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Healthcare Environmental Footprint: Proposal to Deliver Sustainability through an Innovative Value Stream Using a Circular Economy Approach

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Abstract. *Over the last 10 years, the most recent innovations in the field of organic chemistry have been significantly driven by both industry needs and environmental concerns. On the former, industrial applications and production processes have evolved to reduce carbon footprint and to reduce the reliance on oil-based organic material precursors. On the latter, increasing concerns around accelerated global warming, have kindled the search for solutions, including lower carbon footprint, recyclability, and upcycling of novel materials.*

To 2015, the healthcare industry accounted for about 5.7% of the carbon emission with a severe impact in carbon, SO_2, Nitrogen and particulate matter. Specifically, what relates to greenhouses, the global contribution accounts to 24 Gton of CO_2, which has largely increased due the immense use of disposable devices during the pandemic. Current evidence points towards a substantial interest in the reduction of carbon footprint in the healthcare settings, yet with limited success across the largest health care providers. This study approaches the topic from a literature review and an empirical approach based on previous and ongoing research on the field of additive manufacturing and the use of bio-based materials for medical devices applications, which has been conducted utilizing mechanical, economic and microbiological assessments to address the research question of how to better address the carbon footprint of the healthcare industry, limited to some surgical procedures. This research points towards the direction that the implementation of an on-site solution may help to address some of the sustainability challenges healthcare facilities face while enhancing their circular economy approach. This research is intended to pave the way for further research including specific research to enhance the understanding of the solutions and how these may fit the current regulatory landscape.

Keywords: additive manufacturing, polylactic acid, device reprocessing, circular economy, sustainability in health care facilities.

Introduction

Health care as an industry, is often far from the spotlight when it is about to think about carbon footprint. Nonetheless, this industry alone is responsible for up to 5% of the global carbon footprint[1]. This estimate is only provided as a reference for the direct impact, which is more likely than not, to increase dramatically if it is to be considered the advanced global integration of the industry, including how intensive its energy consumption is and the different procurement streams required for its normal functioning. On the latter, several can be pointed out as impactful streams including those related to procurement and the extreme dependence of the industry of disposable devices, yet this is not limited to it as several gasses are generated in a regular basis on any health care facility operation, both greenhouse and generally pollutants gasses as organic volatile compounds, with the latter heavily increased by facilities where complex and long surgical procedures are conducted, mostly attributed to anesthesia gasses. Also, the healthcare industry is heavily dependent on the use of disposable materials that often are brought over from long

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distances and manufacturing hubs (e.g., China, India, Pakistan) which only emphasize the environmental impact due to transportation.

Among the number of supplies required by health care facilities, medical and surgical instruments are required in large numbers to address the need for surgical procedures. These devices are often manufactured from several metal alloys, which give them the ability to be reprocessed after a thorough decontamination process. These processes are intensive in labor, energy, water and cleaning chemicals. Conversely, some devices are designed to be used only once, and are often manufactured from multiple polymeric materials based on their design and their desired mechanical properties. Among these two options, it is arguable which one is better from an environmental impact point of view: reusable solutions require energy and large amounts of water[2] which is polluted with chemical and biohazard residues, while disposable solutions are extremely difficult to recycle due the number of polymers used on their construction, rendering the recycling process extremely difficult even for advance recycling facilities. Moreover, on the use of disposable devices, the healthcare industry has historically adopted disposables due two primary elements: convenience and patient safety. The ability to readily use devices, materials and supplies used in everyday medical procedures pose a direct benefit which streamlines the delivery of care. On the patient safety side, there are several arguments around standardized process of decontamination of medical devices that make them safer to use on patients, and cheaper to obtain when compared with reusable devices, which need to sustain a series of decontamination and reprocessing steps to remove contamination and render them safe to use on patients. These decontamination and reprocessing steps are notorious for its energy and water usage, as they involve the decontamination using water and several cleaning chemicals as well as sterilization which is often achieved by saturated steam or by chemical means, including hydrogen peroxide and ethylene oxide[3, 4, 5.]

