

Design of a Hemostatic Ring for Mohs Micrographic Surgery
(Technical Report)

Preventative Healthcare as a Sustainable Transition
(STS Research Paper)

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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

Diagnosis of skin cancer in the United States has risen over the past several decades. The two most common forms of skin cancer, basal cell carcinomas and squamous cell carcinomas, are often treated with Mohs micrographic surgery (MMS), as it is considered the most effective form of treatment.

The technical report written encompasses the design of a device that induces hemostasis surrounding a circular incision made in MMS through the application of pressure to better allow for clinician visualization of the wound and for the identification of excessive bleeding sites. Nearly 40% of complications in MMS are a result of excessive bleeding (Bunick & Aasi, 2011). Excessive bleeding can also cause increased clinician frustration, longer surgical time, and greater amounts of scar tissue upon healing. But the need for MMS, and the resultant frustration, cost, and recovery it entails, is preventable; this is due to the fact that skin cancer is a preventable form of cancer. One of the main causes of the development of skin cancer is excessive exposure to UV light (Centers for Disease Control and Prevention, 2021). There are many ways in which individuals can ensure protection from UV rays including knowing when the UV rays are the strongest, avoiding tanning, and using broad-spectrum sunscreens. However, individuals can also visit a dermatologist at least once a year for a professional skin exam to ensure there are no areas of the skin that raise a concern or appear abnormal. By gaining a professional opinion, areas of the skin that are found to raise a concern can be monitored more closely, and a course of treatment can be taken if necessary. Typically, when individuals do not have this maintained yearly observation, the point in time in which they are able to self-identify an abnormal area of the skin is likely much later, and the abnormality (potentially cancerous area) is more developed than when a professional would have been able to identify the area as abnormal. Preventative healthcare measures and programs implemented within communities promote better community health through enabling community members to have better access to the knowledge, care, or support they need. **The topic that will be studied within this STS paper is that of the sustainable transition within**

healthcare to a focus on preventative (upstream) care and the stakeholders within the healthcare regime that promote or inhibit this transition.

Technical Topic

Mohs micrographic surgery (MMS) is a surgical procedure typically used to treat skin cancer. In the surgery, the visible tumor and a small segment of surrounding skin are removed. The tissue that is removed is then examined under a microscope to observe cancer cells or the lack thereof. If cancer cells are found, a deeper layer of skin is removed and observed under the microscope. This feedback loop continues until there are no cancer cells found in the observed layer of tissue. While an individual is having this procedure done, they are not asleep, but rather the area of operation is numbed (Prickett & Ramsey, 2021). This means that the patient is aware of the progression of the procedure and also the state of the clinician. If a surgical incision point is bleeding excessively then the clinician may have an inhibited ability to perform optimally, which may cause clinician frustration. As the patient is awake throughout the procedure, they may be able to sense clinician frustration, which may produce patient frustration or for the patient to lose confidence in the ability of the clinician, both compromising the surgical experience and damaging the patient-clinician relationship.

A device that allows for hemostasis to be induced surrounding the incision in MMS can allow for clinicians to inhibit excessive bleeding. The technical project surrounds the creation of such a device. By creating hemostasis around the incision site, clinicians are able to more easily cauterize the vessels that are compressed using an electrosurgical pen (a separate device), as without blood flow inhibition, the electrosurgical pen is much less effective. Once the vessels are cauterized the clinician is able to have a better field of view. A device was created in 1954 that aimed to create hemostasis around incision sites, but the device was made of plastic making it difficult to properly sterilize and was difficult to use properly. Thus, it was not adopted by many clinicians (Osborn, 1954).

At this point in time, initial prototypes with various extremes have been designed and are in the process of being printed. The initial prototypes adhere to the constraints of the requests of Dr. Mark Russell. Such constraints include: able to withstand 20N of force across all points, can be sterilized, has a handle length of 12-15 cm, weighs 2.5-10 ounces, and has two separate ring sizes of 2 and 3.5 cm (meaning there are two usable rings on a single device). Over the next semester, various prototypes will be made - initially based on the specifications of Dr. Mark Russell, and with each iteration of prototypes, the amount of clinician feedback gathered will be increased and considered for the next generation of prototypes. Currently, it is planned that a new generation of prototypes will be designed and printed every two weeks for at least three generations. Prototypes will be designed on Fusion and printed to scale in polylactic acid (PLA) using a 3D printer available through the UVA engineering department. Once a particular prototype is chosen, a virtual simulation would allow the design in stainless-steel to be tested for stress application and permanent deformation or breaking. If the prototype chosen is able to withstand the stress application needed, the prototype can be made in stainless steel either via 3D printing or through mold injection. The physical stainless-steel device then needs to be tested for its ability to induce hemostasis surrounding an incision made during MMS. There is no known physical method of testing for this desired finding. A method and model of testing must be derived by team members. The model constraints include that the stiffness of facial tissue must be resembled and blood flow must be modeled. The success of the physical model will be based qualitatively on ability to induce hemostasis, while the success of the virtual simulation will be based on quantitative safety factors. The spring semester will focus on a clinical trial of the device. Both team members will contribute equally to each step of the design process rather than assigning a specific step in the process to each member.

