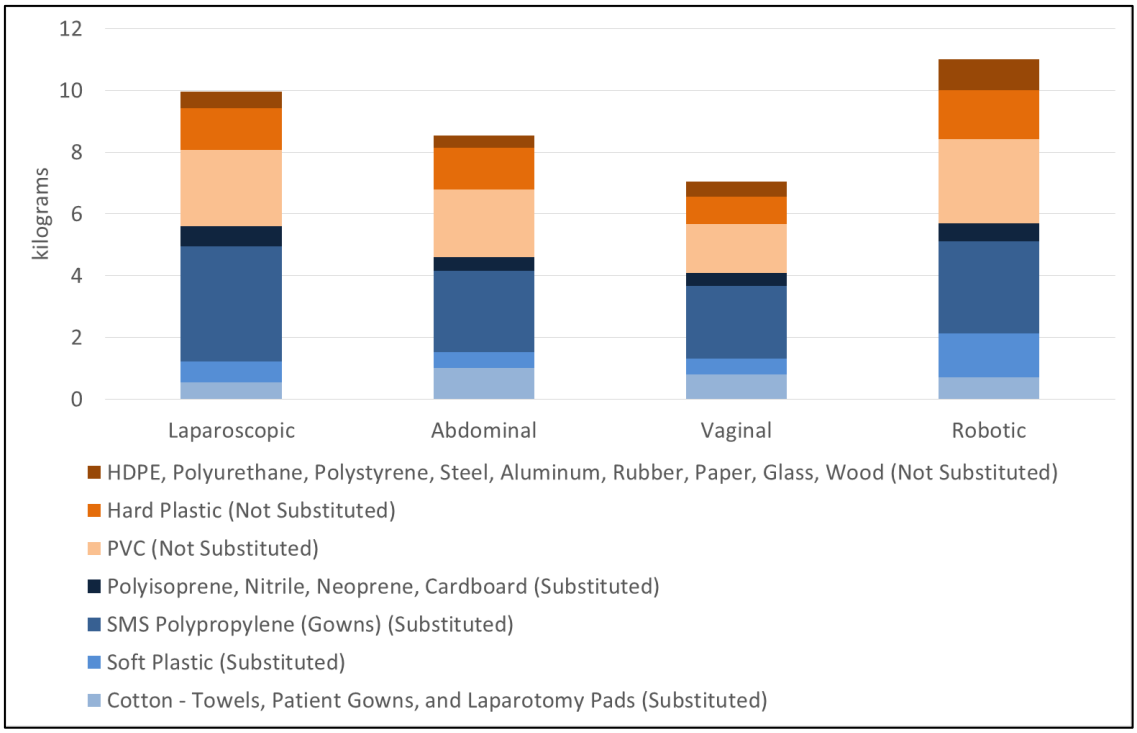


Figure 12. Average Material Composition of MSW from a Single Hysterectomy by Surgery Type with Assumed Biopolymer Substitution. Adapted from (Thiel et al., 2014).

(Caption Text) This figure shows the total waste produced from the four hysterectomy procedures. Materials substituted for biopolymers are colored shades of blue, and non-substituted materials are colored shades of orange. Similarly, all materials with (Substituted) following their name are materials that were substituted for biopolymers. All materials with (Not Substituted) following their name are materials that were not substituted for biopolymers.

The number of medical devices and products used in each type of hysterectomy and the quantity of plastic(s) within each product were included in the analysis using the inventory data collected in a previous study (Thiel et al., 2014). Specific types of biopolymers were designated as substitutions to replace the plastics found in each device. The choice of substituted biopolymer was based on which biopolymer has appropriate material and functional properties to

that of the original plastic. The system boundary encompasses activities associated with the raw material extraction, production, use, and end-of-life (EOL) for the products containing plastic in each type of hysterectomy.

There were 8 products and 1 device for which biopolymers were substituted for petroleum-based plastics, which are further detailed in Table 4. The bladeless obturator twists radially to wedge through muscle fiber layers to cut through to the abdominal cavity. Drapes are used to cover portions of the patient's body in order to separate sterile areas from nonsterile areas. Blue wrap is intended to keep medical instruments sterile prior to surgery. And gloves are used during procedures to help prevent contamination between caregivers and patients.

Waste audits of 62 hysterectomies were conducted by Thiel et al (2014) (15 each abdominal, vaginal, and robotic, and 17 laparoscopic). The waste audits were done to collect the material inputs and to quantify and characterize the products and materials entering Magee's municipal solid waste, recycling streams, and RMW. The waste audits began with a visual inspection of the OR prior to the surgery to ensure all previously generated waste was eliminated. Immediately following the surgery, the MSW was collected, labeled with the case identification number, and moved to a secure storage location for sorting and weighing. RMW was estimated by quantifying the type of "peel packs" or package labels found in the MSW. All MSW was landfilled, while RMW underwent autoclaving prior to landfilling.

Table 4. Potential Biopolymer Substitutions for Petroleum Plastics. Adapted from (Thiel et al., 2014).

Plastic found in original waste audit	Substituted Biopolymer (and abbreviation used in figures)	Product	Device
Low-density polyethylene (LDPE)	PLA (P)	Laparotomy drape	8 mm bladeless obturator
Polypropylene	PLA (P)	Gowns; laparotomy drapes; bare warm air drape; blue drape; blue wrap	None
Polyisoprene	Guayule-derived latex (G)	Tan glove; blue glove	None
Nitrile	Guayule-derived latex (G)	Purple glove	None
Neoprene	Guayule-derived latex (G)	Green glove	None
Cardboard	Thermoplastic starch (T)	Bare warm air drape	None

(Caption Text) Materials found in products and/or devices for robotic, abdominal, laparoscopic, and vaginal hysterectomies performed at Magee. Plastic, product, and device information from (Thiel et al., 2014). The potential biopolymer substitution was determined for the purposes of this study based on biopolymers with similar characteristics.

Life-cycle processes related to woven nylon, adhesive, electric cords, diodes, batteries, copper, and titanium were omitted from analysis. These products were omitted because they constituted only 6% of the total waste (by weight) generated by Magee and including them in the analysis would not offer valuable insights because these products would have identical values for

all generated scenarios. Manufacturing processes, such as plastic shaping and moulding, were not included due to lack of inventory data and the similarity of manufacturing processes between biopolymers and petroleum-based plastics (Shen, Worrell, & Patel, 2010).

One tool, the laparoscopic morcellator, was used in a number of analyzed hysterectomies; however, in 2014 the FDA contraindicated the morcellator, stating that "use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease the long-term survival of patients" (USFDA, 2015). Because the FDA has recommended that the morcellator not be used in hysterectomies, the morcellator's associated life-cycle inventory was omitted from this study's system boundary.

b. Inventory Analysis

The following plastics were identified in the four types of hysterectomies at Magee: low-density polyethylene (LDPE), polypropylene (PP), polyisoprene, nitrile, and neoprene. Based on their physical properties and delivered function, the weights of plastics found in each device were substituted with an equal weight of suitable biopolymers. Guayule-derived latex was substituted for all products and/or devices containing nitrile, neoprene, polyisoprene. PLA was substituted for all products and/or devices containing LDPE and polypropylene. Thermoplastic starch was substituted for all products containing cardboard. While cardboard is considerable a renewable material, thermoplastic starch was substituted because of its suitability as a cardboard substitute.

PLA is a suitable LDPE substitute, as PLA has properties that make it appropriate for thin film applications including disposable products and packaging. Research is continuing to expand the number of applications for PLA as the potential material characteristics are broadened (Reddy, Vivekanandhan, Misra, Bhatia, & Mohanty, 2013; Shen, Haufe, & Patel, 2009). Similar to LDPE, PP in film applications and packaging can be replaced with disposable PLA products (Shen et al., 2010). Starch is well established as a low cost material for packaging applications which can be blended with cardboard and other fibers to achieve a wide range of application specific properties. While cardboard is an effective biobased material, starch may perform favorably and a comparison of environmental impacts will help assess any tradeoffs that exist (Bastioli, 1998; Mohammadi Nafchi, Moradpour, Saeidi, & Alias, 2013; Shen et al., 2009). Clinical and performance trials have also shown that guayule-derived latexs have high molecular weights, and products made from guayule-derived latexs have desirable performance properties in a clinical setting (Rasutis et al., 2015). Guayule-derived latex has also been shown to be safe for people with Type I latex allergy, where typical latex materials (e.g., nitrile, neoprene) contain allergenic proteins that affect those with Type I latex allergy (Foster & Coffelt, 2005; Siler, Cornish, & Hamilton, 1996).

While a seeming departure from plastics, cotton was also investigated as a part of this work as previous studies have shown that cotton production represents a disproportionate percentage of toxicity impacts for LC-effects of surgeries and medical devices (Campion et al., 2015; Unger & Landis, 2014). Woven cotton is found in a number of surgical materials, including towels, patient gowns, and laparotomy pads. Because of emissions associated with cotton, a cotton reuse scenario was developed to assess the potential for reducing environmental

and human health impacts through cotton laundering services. An analysis was performed to determine how the reuse of woven cotton products would affect environmental and human health impacts.

This study utilized life cycle inventory data developed in a study that evaluated materials used in hospital custom packs (Campion et al., 2015). Campion et al. (2015) collected life cycle data from a commercial laundry facility that serviced Western PA hospitals. The life cycle data included: distance traveled for trucks, inventory related to the 18-chamber machine batch process, and typical processes for reusable cotton materials (i.e., washing, pressing, ironing, and folding). The analysis assumed a lifespan of 50 washes for reusable cotton materials, which is a typical lifespan for cotton products (Cartwright et al., 2011). The 18-chamber machine data was cross-referenced with industry specs, the electrical consumption was configured for a Western PA electricity mix, the chemical wash was determined from published reports and chemical MSDS, and the transportation distance was measured via Google Maps from Magee to their commercial laundry facility (ACI, 2013; Altenbaher, Šostar Turk, & Fijan, 2011; DOE, 2013; Fijan, Fijan, & Šostar-Turk, 2008; Overcash, 2012b). Unit processes were provided by the ecoinvent database, the USLCI database, and the Industry 2.0 database, and were used within this study in the same manner presented by Campion et al.

Biopolymer upstream (i.e., raw material extraction, manufacturing) life cycle inventory data were derived from existing databases and literature. PLA inventory values were taken from ecoinvent v2.2. Guayule-derived latex inventory values were derived from (Rasutis et al., 2015). Thermoplastic starch values were provided by ecoinvent v.2.2 (Frischknecht et al., 2005). All

inventory database selections were determined by comparing the physical description and application of the material to the unit process description in each respective life cycle inventory database. Table 2 shows the utilized life cycle inventory databases and processes for all analyzed materials.

Table 5. Utilized Life-Cycle Inventory Databases and Processes.

