SOCIOTECHNICAL CAUSES OF ORGAN SCARCITY AND EFFORTS TO RESOLVE THEM

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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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THE EXTENT OF ORGAN SHORTAGE

WORLDWIDE ORGAN TRANSPLANT SHORTAGE

Organ transplants can be a critical component in an individual's recovery from chronic disease; however, treatment remains unavailable even in the developed world. According to statistics published by the United States Health Resources and Services Administration, over 100,000 patients reside on transplant waiting lists, but only 39,000 procedures were performed in 2020. Kidneys particularly suffer a vast shortage. In 2021, the waiting list for kidneys alone exceeds the waitlist for all other organs combined by more than a factor of 5. Patients remaining on an organ waiting list suffer a greatly increased mortality rate relative to the rest of the population. It is estimated that on average, 17 individuals die every day while waiting for a life-saving donation (*Organ Donation Statistics,* 2021).

The complications that give rise to this issue appear on multiple fronts, both sociological and biological. The chief limiting factor to organ donation is supply. Transplants in many cases cannot be obtained from live individuals, and even in the exceptional cases, such as kidney transplants, willing living donors are scarce and further complicate the procedure. As for the biological facet, a degree of transplant compatibility must exist between the donor and recipient's bodies. This further limits the availability of transplants for patients. Even in successful cases, patients typically find themselves requiring immunosuppressant drugs for the remainder of their lives. Immunocompromise results in previously ill patients becoming further susceptible to disease.

INSUFFICIENT TOOLS FOR EFFICIENT RESEARCH

Instead of sourcing preexisting organs for transplant, bioprinting seeks to combat the enumerated issues plaguing organ transplantation by manufacturing tissues and organs using a patient's own cells, or *de novo*. However, the field is still emerging and requires a laundry list of technological innovations in order to address the underlying issues of organ scarcity. Under the advisory of assistant professor of biomedical and chemical engineering Christopher Highley, a team consisting of Timothy Luu, Matthew Runyan, and Garrett McQuain created an automated micromanipulator that can aspirate and place cell clusters within bioprinted constructs. This seeks to further the field of bioprinting by creating new research tools and methods to increase throughput and repeatability (Jakab et al., 2004). The end goal of this work is to elevate the bioprinting field closer to the level of widespread, reproducible usage in *de novo* organ creation. The intended timeline of this project is to have assembled a physical prototype device by April 2022 and to incorporate coding and verification by May of 2022.

RELUCTANCE TO ADOPT DECEASED DONOR PROGRAMS

The STS research topic analyzes the underlying reasons behind why deceased donor programs have not been implemented and attempt to design a system that would be more readily adopted worldwide, focusing particularly on cultural values and education. Kidney transplants comprise the majority of transplant surgeries worldwide, thus it makes an apt model organ to analyze. First, the existing situation preventing the current best practice deceased donor system, the Spanish Model, from being adopted worldwide will be evaluated under the lens of diffusion of innovations (Rogers, 2003). Further, the barriers to implementation will be more closely analyzed using a Systems in Context model (Carlson, 2009). Next, this data will be incorporated

into modifications to current model deceased donor programs, prioritizing key deterministic factors outlined by Rumsey et al (2003): education, religion, and knowledge of a deceased organ donor or recipient (para. 1). The Spanish Model itself is a system designed by the Spanish National Transplant Organization (ONT) in 2008. Analysis of procedures used by hospitals in regions with the highest donation rates yielded the foundation for these protocols (Matesanz et al., 2017, para. 7). The success of this program was verified when in 2015 Spain reached the goal of 40 donors per million population set by the ONT (Matesanz et al., 2017, para. 3). In contrast, in 2014 the US reported 8596 deceased donors, equating to only 27 donors per million population at the time (Girlanda, 2016, para. 20). Though Spain owes much to the efficacy of the methods outlined by the ONT, modifications can yet be made based on an evaluation of its performance in countries hesitant to adopt deceased donor practices. The end goal of this research topic is to create a more holistic approach to implementing deceased organ donor systems in hesitant societies worldwide.

