How Industry 4.0 and advanced manufacturing could help to reduce procedural caused medical waste?

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Abstract: The Industry 4.0 revolution has already started to redefine the way we order, produce and consume 'things' today. By implementing advanced manufacturing methods, the medical industry can benefit from a faster and more accurate medical device and material management model to reduce procedure-caused medical redundancies, and reduce the material waste generated. Such change is also reflected in the way medical devices are made and the functionality they deliver. In the current medical industry, doctors and surgeons need to cope with the medical material redundancy issue in their daily routine of diagnosis and treatment. Such redundancies are vital to ensure the safety of patients. However, it also generates a huge amount of waste. Many products and materials become redundant only because they have been exposed to an infectious environment but were never used. The reuse of these products and materials is not preferred due to clinical challenges of safety and sterility.

The use of autonomous robots and artificial intelligence has shown significant reduction of time and human effort required in industries like automobile manufacturing, however, their potential use in the medical industry is yet to be fully developed. This review paper examines the potential of implementing Industry 4.0 and advanced manufacturing methods in reducing the redundancies in medical procedures and hence reduce the amount of waste generated. The key factors identified in this paper will also help laying the groundwork on the existing medical device manufacturing and management model, which aim at a) reducing the inaccuracy of diagnostic data; b) preventing high-risks in the treatment procedures due to limited visualization and simulation support; and c) enhancing the adaptability and customization to specific process requirements.

Keywords: **Systems Design, Medical Devices, Waste Management, Sustainability, Industry 4.0, Advanced Manufacturing.**

1. Introduction

This paper investigates a non-exhaustive account of ways in which concepts of Industry 4.0 and advanced manufacturing can help reduce medical waste generated from diagnostic, treatment and rehabilitation procedures. The paper begins by exploring various definitions of Industry 4.0, advanced manufacturing and medical waste. This study has a specific focus on waste produced by medical procedures, and four aspects of Industry 4.0 which can have a strong impact on reducing procedural waste; lean production systems, internet of things (IoT), artificial intelligence and additive manufacturing. The paper concludes with some areas identified for further research.

1.1 Industry 4.0 (I4)?

Industry 4.0 is believed to be the next leap in technology that will create a paradigm shift in the industrialization of our world (Lasi, Kemper, Fettke, Feld, & Hoffmann, 2014). Riding on the success of digitization in the third industrial revolution, Industry 4.0 is preempted to re-define industrial production through a combination of smart objects and advanced digitization of production units. It was first announced by the German government as a key initiative towards a new industrial revolution (Ustundag & Cevikcan, 2018). The have imagined a future with products controlled by their own manufacturing process instead of people determining the manufacturing of products, while maintaining economic competition. Among the many social, economic and political advantages that this revolution brings, is the efficient use of resources. As society gears up for the shortage in supply of essential mineral ores and the impending ecological changes that are taking place, Industry 4.0 brings a stronger focus on sustainability in industrial production and consumption, while ensuring economic feasibility. This paper will focus on how this tenet of the fourth industrial revolution impacts the medical device industry (Lasi et al., 2014).

Sustainable industrial value creation is also believed to be one of the inherent advantages of Industry 4.0 (Stock & Seliger, 2016). At the macro scale, new business models will focus more on selling functionality and accessibility to the consumers, rather than the tangible product itself. As the industry retains ownership of the product, there will be a larger incentive to ensure long-term use of the product before disposal. The business models will also focus more on long-term economic sustainability, which may have a positive impact on the environment by lengthening the value cycles of the materials used. Industry 4.0 encourages closed loop product cycles, and cross-linked value creation networks, which improves the efficiency of resources usage (both material and energy). The inter-connected data streams allow horizontal integration of the product life-cycle, facilitating the interaction of various phases of product development and identification of efficient routes of value creation.