Material	Production		Disposal	
	Database or Source	Process Name	Database or Source	Process Name
Aluminum	USLCI	Aluminum, secondary, shape casted/RNA	ecoinvent	Disposal, aluminum, 0% water, to sanitary landfill/CH U
Cotton	ecoinvent	Textile, woven cotton, at plant/GLO U	ecoinvent	Disposal, inert material, 0% water, to sanitary landfill/CH U
Glass	ecoinvent	Packaging glass, white, at plant/RER U	ecoinvent	Disposal, glass, 0% water, to inert material landfill/CH U
Guayule-Derived Latex	(Rasutis et al., 2015)	Guayule-derived latex	(Rasutis et al., 2015)	Biowaste treatment of, composting/CH U
HDPE	ecoinvent	Polyethylene, HDPE, granulate, at plant/RER U	ecoinvent	Disposal, polyethylene, 0.4% water, to sanitary landfill/CH U
Isoprene	ecoinvent	Synthetic rubber, at plant/RER U	ecoinvent	Disposal, plastics, mixture, 15.3% water, to sanitary landfill/CH U
LDPE	ecoinvent	Polyethylene, LDPE, granulate, at plant/RER U	ecoinvent	Disposal, polyethylene, 0.4% water, to sanitary landfill/CH U
Neoprene	ecoinvent	Synthetic rubber, at plant/RER U	ecoinvent	Disposal, plastics, mixture, 15.3% water,

				to sanitary landfill/CH U
Nitrile	USLCI	Polybutadiene, at plant/RNA	ecoinvent	Disposal, plastics, mixture, 15.3% water, to sanitary landfill/CH U
Paper	ecoinvent	Kraft paper, bleached, at plant/RER U	ecoinvent	Disposal, paper, 11.2% water, to sanitary landfill/CH U
Paperboard	ecoinvent	Solid bleached board, SBB, at plant/RER U	ecoinvent	Process-specific burdens, sanitary landfill/CH U
PLA	(Vink, Davies, & Kolstad, 2010)	Polylactide	ecoinvent	Biowaste treatment of, composting/CH U
PP	ecoinvent	SMS PP Disposable Gown - Ponder w/ energy	ecoinvent	Disposal, polypropylene, 15.9% water, to sanitary landfill/CH U
PU Foam	ecoinvent	Polyurethane, flexible foam, at plant/RER S	ecoinvent	Disposal, polyurethane, 0.2% water, to sanitary landfill/CH U
PVC	ecoinvent	Polyvinylchloride, at regional storage/RER U	ecoinvent	Disposal, polyvinylchloride, 0.2% water, to sanitary landfill/CH U
Rubber	ecoinvent	Synthetic rubber, at plant/RER U	ecoinvent	Disposal, plastics, mixture, 15.3% water, to sanitary landfill/CH U
Stainless Steel	ecoinvent	Stainless steel hot rolled coil, annealed & pickled, elec. arc furnace route, prod. mix, grade 304 RER U	ecoinvent	Disposal, steel, 0% water, to inert material landfill/CH U
Styrofoam	ecoinvent	Polystyrene, general purpose, GPPS, at plant/RER U	ecoinvent	Disposal, polystyrene, 0.2% water, to sanitary landfill/CH U

Thermoplastic starch	ecoinvent	Modified starch, at plant/RER U	ecoinvent	Biowaste treatment of, composting/CH U
Towel-laundering	(Campion et al., 2015)	Towel-laundering	(Campion et al., 2015)	Disposal, inert material, 0% water, to sanitary landfill/CH U
Wood	USLCI	Plywood, at plywood plant, US SE/kg/US	ecoinvent	Process-specific burdens, sanitary landfill/CH U

All MSW and RMW were included in the system boundary. Additionally, the three biopolymers (i.e., PLA, guayule-derived latex, thermoplastic starch) were assumed to be composted. Regardless of whether the medical product contained biopolymers, all medical products were assumed to be disassembled and disaggregated based on three possible waste streams: RMW, MSW, and composted waste. Because biopolymers are made from the carbon captured in their plant-based resources, the release of CO_2 during EOL does not contribute to an increase of anthropogenic atmospheric carbon (Song, Murphy, Narayan, & Davies, 2009). On the other hand, if a biopolymer material enters the landfill and does not degrade, that carbon can then be considered sequestered because it was removed from the atmosphere via the life-cycle of the product.

Life-cycle impacts related to the transportation of material wastes were also calculated using distances from the hospital to the incineration and landfill facilities based on waste handler data provided by Magee's facility management. Both MSW and RMW traveled from Magee to the waste handler, and from the waste handler to the landfill. The total distance traveled by two

waste streams was 19.3 km. RMW was incinerated before being landfilled, and MSW was sent directly from the waste handler to the landfill without being incinerated.

c. Impact Assessment

Environmental and human health impacts resulting from the calculated inputs and outputs were calculated using the Tool for Reduction and Assessment of Chemical (TRACI) 2.1 (J. C. Bare, 2002), which was created by the United States Environmental Protection Agency (EPA) to assist in impact assessment. The following impacts were calculated and reported from TRACI: ozone depletion, global warming, smog, acidification, eutrophication, carcinogenics, non-carcinogenics, respiratory effects, and ecotoxicity.

d. 2^3 Factorial Design Experiment

A 2^3 factorial experiment was used to demonstrate the variances of environmental and human health impacts resulting from different substitutions of PLA, guayule-derived latex, and thermoplastic starch. The 2^3 factorial design experiment factors were the three substituted plastics (i.e., PLA, guayule-derived latex, thermoplastic starch) and the two factor levels were whether or not biopolymers were substituted for the three design experiment factors.

3. Results

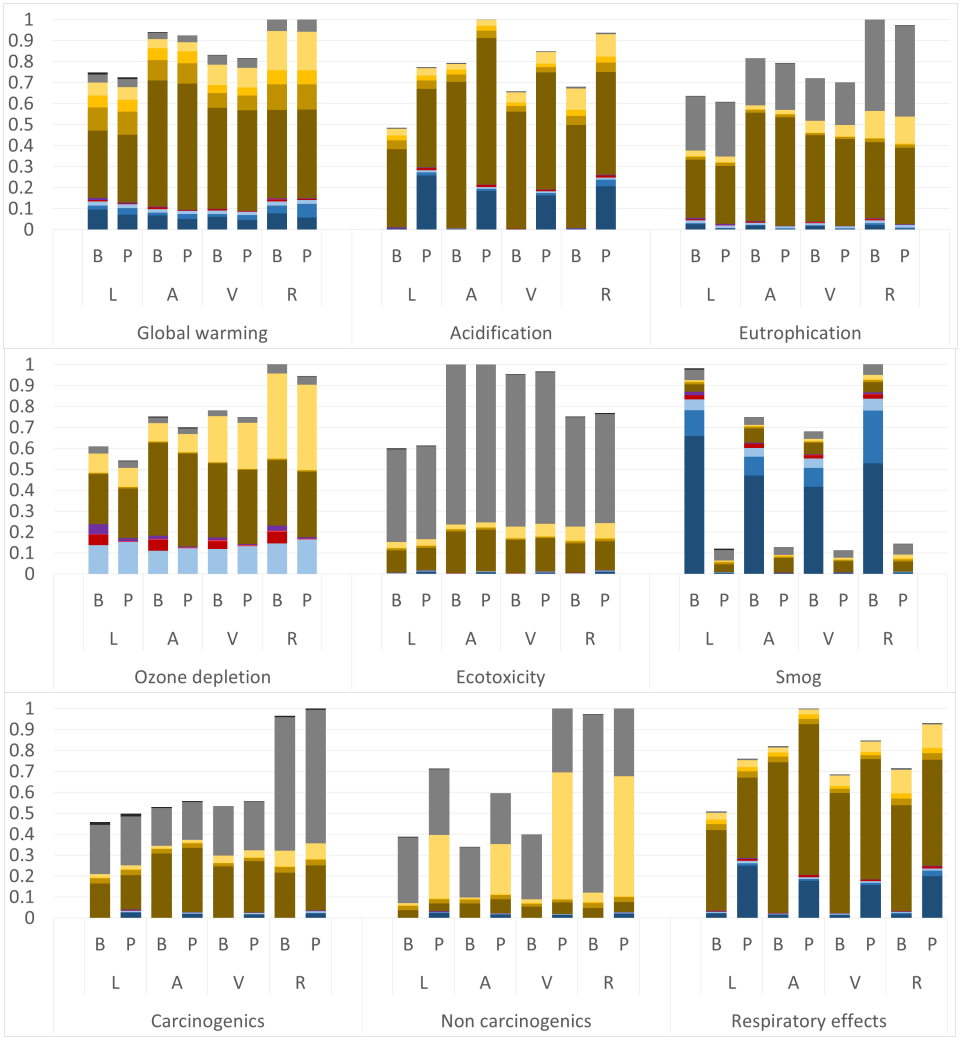
Figure 13 shows the comparative environmental and human health impacts resulting from hysterectomies using (1) standard medical products containing petroleum-based plastics and (2) medical products with biopolymers substituted. For each impact category, the results are normalized to the hysterectomy with the greatest overall impact when considering both base-case and biopolymer substitution scenarios. Because the impact categories are normalized for comparative purposes, the generated values may not necessarily reflect the overall magnitude of impact for individual impact categories.

The use of biopolymers in surgical devices is preferable by a small margin in several impact categories which include acidification, carcinogenics, non-carcinogenics, respiratory effects, and ecotoxicity as shown in Figure 13. Because the manufacturing of petroleum-based plastics is associated with considerable human health impacts, the substitution of manufactured biopolymers for manufactured petroleum-based plastics results in the reduction of adverse human health impacts. However, medical devices with petroleum-based plastics that do not include any quantity of biopolymers perform better in several other impact categories. These impact categories include global warming, eutrophication, ozone depletion, and smog. While the utilization of biopolymers offers human health benefits, the agricultural activities associated with manufacturing biopolymers exacerbate a number of environmental impacts. Significant agricultural activities are associated with manufacturing biopolymers, where these agricultural activities exacerbate impacts related to global warming, eutrophication, ozone depletion, and smog. The relatively high increases for the impact categories smog and ozone depletion are due

to the emission of ozone-depleting substances during PLA manufacturing. On the other hand, guayule-derived latex and thermoplastic starch are correlated with much lower levels of ozone-depleting substances during their associated manufacturing processes.

The production of woven cotton requires agricultural inputs, which is coupled with significant acidification and ecotoxicity impacts that result from fertilizer inputs. Because higher quantities of cotton were used in abdominal hysterectomies, acidification impacts and ecotoxicity impacts for abdominal hysterectomies were higher than robotic, laparoscopic, and vaginal hysterectomies. Figure 13 shows that most environmental and human health impacts were driven by the manufacturing of woven cotton.

In terms of analyzed mass, MSW waste was more than two orders of magnitude greater than that of RMW waste. Hence, the results reflect overall impacts resulting from hysterectomies as opposed to a comparison of MSW and RMW on an equivalent weight-basis. It should be noted, however, that on a per-weight basis, many impact categories favor that of MSW as opposed to RMW which, is not demonstrated in the results. RMW results in greater impacts because of the additional processes (e.g., autoclaving, incineration) required to render RMW suitable for landfilling.



Production	
Polypropylene **or** PLA	
Soft Plastic **or** PLA	
Polyisoprene **or** PLA	
Nitrile **or** Guayule-Derived Latex	
Neoprene **or** Guayule-Derived Latex	
Cardboard **or** Thermo-Plastic Starch	
Cotton[1]	
PVC[1]	
Hard Plastic[1]	
Other Materials[12]	

EOL	
MSW	
RMW	

B	Biopolymers Substituted
P	Petroleum-Based Plastics
L	Laparoscopic
A	Abdominal
V	Vaginal
R	Robotic

[1]Non Substituted Material

[2]Includes Polystyrene, Steel, Aluminum, Rubber, Paper, Glass, Wood, HDPE, and Polyurethane. All of these materials composed less than 2% (by weight) of Magee's total analyzed waste stream.

EOL: End-of-Life; MSW: Material Solid Waste; RMW: Regulated Medical Waste

Figure 13. Normalized TRACI Impacts for Medical Products Containing Petroleum-Based Plastics versus Medical Products Potentially Containing Biopolymers Used in Hysterectomies.

Using results from the 2^3 factorial design experiment, Figure 14 shows the relative increase or decrease in all impact categories from various combinations of biopolymer substitutions. The error bars in Figure 14 show the most significant increase or decrease for all impact categories using values generated from the 2^3 factorial design experiment. The increase of impacts related to global warming, eutrophication, ozone depletion, and smog resulted when PLA, guayule-derived latex, and thermoplastic starch were substituted for typically used materials. The increase of acidification-related impacts resulted when thermoplastic starch was substituted for cardboard. The increase of ecotoxicity related impacts resulted when PLA and guayule-derived latex were substituted for typically used materials. Conversely, the decrease of impacts related to carcinogenics, non-carcinogenics, and respiratory effects resulted when PLA, guayule-derived latex, and thermoplastic starch were substituted for petroleum-based materials. The substitution of biopolymers for petroleum-based plastics increased smog-related impacts by approximately 900% for laparoscopic and robotic hysterectomies, and increased ozone depletion-related impacts by approximately 125% for laparoscopic and robotic hysterectomies.