STS Topic

In many countries, including the United States, it is common that the top percent of healthcare users account for a substantial amount of the nation's healthcare spending. In 2016, the top one percent of individuals ranked by their healthcare spending were responsible for 21.9 percent of total U.S. healthcare

expenditures, having a mean expense of \$110,003. The top five percent of individuals ranked by their healthcare spending were responsible for 50 percent of the nation's healthcare expenditures, having an average expense of \$50,077 (Mitchell, 2019). In 2014 60% of Americans had at least one chronic disease with 42% diagnosed with more than one chronic disease (Buttorff et al., 2017). These chronic diseases include heart disease, cancers, Alzheimer's disease, diabetes, and chronic lung or kidney disease; the treatment of chronic disease is the leading agent of healthcare costs (Centers for Disease Control and Prevention, 2021). To intervene in the trends of the highest cost populations, **communities would benefit from the implementation of upstream prevention programs - or preventative healthcare practices.** Prevention programs enable the reduction of expenditure on healthcare or the improved quality of life for the individuals within the community.

This paper will discuss implemented methods of primordial, primary, and secondary prevention as these levels of prevention are not seen as necessarily medically mandatory as no disease is known to be present in the use of these levels of prevention (Kisling & M Das, 2021). The primordial level of prevention describes preventative measures that are taken on a societal or population level. Primary prevention describes preventative measures that aim to reduce the risk factors that lead to disease development for a specific individual. Typically, this level of prevention requires changes in individual exposure or behavior. Secondary prevention describes clinical preventative measures to ensure early or cost-effective intervention; the most common secondary prevention procedures are screening procedures. In the United States, only 8% of individuals undergo preventative healthcare screenings (Batarseh et al., 2020). This shows that the importance of preventative care in the United States is greatly neglected. **It is important to distinguish the levels of prevention because each level involves different stakeholders and has a dissimilar degree of difficulty in achievement.**

The top five percent of individuals ranked by their healthcare expenditures in the United States can be categorized as high-risk/high-cost individuals. These individuals likely already have at least one chronic condition diagnosis. However, those who are ranked between the top 65%-95% of healthcare

spenders can be categorized as rising risk. Those categorized as rising risk could profoundly benefit from primordial, primary, and secondary prevention as their incidence of chronic disease and disability or death due to chronic disease can be substantially reduced (Centers for Disease Control and Prevention, 2009). Various preventative healthcare programs that use primordial, primary, and secondary prevention have already shown to have a positive health effect on the community in which the program was implemented. Such programs include REACH Urban Communities (Society for Public Health Education, 2019), REACH Rural Communities (Society for Public Health Education, 2020), the 7-Day Pledge (Camden Coalition, 2019), and the South Jersey Behavioral Health Innovation Collaborative (South Jersey Behavioral Health Innovation Collaborative, 2016). Their benefits range from increased physical activity within the community to access to community gardens for healthy eating to improved housing support.

Despite the known benefits of preventative healthcare due to its ability to ease the prevalence of chronic disease and the evidence that supports its effectiveness, preventative healthcare remains underutilized due to various barriers including cost and knowledge gaps (Adepoju et al., 2015).

Preventative healthcare programs or initiatives have the ability to remove these barriers to preventative care.

The CDC conducted an interview in 2019 with individuals who had a minimum of ten years of experience within health care decision making in various stakeholder groups within the healthcare regime. Such stakeholder groups included health systems, hospitals, physician groups, commercial payers, or state Medicaid agencies. The interview purpose was to determine the factors that impact the participation of these major stakeholder groups in preventative healthcare programs. It was found that financial and economic considerations most greatly influenced the acceptance or rejection of a healthcare program. This means that, as quoted by one individual interviewed, “With no margin, there is no mission.” It was also a popular belief that transition to value-based healthcare from a volume-based system has not gained enough popularity in the United States. Thus, the healthcare regime does not feel pressured to make an exerted effort to make said transition (Levine, 2019).

The implementation of preventative healthcare programs exists as a sustainable transition within healthcare, but due to the aforementioned conflicts, universal transition within the United States is not guaranteed. Here I use Markard et al.'s (2012) definition of sustainable transitions as “long-term, multi-dimensional, and fundamental transformation processes through which established socio-technical systems shift to more sustainable modes of production and consumption.” Economics, geographical, and political influences within communities all impact the progression of the sustainable transition to an increase in preventative programs within the healthcare regime. This paper will discuss how the sustainable transition is both supported and impeded. Various preventative programs that have both become successful or failed at any given stage will be analyzed to determine how both community and healthcare stakeholder approval or inhibition impacts the sustainable transition. At the paper’s end, the reader should have a strong understanding of stakeholder influence within the healthcare regime on the development of the sustainable preventative healthcare transition.