At the micro scale, there are multiple opportunities for the implementation of sustainability strategies at various stages of the product life-cycle as described below. The manufacturing units can retrofit sensors and actuators on existing machines to create a Cyber-Physical System where machinery can interact and communicate with each other to optimize processes. This reduces time, energy and material consumption in the manufacturing process. The role of humans will shift from machine operation to operation management. They will oversee production and identify opportunities to improve the operation flow, reduce lag time, and eliminate redundancies, all of which contributes to reducing time, human effort, material and energy usage. The role of organizations becomes optimizing logistics for a smooth operation flow, and building the value creation network to improve end-to-end value cycles. In this entire system, the products created will be built for closed loop life cycles, encouraging, reuse and remanufacturing by implementing cradle-to-cradle principles. The usage data collected from the products will also help redesign products for better customer satisfaction, and reduce customer grievance time due to damage or bugs in the product function (Stock & Seliger, 2016).

1.2 Advanced manufacturing

Although advanced manufacturing has no single definition, the term has existed since the 1980s often associated with the advent of digitized production for the masses (Craven & Slatter, 1988). In the context of Industry 4.0, advanced manufacturing refers to new forms of cyber-physical systems, that provide the flexibility of manufacturing varying batch-sizes without compromising on the associated costs. These systems will run from decentralized 'smart' factories, which organize and manage themselves with minimum human effort and risk. The aim of advanced manufacturing systems is to reduce human effort, maximize efficiency, and serve human requirements in better ways than what exists today (Lasi et al., 2014). Since Industry 4.0 was defined ex ante, these definitions are not set in stone, and may change in form and meaning as the revolution takes place.

1.3 Medical waste and its causes

Healthcare waste is defined by the WHO as the waste produced by healthcare facilities (including laboratories and research centres) related to medical procedures. This also includes waste produced through healthcare related activities in households (Chartier et al., 2014).

The unregulated production and disposal of medical waste has a strong link to the big "plastics" explosion of the 1950s. The advent of plastics in industrial production empowered manufacturers to produce cost-effective devices which could be sterilized using Ethylene Oxide (ETO) or radiation. But hospitals found it cheaper to use and dispose of these devices than to sterilize and reuse them because the plastics would melt in traditional autoclave machines, and ETO and radiation methods were expensive and inaccessible to most hospitals (Greene, 1986). Today, the trend of single-use disposable products rides on the ambiguity of the safety of sterilization and reprocessing services, 'ensuring' that infections are not re-introduced in the system. This occurs despite studies by the FDA that show there is no increased risk of infection due to the use of reprocessed devices (GAO, 2008). The report reasserted that the adverse health events associated with the use of reprocessed devices were the same types and rates associated with non-reprocessed, new devices (GAO, 2008). There is also a huge impetus for the industry to be cautiously wasteful to avoid legal implications of malpractice or negligence (**reference required**). The result is the generation of a large amount of medical waste, and countries with a high GDP tending to produce a larger amount of medical waste per patient per day (Minoglou, Gerassimidou, & Komilis, 2017). A study by Minoglou et al. (2017) observed the healthcare waste generated by 42 countries and their associated GDPs. The average amount of waste generated by a patient per hospital per day ranges from 0.44 kg in countries like Mauritius to 8.4 kg in the US.

A significant proportion of this waste is produced from medical procedures. Sa et al., (2016) conducted a surgical waste audit for hip arthroscopies and found that just 5 cases resulted in a total of 47.4 kg of waste. While 21.7kg of that waste was biohazard, the rest was composed of sterile wraps, recyclables, non-hazardous waste and sharps (Sa et al., 2016). There is also a proportion of the waste which comes from expired or redundant inventory. In a review paper, Yazer, (2018) talks about how there is a significant number of blood units collected by blood banks that get wasted due to expiration at the bank itself, or when in transit between the hospital and the blood bank. The waste produced, is not only an inefficient use of resources, but also has a financial impact on the stakeholders. In Canada, over 64,000 cases of total knee arthroplasty procedures take place annually (Yan et al., 2018). For each procedure, an average of 118g of bone cement is used, out of which 91.2g (77.2% by weight) gets wasted. This costs the Canadian Government $186 CAD per procedure, which when extrapolated for the annual number of procedures, results in a wasteful expense of almost $12 Million CAD per year (Yan et al., 2018).

