

**FEA FOR A FOCUSED-ULTRASOUND TRANSDUCER PROTOTYPE INTENDED
FOR THE PULVERIZATION OF HEART CALCIFICATION**

**RETHINKING INFORMED CONSENT: HOW CAN LAY PATIENTS DISCERN HIGH-
TECH INTERVENTIONS?**

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
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Bachelor of Science in Biomedical Engineering

By
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An Independent Investigation

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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Moral and Social Considerations for Patient-Centered Care: Exploring the Use of Novel, Innovative Technologies in Medicine

Overview:

My technical project involves analyzing the ethical and social considerations surrounding patient decision-making and access to care for novel, innovative medical technologies, such as the use of high-powered focused ultrasound for the treatment of degenerative mitral stenosis (DMS). Drawing on the approach of Annemarie Mol's actor-network theory, I will attend to the ways in which patients, providers, and technologies interact and shape one another, and develop a nuanced understanding of the complex networks that contribute to healthcare delivery and patient outcomes. Through this analysis, I aim to identify opportunities for improving care delivery and promoting more equitable access to care. One cool thing readers will learn from my work is the potential for innovative technologies and solutions to improve patient outcomes and promote more equitable access to care.

Positionality:

I have grown up in Loudoun County, which has been ranked the wealthiest county in America. My schools from elementary to high school have been predominantly white with a small Hispanic population and an even smaller proportion of African Americans. I attended a STEM magnet school every other day in high school which contributed to my love for math and science I held from a young age. I first became interested in Biomedical Engineering (BME) in high school when I was looking at different colleges. I always knew I wanted to be an engineer, especially because of the influence of my father and my older brother who are also. BME appealed to me because of my interest in Biology, especially human physiology.

I have also recently converted to the Catholic faith which forms my moral framework and paradigm for approaching solutions. This has led me to believe in the dignity of every individual person, which is my motivation for working to find novel therapeutics to improve patients' quality of life.

Problematization:

The focus of my research will be on analyzing different moral considerations surrounding patient knowledge and awareness for decision making in complicated medical situations as well as disparities in access to high-quality and novel medical care. The source of this issue is multifaceted and cannot be comprehensively explored by a brief investigation, but a couple of broad key factors are financial incentives which prevent universal access and lack of motivation or awareness of crucial considerations for moral discernment. The former is primarily a question of resource distribution which occurs between patients and healthcare providers. The latter delves into ethical considerations ranging from high-level theorization down to extremely specific, often ambiguous judgements, which represent a mostly interior struggle.

Guiding Question:

What is the most effective way to assist patients in reasoning through and making challenging medical decisions and navigating disparity of access? And, is there any way to implement foresight in the design process to facilitate these negotiations?

Projected Outcomes:

Through my (likely indirect) encounters with individuals who have been in such situations, I will be able to use their perspectives to do two things: firstly, to better equip others who will go through similar circumstances, and secondly to propose guidelines for design that take into account these perspectives which will benefit the patients. This will be opposed to the present model of profit optimization and top-down advertising.

Technical Project Description:

The innovative method for treatment of degenerative mitral stenosis caused by heart calcification is high-powered focused ultrasound administered via transesophageal transducer. My role in the project is to use a software called OnScale to perform finite element analysis simulations on the transducer prototype and how it will theoretically perform under different conditions. Initial tests have been done with a four-transducer setup on a fixed imaging square in a lab environment, and these have exhibited the ability to pulverize a plaster model representing heart calcification. The end goal is to have a transducer placed on an aperture fixed on the tip of an esophageal endoscope, which will obviously have modified size and other constraints. If it is shown that at each progressive stage of dimensional modification the ultrasound signal does not have significant loss, then we will proceed with prototyping, which will also be based off the modeling as regards material, shaping, etc. If this works, then it will revolutionize the treatment of onset heart disease caused by calcification.

Preliminary Literature Review & Findings:

Several sources highlight the importance of patient-centered approaches to healthcare (Institute of Medicine, 2001; Epstein & Street, 2007; Berry et al., 2012), emphasizing the need for patients to be informed about their condition and treatment options in order to make informed decisions. This approach to healthcare delivery acknowledges the patient as an active participant in their care and emphasizes the importance of patient-provider communication and shared decision-making. Other sources address the issue of healthcare disparities (Braveman et al., 2011; Williams & Wyatt, 2015), exploring the impact of social determinants of health on access to care, particularly for underserved populations. Dahlgren and Whitehead (2007) propose a model that outlines how SDOH can affect an individual's health outcomes, arguing that SDOH factors such as income, education, and housing are key determinants of health disparities. Marmot et al. (2020) further stress the need for action to address health inequities, as they argue that these disparities are largely preventable.

Brey (2000) argues that technologies are not neutral, but rather embody certain values and biases that are shaped by their designers and the social and cultural contexts in which they are developed. Winner (1986) similarly contends that technological artifacts are "morally loaded" and have important implications for society. Suchman (1994) emphasizes the importance

of understanding how users interpret and make sense of technologies in order to design more effective and user-friendly systems.

Research also points to the importance of cultural competence in healthcare: Betancourt et al. (2003) emphasize the need for healthcare providers to understand and address cultural differences in order to provide effective care to diverse patient populations. Similarly, Campinha-Bacote (2002) argues that cultural competence involves ongoing learning and development of skills to effectively provide care for diverse patient populations. Finally, several sources address the need for health communication to be tailored to diverse audiences. Kreuter et al. (2003) suggest that effective health communication must consider the needs and values of diverse audiences in order to effectively communicate health information. The National Academies of Sciences, Engineering, and Medicine (2016) similarly argue for the need to tailor communication to diverse audiences and stress the importance of health literacy in promoting health equity.

