Device for Removal of Synovial Fluid for Treatment of Knee Effusion
(Technical Paper)

Liver Transplantation: Policy and Technology
(STS Paper)

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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

General Research Problem: Improving Patient Outcome in the U.S. Healthcare System

How can patient outcome be improved for individual patients and on a system wide scale?

There is a continual need for improvement of patient outcome in the current healthcare system. Improved patient outcome may be considered on large or small scales, ranging from improving a patient's experience interacting with their healthcare provider, to improving the survival rate of patients with a certain condition. In my technical research, I aim to directly improve patient outcome by developing and implementing technology that addresses a specific patient need. In my sociotechnical research, I will explore how technological and political progress interact to improve patient outcome on a larger scale and address inequalities in the healthcare system.

Device for Removal of Synovial Fluid for Treatment of Knee Effusion

How can arthrocentesis be made more efficient and comfortable for both the patient and physician?

The knee, the largest weight bearing joint, is particularly susceptible to pain and injury. Knee swelling is a common sign of knee effusion, a condition in which excess synovial fluid, a natural joint lubricant, accumulates in the joint. Knee effusions may result from a variety of conditions such as trauma, infection, overuse, or chronic illness. Knee effusions are accompanied by inflammation and are extremely painful for the patient, often limiting mobility (Gupte & St Mart, 2013).

Arthrocentesis is a treatment and diagnostic procedure used to address knee effusions. During arthrocentesis, synovial fluid is removed from the joint to reduce swelling and pain and analyzed for diagnostic purposes.

Currently, arthrocentesis is performed using a needle and syringe. This process is not efficient for a single set of physician hands: one hand is used for holding the syringe in place, another for pulling back the plunger of the syringe to extract the fluid. Since the fluid buildup is not localized, the physician must also manipulate, or "milk," the fluid in order to concentrate fluid to facilitate removal. Currently, physicians are unable to stabilize the needle, pull the plunger, and maneuver the fluid simultaneously. The resulting procedure is lengthy and cumbersome for both the patient and physician. Patients report pain beginning at needle insertion and continuing through the end of fluid aspiration, and the prolonged procedure time only exacerbates this pain (Baritaud, C., Personal Communication, October 2019). Physicians have to constantly reposition themselves to accomplish all tasks required of the procedure.

Our goal is to develop a more efficient protocol by developing a device to facilitate arthrocentesis. The proposed knee aspirator will allow a doctor to perform arthrocentesis by extracting fluid using the aspirator in one hand, and milking the fluid with the other hand. The design will be ergonomic, making the procedure more comfortable for the physician. Because the doctor will be able to manipulate and extract the fluid simultaneously, the procedure time is expected to decrease when using the knee aspirator device. A shorter procedure time will improve patient comfort by reducing experienced pain.

In order to achieve this goal, we will design and prototype a device that meets the functional requirements for sterilely aspirating and storing synovial fluid from the knee, starting by compiling design constraints and designing and prototyping the device using CAD software and 3D printing. We will then test the functionality of the model through a series of knee aspiration simulation tests. Additionally, we will observe physician use of our model at multiple stages throughout the design process to ensure our design meets current needs.

The design will be of similar structure to devices used to inject large quantities of medicinal fluid into a joint, such as for treating gout or rheumatoid arthritis, but of different functionality (Zuber, 2002). The "Gray Syringe Assist with Ergonomic Handle" by Innomed is one such device which works to prevent hand physician fatigue when injecting large quantities (Innomed, n.d.). This device attaches to a syringe and uses ratcheting mechanisms and an attached trigger-pull to push fluid out of the syringe. This gun-like design with syringe attachment will be applied to the model of the knee aspirator due to the ease-of-use, and general physician familiarity with common devices of similar functionality, such as a caulking gun. Many of the design considerations for this device are common among orthopedic medical devices, however the proposed device provides a new application for these designs and mechanisms.

Arthrocentesis is widely used in the clinical practice of orthopedics and is applied to synovial fluid buildup in a variety of joints such as the shoulder, ankle and elbow. Currently, syringes are the only tools used for extraction of fluid during this procedure, regardless of joint. If the proposed aims are successful, the aspiration device may be applied to arthrocentesis procedures of many joints and improve procedure efficiency for a variety of applications.