HOW CAN NEW MEDICAL TECHNOLOGY AND METHODS BE MADE MORE ACCEPTABLE?

The two topics are tightly coupled, as innovations to both bioprinting and deceased donor programs will show positive impacts on donor scarcity worldwide. However, if bioprinting technology faces the same barriers to implementation as deceased donor programs, benefits will only be localized to already successful, readily adopting countries. Thus, in order to successfully implement future technology, it is necessary to understand the shortcomings of modern systems and design improvements that place public policy and social acceptance at its core. This STS research paper seeks to answer the question of how medical innovations can be made more

acceptable to hesitant cultures. The innovation studied will be the Spanish Model of deceased organ transplantation, though the guiding principles and fruits of this research will hopefully carry over to future medical innovations such that they may reach patients in dire need. By pairing these two topics together, this research paper aims to address how new medical technology can more readily diffuse into areas of reluctance.

BARRIERS TO IMPLEMENTING ORGAN DONOR PROGRAMS

BASIS IN DUTY ETHICS

According to Kantian duty ethics, failure to provide support for an individual when it comes at little cost to the self is immoral. Kant proposes that maintaining respect for another morally compels assisting those in desperate need (Martin & Schinzinger, 2007, p. 53). It stands to reason, then, that donating one's organs after passing is an ethical duty. However, not all cultures share the same sentiment. Assuming that individuals do not intentionally act unethically, it is hypothesized by this research paper that reluctant cultures are dominated by a different set of guiding ethics of which deceased donation is in violation. This issue analysis research paper attempts to propose a means by which current standard deceased organ donation models can be modified to be more readily appealing to these opposing ethical frameworks.

A BACKGROUND ON THE SPANISH MODEL

Sociotechnical targeting and ammenability would be mere postulation if not backed by a robust model deceased donor program. The Spanish Model, beginning in 2008, serves as the backbone of the deceased donor program proposed in this STS topic. The success of this system

cannot be understated. Using the methods devised by the ONT, Spain was able to reach a deceased donation rate of 40 per million population within 7 years of implementation. This equates to an over 48% increase relative to the United States in the same time period (Girlanda, 2016, para. 20; Matesanz et al., 2017, para. 3). Central to the function of the Spanish Model is the distinction between life-sustaining procedures and intensive care to facilitate organ donation (ICOD). Early identification of patients unlikely to recover allows for authorization and mobilization of procedures that provide the highest likelihood to produce useful transplants (Matesanz et al., 2017, para. 9). The crux of the system is an educated workforce of healthcare professionals with a mindset of providing the highest level of care while remaining open to the idea that the best option may be to transition to end-of-life care practices. To this end, it is of paramount importance that healthcare providers be informed and trained in recognizing and carrying out the necessary procedures, yet this system has failed to take root in multiple countries.

Pakistan is a country that, while deceased donation is legal, the practice is exceedingly rare. Usage of transplants sourced from deceased donors is barred by permission from the Human Organ Transplant Authority of Pakistan. In many cases, these restrictive rulings have made it so that the only available transplants must be sourced from other living donors (Ahmad et al., 2021, para. 5). This severely limits the availability of donor organs. A living donor must be both compatible and actively willing to undergo an invasive surgery at the expense of another person. Additionally, this further complicates surgical procedures. Involving a second patient as the live donor requires surgeons to essentially perform an organ transplant twice for every one organ. Both individuals require anesthesia and a full invasive procedure to move the organ (Ahmad et al., 2021, para. 10). The issue is not localized to Pakistan. Iran, another nation

diverging from western culture, also suffers from an underutilized deceased donor program (Einollahi, 2009, para. 2). In order to tailor a solution to the barriers preventing the proliferation of deceased donor programs, it is critical to fully understand the nature of the issue.