Table 6 through Table 14 in the supplementary information display the design of experiments (DOE) results for all nine impact categories.

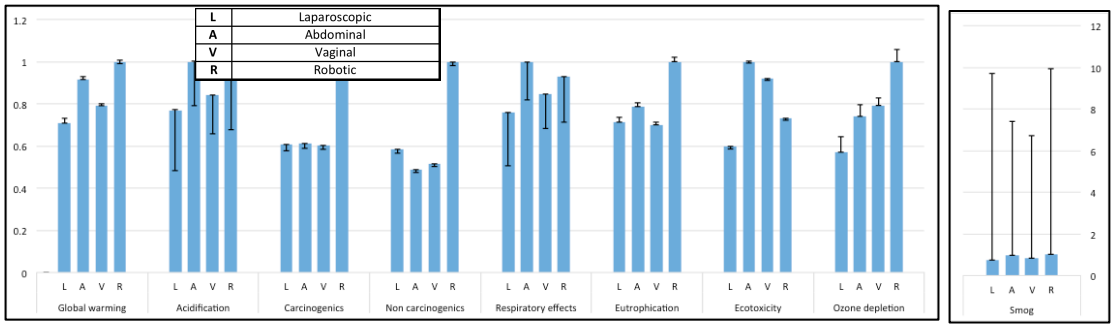
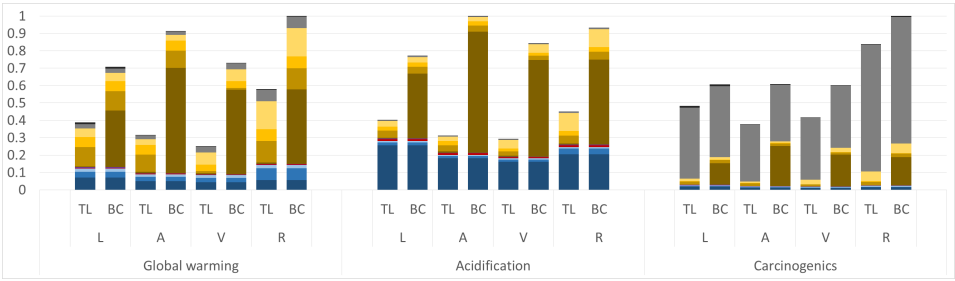


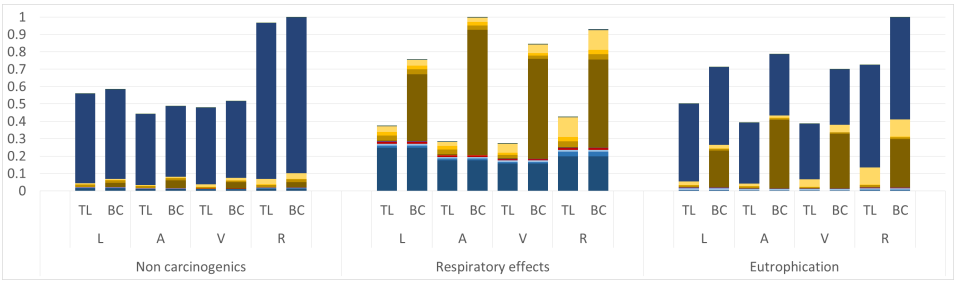
Figure 14. Variability/Percent Increase or Decrease Resulting from Biopolymer Substitutions Using Values Generated from 2^3 Factorial Design Experiment.

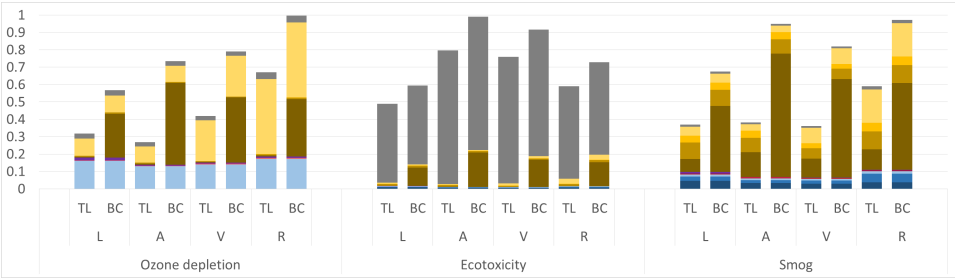
(Caption Text) The error bars in Figure 14 show the most significant increase or decrease for all impact categories using values generated from the 2^3 factorial design experiment.

Figure 15 shows the environmental and human health impacts associated with laundering reusable cotton products used in the four hysterectomies. The columns labeled TL show the environmental and human health impacts that result when reusable cotton products are laundered. The columns labeled BC show the base-case results that do not include any laundering of cotton products. The laundering of reusable cotton products resulted in an overall net decrease of at least one order of magnitude in eight of the nine of the TRACI impact categories. The remaining TRACI impact category, smog, was still associated with approximately a 50% reduction when reusable cotton products were laundered. The cultivation and manufacturing of woven-cotton requires significant amounts of energy and water; where, the quantities of energy and water for cultivation and manufacturing of woven-cotton outweigh the

quantities of energy and water used to launder reusable cotton products. The laundering of reusable cotton products was also preferable to disposing cotton in all nine respective TRACI impact categories. Similar reusable cotton products have been shown to have a lifespan of over 50 washes (Cartwright et al., 2011); which, would reduce MSW from reusable cotton products by approximately 98%.







Production	
Polypropylene	
Soft Plastic	
Polyisoprene	
Nitrile	
Neoprene	
Cardboard	
Reusable Cotton	
Cotton	
PVC	
Hard Plastic	
Other Materials[1]	

EOL	
MSW	
RMW	

TL	Laundering of Reusable Cotton
BC	Base Case (No Laundering)
L	Laparoscopic
A	Abdominal
V	Vaginal
R	Robotic

[1]Includes Polystyrene, Steel, Aluminum, Rubber, Paper, Glass, Wood, HDPE, and Polyurethane. All of these materials composed less than 2% (by weight) of Magee's total analyzed waste stream.

EOL: End-of-Life; MSW: Material Solid Waste; RMW: Regulated Medical Waste

Figure 15. Life Cycle Impacts of Disposable Medical Products Used in Hysterectomies With and Without Laundering of Cotton Products.

4. Discussion

The integration of biopolymers into medical products is correlated with reductions in carcinogenic impacts, non-carcinogenic impacts, and respiratory effects. However, the significant agricultural inputs associated with manufacturing biopolymers exacerbates environmental impacts of products and devices made out of biopolymers. The results showed that the PLA and guayule-derived latex substitutions resulted in significant smog-related impacts. Both PLA and guayule-derived latex have smog-related life-cycle impact factors that are at least 40 times greater than that of their respective substituted plastic (e.g., LDPE for polypropylene, guayule-derived latex for polyisoprene). The substitution of polypropylene for PLA resulted in the most significant smog-related impacts, where PLA has a smog life-cycle impact factor that is more than 140 times greater than that of polypropylene. Hence, due to the significant agricultural inputs associated with cultivating biopolymers and their corresponding high life-cycle impact factors, the substitution of biopolymers exacerbated smog-related impacts. If the biopolymers are cultivated in a locale with high-levels of existing smog (e.g., urban areas), the use of biopolymers is not necessarily favorable. On the other hand, if the biopolymers are

cultivated in a locale with low-levels of existing smog (e.g., rural areas), the use of biopolymers is potentially favorable when considering smog-related impacts.

When utilized as a single-use product, cotton was found to be a significant contributor of environmental effects. This result is in-line with other contemporary environmental assessments of medical devices, products, and/or services (Campion et al., 2015; Unger & Landis, 2014). These environmental effects can effectively be reduced through cotton laundering services, and the strategic use of suitable cotton-alternatives that have lower environmental footprints. A study by the authors showed that onsite healthcare cleaning processes should be efficiently deployed to maximize environmental benefits (Unger & Landis, 2014). The efficient deployment of healthcare cleaning processes can be achieved by minimizing the use of detergents, water, and energy. Efficient cleaning processes can also be achieved by maximizing the number of medical products within the cleaning equipment. The efficient deployment of laundering services also typically results in lower economic costs incurred by the hospital. A review article that examined the economic costs of reusable cotton gowns and cotton drapes found that reusable gowns and drapes were also less expensive than disposable gowns and drapes; where, reusable gowns ranged anywhere from $8 to $16 in total life-cycle costs, and disposable gowns ranged anywhere from $9 to $33 in total life-cycle costs (Overcash, 2012a).

Effective composting of biopolymers used in medical products would decrease environmental and human health impacts resulting from RMW and MSW. Primary concerns with composting medical waste include existing regulatory barriers associated with composting medical waste, as well as the necessary life-cycle processes and labor required for composting.

For example, implementing a composting waste stream at a hospital would require: healthcare personnel to distinguish compostable from non-compostable products; consistent upkeep and maintenance of composting bins and equipment to ensure their sterility in medical environment; and, disassembly of medical products that are only partially composed of compostable material before those products enter a composting stream. Despite these concerns, composting would decrease environmental and human health impacts because composting provides an opportunity to process wastes with fewer harmful emissions than landfill, while still retaining nutrients and value in the composted waste.

While the increased use of PLA, guayule-derived latex, and thermoplastic starch result in varying environmental and human health impacts, the reuse of cotton products results in net decreases of human health and environmental impacts. Therefore, improvements to life-cycle environmental impacts can be achieved when laundering reusable cotton healthcare products as opposed to treating them as single-use disposable products.

5. Supplementary Information

a. 2^3 Factorial Design Experiment

Table 6 through Table 14 shows the results for the two-level factorial design. The standard column represents each calculated scenario. Regarding the Main Effects column, 1 designates a particular biopolymer being substituted for an original material, and -1 designates a particular biopolymer not being substituted for an original material. In addition, the P represents PLA, G represents guayule-derived latex, and T represents thermoplastic starch. The column furthest to the right is designated by Y_1 and represents the impact factor for each respective scenario.

Table 6. Two-Level Factorial Design Table for Global Warming.

	Standard	Main Effects			Y1 (kg CO2 eq)
		P	G	T	
Laparoscopic	1	-1	-1	-1	32.13
	2	1	-1	-1	33.07
	3	-1	1	-1	32.51
	4	-1	-1	1	31.89
	5	1	1	-1	31.77
	6	1	-1	1	32.85

	7	-1	1	1	32.77
	8	1	1	1	31.93
Abdominal	1	-1	-1	-1	41.18
	2	1	-1	-1	41.85
	3	-1	1	-1	41.45
	4	-1	-1	1	41.09
	5	1	1	-1	40.85
	6	1	-1	1	41.77
	7	-1	1	1	41.64
	8	1	1	1	41.11
Vaginal	1	-1	-1	-1	35.56
	2	1	-1	-1	36.07
	3	-1	1	-1	35.74
	4	-1	-1	1	35.46
	5	1	1	-1	35.25
	6	1	-1	1	36.01
	7	-1	1	1	36.10
	8	1	1	1	35.47
Robotic	1	-1	-1	-1	45.10
	2	1	-1	-1	45.08
	3	-1	1	-1	44.60
	4	-1	-1	1	44.91

	5	1	1	-1	44.66
	6	1	-1	1	44.96
	7	-1	1	1	45.33
	8	1	1	1	44.93

Table 7. Two-Level Factorial Design Table for Acidification.

