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Adoption and Diffusion of Disruptive Technologies: The Case of Additive Manufacturing in Medical Technology Industry in Australia

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Abstract

This paper provides the preliminary findings of a newly granted two-year project investigating the adoption of disruptive technologies, by focusing on the case of additive manufacturing (AM) in the medical technology (MedTech) industry, particularly implant applications. This is done by (I) stakeholder mapping of the industry in Australia. This included members of industry, researchers, academics, regulatory experts and MedTech consultants. (II) Identifying the top four major opportunity areas in which innovation can foster the adoption of AM implants, them being developments in Materials Science, Technology, Business Models, and Regulation & Quality Management. (III) Identifying and discussing the barriers in realizing such opportunity areas in practice, and finally (IV) recommending solutions based on the discussion and understanding of the proposed barriers that are hindering the widespread adoption and diffusion of 3-D printed medical implants. The impact of the project will be to unlock the potential of AM applications in the medical technology, which will benefit potential new entrants to the industry, incumbent firms, health care system, and patients in Australia.

Keywords: Innovation adoption; Additive manufacturing; 3D printing; Medical device industry; Stakeholder

1. Introduction and motivation

The Australian medical technology (MedTech) industry is comprised of about 400 companies employing over 19,000 people [1]. The majority of the companies are small to medium sized enterprises (SMEs) with less than 20 employees and revenue of less than $2 million [2]. Australia's market for medical devices was valued at $6.81 billion USD in 2016 [1]. A recent report from the Commonwealth Scientific and Industrial Research Organization

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(CSIRO) shows how the MedTech industry can potentially add $18 billion to the Australian economy and about 28,000 new jobs within the next eight years through the development of technologies that are identified as opportunities for growth [3]. One of the technologies listed are orthopedic implants, however there are only a handful of firms in Australia are active in the implant sector of the MedTech industry. This is due to fierce competition from manufacturers in the USA, UK and Japan.

Australian MedTech companies are exploring the disruptive technology of additive manufacturing (AM) to aid surgery planning and manufacture orthopedic implants. In a 2018 published Belgian report; 'Responsible Use of High-Risk Medical Devices: The Example of 3D Printed Medical Devices' summaries numerous papers on the medical, economic and legal literature of the implementation of 3-D printed implants [4]. Given the upcoming international harmonization between regulatory bodies across Europe, America and Australia on such medical devices, the findings have given relevant insight. It reported that certain AM devices and AM-related surgical planning methods lead to a reduction of surgical complication rates reduced pre-operation time, hospital length of stay and total cost [4]. If the technology is adopted, in addition to the potential costs saved for the patient and healthcare system, it could provide more sustainable manufacturing and logistical processes. The current system employed by hospitals involves multiple sterile implants of various sizes being transported to the surgical theatre for each operation of which one device is used with the rest having to be either re-transported and sterilized or disposed as biological waste. Having superior pre-planning methods and patient-specific devices, enabled by AM manufacturing, would lead to a more efficient logistical system. However, regulations are set to change to acknowledge customized devices for patients. Both in Australia and in the Belgian paper, regulation is set to change the "enjoyed low regulatory burden" and will now have to comply with certain quality and safety requirements. Meeting these requirements can be a long and rigorous process [5]. Due to the Australia's low population and the highly regulated maze associated with 3D printing implantable medical devices [6], they are expensive to develop and especially difficult to commercialize in Australia, leading to companies taking their technologies offshore.

The aim of this paper is to reflect the outline and preliminary findings of a newly granted, RMIT University and Stryker collaborated project, on the investigation of the adoption of disruptive technologies by focusing on the case of AM in the MedTech industry. With particular focus on medical, implant applications. This was first completed by (I) stakeholder mapping of the industry in Australia. This included members of industry, researchers, academics, regulatory experts and MedTech consultants. (II) Identifying the top four major opportunity areas in which innovation can foster the adoption of AM implants, them being developments in Materials Science, Technology, Business Models, and Regulation & Quality. (III) Identifying and discussing the barriers in realizing such opportunity areas in practice. In which (IV) recommending solutions based on the discussion and understanding of the proposed barriers that are hindering the widespread adoption and diffusion of 3-D printed medical implants.