STS Project Proposal:

Science, Technology, and Society (STS) is an interdisciplinary field that examines the social, cultural, and political aspects of science and technology. It studies how these elements shape and are shaped by society, as well as how they affect human lives and the environment. My project is an STS project because it involves the examination of the social and ethical implications of innovative medical technology, guided by the belief that technology is not neutral and has societal implications. My approach aligns with the ecosystem of knowledge in STS that focuses on ethics and values, particularly in healthcare. Authors I plan on using include Annemarie Mol and Langdon Winner, among others. I find their work interesting and valuable as they delve into the complexities of technology, including how it shapes our bodies, relationships, and experiences, as well as reinforcing broader political structures. Mol's work in "The Logic of Care: Health and the Problem of Patient Choice" is particularly relevant to my project as it examines the challenges of decision-making in healthcare, emphasizing the importance of care and relationships in medical practice. In terms of a theory/approach/analytic framework, I plan on using Annemarie Mol's actor-network theory (ANT). This approach allows me to explore the role of technology in shaping medical decision-making, while also considering the social and ethical implications of such technologies. By using ANT, I can focus on the networks of actors involved in the development, implementation, and use of the technology, including healthcare providers, patients, regulatory bodies, and industry stakeholders. For my anticipated method, I plan on conducting a literature review and discourse analysis of scientific articles, media reports, and regulatory documents related to innovative medical technology. Specifically, I will analyze how medical innovation and social justice intersect in the context of patient knowledge, decision-making, and access to care. I will also examine how different technologies are developed and implemented with the goal of identifying best practices that can promote equity and justice in healthcare. By using these methods, I can gain a comprehensive understanding of the complex network of actors involved in the development and use of the technology, and the social and ethical implications of such technology for patients, healthcare providers, and society as a whole.

Barriers & Boons

As a researcher conducting a literature review, despite not conducting fieldwork or interviews, I may encounter financial barriers in accessing certain academic journals or databases that require a subscription. In addition, a time barrier may arise as I have to sift through a vast amount of literature to find relevant information, and it can be time-consuming to read and analyze the texts thoroughly. Communication and rapport barriers may also exist as I may not have access to experts or scholars in the field, and I may not be able to ask follow-up questions or seek clarifications directly from them. I may also lack collaborative opportunities, such as working with a research team or co-author, which could bring diverse perspectives and strengths.

I recognize that my positionality may influence my interpretation of the materials and the conclusions I draw. Growing up in Loudoun County, which has been ranked as the wealthiest county in America, and attending predominantly white schools with a small Hispanic population and an even smaller proportion of African Americans, may limit my understanding of the experiences of individuals from different socioeconomic and racial backgrounds. Additionally, my recent conversion to the Catholic faith may inform my perspective on certain ethical and moral issues. I acknowledge that my positionality may impact my ability to fully comprehend and convey the perspectives of individuals from diverse backgrounds, and this could limit the scope of my literature review. However, I am committed to working to address these potential blind spots by thoroughly researching the literature and engaging with diverse perspectives. I plan to seek out literature and resources from a variety of sources and seek feedback from colleagues and mentors to ensure that my literature review is as comprehensive and inclusive as possible.

References

- Berry, L. L., et al. (2012). "Patient engagement: what is it?". *Annals of Internal Medicine*, 157(5), 363-370.
- Betancourt, J. R., et al. (2003). "Cultural competence and health care disparities: key perspectives and trends". *Health Affairs*, 22(4), 167-179.
- Braveman, P., et al. (2011). "Social determinants of health: expanding the view of evidence-based medicine". *American Journal of Preventive Medicine*, 40(1), S5-S13.
- Campinha-Bacote, J. (2002). "The process of cultural competence in the delivery of healthcare services: a model of care". *Journal of Transcultural Nursing*, 13(3), 181-184.
- Dahlgren, G., & Whitehead, M. (2007). "Policies and strategies to promote social equity in health". Background document to the WHO Strategy Paper for Europe, 10-14.
- Epstein, R. M., & Street Jr, R. L. (2007). "Patient-centered communication in cancer care: promoting healing and reducing suffering". National Cancer Institute.
- Institute of Medicine (US) Committee on Quality of Health Care in America. (2001). "Crossing the quality chasm: a new health system for the 21st century". National Academies Press.
- Kreuter, M. W., et al. (2003). "What makes cancer news coverage good or bad? An audience feedback analysis". *Journal of Health Communication*, 8(3), 173-195.
- Marmot, M., et al. (2020). "Build back fairer: the COVID-19 Marmot review". The Health Foundation.
- National Academies of Sciences, Engineering, and Medicine. (2016). "Advancing health equity through improved measurement, action, and accountability". National Academies Press.
- Suchman, L. A. (1994). "Do categories have politics? The language/action perspective reconsidered". *Computer Supported Cooperative Work (CSCW)*, 2(1-2), 177-190.
- Williams, D. R., & Wyatt, R. (2015). "Racial bias in health care and health: challenges and opportunities". *Journal of the American Medical Association*, 314(6), 555-556.

Chat GPT was used in researching/writing this prospectus.