	Standard	**Main Effects**			**Y1 (H+ moles eq)**
		P	**G**	**T**	
Laparoscopic	1	-1	-1	-1	14.50
	2	1	-1	-1	9.11
	3	-1	1	-1	9.43
	4	-1	-1	1	14.17
	5	1	1	-1	14.54
	6	1	-1	1	9.08
	7	-1	1	1	9.45
	8	1	1	1	14.16
Abdominal	1	-1	-1	-1	18.84
	2	1	-1	-1	14.92
	3	-1	1	-1	15.23
	4	-1	-1	1	18.53
	5	1	1	-1	18.87

	6	1	-1	1	14.91
	7	-1	1	1	15.24
	8	1	1	1	18.53
Vaginal	1	-1	-1	-1	15.87
	2	1	-1	-1	12.37
	3	-1	1	-1	12.64
	4	-1	-1	1	15.60
	5	1	1	-1	15.89
	6	1	-1	1	12.36
	7	-1	1	1	12.65
	8	1	1	1	15.60
Robotic	1	-1	-1	-1	17.53
	2	1	-1	-1	12.77
	3	-1	1	-1	13.13
	4	-1	-1	1	17.17
	5	1	1	-1	17.56
	6	1	-1	1	12.75
	7	-1	1	1	13.15
	8	1	1	1	17.17

Table 8. Two-Level Factorial Design Table for Carcinogenics.

	Standard	Main Effects			Y1 (kg benzene eq)
		P	G	T	
Laparoscopic	1	-1	-1	-1	0.16
	2	1	-1	-1	0.14
	3	-1	1	-1	0.21
	4	-1	-1	1	0.19
	5	1	1	-1	0.25
	6	1	-1	1	0.14
	7	-1	1	1	0.21
	8	1	1	1	0.19
Abdominal	1	-1	-1	-1	0.17
	2	1	-1	-1	0.17
	3	-1	1	-1	0.22
	4	-1	-1	1	0.20
	5	1	1	-1	0.25
	6	1	-1	1	0.17
	7	-1	1	1	0.23
	8	1	1	1	0.20
Vaginal	1	-1	-1	-1	0.17
	2	1	-1	-1	0.17

	3	-1	1	-1	0.22
	4	-1	-1	1	0.19
	5	1	1	-1	0.25
	6	1	-1	1	0.17
	7	-1	1	1	0.23
	8	1	1	1	0.19
Robotic	1	-1	-1	-1	0.31
	2	1	-1	-1	0.30
	3	-1	1	-1	0.37
	4	-1	-1	1	0.34
	5	1	1	-1	0.41
	6	1	-1	1	0.30
	7	-1	1	1	0.39
	8	1	1	1	0.34

Table 9. Two-Level Factorial Design Table for Non-Carcinogenics.

	Standard	**Main Effects**			**Y1 (kg toluene eq)**
		P	**G**	**T**	
Laparoscopic	1	-1	-1	-1	3224.64
	2	1	-1	-1	2981.08
	3	-1	1	-1	5170.67

	4	-1	-1	1	4451.52
	5	1	1	-1	6579.76
	6	1	-1	1	3011.76
	7	-1	1	1	5140.00
	8	1	1	1	4451.52
Abdominal	1	-1	-1	-1	2762.08
	2	1	-1	-1	2596.51
	3	-1	1	-1	4484.04
	4	-1	-1	1	3637.23
	5	1	1	-1	5502.89
	6	1	-1	1	2607.45
	7	-1	1	1	4638.12
	8	1	1	1	3637.23
Vaginal	1	-1	-1	-1	3191.58
	2	1	-1	-1	3042.32
	3	-1	1	-1	4882.86
	4	-1	-1	1	3985.36
	5	1	1	-1	5809.58
	6	1	-1	1	3050.48
	7	-1	1	1	5040.69
	8	1	1	1	3985.36
tic	1	-1	-1	-1	7682.40

	2	1	-1	-1	7470.75
	3	-1	1	-1	9820.54
	4	-1	-1	1	8942.99
	5	1	1	-1	11260.13
	6	1	-1	1	7487.07
	7	-1	1	1	10269.75
	8	1	1	1	8942.98

Table 10. Two-Level Factorial Design Table for Respiratory Effects.

	Standard	**Main Effects**			**Y1 (kg PM2.5 eq)**
		P	**G**	**T**	
Laparoscopic	1	-1	-1	-1	0.07
	2	1	-1	-1	0.05
	3	-1	1	-1	0.05
	4	-1	-1	1	0.07
	5	1	1	-1	0.07
	6	1	-1	1	0.05
	7	-1	1	1	0.05
	8	1	1	1	0.07
Abdominal	1	-1	-1	-1	0.09
	2	1	-1	-1	0.07

	3	-1	1	-1	0.08
	4	-1	-1	1	0.09
	5	1	1	-1	0.09
	6	1	-1	1	0.07
	7	-1	1	1	0.08
	8	1	1	1	0.09
Vaginal	1	-1	-1	-1	0.08
	2	1	-1	-1	0.06
	3	-1	1	-1	0.06
	4	-1	-1	1	0.08
	5	1	1	-1	0.08
	6	1	-1	1	0.06
	7	-1	1	1	0.06
	8	1	1	1	0.08
Robotic	1	-1	-1	-1	0.08
	2	1	-1	-1	0.06
	3	-1	1	-1	0.07
	4	-1	-1	1	0.08
	5	1	1	-1	0.08
	6	1	-1	1	0.06
	7	-1	1	1	0.07
	8	1	1	1	0.08

Table 11. Two-Level Factorial Design Table for Eutrophication.

	Standard	Main Effects			Y1 (kg N eq)
		P	G	T	
Laparoscopic	1	-1	-1	-1	0.11
	2	1	-1	-1	0.12
	3	-1	1	-1	0.12
	4	-1	-1	1	0.17
	5	1	1	-1	0.17
	6	1	-1	1	0.12
	7	-1	1	1	0.12
	8	1	1	1	0.17
Abdominal	1	-1	-1	-1	0.15
	2	1	-1	-1	0.15
	3	-1	1	-1	0.16
	4	-1	-1	1	0.19
	5	1	1	-1	0.19
	6	1	-1	1	0.15
	7	-1	1	1	0.16
	8	1	1	1	0.19
Vaginal	1	-1	-1	-1	0.13

	2	1	-1	-1	0.13
	3	-1	1	-1	0.14
	4	-1	-1	1	0.17
	5	1	1	-1	0.17
	6	1	-1	1	0.13
	7	-1	1	1	0.15
	8	1	1	1	0.17
Robotic	1	-1	-1	-1	0.18
	2	1	-1	-1	0.19
	3	-1	1	-1	0.19
	4	-1	-1	1	0.24
	5	1	1	-1	0.24
	6	1	-1	1	0.19
	7	-1	1	1	0.21
	8	1	1	1	0.24

Table 12. Two-Level Factorial Design Table for Ozone Depletion.

	Standard	Main Effects			Y1 (kg CFC-11)
		P	G	T	
Laparoscopic	1	-1	-1	-1	0.0000007
	2	1	-1	-1	0.0000008
	3	-1	1	-1	0.0000007
	4	-1	-1	1	0.0000007
	5	1	1	-1	0.0000007
	6	1	-1	1	0.0000007
	7	-1	1	1	0.0000007
	8	1	1	1	0.0000007
Abdominal	1	-1	-1	-1	0.0000009
	2	1	-1	-1	0.0000010
	3	-1	1	-1	0.0000009
	4	-1	-1	1	0.0000009
	5	1	1	-1	0.0000009
	6	1	-1	1	0.0000009
	7	-1	1	1	0.0000009
	8	1	1	1	0.0000009
Vaginal	1	-1	-1	-1	0.0000010
	2	1	-1	-1	0.0000010

	3	-1	1	-1	0.0000010
	4	-1	-1	1	0.0000010
	5	1	1	-1	0.0000010
	6	1	-1	1	0.0000010
	7	-1	1	1	0.0000010
	8	1	1	1	0.0000010
Robotic	1	-1	-1	-1	0.0000012
	2	1	-1	-1	0.0000013
	3	-1	1	-1	0.0000012
	4	-1	-1	1	0.0000013
	5	1	1	-1	0.0000012
	6	1	-1	1	0.0000013
	7	-1	1	1	0.0000012
	8	1	1	1	0.0000013

Table 13. Two-Level Factorial Design Table for Ecotoxicity.

	Standard	**Main Effects**			**Y1 (kg 2,4-D)**
		P	**G**	**T**	
Laparoscopic	1	-1	-1	-1	240.22
	2	1	-1	-1	235.23
	3	-1	1	-1	237.31

	4	-1	-1	1	245.03
	5	1	1	-1	246.26
	6	1	-1	1	235.65
	7	-1	1	1	236.92
	8	1	1	1	245.07
Abdominal	1	-1	-1	-1	407.27
	2	1	-1	-1	403.99
	3	-1	1	-1	405.50
	4	-1	-1	1	410.85
	5	1	1	-1	412.05
	6	1	-1	1	404.14
	7	-1	1	1	406.14
	8	1	1	1	410.86
Vaginal	1	-1	-1	-1	374.23
	2	1	-1	-1	371.18
	3	-1	1	-1	372.75
	4	-1	-1	1	377.37
	5	1	1	-1	378.72
	6	1	-1	1	371.29
	7	-1	1	1	373.62
	8	1	1	1	377.38
tic	1	-1	-1	-1	295.05

	2	1	-1	-1	290.45
	3	-1	1	-1	292.46
	4	-1	-1	1	300.06
	5	1	1	-1	301.62
	6	1	-1	1	290.67
	7	-1	1	1	294.75
	8	1	1	1	300.08

Table 14. Two-Level Factorial Design Table for Smog.

	Standard	**Main Effects**			**Y1 (kg CFC-11)**
		P	**G**	**T**	
Laparoscopic	1	-1	-1	-1	0.14
	2	1	-1	-1	1.15
	3	-1	1	-1	1.04
	4	-1	-1	1	0.17
	5	1	1	-1	0.10
	6	1	-1	1	1.13
	7	-1	1	1	1.07
	8	1	1	1	0.17
Abdominal	1	-1	-1	-1	0.15
	2	1	-1	-1	0.88

	3	-1	1	-1	0.80
	4	-1	-1	1	0.18
	5	1	1	-1	0.12
	6	1	-1	1	0.87
	7	-1	1	1	0.81
	8	1	1	1	0.19
Vaginal	1	-1	-1	-1	0.13
	2	1	-1	-1	0.79
	3	-1	1	-1	0.72
	4	-1	-1	1	0.17
	5	1	1	-1	0.10
	6	1	-1	1	0.79
	7	-1	1	1	0.73
	8	1	1	1	0.17
Robotic	1	-1	-1	-1	0.17
	2	1	-1	-1	1.18
	3	-1	1	-1	1.07
	4	-1	-1	1	0.21
	5	1	1	-1	0.12
	6	1	-1	1	1.16
	7	-1	1	1	1.11
	8	1	1	1	0.21

CHAPTER 5

EVALUATING QUANTIFIABLE METRICS FOR HOSPITAL GREEN CHECKLISTS

This chapter addresses the dissertation research question 3) synthesize and prioritize the salient conclusions from the first two research questions, as well as from recent studies focusing on the environmental impacts of various medical products and/or services for the use of hospital administrators and employees.

1. Introduction

An increasing number of hospitals are placing a higher emphasis on sustainability and tracking the success of their sustainability initiatives. The foci of these sustainability initiatives include (but are not limited to) a hospital's: built environment, energy efficiency, water efficiency, green purchasing, waste diversion strategies, healthy food purchasing and disposal, and impacts from employee and patient behaviors and emerging technologies (Janet, 2013; Kaplan et al., 2012; Kwakye et al., 2011). These strategies were previously deployed with little or no scientific validation of their environmental impacts, but these initiatives and their associated environmental, human-health, and economic impacts are increasingly being assessed by peer-reviewed publications. The publications in this field range in foci and scope; where, some of these studies have relatively small scopes and focus on individual items used in hospitals (e.g., surgical gowns, laparotomy pads) (Kümmerer et al., 1996; Overcash, 2012a). Other studies have widened their scope beyond textiles to analyze more complex medical equipment used in hospitals (Matthew Eckelman, Margo Mosher, Andres Gonzalez, & Jodi

Sherman, 2012; Forbes McGain, McAlister, McGavin, & Story, 2012). Larger-scoped studies have examined the environmental impacts of hospital operating rooms, showing that multiple components of medical procedures have significant impacts, including: facility systems, healthcare products, and procedures (Campion et al., 2012a; Thiel et al., 2014).