In hospitals in the UK, under the NHS, decisions regarding the purchase of medical devices is on the discretion of the purchase department, on instruction of clinical staff and other users of the devices (Ison & Miller, 2000). The decision to purchase a specific device is based on two criteria; the risks it poses to the patients and the users, and the price of the device. Two of many effects not factored in this decision are; financial cost of treatment and disposal of the device, and the environmental impact of the device (Ison & Miller, 2000).

Although not directly under the definition of medical waste, another factor that needs to be looked at is the environmental impact of medical procedures. Wasteful processes are inherently also increasing the energy and resource utilization, which can be quantified in terms of the carbon footprint generated and the toxic emissions released. Thiel et al., (2015) conducted hybrid life cycle analyses for 62 hysterectomies and found a notable environmental impact of the disposables, single-use devices, energy used for heating, ventilation, air-conditioning and the anesthetic gases. Based on the identified culprits of emissions, they also proposed less environmentally harmful ways of providing the required care to the patient.

2. Existing solutions and future prospects

This section investigates the current uses of advanced manufacturing and Industry 4.0 concepts in the healthcare industry, how they tackle the problem of waste generation, and future prospects of transitioning to cyber-physical systems. The section has been divided into 4 seperate levels, using a top-down approach to look at system-level, procedural-level, service-level and product-level interventions to tackle waste generation using advanced manufacturing and I4. The system-level explores uses of lean approaches to reduce waste from a systemic perspective in medical procedures. The procedural and service levels explore the interventions such as use of Internet of Things, digitization, automation and artificial intelligence in streamlining medical procedures. The product-level focuses on the role of additive manufacturing in creating products for medical procedures. Although each of the sections are interlinked, this top-down approach to the study helps identify multiple points of intervention to make the industry less wasteful.

2.1 Lean approaches to reducing procedural caused waste

Lean production is an approach to manufacturing that adopts the philosophy of doing more with less. First witnessed in Toyota's Production System (Ohno, 1988), the main purpose of this ideology is to streamline processes by eliminating various kinds of waste embedded in the system by continuously improving methods. The concept of lean thinking sits well with industry 4.0 through the creation of smart factories, connected systems and the goal of achieving efficient processes in industrial systems (Ustundag & Cevikcan, 2018) (Sanders, Elangeswaran, & Wulfsberg, 2016).

When conceptualising lean methods for healthcare procedures, there has been some amount of progress achieved. As Edwards, Nielsen, & Jacobsen, (2012) summarise in their review paper, most papers exploring lean in healthcare are motivated from the organizational perspective, often related to patients undergoing procedures with distinct mechanical components and linear task flows like X-rays and CT scans. There is not much literature to suggest that lean systems can be implemented in complex procedures and emergency situations. This is because the concept of lean is built on predictability and standardization, neither of which is yet achievable when treating individuals with unique conditions and physiologies (Edwards et al., 2012). But there is certainly a need for more efficient systems in healthcare, as Caloyeras et al., (2018) clearly point out in their survey, which observed that nearly 15% of the time spent by physicians on work can be handled by non-physicians, and almost 10-15% of treatment provided was inappropriate.

Overage constitutes items that are asked for by surgeons to be opened in the sterile field before a procedure, but do not get used. A study by Rigante, Moudrous, Vries, & Grotenhuis, (2017) shows that overage constitutes almost 95% of the waste produced in neurointerventional procedures, evaluated at 676.49 EUR wasted per case. This is one part of medical waste that is produced purely because of probabilistic emergencies or unknowns which could be reduced with better protocols for immediate action, and better planning on procedures. Similarly, Ahmadi et al., (2018) have compiled multiple gaps in knowledge in inventory management of surgical supplies, ranging from optimization methods to problems faced by practitioners. Some of their suggestions directly correlate with Industry 4.0 concepts, such as digitization, connected systems to reduce redundancy in supplies and analysing past usage statistics to efficiently prepare supplies for procedures.