Next Steps

In regards to the continuation of this STS paper, a variety of sources including existing preventative healthcare programs will be analyzed and referenced to articulate the many stakeholders involved in the sustainable transition to preventative healthcare. As each stakeholder is discussed, it will be tied actions or beliefs that inhibit or support the transition, allowing readers to understand the factors that influence the progression of the transition based on political, economic, and geographical circumstances.

This research is valuable because it looks beyond the understanding of preventative healthcare as a functional, even beneficial, alternative to excessive chronic disease care. It is able to show individuals that integration of alternative methods of healthcare to the current system is a complex task with many stakeholders at risk for loss or gain, and why the healthcare regime remains in a disposition to reactive care and is rigid to a transition to preventative care.

For the technical project, it is aimed to have chosen a desired prototype printed in stainless-steel by the end of the fall semester. The steps to achieve this prototype edition and the manner in which the device's success will be tested are discussed in the technical section. The physical testing method and model design will also be completed by the end of the fall semester. Entering the spring, it is anticipated to begin clinical testing.

The research conducted for the STS paper can be used to influence the manner in which the clinical trial is implemented because there will be a clearer understanding of the values of various stakeholders within the healthcare regime. The device can be designed in a way that aligns with the current healthcare needs or norms to be more successful.

References

- Adepoju, O. E., Preston, M. A., & Gonzales, G. (2015). Health Care Disparities in the Post–Affordable Care Act Era. *American Journal of Public Health*, 105(Suppl 5), S665–S667.
<https://doi.org/10.2105/AJPH.2015.302611>
- Batarseh, F. A., Ghassib, I., Chong, D. (Sondor), & Su, P.-H. (2020). Preventive healthcare policies in the US: Solutions for disease management using Big Data Analytics. *Journal of Big Data*, 7(1), 38.
<https://doi.org/10.1186/s40537-020-00315-8>
- Bunick, C. G., & Aasi, S. Z. (2011). Hemorrhagic complications in dermatologic surgery. *Dermatologic Therapy*, 24(6), 537–550. <https://doi.org/10.1111/j.1529-8019.2012.01454.x>
- Buttorff, C., Ruder, T., & Bauman, M. (2017). *Multiple Chronic Conditions in the United States*. Rand Corporation.
- Camden Coalition. (2019). *7-Day Pledge: Partnering to reduce readmissions in Camden*.
<https://camdenhealth.org/wp-content/uploads/2019/01/Redesign-Brief-7DP-1.pdf>
- Centers for Disease Control and Prevention. (2009). *The Power of Prevention*. National Center for Chronic Disease Prevention and Health Promotion.
<https://www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf>
- Centers for Disease Control and Prevention. (2021, April 29). *What Is Skin Cancer?* | CDC.
https://www.cdc.gov/cancer/skin/basic_info/what-is-skin-cancer.htm
- Centers for Disease Control and Prevention. (2021, June 23). *Health and Economic Costs of Chronic Diseases* | CDC. <https://www.cdc.gov/chronicdisease/about/costs/index.htm>
- Kisling, L. A., & M Das, J. (2021). Prevention Strategies. In *StatPearls*. StatPearls Publishing.
<http://www.ncbi.nlm.nih.gov/books/NBK537222/>
- Levine, S. (2019). Health Care Industry Insights: Why the Use of Preventive Services Is Still Low. *Preventing Chronic Disease*, 16. <https://doi.org/10.5888/pcd16.180625>

Markard, J., Raven, R., & Truffer, B. (2012). Sustainability transitions: An emerging field of research and its prospects. *Research Policy*, 41(6), 955–967. <https://doi.org/10.1016/j.respol.2012.02.013>

Mitchell, E. (2019). *STATISTICAL BRIEF #521: Concentration of Health Expenditures and Selected Characteristics of High Spenders, U.S. Civilian Noninstitutionalized Population, 2016*. https://meps.ahrq.gov/data_files/publications/st521/stat521.shtml

Osbourn, R. A. (1954). Plastic Pressure Ring for Hemostasis. *A.M.A. Archives of Dermatology and Syphilology*, 69(5), 612–613.

Prickett, K. A., & Ramsey, M. L. (2021). Mohs Micrographic Surgery. In *StatPearls*. StatPearls Publishing. <http://www.ncbi.nlm.nih.gov/books/NBK441833/>

Society for Public Health Education. (2019). *REACH Urban Communities*. Society for Public Health Education - SOPHE. <https://www.sophe.org/focus-areas/health-equity/reach/reach-urban-communities/>

Society for Public Health Education. (2020). *REACH Rural Areas*. Society for Public Health Education - SOPHE. <https://www.sophe.org/focus-areas/health-equity/reach/reach-rural-areas/>

South Jersey Behavioral Health Innovation Collaborative. (2016). *South Jersey Behavioral Health Innovation Collaborative: Year One Final Report*. Camden Health. <https://camdenhealth.org/wp-content/uploads/2018/10/SJBHIC-Year-One-Final-Report.pdf>