An alternative to these two options, is the use of disposable materials manufactured with bio-base materials that can be easily recycled, upcycled or disposed of in conventional landfills, to later on be degraded by natural pathways. The most promising of them is polylactic acid. Polylactic acid, has demonstrated to be a promising one: can be sourced from corn, (Figure 1) more specifically through multiple polymerization processes, enabling the formation of complex chains of Polylactic acid. Once the Polylactic acid has been synthesized, it can take the form of pellets for injection molding or extruded to create reels with filament to be used on additive manufacturing. The latter process can be used to add copper nanoparticles to provide antimicrobial characteristics, which is generically referred to as Active PLA. Despite the promising benefits of this novel material, limited research and applications can be found in the medical devices industry. This material is the one used during this research to assess its use, environmental benefits and potential circular economy claims.

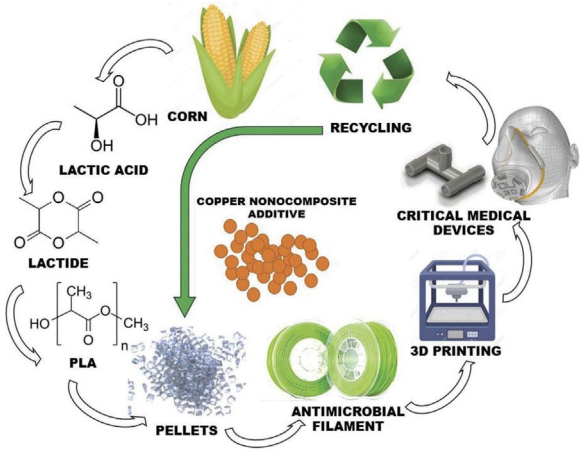

Figure 1. Polylactic acid synthesis.

Source: Cortez [6]

In the United States, the national institute of Health (NIH) has granted funding to expand research on the use of novel materials, primarily for aerospace applications. This has led to several non-surgical applications with significant success[7,8] however focused on non-critical devices which required a limited compliance when it is about to their microbiological properties and do not require decontamination or sterilization.

From a current workflow and environmental impact perspective, it is important to understand that health care facilities deliver a plethora of patient care activities including patient consults, ambulatory care, minimally invasive procedures, and large and complex surgical procedures, is important to narrow the scope of the research to explore specific impacts on the adoption of a specific care pathway. Among the many care pathways, those related to surgical procedures are the most impactful in terms of environmental impact, with overall waste estimates between 0.8 Kg up to 14 Kg per surgical procedure[9] with this being only conservative numbers for less invasive surgical procedures. The waste generated after surgical procedures can be classified as mostly non-recyclable materials, as most of them are polymeric materials from different nature, rendering the recycling process impractical which is exacerbated due the microbiological burden of the disposed materials. Reducing the overall volume and utilizing materials that may have a clear recycling pathway is one of the options to explore.

For a quantification perspective, this study will focus on 3 specific aspects: surgical procedures known to be beneficial of the use of new materials, waste, and water use of the decontamination of such devices and the overall cost estimation for the implementation of a pilot plan using the proposed technology.

The present research is pursuing to bridge the current evidence which is divided between the environmental footprint and circular economy views and the technical aspects of the use of both disposable and reusable devices; providing an applied approach as well as practical framework to further explore this field. Moreover, it pursues a discussion on the use of novel materials matched by newer technologies that may enable a different approach to address ongoing challenges. This research is set in generally available materials, technologies, and empirical knowledge to increase the likelihood of adoption, albeit perhaps in low scale fashion, would nonetheless be relevant to explore the potential impact of this approach.

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Literature review

The evidence around the environmental impact of the healthcare industry points towards a significant footprint that may jeopardize the goals of global warming reduction set forth by the Climate Change Conference of 2021 (COP21) both because of the impact of the COVID-19 pandemic and the limited understanding and lack of clear quantification of the actual impact this industry has in the emission of greenhouse gasses and its carbon footprint. According to Lenzen *et al*[1], the negative feedback contribution of the pollution generated by the healthcare industry is known on a limited basis. Their study does provide a systematic approach and well documented modeling strategy, to further assess health care industry carbon and environmental footprint through the optic of the plethora of differences observed across countries with different economic development. The study does not provide a clear view of the overall extended impact generated by adjacent industrial processes that lead to health care services and products including the local procurement of materials, the traceability of precursors and the energy consumption of elements across the value stream that leads to health care delivery.