2.2 Using IoT in medical procedures

The Internet of Things has a very important role in Industry 4.0. It forms the basis of a connected system, where various parts of an economic chain can communicate with each other (Ustundag & Cevikcan, 2018). In the industrial internet, connected systems have an important role in medical procedures. In their review paper, Mitrasinovic et al., (2015) explore the uses of smart glasses in healthcare. The use of smart glasses for augmented reality assisted surgery has multiple benefits in visualization, simulation and diagnostic interventions for minor surgeries and minimally invasive procedures (Mitrasinovic et al., 2015).

The data generated and communicated by smart products depends upon the sensors used to collect this data, which forms the foundation of the ubiquitous computing society (Wang, S.J., 2013). There has been a significant evolution in sensors over the last decade, which now enables robots to perceive information as well as, if not better than the human senses (Ustundag & Cevikcan, 2018). Robots are now developed to automatically detect parts, handle them, navigate through obstacles, and complete complex movements to fulfil a task. This opens up a dialogue for robot-assisted medical procedures, especially when dealing with microscopic and nano-particles. The dexterity and precision with which robots can perform tasks, supersedes human abilities and can be constructively used for complex procedures. As summarised by Taylor et al., (2016), the role of medical robotics is not to replace clinicians, rather it is to aid them by transcending human limitations, and improving the safety, consistency, efficiency and overall quality of treatment provided.

While robots may make procedures safer and more efficient, they are not necessarily the most environmentally sustainable. A study by Woods et al., (2015) compared the carbon footprint of robotically assisted laparoscopy, laparoscopy, and laparotomy. Based on the solid waste generated and the energy consumed in each procedure, they concluded that the robotically assisted laparoscopy had a much higher carbon footprint than either of the other two (38% more than the laparoscopy and 77% more than the laparotomy).

2.3 Digitization and AI in the medical industry

When it comes to patient treatment, most treatments prescribed are probabilistic with no realistic predictions of their effects until after the treatment occurs. Using data mining and artificial intelligence, it may now be possible to shift from probabilistic to definitive treatment, and allow doctors to focus more on the delivery of actual patient care (Bennett & Hauser, 2013).

Our imaging techniques are now far ahead of the static imaging of X-Rays and CT scans that we are used to. New imaging technology not only allows us to better visualize human structures and disease states, but also allows us to generatively predict the onset and spread of disease in the body. The ability to simulate disease states before the onset provides opportunities for localised rehabilitation, control and limit the disease from spreading, and even prevention of onset of the disease, thus saving huge investments in probabilistic treatment and care (Dukart et al., 2013).

Data mining and predictive modelling of Electronic Health Records can help predict the optimal clinical treatment for a patient. This in turn reduces the reliance on corrective procedures, post-procedural care and treatment redundancies in cases of un-effective treatment (Bennett & Doub, 2010).

The enormous amount of data generated at healthcare centres opens up multiple opportunities to use predictive analytics to reduce decompensations and hospital readmissions, estimate the risk of procedural complications (triage), and predict adverse effects such as multiple organ failures (Bates, Saria, Ohno-Machado, Shah, & Escobar, 2014). These analyses can warrant timely action, and thus reduce resource consumption at hospitals.

Big data and real-time monitoring of patient data can help reduce the stress on hospitals by encouraging home care for non-critical patients. Remote monitoring of patients with wearable and implantable devices can help manage and prevent their re-hospitalization (Wang & Moriarty, 2018; Arun Kumar, 2014). This will benefit elderly patients by identifying both short-term critical conditions, and long-term patterns that help build personalized treatment (Grossglauser & Saner, 2014).

2.4 Additive Manufacturing in the medical industry

One of the key advances in technology to reduce waste in the manufacturing process is the development of additive manufacturing. As opposed to the traditional method of subtracting and morphing material to develop the required part, additive manufacturing uses a 3D digital model to precisely create the required part layer by layer. This not only saves material, but also enables the generation of complex structures previously not feasible using subtractive manufacturing. The reduced time required to generate a prototype, reduced labour, and the flexibility in customizing prototypes makes this technology a go-to strategy for efficient resource consumption.