ISSUES OBSTRUCTING DIFFUSION OF TECHNOLOGY

The adoption and practice of any innovation hinges upon its acceptance by the general public. The Spanish Model is a form of technology in that it is a designed system that maximizes the turnover rates for potential deceased organ donors into life saving transplants. With this in mind, this STS topic seeks to evaluate the spread of the Spanish Model using the Diffusion of Innovation framework outlined by Rogers (2003) and visualized in Figure 1 on page 7.

Rogers posits that innovation reaches four distinct subgroups of a population at different times. Initially, a technological innovation is received by early adopters, making up 16% of the population. From there, it spreads to the early majority, rounding out the first half of the populus at 34%. Next, innovation reaches the late majority and laggards, which make up the latter half of the population in mirrored ratios. However, in the case of Pakistan and other hesitant countries, there is a point of arrest where the innovation of the Spanish Model is bottlenecked and unable to proceed. The technology has failed to reach the early majority stage, as access to deceased donations is still scarcer than 50% availability. Thus, the diffusion of innovation is being prevented between the early adopters and early majority phases (Ahmad et al., 2021; Einollahi, 2009). Figure 1 visualizes this point of arrest as a large vertical line dividing the early adopters from the rest of society. Barriers to acceptance prevent the spread of innovative end-of-life care methods from early adopters to the majority of the population, in this case the subset of

healthcare providers. According to Rogers' model, the Spanish Model is operating at only 16% efficacy within hesitant countries where barriers to acceptance exist.

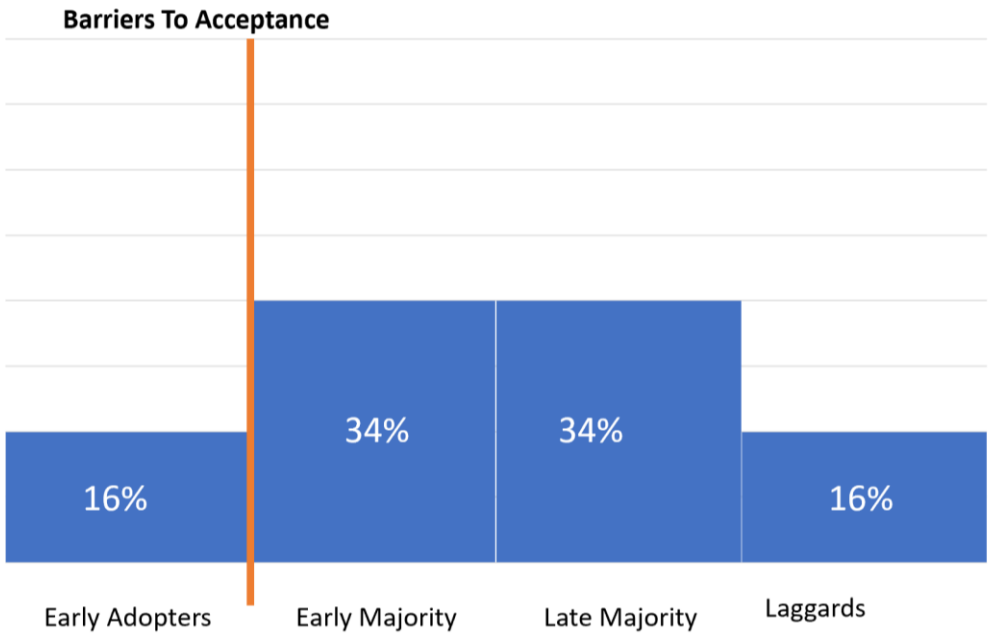

Figure 1: Diffusion of innovation disrupted. The graph outlines a typical diffusion of innovation curve outlined by Rogers with the visualization of the point where diffusion has been halted. This prevention is the product of sociotechnical differences between the engineering and receiving cultures. (Adapted by Luu (2022) from Rogers (2003)).