On the clinical side of the matter, there are several hundreds of medical care procedures from low carbon footprint like doctor visits or e-visits, to others with a significant footprint. On the latter, whenever medical care leans towards surgical procedures, there will be a significant impact on waste and overall CO_2. From all the surgical procedures, some are more intensive in the use of medical devices that will be disposed of after the surgical procedure. According to Bronzatti[9], plastic and cosmetic procedures are intensive on the use of some devices generally referred to as suction cannulas, which need to be decontaminated and sterilized after use. Despite current technologies, sterility assurance is often not achieved which poses a significant risk to patient safety, specifically in what relates to surgical site infections which in turn may lead to several potentially deadly complications.

One of the technologies explored as part of this research, is the use of bio-based polymers with antimicrobial features, which make them suitable for use as medical devices. Along these lines, the research conducted by Gonzalez-Henriquez[8] points towards the benefits of novel materials to reduce the likelihood of microbiological contamination which in more specific terms, leads to a reduced bioburden, enabling an easier decontamination and sterilization, enhancing the patient's safety.

After reviewing the current literature, there are gaps when it is about to connect the 3 elements outlined here: clinical aspects and patient safety related impact, use of new technologies and proposed approaches to address the current environmental challenges.

Methodology

This research is based on a quantitative applied methodological approach to assess the impact of the proposed solution with the primary hypothesis being that the use of this novel approach, may deliver a reduction of carbon footprint and a sustained benefit to the health care facility to address their needs to drive activities towards a circular economy operation. More specifically, the research is pursued to validate a test model to demonstrate the benefits of the proposed approach to address challenges around elimination or reduction of pollution or waste, increase the circulation and reuse of raw materials and enable the regeneration of natural, renewable sources. This methodology is developed in 4 steps:

- **a.** Determination of specific applications of the technology
- **b.** Validation of the technology and use of novel materials
- **c.** Quantification of implementation cost and estimation of economic impact
- **d.** Justification of the benefits of the circular approach when it is regarding the health care facilities challenges.

Results and discussions

Determination of specific applications of the technology:

To narrow down the number of applications to explore, mostly due the extremely large number of different medical devices used in surgical procedures, it was determined that devices that are simple in their design and functional scope of use were going to be used. After that, the determination led to the exploration of suction devices and its variations, which are commonly used in procedures to remove fluids or non-critical tissues from patients, like those in plastic or cosmetic surgeries.

From a manufacturing point of view, the devices can be manufactured using additive manufacturing technology which is an excellent alternative for low volume manufacturing, primarily used for testing and modeling. The technology chosen was the Ultimaker 2+(Ultimaker 2+ is a trademark from Ultimaker Holding BC, Utrecht, The Netherlands. This technology

demonstrated the ability to manufacture testing coupons in an effective way in compliance with internationally adopted standards.

Validation of the technology and use of novel materials:
The validation of the technology requires the assessment of novel materials, the manufacturing technology and the selection of specific testing protocols that are standardized globally and used within the medical device industry. Such protocol is well documented in internationally adopted standards (i.e., ISO 22196:2011) which was utilized during the microbiological testing. After the testing, the microbiological performance of the selected materials was adequate to be used in medical devices and the results were in line with those similar results obtained by Cortes and Zuniga[6] in previous studies.

Quantification of key variable of process and implementation costs
The quantification of the implementation variables includes the assessment of the number of surgical procedures that will be performed over a unit of time as well as the costs related to implementation, operation, and the benefits from a waste perspective. There are some general assumptions related to the type of health care facility that would benefit from this as a pilot project, which leads towards mid-size health care facilities of primary or secondary level, with a surgical load of 20-50 surgical procedures a day, of which at least 12 must require the use of the developed devices, with a total of 12 procedures per day, 6 devices utilized in each procedure and a total of 1584 devices required over a monthly period (Figure 1).