Liver Transplantation: Policy and Technology

How has and will organ transplant technology interact with liver transplant policy to address inequalities in the current liver distribution system?

Inequality in the Liver Distribution System:

Despite advancements in organ transplant technologies that allow for more successful and efficient transplant surgeries, the gap between supply and demand for viable organs is growing ("The Need Continues to Grow—OPTN," n.d.). Today, there are 112,932 people on the transplant list, awaiting an organ that will save their life. So far this year, there have been 12,740 donors ("Transplant trends," n.d.). This disparity in organs needed and organs available creates a challenge when deciding how available organs should be distributed. Currently, the United States is broken up into 11 Organ Procurement and Transplant Network (OPTN) regions. People in need of organs are placed on the waitlist within their region and are matched with organs based on a number of medical factors as well as their distance from the donor. These regions have different supplies and demands for organs, resulting in certain lists having higher likelihoods for patients to receive organs. In 2018, there were 1,387 livers donated and transplanted in region 3, while only 315 livers were donated and transplanted in region 1. As of October 2019, 1,058 and 1,318 are registered for a liver in regions 1 and 3 respectively, demonstrating the similar demand but varying supply in the regions ("Regions—OPTN," n.d.). These differences lead to people with adequate resources listing themselves in multiple regions, increasing their likelihood of receiving a lifesaving organ. In order to be listed in multiple regions, patients must be accepted to the transplant center in which they are attempting to join. Often, this requires patients to agree to conditions such as ability to come to the hospital within a certain timeframe if an organ were to become available ("Multiple listing," n.d.). This puts additional travel and lodging costs on the patients and their caretakers. Additionally, extended stay in the new transplant center area may be required if post-operative care cannot be performed at a facility close to the patient's home. Those without the resources to do this, or specifically, those who have Medicaid, which will not pay for transplants outside of the patients' designated region, must continue to wait for an organ, with the likely possibility of never receiving one.

The length of time between organ procurement and transplantation has been identified as one of the three major risk factors associated with the success of a liver transplant due to deteriorating quality of procured organs over time (Moore et al., 2005). Existing technologies, such as advanced preservation solutions, and developing technologies, such as normothermic profusion, work to keep organs viable longer by mimicking the physiological environment of the liver, a key step in a successful transplant. Other developing technologies, such as unmanned drone delivery of organs, will allow organs to reach their destination faster and unharmed, another key step for successful transplantation. Typical methods for delivering organs include motor vehicles and commercial or small aircraft, which are slow and or expensive. Drones would provide the advantage of quickly and inexpensively delivering an organ directly from point A to point B. These technologies that together allow for easier transportation of organs, enabling organs to go farther from the donor faster, raise questions about the reasons for keeping these OPTN regions. These technologies may enable recipients to be geographically farther from donor, if policy surrounding liver allocation will allow for it.

The potential for developing technology to impact the liver transplant system led to my interest in studying the policy surrounding liver allocation, specifically regarding the recipient's distance from the donor. I want to find out how technologies that enable organ receivers to be farther from donors have influenced how organs are allocated. This information will help people understand the potential for organ transplantation technology to address regional inequalities in the current organ allocation system.

Current State of Liver Distribution Policy

The liver issuance process works in two stages, allocation and distribution. Allocation is the order of the patient waiting list, based on Model End Stage Liver Disease (MELD) scores, which use a variety of medical factors to indicate the urgency of the patients' need for a new liver. Distribution is based off of the region and more specific local donation service area (DSA) in which a recipient patient resides. Livers that are medical matches for recipients are first shared within a DSA, then regionally and then nationally (Elwir & Lake, 2016). In 2013, policy shifted towards wider sharing of organs with implementation of the Regional Share 35 and National Share 15 policies. The Regional Share 35 policy calls for primary regional sharing before local sharing for patients with MELD scores of 35 or higher (high risk of death without transplant). The National Share 15 policy requires that if there are no matches with a MELD score over 15 locally, organs are offered regionally, then nationally, before being given to a local recipient with a score under 15 (Elwir & Lake, 2016).