While analysis under Diffusion of Innovation gives credence to the existence of a point of arrest and the projected efficacy of an optimized system, the model does not account for the underlying reasons behind this barrier. To that end, this STS topic also employs an evaluation of cultural barriers to deceased donor acceptance using a modified Systems in Context model proposed in Carlson (2009). In the context of this model, there is a system bounded by social context. Engineers operate within and outside of the social context, while other engineers act as the gatekeepers to the bounded system. Figure 2 located on page 8 applies these concepts to the

transfer of deceased donor program innovations. The engineer outside of the system originating the technology is representative of the ONT, who developed the guidelines for the effective deceased donor protocols characteristic of the Spanish Method. The healthcare system of a hesitant country is bound by culturual values and is gatekept by healthcare professionals. In the context of the Spanish Model, practitioners are the primary advocate for the transition from patient care to ICOD procedures. Thus, for patients within the healthcare system to become either donors or recipients of deceased transplants, healthcare professionals must adopt and allow the innovation to pass. As it stands, healthcare professionals act as obstructive gatekeepers preventing therapeutic technologies from reaching patients due to their perceived duty to maintain cultural norms (Siddiqui et al., 2012). However, a program targeting healthcare providers that depicts deceased donation programs in a positive light and builds trust has the potential to allow innovative and robust deceased donation systems to reach patients.

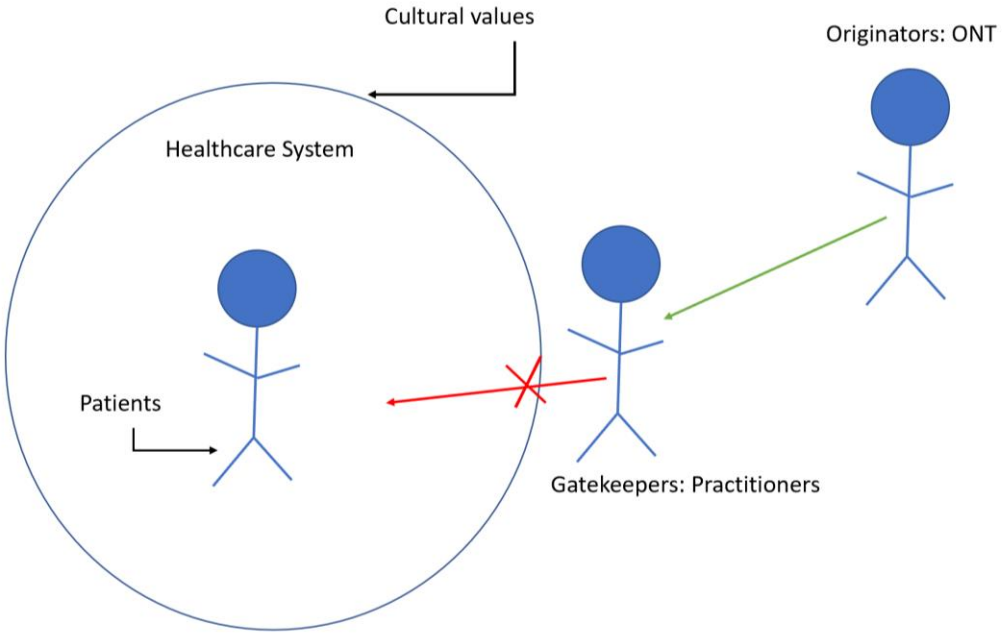

Figure 2: Permission and rejection of deceased donor programs. An evaluation of how obstruction to the spread of organ transplant systems and technology can prevent it from reaching patients. (Adapted by Luu (2022) from Carlson (2009)).

