Prospectus

The Double-Barreled Syringe (Technical Topic)

3D Printing Innovation in Healthcare (STS Topic)

By

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction:

My technical Capstone project is the development of an augmented syringe device for the UVA Family Medicine Primary Care Center of the UVA Hospital. The main requirements of our medical device are to be able to inject and aspirate two separate medicines with ease and independence from of each other. By creating the "double-barreled syringe" with a physician in family medicine, Dr. Kent, my group expects to utilize iterative prototyping through 3D printing (3DP) to develop a patent later in the process. Innovations such as 3DP provide rapid and accessible prototyping technologies to an increasing portion of the population by lowering barriers to entry for basic prototyping allowing me and my team to benefit throughout this project. Additionally, healthcare professionals interested in possible improvements in their field can now easily utilize cheap and effective means of product development to test prospective solutions without risking major capital investments. 3DP in the healthcare industry allows physicians and others to propose innovations and potentially change their field given adoption from other stakeholders such as patients, nurses, and physicians. I decided to focus my research on tracking how the emergence of 3DP has disrupted healthcare in the modern world and aided in spreading innovation to areas in the developing world. Overall, new technologies such as 3DP are "giving individuals the power over the means of production, allowing for bottom-up entrepreneurship and distributed innovation" (Savvides, 2019). My research will be focused on how this accessibility of basic manufacturing has served to be a significant enabling factor for both entrepreneurs and social activists to improve healthcare of both developed and emerging countries.

Technical Topic:

The current single syringe and needle method is inadequate for performing and undergoing musculoskeletal injections for doctors and patients respectively. Currently, musculoskeletal injections of therapeutic substances into joints or ligaments constitute nearly 50,000 procedures annually (The Burden of Musculoskeletal Diseases in the United States (BMUS) 3rd Edition (Dated 12.31.16). Pdf, n.d.). In a study from the Mayo Clinic's GIM Musculoskeletal Injection Clinic, the three most commonly injected sites found were the knee (208 injections, 37%), greater trochanteric bursa or hip (197 injections, 35%), and glenohumeral joint or shoulder (96 injections, 17%)(Wittich et al., 2009). The application of these injections ranges widely in age and demographic. To narrow our sample, we will focus our attention on the importance of this procedure in the context of general practice medicine, including sports medicine and family medicine. As Wittich notes, "musculoskeletal problems are common in primary care and often respond to injections containing both corticosteroids and short-acting anesthetics" (Wittich et al., 2009). For use in sports medicine, the average age of patients is about 20 years old with the common cause of injury being overuse (J. Kent, personal communication, October 13, 2020). However, the majority of these injections are performed in family medicine and are applied to patients between the ages of 40 and 60 (J. Kent, personal communication, October 13, 2020). These injections are used for treating ailments such as arthritis, which is associated with sedentary lifestyles and comorbidities like obesity. Specific to our concern of ultrasound (US) guided musculoskeletal injections, a significant barrier to progress arises from the existence of prior art as similar devices have been proposed for other disciplines of medicine such as dentistry and veterinary medicine. This ultimately limits the scalability and generalizability of such a device in the long term.

With the introduction of a double-barreled syringe, the field of musculoskeletal injections would be greatly impacted by the ability of a single device to inject and aspirate with full autonomy using one hand. Technically, this device would give physicians freedom to inject and aspirate freely without having to follow a predetermined sequence of separate injections or aspirations. Moreover, many musculoskeletal injections are guided by ultrasound and require two injections to carry out the procedure requiring a physician to hold and manipulate a US probe and syringe simultaneously. When using multiple syringes to perform multiple injections, patients experience discomfort at the injection site(s) since one syringe is switched out with another, leaving the needle in the patient. Clinically, a dual-injection system would increase the efficiency of injection procedures for physicians and improve overall patient experience. These goals of increased efficiency and patient comfort would be accomplished by not requiring an exchange of syringes mid-procedure, effectively streamlining the process for the physician, and simultaneously lowering patient discomfort. As previously mentioned, around 50,000 injections of therapeutic substances into joints or ligaments occur every year. It is estimated that using a dual-injection device would save 40 seconds per procedure, equating to roughly 555 hours every year (23 days) (J. Kent, personal communication, October 13, 2020). An additional technical capability required to improve clinical outcome is a compact device that allows maneuverability at the skin interface so that an injection can be made almost parallel to the skin interface.

If the aforementioned proposed aims are achieved, the field will have the choice to adopt this new device in the vast majority of procedures that require multiple injections or aspirations. Additional positive byproducts of this change include decreasing time per procedure and increasing patient satisfaction per procedure.