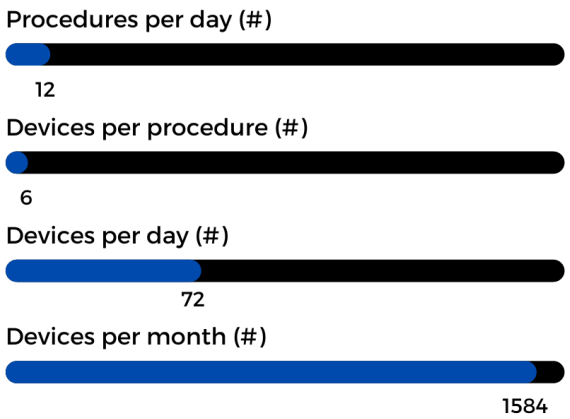

Figure 1. Pilot project estimates

Source: Author.

For the proposed alternative, and specifically on the implementation side, the initial investment is of the order of $10400 which can be utilized to manufacture about 10^6 individual devices. The energy related costs are $0.1241, and the cost of consumables is $0.5981, both per manufactured unit. The projected monthly cost of this operation is $947 (Figure 2) with wastewater and additional energy use estimated as 0 Liters and 0 KW/h (Figure 3).

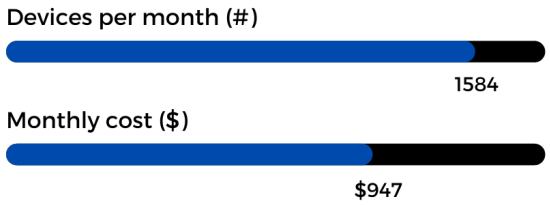

Figure 2. monthly manufacturing estimates and operation costs

Source: Author.



Figure 3. Incremental wastewater and energy use

Source: Author.

For the current process, the energy related costs are $0.18 with an additional unit cost for reprocessing (i.e., decontamination, inspection, package, and sterilization including monitoring) each unit $0.65. The overall monthly cost of the current approach is estimated at $1036.1 (Figure 4) with an additional burden of 1647.5 liters of water dumped into the waste stream and 2430 KW/h, also monthly (Figure 5).

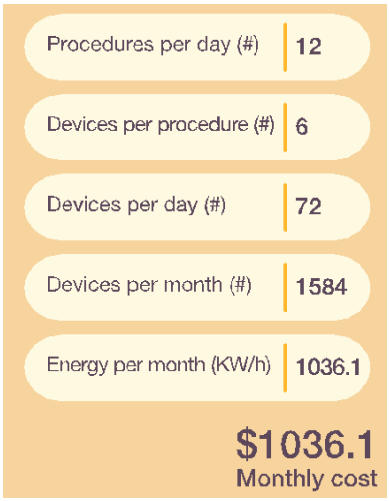

Figure 4. Current process information

Source: Author.

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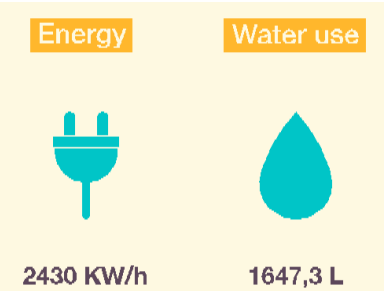

Figure 3. Current wastewater and energy use

Source: Author.

The next benefit of the proposed approach is therefore net monthly cost reduction of $88.69 with an energy reduction of 2430 KW/h and a reduction of the wastewater of 1647.5 liters.

All the monetary units on this paper are United States Dollars. No hand labor costs have been included due the multiple variables this would entail based on different local employment laws.

Justification of the benefits of the circular approach when it is regarding the health care facilities challenges.

There is a general belief that the use of disposable devices in the healthcare industry is inherently the most wasteful approach with lesser environmental benefits, which is arguably true when the disposables are products manufactured with multiple materials, making the recycling or upcycling virtually impossible even in advanced recycling centers. This is not the case as the proposed alternative relies on a bio-base material that can be quickly recycled or upcycle to be fully or partially utilized.