The structure of this paper is sectioned in 7 parts, in which the first is the introduction. Section 2 provides a brief overview of the project, which includes the aim and partners. Section 3 describes the workshop that was held on May 30, 2018, where a wide range of stakeholders were brought together to discuss and collect data on the opportunity areas and associated barriers. In Sections 4 and 5 we provide the results and discussion from the workshop, identifying the opportunity areas for AM in MedTech and analyzing the results from a survey which ranks the barriers for adoption of AM in MedTech. Section 6 is the conclusion and 7 is the reference list.

2. Overview of the project

The two-year project investigates the adoption of disruptive technologies and emergence of entrepreneurial opportunities by focusing on the case of AM implants in the MedTech industry. The expected outcome is a comprehensive guideline and/or an accepted regulatory framework for the adoption and diffusion of implants applications of AM. This is done by developing solutions to remove the technological, market and regulatory barriers for both patient-specific and off-the-shelf implants. The impact will be to unlock the potential of AM applications in the MedTech industry, which will benefit potential new entrants, incumbent firms, health care system and patients in Australia. It will also offer a benchmark in University-Industry collaboration.

To understand the perspective of researchers, SME and large manufacturers alike, the project is partnered with the Innovative Manufacturing Cooperative Research Centre (IMCRC), OMX Solutions and Stryker. The project has

also had consultation from the Therapeutic Goods Administration (TGA) the regulatory body for therapeutic goods in Australia, regulation consultants and AM economics experts.

3. Methodology

3.1 Workshop Description

The data for this paper was collected in a workshop that was held on May 30, 2018. In this workshop, a systematic stakeholder mapping was conducted, categorizing members of the Australian AM MedTech industry into SMEs, Large Manufacturers, Government Regulators, Industry Associations, Research Centers, Hospitals, Surgeons and Health Insurers. A total of 112 representatives were invited to the workshop, of which 55 attended. The 55 attendees were categorized as follows: 20 researchers, 14 manufacturers, 8 representatives of industry associations, 8 regulations specialists, 3 health insurance representatives and 2 surgeons.

The workshop had a morning session and an afternoon. The morning session consisted of an introduction by the project leader and 8 panelist talks from different stakeholders, followed by a question-and-answer discussion between the audience and 8 panelists. Each panelist had a shared theme in which they stated the benefits that AM brings to their patients, products or customers, followed by the barriers that they face in their sector of the industry. The goal of the morning session was to bring all attendees to a shared baseline of knowledge and instigate ideas for the afternoon session, which had specific data-gathering activities.

The afternoon session had 29 participants who were split up into 5 tables where each stakeholder category could be represented where possible. Of the 29 participants, there were 13 researchers, 9 manufacturers, 5 regulations experts and 2 health insurers. The afternoon session content consisted of three data-gathering activities, of which the discussion between the stakeholders was captured using voice recorders on each table and later transcribed for further analysis. The first activity was a roundtable discussion addressing a question on each of the four opportunity areas; materials science, technology, business models and regulation and quality. The second activity was a survey where the most influential potential barriers to the adoption of AM implants in MedTech were sorted. The sorting was on the basis on whether stakeholders agreed or not on what was a potential barrier. The third activity involved merging the participants into four tables and each table being responsible for drafting industry roadmaps in one of the opportunity areas.

3.2 Data-gathering activities

The four questions for the first activity were developed under consultation from an established MedTech consultant, who was also the workshop facilitator. The question for the opportunity area of materials science was; “Based on our current knowledge of 3D printing technology and applications, where and how does science need to progress to improve medical device performance?” For technology, “What do you believe are the greatest technological challenges limiting the widespread use of 3d printing for the manufacture of medical devices?” For business models; “As adoption increases, how do we anticipate business models changing and affecting the manufacturing of medical devices?” and regulation; “What are the key regulatory and quality management issues (including risk) that need to be considered and actioned to provide improved patient healthcare?”