How Liver Policy Changes

The CEO of UNOS, Brain Shepard, states that "the transplant community shares the common goal of saving as many lives through transplantation as possible" ("Liver distribution," n.d.). This goal encompasses fairly sharing available organs among transplant candidates as well as optimizing distribution so that organs are given to those who are most likely to die soon, ultimately saving more lives. Policy changes are continually proposed, attempting to achieve this optimization. In order to understand how technology could influence policy and vice versa, to achieve this optimization, it is necessary to understand how the specific policy making process works for liver transplantation. Liver donation is controlled by the OPTN (Organ Procurement and Transplantation Network) and administered by UNOS (United Network for Organ Sharing). Policy change begins with an OPTN committee that research and identify issues then draft a proposal. The committee then distributes the proposal to the public for comments by professionals and the general public. After revisions, the proposal is given to the OPTN Board of Directors which votes on all policy proposals ("How we develop policy," n.d.). From this process, it will be useful for me to not only look at the final approved policy proposals, but the proposal drafts and associated public comment. In order to analyze public comment on policy documents, it will likely be useful to categorize/code responses. All of these resources are available on the OTPN website.

Data Collection and Analysis

I will begin to address this problem by looking at how liver allocation policy has evolved over time. I will need to analyze policy documents, both public comment on proposal drafts and finalized approved policy proposals, beginning in the 1960s (when the first successful liver transplant occurred) to present day, specifically noting when technologies, such as advanced preservation solutions, were widely adopted. From the different proposal versions, I will be able to identify from which groups, outside of OPTN committees, change stems from, such as organ recipients and donor families. Additionally, I will look through databases for literature on what the state of the current liver transplant technology is. Once I establish dates for when significant changes in transplant policy occurred, I will search for literature by date regarding transplant technology. This will allow me to observe the parallel timelines of organ transplant technological development and transplant policy. I may observe influence the two have on one another which will help me answer the question as to whether policy is changing in response to technological progress and what groups have the biggest influence on policy changes. I hope to also discover what combination of technological and political progression will result in a significant change in the system.

Future Applications

More broadly, I hope my sociotechnical research will help me answer the question of how technology and policy are working together to save more lives through liver transplants, improving patient outcome. My work will help me see how improvements in technology may be able to work with policy to improve patient outcome on a wider systematic scale. This work may help engineers understand how to maximize the positive impact of their technology. If the proposed technical aims regarding the knee aspiration device are successful, similar methods must be utilized to understand the sociotechnical network surrounding arthrocentesis. This analysis will establish what social and technical factors, including medical device policy, might shape or obstruct the successful implementation of the device.

References:

Elwir, S., & Lake, J. (2016). Current Status of Liver Allocation in the United States. *Gastroenterology & Hepatology*, *12*(3), 166–170.

Gupte, C., & St Mart, J.-P. (2013). The acute swollen knee: Diagnosis and management. *Journal of the Royal Society of Medicine*, *106*(7), 259–268. https://doi.org/10.1177/0141076813482831

How we develop policy. (n.d.). Retrieved October 8, 2019, from UNOS website: https://unos.org/policy/how-we-develop-policy/

Liver distribution. (n.d.). Retrieved October 8, 2019, from UNOS website: https://unos.org/policy/liver-distribution/

Moore, D. E., Feurer, I. D., Speroff, T., Gorden, D. L., Wright, J. K., Chari, R. S., & Pinson, C. W. (2005). Impact of Donor, Technical, and Recipient Risk Factors on Survival and Quality of Life After Liver Transplantation. *Archives of Surgery*, *140*(3), 273–277. https://doi.org/10.1001/archsurg.140.3.273

Multiple listing. (n.d.). Retrieved December 4, 2019, from Transplant Living website: https://transplantliving.org/before-the-transplant/waiting-for-your-transplant/multiple-listing/

Regions—OPTN. (n.d.). Retrieved October 31, 2019, from https://optn.transplant.hrsa.gov/members/regions/

The Need Continues to Grow—OPTN. (n.d.). Retrieved September 25, 2019, from https://optn.transplant.hrsa.gov/need-continues-to-grow/

Transplant trends. (n.d.). Retrieved September 25, 2019, from UNOS website: https://unos.org/data/transplant-trends/

Zuber, T. J. (2002). Joint Aspiration and Injection. *American Family Physician*, *66*(8), 1511.