The use of the previously used devices as raw material for the next device, provides benefits on the waste stream, which is dramatically reducing pollution, enable the circulation of products through the reuse of previously reprocessed materials (with a significant energy and water consumption) while the use of bio-based materials enables a different dynamic in the use of resources. Moreover, countries where the agricultural industry has a significant impact on their GDP (e.g., USA, China, Brazil, Ukraine, and Romania), as bio-based materials are created from precursors coming from corn.

There are additional benefits of this sort of approach, as this may help to streamline the current workflow of decontamination of surgical devices within the health care facilities.

Overall assessment within the regulatory framework of medical devices.

Medical devices are highly regulated by government agencies. In the United States, the Food and Drug Administration is the regulatory body whilst in the European Union, the European Council created the Medical Device Regulation is responsible for the same role. In other geographies, there are several regulatory bodies that define requirements for medical devices, its manufacturing, use, reprocessing and in some cases, disposals.

The current approach needs to effectively navigate through these regulations, as the manufacturing of medical devices is globally seen as an activity that must be conducted in a manufacturing setting in compliance with specific quality standards (i.e., ISO 13485-2016). While the current regulatory framework would not quickly accept the proposal, health care facilities could indeed, prepare specific areas to drive this change, therefore, benefiting from this change.

Discussion.

The hypothesis seems to be demonstrated from the perspective of a reduced carbon footprint, a more sustainable approach, and the benefits of adopting circular economy principles. However, there are several steps to be taken to directly benefit from this approach, including the assessment of specific regulatory framework, the type of facility that would benefit most of the implementation of such approach and the specific impacts both in financial and environmental terms. Moreover, further assessment should be conducted for specific facilities and their settings, as well as the procurement and supply chain aspects of implementing a new workflow within a hospital or clinic.

From the research point of view, further initiatives currently under development; are pursuing to develop a more accurate estimation of the implementation including hand labor, employment market and its regulations and the specific requirements from laborer's to conduct the required activities. More specifically, an emphasis must be taken onto the consideration of specific market nuances in hand labor qualification, employee turnover and onboarding, training, supervision, and employee development.

From an environmental footprint and circular economy perspective, current evidence[10, 11, 12, 13] points towards the areas within the healthcare facility which are still rather generic, for which specific assessments are still required to assess the real footprint by the specific care settings and across the entire patient care continuum. This brings the opportunity to strengthen the evidence supporting initiatives like that proposed on this research to expand the accuracy of both the current impacts and potential benefits.

Novel materials are often lagging in their use due a plethora of reasons although most of them lean towards the economic aspects: the cost of polylactic acid is significantly higher than those of currently use polymers (e.g., PVC, ABS, PC, PE or PPE) which is partially explain by the demand but more importantly due the origin of its precursors. While there are many potentially beneficial materials to use to address the environmental challenges in both the healthcare industry and others; the technological breakthrough to implement them and obtain benefits from is often delayed by cultural and adoption roadblocks, often posed by competing industries but also by potential users. This invites the multiple stakeholders to explore current challenges, potential solutions and benefits and drive the implementation of these solutions like in this case, through the validation of a feasible concept to explore further expansion later.

Conclusion

Health care facilities globally face the challenges of global warming, whereas it is because of the lack of water, the scarcity of raw materials needed to procure products, or the challenges related to the increased demand of care while facing inflationary measures. Under this outlook, pursuing attempts of delivering care in observation of broader objectives like sustainability or circular economy is seldom successful. Moreover, health care facilities globally; remain as a relevant polluter and while technologies are available, the understanding on how to capture their benefits to enable implementation of new approaches, prove challenging. This research assesses current technologies and proposes a new approach to address, albeit in a pilot or experimental fashion; a solution to one of the problems. The research also points towards the benefits of pursuing this approach and how this can be implemented. Further research must be conducted to accurately assess its implementation in specific countries based on their labor market, regulatory aspects, and other elements, however this research set a general framework to build upon,

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