The objective of the second activity was to identify and rank the barriers to adoption and 26 participants filled out the survey. Barriers are defined as systematic blockages that inhibit the widespread adoption of a technology. Looking at scientific literature, attending conferences and under further consultation from the workshop facilitator, a list of 21 potential barriers were proposed and they are depicted in figure (2). To see which potential barriers were the most prevalent among each stakeholder category, the participants were asked to state the category that best describes them.

The objective of drafting industry roadmaps was to produce a visual guide to identify the industry drivers, identify barriers that prevent adoption and suggest methods of overcoming the barriers. In total, four roadmaps were drafted; one for each opportunity area. As the roadmaps were expansive in both data and size, they are not suitable for this streamlined report.

4. Opportunity areas

The four main opportunity areas proposed for the adoption of Additive Manufacturing in MedTech are materials science, technology, business models and regulation and quality. Each determined to be a key area in the fruition of adoption and diffusion of Additive Manufacturing for medical devices. See below for a brief outline on how each of the following opportunity area relate to each other and the ultimate goal.

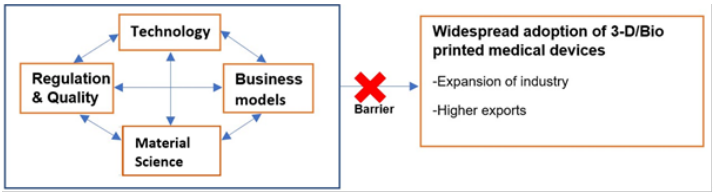

Fig. 1. The relationship between opportunity areas for the outcome of widespread adoption of 3-D/Bio printed medical devices.

4.1. Materials science

The underlying performance of an AM medical device proposed was the material choice and the application of the selected material. Currently titanium-based implants are what are used, as they have been the industry standard for decades and are TGA certified for class III medical devices. With additive manufacturing reaching medical technology, this was an opportunity to look into new materials. Stakeholders proposed that the next step to use of non-biological materials would be biodegradable materials that facilitate tissue growth and eventually tissue engineering.

4.2. Technology

Technology has so much to offer for the advent of AM in the MedTech industry. The proposed focus of the held workshop was to emphasize on surface finish of implants, investigation of printing related parameters (powder consistency, printing setting, etc.), in situ monitoring and computer simulations of patient specific implants. Technology was key to the mass customization of medical devices and therefore part of the next step in the trajectory of medicine. It was also agreed amongst stakeholders that the current path of MedTech would intersect with other advancements. Specifically, artificial intelligence for the aforementioned applications of in situ monitoring and parameter optimization.

4.3. Business models

With additive manufacturing (AM) enabling anyone to make a product on site, the logistics; consequently, now changes. In the workshop held, stakeholders contended that the future with AM medical implants would shift from a centralized model into a decentralized model for SME's. The centralized model would remain for large companies, which may choose to provide services and/or sell digital and physical templates of implants to smaller companies and hospitals. Hospitals and small companies can then manufacture it to a patient's specifications. Another point presented by stakeholders was where bureaus that would offer 3-D printing services. If a business possesses the economic viability and skill set, they would opt to print in house additive manufacturing. If the contrary, the business would opt to outsource what needs to be printed to a bureau.

4.4. Regulation and quality

Regulation and quality management for patient specific medical implants has been a recent topic of focus for the TGA and other government health regulation bodies around the world. The foremost objective was to harmonize definitions and standards amongst all these bodies to create an internationally recognized regulation platform. Currently, the TGA was figuring how to account for the unique nature of having such customized devices, and are

reviewing the current protocol to assess them so that patient safety was upheld while their medical needs are met. This entails many consultations with stakeholders (i.e. manufacturers, surgeons, etc.). As part of accounting for the patient-specific nature of these implants, it has been proposed the TGA (and other regulating bodies) need to be more willing to accept computer simulated models to predict performance and more post-market follow up studies.