Additive manufacturing is now being extensively used in dentistry (Torabi, Farjood, & Hamedani, 2015), maxillofacial surgery (Suomalainen, Stoor, Mesimäki, & Kontio, 2015), head and neck surgery (Chan et al., 2015), correction of bone deformities (Yang et al., 2015), and plastic surgery (Choi & Kim, 2015) to name a few sectors. Although the uses of additive manufacturing are plenty in the medical industry, the technology is yet to evolve to become faster, more accurate, more efficient and cheaper, for the use to be accessible to all (Martelli et al., 2016).

The use of additive manufacturing in the medical industry has been gaining speed over the last few years (Javaid & Haleem, 2018). Rapid prototyping enables clinicians not only visualize the human body, but also provide tactile insights into physiological processes and complex pathologies (Nocerino, Remondino, Kessler, & Uccheddu, 2016). As research in additive manufacturing continues, new materials and processes need not be limited to a solid re-creation of a digital model, but also the recreation of states of matter, textures and even the response to human touch that materials can generate (Giesel, Mehndiratta, Tengg-kobligk, Schaeffer, & Teh, 2009).

3. Discussion

As mentioned above, Industry 4.0 can be beneficial in reducing procedural caused medical waste, but it is important to note here, that the implementation of industry 4.0 can be highly complex and require huge investments of time and money.The transition to a completely digitized system requires a large infrastructural overhaul and a considerable change in mindset and behaviour of hospital staff and clinicians. A digitized system also requires ethical clearances from patients to participate and contribute their data, and hospitals will need to provide adequate assurances that this data will not be misused or shared with other parties.

This paper explores concepts of industry 4.0 that have generated significant interest in the healthcare community and can be very impactful, but Industry 4.0 is not limited to the concepts explored here. There is scope to expand on this topic and put forth many more ways in which procedural waste can be reduced in the medical industry.

Another aspect worth investigating is the clear distribution of the waste produced from various units in a hospital. The concept of waste audits is worth conducting at medical institutions to identify the composition of the waste generated, the contribution of waste from each unit of the hospital and how the waste is being segregated. The information from waste audits can allow for targeted solutions to process redundancies, design related issues or inventory management concerns. The existing literature that was explored in this area was found to be not clear and focused on overall waste management and system level problems only.

4. Conclusion

Healthcare systems today are far from sustainable in their practice, this includes the waste in material, waste in time, waste in expenditure or even redundancies in treatment provided to the patient. With growing concerns on the environmental impacts of healthcare waste, and the concerns of needless expenses by hospitals, there is a need for timely solutions to reduce the production of procedural waste in the medical industry.

The concept of industry 4.0 and advanced manufacturing systems could potentially provide multiple avenues to tackle this problem at various levels. Lean production strategies are one way to streamline processes and treatment procedures and make the system more efficient. By connecting healthcare devices and creating cyber-physical systems in healthcare, procedures requiring skill beyond human abilities can be assisted by robots. These assistive robots, can then feed in procedure statistics and patient data through sensors back to the clinicians creating a feedback loop which allows the system, and the clinicians to learn more with every procedure.

Overall, the digitization of systems and the use of data through artificial intelligence can shift the clinician's role from probabilistic treatment to definitive treatment. Real-time monitoring of the patient can prevent unnecessary hospitalization, provide timely treatment and reduce chances of decompensation. From a manufacturing standpoint, additive manufacturing has revolutionized the way in which we produce structures and parts essential for medical practice and for the wellbeing of patients. The ability to produce customized parts created for human structural reconstruction, and to use this capability in procedure simulation, part reconstruction and even as a tool to educate future clinicians has a timely role in reducing procedure-caused medical waste and redundancies.

As we see pockets of industry 4.0 crop up in various aspects of this industry, it is important to democratize this knowledge and plan the transition in an efficient and effective manner. Multiple roadblocks are yet to be overcome in terms of data privacy. It is also necessary to develop a structured process for this transition to a smart digitized system so that adoption of new technology is simplified, and under-developed nations can leapfrog the mistakes made by developed nations to provide universal access to sustainable healthcare.

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