Beyond peer-reviewed publications, organizations such as Practice GreenHealth, Health Care Without Harm, Hospitals for a Healthy Environment, Kaiser Permanente and The Collaborative for Health and the Environment have come to forefront as leading groups in the sustainable healthcare movement. Noteworthy achievements of Health Care Without Harm include the closing of over 5,000 medical incinerators, the elimination of mercury thermometers in US hospitals, and the establishment of a health-based green building system for hospitals (HCWH, 2015). With a membership exceeding 1,300, Practice Greenhealth is the US's leading membership and networking organization for institutions in the healthcare community that have made a commitment to sustainable, environmentally preferable practices (PG, 2015c). Practice Greenhealth has published the "Greenhealth Eco-Checklist for Operations" which gives healthcare personnel a wide array criteria (e.g., education, waste management and reduction, transportation operations) intended to provide guidance on the sustainability of a hospital's medical products and services (PG, 2015b). In 2015, Practice Greenhealth reported that its top-performing member institutions, who presumably used some form of Practice Greenhealth's Eco-Checklist for Operations, saved an average of 338 tons of waste, 901 thousand gallons of water, and 1.85% of their energy use on an annual basis (PG, 2015a). Kaiser Permanente has also published the Generation II Medical Sustainability Scorecard, which also reports a set of criteria

(e.g., chemical management, natural resources/waste) that similarly validates the sustainability of a hospital's medical devices and services (KP, 2010).

While these studies, organizations, and checklists have helped to advance sustainability in healthcare, the healthcare industry still lacks a framework to effectively inform decision making and *quantitatively* assess the success of sustainability initiatives for medical devices and services (Kwakye, Pronovost, & Makary, 2010). Several studies have already expressed the need for better ways to quantify sustainable healthcare practices (Daschner & Dettenkofer, 1997; Karlsson & Pigretti-Ohman, 2005; Kreisberg, 2007; Shanks, 2009; Jodi Sherman & Ryan, 2010). To address these needs, this research compared the cradle-to-grave environmental and economic impacts of some of the most common recommendations from checklists: reusable versus disposable medical products, and changes to common medical services. Several changes to medical services include streamlining custom packs, reducing medical waste, increasing utilization of reprocessed medical products, and increasing biopolymer content in medical products.

Salient results and conclusions from recent studies focusing on the environmental and economic impacts of various reusable versus disposable medical products and different medical services were synthesized and prioritized. All relevant results related to environmental and economic impacts of reusable versus disposable medical products and the analyzed medical services were also correlated with existing sustainable checklists. The recommended practices of each sustainable healthcare checklist were first evaluated based on their encapsulation of cradle-to-grave impacts; where, the evaluation of cradle-to-grave impacts contributes to the validation

of sustainable healthcare checklists and their aim to increase sustainability at healthcare institutions. Where applicable, recommendations for improvement of sustainable healthcare checklists were made based on cradle-to-grave environmental impact results synthesized from this study. One aim of this research is for hospital employees and administrators to utilize in order to make more informed decisions about the sustainability of their products and services.

2. Methods

This research collected, characterized, and normalized recent studies focusing on the environmental and economic impacts resulting from the use of reusable medical products, comparable disposable medical products, and a series of medical services (Adler et al., 2005; Campion et al., 2012b; Campion et al., 2015; M. Eckelman et al., 2012; Ibbotson, Dettmer, Kara, & Herrmann, 2013; F. McGain, Sussex, O'Toole, & Story, 2011; Overcash, 2012a; Sorensen & Wenzel, 2014; Unger et al., 2015; Unger & Landis, 2014, 2015; Zhao et al., 2009). The disposable and/or reusable medical products included a: bedpan, central venous catheter insertion kit, dental bur, gown, laparoscopic cholecystectomy instruments, laryngeal mask airway, scissors, trocar, and veress cannula. The assessed medical services included: custom packs used in vaginal deliveries, medical waste treatments, infant delivery, reprocessed products, and products with increased biopolymer content. All studies used life cycle assessment (LCA) and/or life cycle cost assessment (LCCA) to evaluate the environmental and economic impacts attributed to the medical products and services. LCA is a method used to assess environmental impacts associated with the stages of a product's life and is defined by ISO 14040 standards (ISO, 2006c).

The stages of a product's life include: raw material extraction, materials processing, manufacture, distribution, use, repair and maintenance, and disposal or recycling (ISO, 2006c). LCCA is a method used to calculate the economic costs associated with all stages of a product's life. Once the studies were collected, they were then characterized based on their evaluated impact categories. Table 15 shows the peer-reviewed studies that provided reusable versus disposable medical products data for this research. All studies use some form of LCA to assess each product's comparative life-cycle environmental impacts; with respect to the product being used as a single-use disposable, versus an alternative reusable products that fulfills the same function as the disposable. Certain studies expanded their analysis to economic impacts, which were quantified through cradle-to-grave LCCA in some instances. All data related to environmental and economic impacts quantified by these studies was collected. The respective system boundaries of the analyzed studies differed in some instances. For example, the laryngeal mask airway study included labor in its system boundary, while all of the other studies did not account for labor in their respective system boundaries. The system boundary discrepancies were not adjusted due to lack of data.

Table 15. Analyzed Medical Products.

Products	Reuse Instances	Disposable Weight (grams)	Reusable Weight (grams)	LCA Method-ology	Cradle-to-Gate	Use-Phase	End-of-Life	Citation
Bedpan	1,000	474	1,210	SimaPro 7.3.2,	Yes	Yes	Yes[3]	(Sorensen & Wenzel, 2014)
Central venous catheter insertion kit	300	N/A	N/A	SimaPro	Yes	No	Yes	(Forbes McGain et al., 2012)
Dental bur	30	1.05*	1.05*	SimaPro; ISO 14040	Yes	Yes	Yes	(Unger & Landis, 2014)
Gowns	50 - 100	137-243	287-546	N/A	N/A	N/A	N/A	(Overcash, 2012a)
Laparo-scopic cholecy-stectomy instru-ments	N/A	N/A	N/A	N/A	No	Yes	No	(Adler et al., 2005)
Laryngeal mask airway	40	42.35	43.26	SimaPro 7.3.2; ISO 14040	Yes	Yes	Yes[3]	(M. Eckelman et al., 2012)
Scissors[1]	N/A	N/A	N/A	N/A	No	Yes	No	(Adler et al., 2005)
Scissors[2]	4,500	N/A	N/A	SimaPro; ISO 14040	Yes	Yes	Yes	(Ibbotson et al., 2013)
Trocar	N/A	N/A	N/A	N/A	No	Yes	No	(Adler et al., 2005)
Veress cannula	N/A	N/A	N/A	N/A	No	Yes	No	(Adler et al., 2005)

N/A Not available because the associated data were not published in the associated study

* Disposable dental bur and reusable dental bur are identical

[1] LCA of scissors performed by Adler et. al, 2005

[2] LCA of scissors performed by Ibbotson et al., 2013

[3] Recycling was used as end-of-life scenario

The collection and synthesization of reusable versus disposable medical product data was characterized by four impact categories: greenhouse gases (GHG), energy use, water consumption, and economic impacts. The following characterization factors were used: GHG – kg CO_2eq; Energy – kWh; Water – liters; and, economic impacts – 2015 United States (US) dollars ($). GHG were reported in terms of all cradle-to-gate processes that drive kg CO_2eq values for each respective medical product. Similarly, economic impacts were reported in terms of all cradle-to-gate processes that drive economic cost values for each respective medical product. Energy and water metrics were reported as the energy associated with cleaning medical products, as well as the water associated with cleaning medical products. Cleaning typically included life-cycle processes associated with utilizing an autoclave, ultrasonic, cleaning solutions, and/or manual scrubbing.

The results from the utilized studies were normalized to one instance of use for all medical products in order to generate a one-to-one comparison of medical products. For example, the results from the LMA study were reported in terms of kg CO_2eq for the entire usable life-cycle of a reusable laryngeal mask airway; which, was then divided by 40 (i.e., reuse instances for the laryngeal mask airway) to generate the kgCO_2eq for one instance of use for a reusable laryngeal mask airway. Many of the studies utilized similar life cycle assessment tools, including ISO 14040 standards and SimaPro life cycle assessment software. The life cycle impact assessment methodologies utilized by the studies differed in some instances (e.g., ReCiPe, TRACI), but the values were always reported in the same (or mathematically convertible) units. For example, MJ were converted to kWh for the gowns and scissors studies.

Once the medical product data were collected, the economic and environmental results were then organized to compare products individually without any time-based factors. For example, of seven products that were examined in a study performed by the authors, it was found that the ligasure, a product used for vessel sealing, offered the greatest economic savings when it was reprocessed; however, the ligasure did not correlate with significant economic savings on an annual basis because of its relatively low annual utilization rate (Unger & Landis, 2015). The one-to-one analysis of medical products without time-based factors gives hospital personnel the ability to scale the results up to match their own hospital's specifications. Additionally, economic and environmental savings are dependent on the temporal utilization of a product or service.

Economic results were normalized to be in terms of 2015 $USD. The price of each product was converted to 2015 values using producer price index industry data provided by the Bureau of Labor Statistics, where specific values were obtained from their industry and product subset entitled "Medical equipment & supplies mfg" (BLS, 2015). The converted present-day-values were then converted from their respective currencies (e.g., Australian dollars, Euros) to US dollars using foreign currency exchanges rates provided by the US federal reserve (USFR, 2015). The utilized exchange rates were: 1.0393 Australian dollars per US dollar in 2012; 1.3538 Euros per US dollar in 2004; and, 1.3779 Euros per US dollar in 2013 (FR, 2015).

Data related to the GHG associated with several medical services were also collected and normalized on an annual basis. Table 16 shows the analyzed services and their respective citation(s) that provide annual utilization data. Several options for each service were included.

Two options were evaluated for custom packs used in vaginal deliveries, which included the minimum and maximum reported kg CO_2eq values (of a total of 15 analyzed custom packs) for the custom packs study. Five medical waste treatments were included, which were incineration with energy recovery efficiency of 30%, non-incineration with electricity generation from landfill gas, non-incineration with landfill gas ignited on site, incineration with energy recovery efficiency of 15%, and incineration without energy recovery. Two types of infant delivery were evaluated, which included vaginal and cesarean-section delivery. Five options were evaluated for reprocessed products, which included four, three, two, one, and zero reprocessing instances. The values reported for reprocessing reflect a single hospital and its suite of reprocessed products, which included: arthroscopic shavers, deep vein thrombosis compression sleeves, endoscopic trocars, ligasures, pulse oximeters, scissors tips, and ultrasonic scalpels. Products with biopolymer content and products without biopolymer content were also included. The values reported for products with and without biopolymer content reflect the substitution of biopolymers (e.g., polylactic acid, guayule-derived latex) for certain fossil-fuel-based plastics (e.g., polypropylene, low-density polyethylene) in products and products used in hysterectomies at a single hospital.

These services were normalized to represent the annual usage of any given service at a hospital with 161 staffed beds (i.e., an average-sized US hospital) (AHA, 2015). In order to determine the annual utilization of any given service at an average-sized US hospital, the aggregate national utilization of a service was divided by the number of staffed beds (i.e., 161) at an average-sized US hospital.

Table 16. Annual Usage of Analyzed Medical Services.

Service	Annual Utilization an Average-sized US Hospital (unit/hospital-year)	LCA Methodology	Citation(s)
Custom packs used in vaginal deliveries	465 custom packs used	N/A	(Campion et al., 2015) and (Martin, Hamilton, Osterman, Curtin, & Mathews, 2013)
Medical waste treatments	969 tons of waste produced	ISO 14040	(Zhao et al., 2009) and (PG, 2015d)
Infants delivered	692 infants delivered	N/A	(Campion et al., 2012a) and (Martin et al., 2013)
Reprocessed products	N/A[1]	SimaPro 8.0.3.14	(Unger & Landis, 2015)
Products with increased biopolymer content	N/A[2]	SimaPro 8.0.3.14	(Unger et al., 2015)

N/A Not available because the associated data were not published in the associated study

(Caption Text) The number of beds (i.e., 161) at the 'Average-sized US hospital' was calculated by dividing the total number of staffed beds in all US registered hospitals (i.e., 914,513) by the total number of U.S. registered hospitals (i.e., 5,686) (AHA, 2015).