5. Barriers of adoption

As part of the conducted workshop, all the invited professionals that attended scaled the importance of numerous proposed barriers that riddle each of the four opportunity areas. Figure 1 in the previous page displays how regulatory related barriers have hindered the prosperity of new materials being used for 3-D printed implants. Overall, each barrier hindering the final goal of the adoption of 3-D printed& bio printed medical devices.

Top 5 barriers agreed upon were 1) Manufacturing Process & Post-Process Approval' at 85% of surveyed stakeholders, 2) Medical and Professional Endorsement' at 85% of surveyed stakeholders, 3) Medical Device Reimbursement' at 77% of surveyed stakeholders, 4) Material Issues' at 73% of surveyed stakeholders, 5) Staff Training' at 73% of surveyed stakeholders. Referring to the top five results, almost each one corresponds to one the four opportunity areas discussed and therefore is an obstacle to achieving each opportunity area.

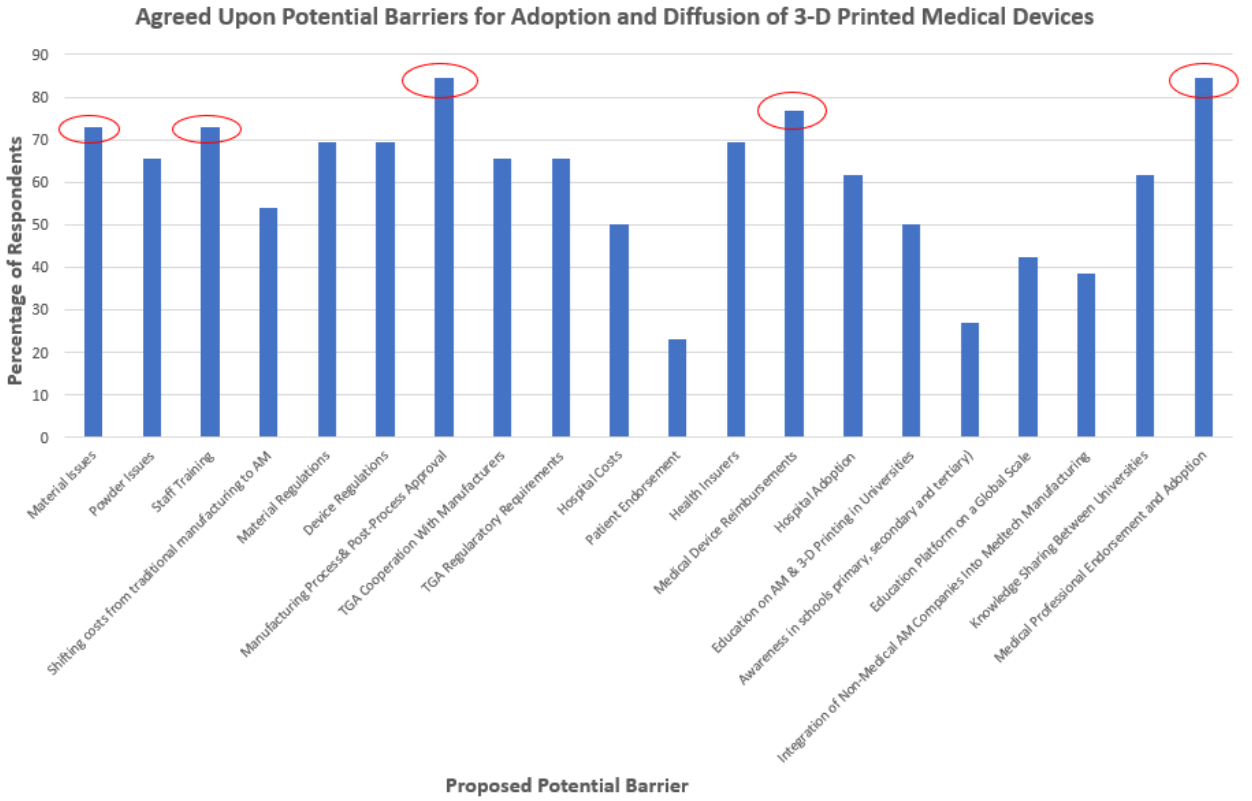

Fig. 2. Agreed on potential barriers from the surveyed workshop participants. The top five potential barriers are circled.