INCORPORATION OF AN EDUCATIONAL SYSTEM

In accordance with the key factors identified in Rumsey et al. (2003), education serves as the primary vehicle of changing opinions. Among the four factors Rumsey identified, the latter two, knowledge of a deceased donor or recipient, are based on the prevalency of the practice. While increasing the rate of successful deceased donations is ideal, this marker serves as an end goal rather than a starting point. Religion is rooted in tradition, and is not readily changed. It is a cultural anchor that this STS topic must work around rather than attempt to enact changes upon. In contrast to immutable religious and cultural views, new education methods can continue to be developed and applied. Key points of education to increase deceased donation advocacy among healthcare providers encompass increasing both knowledge and perception of deceased donation.

In a study of Pakistani healthcare providers by Siddiqui et al. (2012), less than half of subjects indicated a belief that brain death was equivalent to absolute death (para. 17). While acknlowledgement of this equivalency is subjective, donation after brain death contributes to between 80-90% of deceased donations in the United States (Girlanda, 2016, para. 4). Denial of this form of death has the potential to severely limit the availability of organ transplants. Additionally, fear that doctors would compromise patient care in pursuit of deceased donation ran rampant among providers. Siddiqui's study found high distrust of doctors, citing that 77.4% of surveyed healthcare professionals held at least one concern (Siddiqui et al., 2012, para. 22). While proceeding with deceased donation is irreversible, early identification of potential donors is critical to the success of the Spanish Model (Matesanz et al., 2017, para. 9). Though doctors have a responsibility to provide the furthest possible care to patients, cases exist where death is clear, evident, and unavoidable. Thus, it is all the more important for healthcare providers to

understand, recognize, and act quickly on cases of irreversible brain death. This can only be accomplished through education programs targeted at healthcare professionals. Assuaging distrust is a major hurdle obstructing deceased donor programs; however, thorough programs for providers, the main advocates for deceased donation, build confidence and trust in the system. Education centered around understanding and identifying cases of brain death vastly increases the potential for healthcare providers to advocate for donation after death.

In a separate Taiwanese study, ICU nurses who had participated in an educational program were statistically more likely to advocate for deceased donation than their control group counterparts (Lin et al., 2014, para. 8). The program administered included photographs, videos, and testimonials from transplant recipients and the families of donors (para. 7). The educational program corroborates with the third and fourth factors posited in Rumsey: that exposure to deceased donors and recipients, though vicarious in this case, increases opinion toward deceased organ donation. In the same manner, the current Spanish Model could be greatly improved by illustrating to healthcare providers the true impacts of deceased donation. Applying methods employed in the Lin study to broader audiences of healthcare providers could yield similar increases in opinion and advocacy for deceased donation. The Spanish Model places healthcare providers at the center for deceased donation advocacy, so targeting them for opinion-changing education would have the greatest benefit. Examples like the case presented by Lin et al. demonstrate that an educational program focusing on actionable behavior have the potential to increase deceased donation advocacy.

SUMMATIVE CHALLENGES AND FUTURE DIRECTIONS

Synthesis of previous studies indicates that increased education is vital to the success of deceased donor programs, not only within the western world but worldwide. Though the Spanish Model sets extensive guidelines for healthcare professionals, it hinges upon the willingness and cooperation of healthcare providers. When these professionals take umbrage with the measures required, compliance will remain low. The undertaking of this STS topic directly responds to this shortcoming by proposing educational programs targeted at healthcare providers that assuages anxieties over a culturally disonant practice. This is accomplished with two proposed programs: thorough training build confidence in the system, while another program introduces an in-depth examination of the benefits of robust deceased donor programs, not only for recipients but also for the families of the deceased. The crux of this proposed solution is the development of an effective educational program administered to healthcare providers. Future directions of study, then, would examine the efficacy of the proposed solution and other such programs, such as Lin et al. (2014), on a larger scale. Determining which programs maximize efficacy of both training and improving opinion will greatly increase the capability of this solution to ameliorate cultural hesitancy toward deceased donor programs and, in the future, *de novo* organ fabrication techniques.

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