[1] This study examined the environmental impacts of reprocessed products at a single hospital and its associated reprocessing supply chain. Other hospitals have reprocessing supply chains that differ from than of the analyzed hospital in this study, where other hospitals will reprocess different types or numbers of products. Therefore, data regarding the number of reprocessed products at an average-sized US hospital is not available because it would only reflect a single hospital and its use of reprocessing services.

[2] This study examined the environmental impacts of increasing biopolymer content in medical products and products used in hysterectomies. Procedures that are not hysterectomies have different potentials for implementing biopolymers into their utilized medical products and products. Therefore, data regarding the number of products with increased biopolymer content in not available because it would only reflect biopolymers used in hysterectomies and not all hospital procedures and activities.

All data related to environmental and economic impacts were also correlated with existing sustainable checklists, which have been published to aid healthcare workers with prioritizing potential sustainable practices. The three sustainable healthcare checklists that were correlated with results from this study were the: provided checklist in "Advancing Life Cycle Assessment: Perspectives from the Building and Healthcare Industries" (Campion, 2015); Practice Greenhealth Eco-Checklist for Operations (PG, 2015b); and, Kaiser Permanente Generation II Medical Sustainability Scorecard (KP, 2010).

The sustainable healthcare checklists and their recommended practices were validated using the synthesized data from this study. Because a majority of the analyzed reusable medical products, disposable medical products, and medical services encompassed cradle-to-grave

impacts, the recommended practices of each sustainable healthcare checklist were first evaluated based on their understanding of cradle-to-grave impacts. Where applicable, the recommended practices were then augmented based on cradle-to-grave environmental impact results synthesized from this study.

3. Results

a. Reusable versus Disposable Medical Products

i. GHG

Several medical products (e.g., scissors, laryngeal mask airways, and in some instances, dental burs), were found to have lower life-cycle GHGs when used as a reusable as opposed to a single-use disposables, shown in Figure 1. Alternatively, bedpans and central venous catheter insertion kits were found to have greater emissions of GHGs when utilized as reusables as opposed to single-use disposables. This result is likely attributed to significant life-cycle inputs associated with cleaning bedpans and central venous insertion catheter kits. Notably, while scissors are relatively small when compared to the other examined medical products, scissors exhibited the highest emissions of CO_2eq when used as a stainless steel single-use disposable. This occurrence was due to the significant life-cycle inputs associated with manufacturing stainless steel; especially when the manufactured stainless steel was intended for utilization as a disposable.

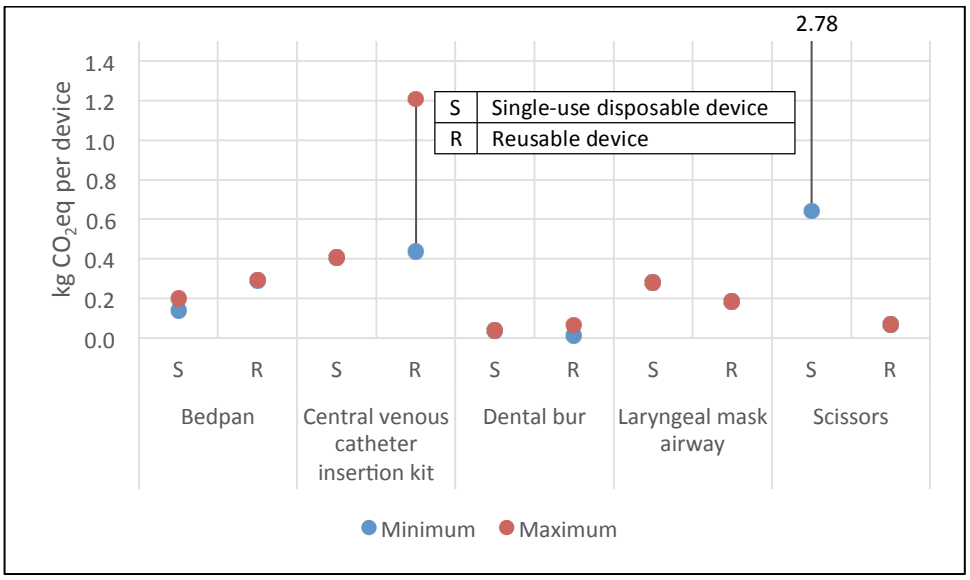


Figure 16. Life-Cycle Greenhouse Gas Emissions for Single-Use versus Reusable Medical Products.

ii. Economics

While certain examined scenarios resulted in greater economic costs associated with reusable medical products, there was no instance where the minimum cost of a reusable product exceeded the minimum cost of the product's corresponding single-use disposable equivalent. Reusable product reviewed were always more affordable than single use products. Figure 17 shows that smaller products were associated with lower economic costs, while larger, more complex products were associated with higher economic costs. In terms of product size, gowns were relatively large compared to the other analyzed products. As such, they exhibited the highest economic costs of the examined products. This result was found to be true for both single-use disposable gowns and reusable gowns.

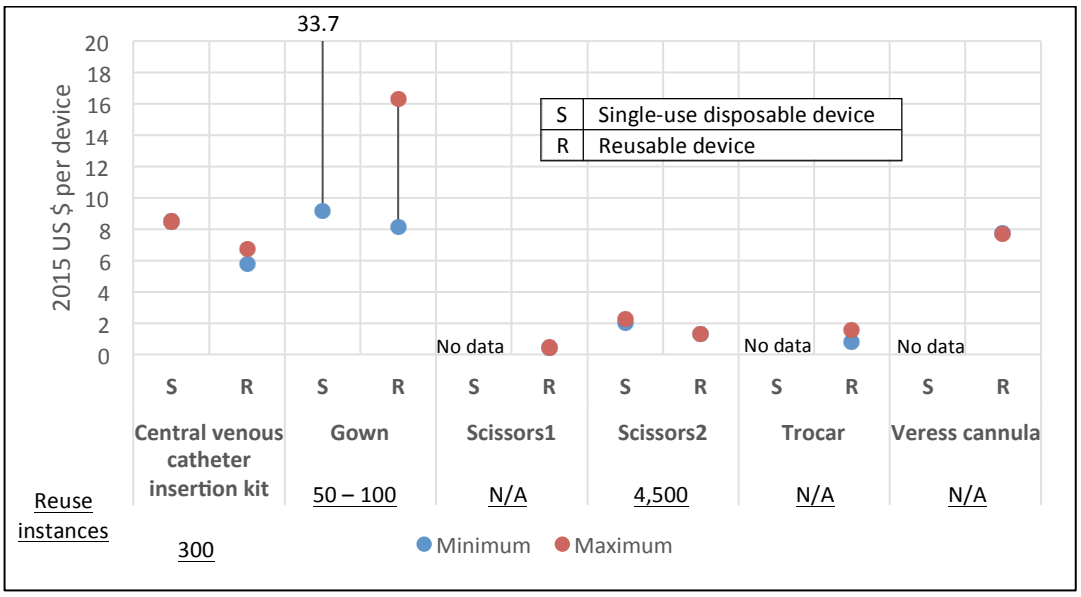


Figure 17. Life-Cycle Economic Costs for Single-Use versus Reusable Medical Products.

(Caption Text) The reusable products exhibit economic costs related to their washing (i.e., water, electricity, detergent) a certain number of instances before eventually being discarded for a new reusable product. The economic costs for the analyzed products are based on differing electricity, water, and product economic costs that were not adjusted for this study.

iii. Energy and Water Associated with Cleaning

Figure 18 shows the energy and water associated with cleaning medical products. Figure 18 shows that energy required for cleaning medical products is lower for smaller (i.e., lower-volume) medical products; and, that energy required for cleaning is comparable for single-use disposable and reusable gowns, and scissors. Figure 18 also shows the liters of water used for cleaning a particular medical product. Similar to economic costs and required energy for cleaning, dental burs required the least amount of water for its associated cleaning processes. This outcome is due to the relatively small size of dental burs and the volume. Laparoscopic

cholecystectomy instruments were associated with highest levels of required water used in cleaning the examined medical product. This result is due the fact that multiple instruments were included in the laparoscopic cholecystectomy instrument analysis; and therefore, the results do not reflect a one-to-one comparison of medical products.

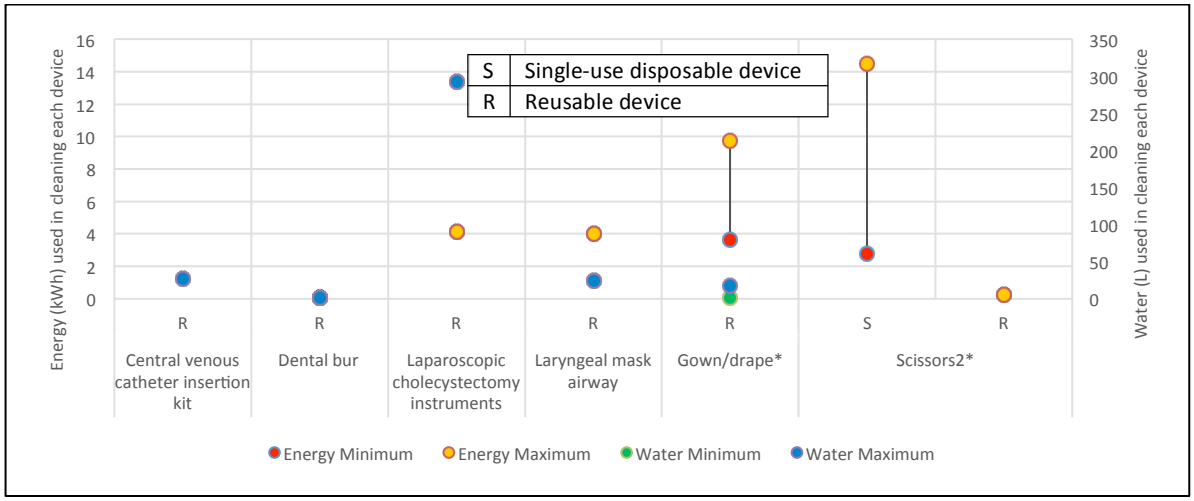


Figure 18. Energy and Water Associated with Cleaning each Medical Product.

(Caption Text) The results for the gown and scissors report lifecycle energy as opposed to energy associated with cleaning. Lifecycle energy represents the energy consumed by all of the processes associated with the raw material extraction, manufacturing, and transport of a medical product.

Table 17 aggregates results from Figure 16 through Figure 18 to compare medical products results for GHG, economics, energy, and water. Cells shaded green are representative as favorable in terms of each column/category (i.e., GHG, economic, energy, and water). Scissors (as studied by Adler et al., 2005, and not Ibbotson et al., 2013) were shown to be favorable with respect to GHG and economics when used as a reusable product as opposed to a

single-use disposable. On the other hand, when used as reusable the central venous catheter insertion kit was found to be less favorable from an economic perspective, and not at all favorable from a GHG perspective.

The cells in the energy and water columns reflect only values based on reusable products, and do not include any values representative of disposable products. These cells reflect only the amount of energy (in kWh) and water (in L) used to clean each product. Larger products will reflect greater utilizations of both energy and water because these cells are not normalized based on a product's size. The dental bur was found to be favorable with respect to GHG, energy, and water. It should be noted that the dental bur's favorability in energy and water does not account and/or normalize for the dental bur's size, which is smaller than any other assessed product.

Table 17. Comparative Environmental Assessment for Reusable versus Single-Use Medical Products.