5.1. Material science

'Material issues' ranked as the most frequent barrier by stakeholders during the workshop. During the workshop's discussion, it was mentioned, "There is a huge hole in our understanding of the science of biomedical 3-D printing. An RMIT study showed that the angle on which a titanium printed caused variation in outcome of cell-metal interaction. There is an underestimated biological complexity to the current understanding of 3-D printing for

implants". This reflects the lack of full utilization of current materials. In addition to full utilization of current materials, it was also raised that many potential materials that are not being used due to high cost needed for research and regulatory validation. One stakeholder stating, "The process of regulating novel materials probably will not get any cheaper than the estimated 10 million (accounts for all of the studies required), but it might be able to be fast-tracked by working with regulatory bodies right from the beginning of their studies as they build up the evidence for the material master file".

5.2. Technology

In tandem with material issues, came 'Manufacturing Process' as the most frequently agreed upon potential barrier. In the discussion segment of the afternoon workshop, stakeholders proposed the technological barriers were quality control, repeatability, validation and surface finish. Quality control entails the concern of outputting a printed device that would be acceptable to use. Repeatability was the ability to reproduce a device and its quality. Validation is having the produced device certified by regulatory bodies (i.e. TGA). Surface finish is how the produced device has its surface prepared for application and implantation.

5.3. Business models

Both 'Medical and Professional Endorsement' and 'Staff Training' on the top five barriers (number two and five respectively) are the business-related barriers. During the discussion in the afternoon, it was specifically expressed that out of all medical professionals, it was the surgeon's willingness to adopt that is paramount. A surgeon's input plays an important role in hospitals adopting on-site 3-D printing, as they are responsible for the implantation of the device into the patient. The other top barrier candidate, 'Staff Training', was discussed to be a key factor in the hospital on-site printing. Since liability and quality assurance was a concern, whomever is printing must be fully competent. This also ties in with a frequently mentioned barrier discussed, which was the issue of liability. If hospitals are to print on-site in the future, the question of "who is liable? The surgeon, hospital or part designer?" was raised. Different stakeholders contended different nominees are responsible if a 3-D printed implant was to fail.

5.4. Regulation and quality

As the only regulations related barrier, 'Medical device reimbursement' came ranked third place with 77% contending it needs to be addressed. Given then only TGA approved medical devices are eligible for government subsidizing, a financial incentive is absent. In tandem with the concern of medical devise reimbursement, the afternoon discussion expressed perceived lack of openness and clarity of the TGA's requirements has been as a frequently mentioned barrier, especially amongst SME's. Stakeholders mentioned that, there needs to be alternate methods of TGA validation for patient-specific devices since "it [current policy] doesn't cope with the fact that you can customize these devices in a predictable manner in order to match certain anatomical parameters and they would give you the same sort of reproducible outcome on model patients, even though it's customized. That's why the TGA has no idea how to deal with this." Overall stakeholders expressed that the lack of communication between TGA's needs and businesses as well as TGA accounting for this new paradigm (3-D printed patient specific implants) are immediate barriers of the regulation opportunity area.

6. Conclusion

For this research project, the first milestone has been successfully achieved which was to essentially develop a stakeholder map and then hold a workshop to understand the opportunity areas and barriers for the adoption of Additive Manufacturing in MedTech. The four main opportunity areas proposed are materials science, technology, business models and regulation and quality management. The top 5 most agreed upon surveyed barriers were 'Manufacturing Process', 'Medical and Professional', Medical Device Reimbursement', 'Material Issues' and 'Staff Training'. The next step of the project would be to attempt to address these barriers to achieve each of the four opportunity areas.

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