STS Topic:

3DP has become increasingly accessible to a large portion of the population. In the early 2000's, only Fortune 500 companies and major research universities had access to 3D printers; however, today people are able to purchase 3D printers for much more affordable prices (Nam Chan et al., 2017). There are clear cost benefits for adoption of 3DP as it can help companies reduce dependence on shipping and inventory as well as allow consumers to save up to ninety-nine percent of commercial pricing for products (Pearce et al., 2020). In addition to cost benefits, the technology has been democratized by the facilitators like Hacker-, Makerspaces, and Fab Labs which provide platforms for hobbyist maker communities, political interventions, and startup incubators (Savvides, 2019). The growth of both adoption and accessibility for 3DP has led to an enabling environment for those who were previously unable to access traditionally expensive manufacturing and prototyping techniques. Actor Network Theory (ANT) can be applied as a framework in this situation in analyzing the disruption in the traditional network of entrepreneurship. ANT can aid to explain in part how many new actors acting in their own self-interest have started to shift the network to become more accessible in order to spread innovation to more groups throughout the world. Examples of these changes include the creation of forum resources such as "Thingiverse", resources such as these "Makerspaces", and design resources such as computer aided design (CAD). These growing resources have convinced others to create a stable, wide network of 3DP. The sociotechnical ecosystem that has emerged created by the new actors has impacted healthcare significantly in both developed and developing nations. As a result, there now exists a revolutionary infrastructure in which people are able to share physical designs and then have them produced anywhere in the world with this technology. My objectives of my analysis are to analyze how the

disruption of 3DP has allowed actors to advance personalized and cheaper healthcare alternatives in developed nations while simultaneously sharing and helping to solve major health problems in developing nations.

With regard to healthcare in the modern world today, the integration of 3DP technology can augment the experience of patients and physicians by improving personalized healthcare and decreasing cost through the work of entrepreneurs equipped with the enabling power of rapid, customized, and cheap prototyping (Aquino et al., 2018). One example of 3DP improving personalized healthcare is the growing interest in the creation of patient-specific pills that could allow individualized dosages and combinations of medication (outsourcing-pharma.com, n.d.). Another case of personalized healthcare innovation is the potential of 3D printed casts which offer a unique fit for patients whereas prior casts and braces were made to accommodate a general anatomical shape (4 Ways 3D Printing Is Changing Orthopedic Casts And Braces, n.d.). 3DP also has the potential to significantly reduce costs of healthcare. For rapidly growing groups like children, constant exchange and fitting of prosthetics is expensive. To remedy this expense, innovation has been made in prosthetic sockets for below-the-knee prosthetic limbs that fit specifically to their tailored recipient and are cheaply produced using 3DP (3D Printed Prosthetic Socket / University of Toronto Scientific Instruments Collection, n.d.). Allowing healthcare to be more customized to the patient as well as being more affordable can help alleviate some of the major issues our healthcare systems face today and should be explored further. 3DP's increasing accessibility has stimulated innovations and benefits to our modern healthcare systems; additionally, the advancements made in the developed world in healthcare through 3DP have also been able to spread to areas with less developed healthcare systems.

With regard to healthcare in the developing world, 3DP designs can easily be created in one country and subsequently shared across the globe for use elsewhere. The use of this farreaching digital infrastructure has made a considerable impact on societal health struggles in water management and disease identification in countries lacking modern health infrastructure. Powered by the shareable network of 3D printed designs, activists are now equipped to take technologies to those without advanced manufacturing capabilities by creating devices and tools with 3DP that can be made on-site. For example, in order to prevent water-born bacterial infections which result in more than 2,000 deaths per day, open source 3D printed microscopes have been produced in remote areas to identify unsafe water before it is consumed. These microscopes provide a simpler, faster, and cheaper method to getting more tests done in a shorter amount of time (Four Ways 3D Printing Is Improving Healthcare in Developing Countries / ManufacturingTomorrow, n.d.). Disease identification has also been improved in areas lacking in hospitals or dedicated laboratories through innovations in blood and saliva tests. One example emerged from the 2014 Ebola Outbreak, FieldLab, developed by Rhodes University in South Africa. They created a solar-powered, partially 3D printed "lab in a box" that could be used to carry out DNA analysis. Another test kit made by PandemicTech also recently emerged and combatted the rise of leishmaniasis by using 3D printed test tubes and caps (Four Ways 3D Printing Is Improving Healthcare in Developing Countries / ManufacturingTomorrow, n.d.). These 3DP enabled innovations are bringing healthcare technology to those who otherwise would be at risk of water contamination or rampant unmonitored disease spread. The benefit to the ability of the 3DP network to spread ideas of innovation to developing nations has also been experienced during the COVID-19 pandemic. 3DP offers a rapid response to emergencies and can accommodate disruptions in supply chains. 3DP has also been used to create mask designs

and other medical equipment designs that can be shared anywhere (Choong et al., 2020). Beyond health crises such as water contamination and pandemics, there is a continuing potential for 3DP to be used for activism in order to solve critical issues in developing nations. 3DP's increasing availability has changed the network of entrepreneurship to create a collaborative and activist community with the ability to share designs with the world.