Products	GHG		Economics		Energy (kWh)		Water (L)	
	Min	Max	Min	Max	Min	Max	Min	Max
Bedpan	1.72	1.74	N/A	N/A	N/A	N/A	N/A	N/A
Central venous catheter insertion kit	1.07	2.98	0.68	0.79	N/A	N/A	27	27
Dental bur	0.35	1.64	N/A	N/A	0.02	0.02	0	0
Gown	N/A	N/A	0.38	0.76	3.61	9.72	0	17
Laparoscopic cholecystectomy instruments	N/A	N/A	N/A	N/A	4.12	4.12	293	293
Laryngeal mask airway	0.65	0.65	N/A	N/A	4.00	4.00	24	25
Scissors[1]	0.04	0.04	0.02	0.02	N/A	N/A	N/A	N/A
Scissors[2]	N/A	N/A	0.59	0.59	0.29	0.29	N/A	N/A
Trocar	N/A	N/A	0.01	0.03	N/A	N/A	N/A	N/A
Veress cannula	N/A	N/A	0.06	0.06	N/A	N/A	N/A	N/A

(Caption Text) The cells in GHG and economics columns are normalized by dividing the reusable value by the single-use disposable value to generate the overall reusability of a products irrespective of the product's size. For example, the bedpan's minimum GHG cell was calculated by dividing the minimum GHG value for the reusable bedpan (i.e., 0.291 $kgCO_2eq$) by the average GHG value for the disposable bedpan (i.e., 0.138 $kgCO_2eq$) to yield a dimensionless value of 2.11. A dimensionless value of 1 would indicate equivalent impacts for GHG or economics in a particular product.

b. Medical Services

i. GHG

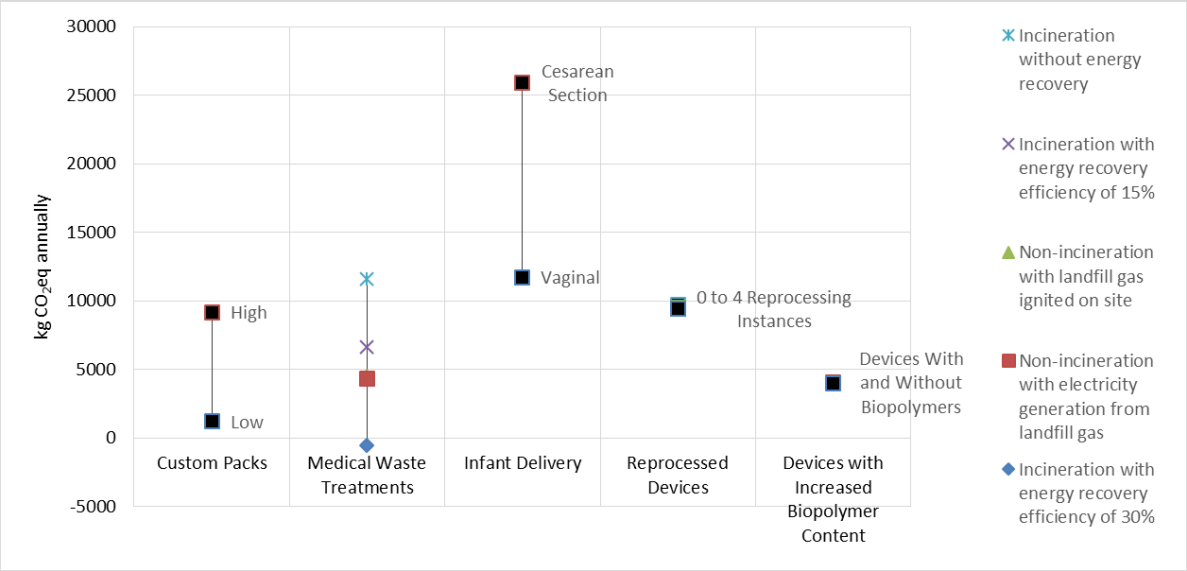


Figure 19 shows the normalized life-cycle greenhouse gas emissions of several medical services and different options within each respective medical service. Option 1 represents the lowest emissions of $kgCO_2eq$ and Option 5 represents the highest emissions of $kgCO_2eq$ for various scenarios. The delivery of infants represents the greatest emission of kg CO_2eq when compared to the other four medical services; which, was found to be true for vaginal and cesarean-section births. The range of kg CO_2eq emissions for medical waste treatments encompassed kg CO_2eq emissions for custom packs used in vaginal deliveries, reprocessed products, and products with increased biopolymer content. Reprocessed products and products with increased biopolymers had ranges that were comparatively small to the other medical services' ranges. For reprocessed products, the best option in terms of GHG emissions was

products that were reprocessed four instances, resulting in 9,406 $kgCO_2eq$ emissions on an annual basis in an average-sized US hospital. Also for reprocessed products, the worst option in terms of GHG was products that were reprocessed zero instances, which resulted in 9,692 $kgCO_2eq$ emissions on an annual basis in an average-sized US hospital. Products with biopolymer content and products without biopolymer content had annual $kgCO_2eq$ emissions of 4,040 and 4,011, respectively. And notably, the medical waste treatment of incineration with energy recovery efficiency of 30% was the only scenario for any medical service that resulted in a net reduction of kg CO_2eq emissions; which, reduced $kgCO_2eq$ emissions by 507 on an annual basis in an average-sized US hospital.

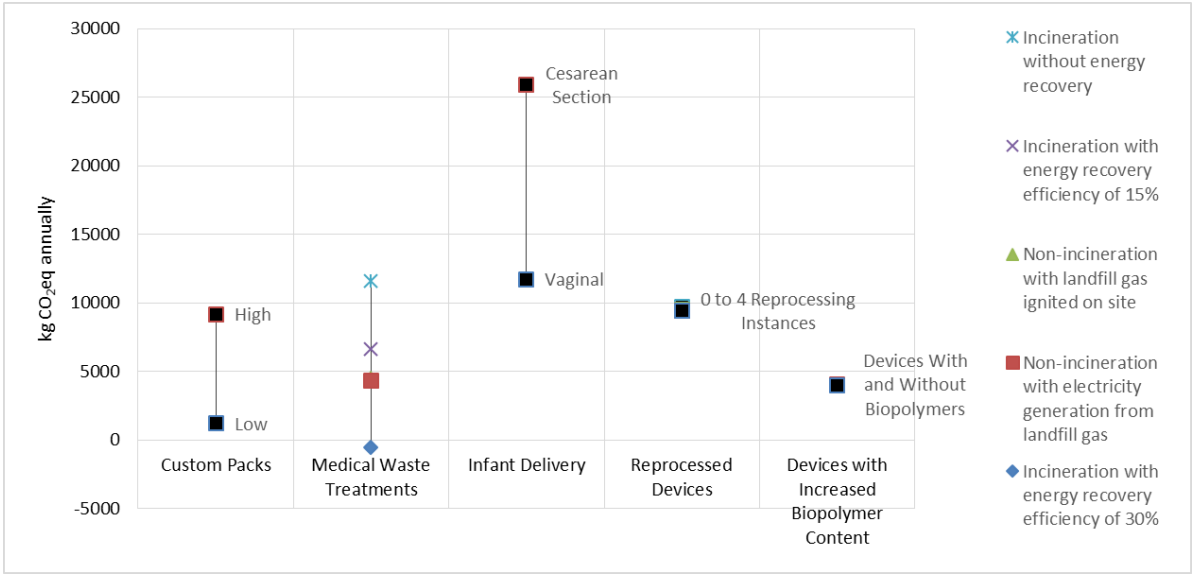


Figure 19. Annual Greenhouse Gas Emissions for Medical Services in an Average-Sized US Hospital.

N/A No alternative option evaluated

[1] Low represents the minimum reported value from the study focusing on custom packs used in vaginal deliveries.

[2] High represents the maximum reported value from the study focusing on custom packs used in vaginal deliveries.

[3] The following products were reprocessed: arthroscopic shavers, deep vein thrombosis compression sleeves, endoscopic trocars, ligasures, pulse oximeters, scissors tips, and ultrasonic scalpels.

c. Sustainable Healthcare Checklists

After assessing the environmental and economic impacts of the analyzed medical products and medical services, the recommended practices of each sustainable healthcare checklist were first evaluated based on their incorporation of cradle-to-grave impacts. With regards to the cradle-to-gate-phase, use-phase, or end-of-life-phase impacts shown in Table 18, the green, orange, and red cells designate either a strong, moderate, or lack of focus, respectively. The presence of green cells in the Life Cycle Phase columns confirm that the three analyzed sustainable healthcare checklists are emphasizing cradle-to-grave life-cycle processes.

Table 18. Life Cycle Phases Addressed by Sustainable Healthcare Checklists and Recommended Augmentations.

Checklist (Citation)	**Recommended Practices**	**Life Cycle Phase**			**Recommended Additions Based on Study's Results**
		Cradle-to-Gate	**Use**	**End-of-Life**	
Checklist in "Advancing	• **Waste reduction** (e.g., initiate recycling				• Optimize reusability of medical products (i.e.,

Life Cycle Assessment: Perspectives from the Building and Healthcare Industries" (Campion, 2015)	programs, evaluate potential for product biodegradability or reuse)				streamline cleaning services, reuse smaller products, where possible) • Reduce products utilized in custom packs • Evaluate energy recovery potential of utilized products
	• **Preferred purchasing** (e.g., identify red list items, observe product use and trends in specific units)				
	• **Food programs** (e.g., research on-site gardening potential, consider composting potential)				---
	• **HVAC and building consumption** (e.g., establishing baseline, identifying trends in utility data, reduction plans)				---
	• **Education** (e.g., seminars, programs, culture)				---
Practice Greenhealth Eco-Checklist for Operations (PG, 2015b)	• **Environmental stewardship structure** (e.g., establishing environmental mission statement, developing a 'green team')				---
	• **Education and communication** (e.g., poster campaigns, sustainability reporting to senior staff)				---
	• **Environmentally preferable purchasing** (e.g., develop list of targeted materials of concern, evaluate energy and water efficiency of products before purchase)				• Optimize reusability of medical products (i.e., streamline cleaning services, reuse smaller products, where possible) • Reduce products utilized in custom packs • Evaluate energy
	• **Waste management and reduction** (e.g.,				

	develop comprehensive waste management plan, establish baselines generation rates of waste)				recovery potential of utilized products
	• **Mercury elimination** (e.g., establish protocol for safe handling of mercury onsite, institute regulated safe disposal of mercury)				---
Kaiser Permanente Generation II Medical Sustainability Scorecard (KP, 2010)	• **General** (e.g., establish environmentally preferable purchasing, publish a sustainability report)				---
	• **Natural resources/waste** (e.g., increase recycling, offer end-of-life take-back programs)				• Optimize reusability of medical products (i.e., streamline cleaning services, reuse smaller products, where possible) • Reduce products utilized in custom packs • Evaluate energy recovery potential of utilized products
	• **Energy/climate** (e.g., measure GHGs and take steps to reduce GHGs, purchase EnergyStar®-rated products)				• Measuring energy at machine, equipment, department, and facility-levels

* The following recommended practices for the Practice Greenhealth Eco-Checklist for Operations were omitted for length purposes: energy, water, and climate; environmental services; food services; sustainable sites management; transportation operations; and, chemical management.

Where applicable, recommendations for improvement of the sustainable healthcare checklists were made based on environmental impact results synthesized from this study. The three checklists were supplemented with five recommended additions based on the results of this study. The first recommended addition is to optimize the reusability of medical products, which includes the streamlining cleaning services (e.g., reducing utilized detergent, reducing utilized water), effectively reusing medical products, and maximizing reuse instances of reusable medical products through effective cleaning and maintenance protocols. The second recommended addition is to reduce products utilized in custom packs. The custom packs study suggested that custom packs used in vaginal deliveries can be reduced by using design for environment strategies and life cycle assessment data in collaboration with healthcare personnel to determine which products should be included in the custom packs. The custom packs study also suggested that reducing disposable cotton products and reuse after laundering can further reduce custom packs (Campion et al., 2015). The third recommendation is to evaluate the energy recovery potential of utilized products, based on the reduction in global warming emissions when medical waste undergoes incineration with energy recovery efficiency of 30%. Increasing the volume of waste with high levels of embodied energy (i.e., high associated levels of energy recovery potential) would further reduce global warming emissions due to the increased energy recovered during incineration. The fourth recommendation is to consistently measure and drive efforts to reduce energy use. Monitoring energy use not only involves measuring medical products and machines with plug-in electric meters, but also expanding the scope of monitoring to department and facility-levels. While it is correct that sustainable healthcare checklists focus on broad purchasing at the facility level, the fifth recommendation is to increase emphasis (or add an element altogether) on custom packs. Custom packs were found to have significant

environmental impacts, but those environmental impacts were variable based on a custom pack's design. Therefore, increasing attention towards the design of custom pack can effectively reduce a healthcare facility's environmental footprint.

4. Discussion

The results showed that reusable products typically required less overall environmental and economic costs than their single-use disposable alternatives. These environmental costs included increased amounts of GHGs, water, and energy. Future work should extend itself to other reusable and disposable products, and materials used in healthcare. Due to the limited number of currently analyzed medical products, there is difficulty in determining overarching conclusions and trends concerning the sustainability of all medical products. Additionally, further research should perform more iterations on identical product utilized in different locations. For example, the overall life-cycle environmental costs of a particular product may differ when used in an urban area as opposed to when that same product is used in a rural area. Discrepancies in environmental costs could be due to differing electricity grids, differing reuse protocols, and differing materials used in products delivering the same function.

Because infant delivery represents the greatest overall emissions of kg CO_2eq for studies analyzed in this paper, adjustments or strategies employed to reduce GHG emissions associated with vaginal or cesarean-section births would have significant benefits. Campion et al. recommended that for all births, strategies should target the production and end-of-life impacts resulting from disposable custom packs in order to reduce the overall the environmental impacts

of birthing options (Campion et al., 2012b). Different medical waste treatments and the use of custom packs presented increased GHG emissions variability when compared to reprocessed products and products with biopolymer content. Therefore, decreasing GHG emissions can effectively be achieved by evaluating the necessity of certain products assembled in custom packs. Future studies on the products comprising custom packs will also further assist in validating preferred-purchasing elements included in sustainable healthcare checklists.

Current sustainable healthcare checklists encompass a variety of cradle-to-grave elements that are pertinent towards increasing sustainability within a hospital. However, current checklists lack substantive data to support their respective recommendations, and further research is needed to support the recommendations of current sustainable healthcare checklists. The results of this study suggest that sustainable healthcare checklists be further validated with more environmental and economic life-cycle analyses related to medical products and services.

CHAPTER 6

CONCLUSIONS

The purpose of Chapter 6 is to: summarize the most significant findings from the three research questions presented in Chapter 1, discuss recommended future work, and discuss the outlook for the healthcare system and its sustainability. A number of medical devices and medical services were assessed for their environmental, human-health, and economic impacts through novel studies performed in Chapters 3 and 4, as well as secondary data collected for Chapter 5. The results and significant findings from these three chapters are summarized based on their respective research question presented in Chapter 1. Followed by the summarization of significant findings from the three research questions, recommended future work is discussed. The recommended future work serves to advance the sustainability of medical devices and medical services. Lastly, the outlook for the sustainability of medical devices and services, and the overall field of sustainable healthcare is discussed.

1. Summary

Chapter 3 answered the research question: *What are the comparative environmental and economic impacts of single-use devices vs. reprocessed devices in a hospital's supply chain?* The study in Chapter 3 used LCA and LCCA to model the environmental and economic impacts of medical device supply chains when varying levels of reprocessed devices were utilized. The study found that given median/mean reprocessing life-cycle inventory inputs, the reprocessing of the seven analyzed devices slightly reduces global warming impacts, but also increases human health impacts (i.e., carcinogenic, non-carcinogenic, respiratory effects). Regardless of the

number of reprocessing instances, the most significant factor in both global warming and human health impacts was the reprocessing life-cycle inventory. This life-cycle inventory data included: the amount of ETO, electricity, and water consumed. Decreased reprocessing inputs were correlated with decreased levels of human health impacts. When limiting reprocessing life-cycle inputs, increased instances of reprocessing were also correlated with decreased levels of human health impacts.

The use of DVT compression sleeves had the highest environmental contribution of all the examined devices. The significant environmental impacts associated with DVT compression sleeves were driven by its high utilization rate, and its composition of 93% cotton on a weight basis. Cotton production has significant energy, chemical, and water inputs, which results in a number of environmental impacts (e.g., acidification, global warming, and eutrophication). Substituting woven cotton for a less environmentally intensive material could reduce impacts associated with DVT compression sleeves. Notably, the high quantities of plastics (i.e., HDPE, LDPE) in ligasures also correlated with significant impacts when used as either reprocessed or disposable devices.

In terms of overall economic impacts, the study presented in Chapter 3 found that increased reprocessing of the seven medical devices correlated with a decrease in overall economic costs. The total savings on an annual basis (versus when no devices were reprocessed) were $182k, $351k, and $520k (in terms of 2013 US dollars) when all seven devices were reprocessed one through three instances, respectively. The cost savings associated with the DVT compression sleeves represented nearly half of the realizable potential savings. When taking into

consideration the economic benefits of reprocessing, the favorability of reprocessing medical devices becomes more apparent. The overall economic and environmental benefits resulting from reprocessed devices are aimed at healthcare administrators. Healthcare administrators will be able to see the environmental and economic benefits of reprocessing, which will motivate those administrators to increase reprocessing at their own healthcare facilities.

Chapter 4 addressed the research question: *What are the opportunities for using biopolymers in healthcare and the resultant comparative environmental impacts of single use disposable devices with increased biopolymer content vs. typically manufactured devices in hysterectomy procedures?* The study in Chapter 4 utilized a comparative LCA on medical devices composed of certain quantities of plastics versus the same medical devices with biopolymers substituted for each device's quantity of plastic. The study found that the use of biopolymers in surgical devices was preferable in several impact categories, which included: acidification, carcinogenics, non-carcinogenics, respiratory effects, and ecotoxicity. Because the manufacturing of petroleum-based plastics was associated with considerable human health impacts, the substitution of manufactured biopolymers for manufactured petroleum-based plastics caused a decrease in human health impacts. While the utilization of biopolymers offers human health benefits, the agricultural activities associated with manufacturing biopolymers exacerbate a number of environmental impacts.

Similar to Chapter 3, the study in Chapter 4 also found that the use of woven cotton resulted in significant environmental and human health impacts. Because higher quantities of cotton were used in abdominal hysterectomies, environmental and human health impacts for

abdominal hysterectomies were higher than robotic, laparoscopic, and vaginal hysterectomies. Woven cotton was found in a number of surgical materials, including towels, patient gowns, and laparotomy pads.

In terms of how the use of biopolymers drove environmental and human health impacts, it was found that the increase of impacts related to global warming, eutrophication, ozone depletion, and smog resulted when PLA, guayule-derived latex, and thermoplastic starch were substituted for typically used materials. With regards to the most significant impacts that resulted when biopolymers were used, the substitution of biopolymers for petroleum-based plastics increased smog-related impacts by approximately 900% for laparoscopic and robotic hysterectomies, and increased ozone depletion-related impacts by approximately 125% for laparoscopic and robotic hysterectomies. The emission of ozone-depleting substances during PLA manufacturing drove the relatively high increases for the impact categories smog and ozone depletion. On the other hand, guayule-derived latex and thermoplastic starch were associated with much lower emissions of ozone-depleting substances during their associated life-cycle processes.

Due to the variable environmental and human health impacts associated with utilizing biopolymers in medical products, special attention should be given to the lifecycle processes associated with biopolymers. For example, the location of biopolymer cultivation may heavily influence a particular biopolymer's environmental favorability. Specifically, because smog-related impacts increase when PLA is cultivated, the cultivation of PLA would be best suited in an area where existing smog levels are relatively low.

The three analyzed biopolymers presented differing advantages and disadvantages. When thermoplastic starch was substituted for cardboard there was an increase of acidification-related impacts. When PLA and guayule-derived latex were substituted for typically-used materials there was an increase of exotoxicity-related impacts. And, when PLA, guayule-derived latex, and thermoplastic starch were substituted for petroleum-based materials, there was a decrease of impacts related to carcinogenics, non-carcinogenics, and respiratory effects.

The study in Chapter 4 also examined the environmental and human health impacts associated with laundering reusable cotton products. The laundering of reusable cotton products used in the four hysterectomies was associated with an overall net decrease of at least one order of magnitude in eight of the nine of the TRACI impact categories. Such reductions were due the cultivation and manufacturing of woven-cotton, where the life-cycle processes associated with cultivation and manufacturing of woven-cotton outweigh the life-cycle processes associated with laundered, reusable cotton products. While this study showed that biopolymers are associated with certain environmental and human health tradeoffs, this study conclusively showed that cotton-laundering significantly reduces environmental and human health impacts. Consequently, this study recommends that hospitals launder cotton products and devices that are suitable for reuse.

The data and results generated from Chapter 4 target several audiences. Medical product manufacturers will gain an increased understanding of the environmental and human health impacts resulting from the use of biopolymers in their respective products; which, will better

equip those manufacturers should they choose to deploy biopolymers in their own products. Additionally, healthcare administrators will better understand the environmental benefits of maintaining onsite laundering facilities; which, will further motivate healthcare administrators to streamline or deploy their own laundering facilities.

Answered by the last study in Chapter 5, the third research question asked: *How can the salient conclusions from the first two research questions, as well as from recent studies focusing on the environmental impacts of various medical products and/or services, be synthesized for the use of hospital administrators and employees?* The study in Chapter 5 addressed this research question by comparing the cradle-to-grave environmental and economic impacts of reusable versus disposable medical products, as well as the environmental and economic impacts of several medical services. The study drew from results in Chapter 3, Chapter 4, and existing studies focusing on the comparative environmental and human health impacts related to medical products and services.

The results conclusively showed that reusable products were less expensive their single-use disposable alternatives. The dental bur also required the least amount of water for its associated cleaning processes, had the lowest total embodied energy, and had the lowest associated GHG emissions. These outcomes were likely due to the fact the burs were, by far, the smallest examined product. Notably, the study also found that the delivery of infants was associated with the greatest emission of kg CO_2eq when compared to the other four analyzed medical services.

In addition, the results in Chapter 5's study were also correlated with existing sustainable checklists, where the recommended practices of each sustainable healthcare checklist were evaluated based on their encapsulation of cradle-to-grave impacts, and then augmented based on cradle-to-grave environmental impact results synthesized from this study. Based on the results derived from the study, healthcare checklists should be updated to include: optimizing the reusability of medical products; reduce products utilized in custom packs; and evaluating energy recovery potential of utilized products.

2. Future Work

There are several areas that future work should focus its attention in order advance the sustainability of medical devices and medical services. These areas are:

- Conduct rigorous, quantitative analyses of environmental, human health, and environmental impacts of medical reusable devices, disposable devices, reprocessed devices, healthcare products, and healthcare materials. These assessments are necessary because there is difficulty in determining overarching conclusions concerning the sustainability of all utilized medical devices and products with the limited number of currently analyzed medical products.
- Increased life cycle assessments on identical devices utilized in different geographical locations. Such iterations are necessary because the overall life-cycle environmental costs of a particular device may differ when used in a particular geographical area as opposed to when that same device is used in a different geographical area.

- Further research is needed to support the recommendations of current sustainable healthcare checklists. Current checklists lack substantive data to support their respective recommendations. Sustainable healthcare checklists should be further validated with more environmental, human health, and economic life-cycle analyses related to medical devices and services.
- Further research should examine the environmental and economic impacts resulting from MSW being diverted to RMW. On a per-weight basis, RMW results in higher levels of environmental impacts; which, is principally due to the high levels of electricity used during RMW lifecycle processes.

3. Outlook

The burgeoning field of sustainable healthcare is producing significant research that has considerable potential to reduce adverse environmental, human health, and economic impacts. Yet while there is increasing activity in the field of sustainable healthcare, further quantitative, peer-reviewed research is needed to truly advance the sustainability of the healthcare system. But this dissertation, and other cotemporary environmental, human health, and economic analyses of medical devices and services are generating more and more useful recommendations that will increase the sustainability of the healthcare system.

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