Next Steps:

The next steps in research would be to explore whether the use of 3DP is manifesting in different ways in developed and developing nations and whether these attitudes toward the use of 3DP are permanent. Specifically, my research would look to improve understanding the different ways 3DP is used in developed nations in relation to developing nations and how cultural norms and customs affect the use of the technology. I am interested in tracking the translation of 3DP technology from developed nations to developing nations further and how the collaborative environment that has been created is likely to progress. Another possible avenue of further research for developed nation innovation would be near future innovations in the realm of healthcare such as 3D printed organs ranging from skin grafts, bone, heart tissue, and cartilage (Murphy & Atala, 2014). These next steps in research could have findings that would impact how 3DP is viewed and utilized as a tool of equity and inclusion of other nations.

References:

- 3D printed prosthetic socket / University of Toronto Scientific Instruments Collection. (n.d.). Retrieved November 2, 2020, from https://utsic.utoronto.ca/wpm_instrument/3d-printedprosthetic-socket/
- 4 Ways 3D Printing Is Changing Orthopedic Casts And Braces. (n.d.). Covering the Specialized Field of Orthopedic Product Development and Manufacturing. Retrieved November 1, 2020, from https://www.odtmag.com/contents/view_online-exclusives/2019-05-29/4ways-3d-printing-is-changing-orthopedic-casts-and-braces/
- Aquino, R. P., Barile, S., Grasso, A., & Saviano, M. (2018). Envisioning smart and sustainable healthcare: 3D Printing technologies for personalized medication. *Futures*, 103, 35–50. https://doi.org/10.1016/j.futures.2018.03.002
- Choong, Y. Y. C., Tan, H. W., Patel, D. C., Choong, W. T. N., Chen, C.-H., Low, H. Y., Tan, M. J., Patel, C. D., & Chua, C. K. (2020). The global rise of 3D printing during the COVID-19 pandemic. *Nature Reviews Materials*, 5(9), 637–639. https://doi.org/10.1038/s41578-020-00234-3
- Four Ways 3D Printing Is Improving Healthcare in Developing Countries / ManufacturingTomorrow. (n.d.). Retrieved November 2, 2020, from https://manufacturingtomorrow.com/news/2018/09/07/four-ways-3d-printing-isimproving-healthcare-in-developing-countries/12111/
- Murphy, S. V., & Atala, A. (2014). 3D bioprinting of tissues and organs. *Nature Biotechnology*, 32(8), 773–785. https://doi.org/10.1038/nbt.2958
- Nam Chan, H., Andrew Tan, M. J., & Wu, H. (2017). Point-of-care testing: Applications of 3D printing. *Lab on a Chip*, *17*(16), 2713–2739. https://doi.org/10.1039/C7LC00397H

- outsourcing-pharma.com. (n.d.). *Next step in personalized medicine enabled by 3D printing*. Outsourcing-Pharma.Com. Retrieved November 2, 2020, from https://www.outsourcing-pharma.com/Article/2019/02/01/Personalized-medicine-enabled-by-3D-printing
- Pearce, J. M., Pearce, J. M., & Pearce, J. M. (2020, April 27). The 3D printing revolution is finally here. Fast Company. https://www.fastcompany.com/90497468/the-3d-printingrevolution-is-finally-here
- Savvides, L. (2019). *3D Printing: Politics, Material Hacking And Grassroots* [Thesis, University of Leicester].

/articles/thesis/3D_Printing_Politics_Material_Hacking_And_Grassroots/10211555/1

The Burden of Musculoskeletal Diseases in the United States (BMUS) 3rd Edition (Dated 12.31.16).pdf. (n.d.). Retrieved October 21, 2020, from https://www.boneandjointburden.org/docs/The%20Burden%20of%20Musculoskeletal%2 0Diseases%20in%20the%20United%20States%20(BMUS)%203rd%20Edition%20(Date d%2012.31.16).pdf

Wittich, C. M., Ficalora, R. D., Mason, T. G., & Beckman, T. J. (2009). Musculoskeletal Injection. *Mayo Clinic Proceedings*, 84(9), 831–837.