DESIGNING A PEDIATRIC INTERVENTIONAL CARDIOLOGY ARM POSITIONING DEVICE

CHILDREN ARE NOT SMALL ADULTS: PRIORITIZATION OF PEDIATRICS IN MEDICAL DEVICE INNOVATION

A Thesis Prospectus
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By
Keelin Reilly

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Technical Team Members:
Amalie Harrison
Anastasia Nicholson

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.

Advisors

Joshua Earle, Department of Engineering and Society

Michael Shorofsky, Department of Pediatric Cardiology

INTRODUCTION

Children are not just small adults, but they do deserve the same quality of medical care. Pediatric patients are different from adults in their physiology, neurodevelopment, disease presentation, diagnosis, and treatment (Dimitri, 2021). Children are constantly growing and developing at different rates, making it difficult to develop standardized medical practices for them. Despite these differences, the National Institute of Health (NIH) allocates less than 12% of its budget to pediatric research, so pediatric medical devices suffer from a lack of availability and innovation (Espinoza, 2021). As a result, pediatric device development lags up to 10 years behind adult devices (Hwang et al., 2015). This is due to a combination of factors, including market size and financial incentives, clinical and technical challenges, regulatory hurdles, and ethical concerns.

Consequently, in clinical settings, health professionals often use adult medical devices on children, even though that is not their intended use. Physicians rely on devices that have not been tested on children and are not FDA-approved for pediatric use because better alternatives are not available (Espinoza et al., 2022). In some cases, the adult medical device equivalent may not work on children, prompting physicians to improvise makeshift solutions, which can lead to significant drawbacks. Pediatric healthcare providers must constantly tailor therapies to their patients, hoping their methods will be sufficient. The FDA has established some regulatory programs, such as the Pediatric and Perinatal Device Program, to incentivize innovation in pediatrics, though there is still much room for improvement (FDA, 2024). The technical design topic, which will focus on developing a pediatric interventional cardiology arm positioning device, and the closely related STS research topic, which will focus on prioritizing pediatrics in medical device innovation, will together address the need for standardized care in pediatric medicine.

My technical project group aims to build an arm positioning device for patients of various sizes, ages zero to twenty-one, because a nonadjustable adult version of this device is the only one currently commercially available. Our device will be particularly helpful for pediatric cardiologists using lateral X-rays for visualization during catheterization procedures. Through this portion of the project, we will answer the research question: How can we design and build an adjustable arm positioning device that safely and effectively accommodates pediatric patients of various sizes? Our project advisor, Dr. Michael Shorofsky, is a pediatric cardiologist at UVA Health. He needs to position pediatric patients' arms above their heads during routine procedures and is seeking a standardized solution. The project team includes Amalie Harrison, Anastasia (Ana Jo) Nicholson, and me.

Through my STS topic, I aim to answer the following research questions: Why are pediatric needs inadequately prioritized in medical device innovation? How does this oversight affect the quality of care in pediatrics? And where can improvements be made to the system? Pediatricians often rely on adult medical devices for "off-label" use as the standard of care, despite the lack of studies on their effectiveness or safety in children (Espinoza et al., 2022). I will investigate the network of relevant stakeholders using the Actor Network Theory framework and research methods of ethnography and history to explore how we can address these issues and ensure pediatrics is considered in future medical innovations.

Both portions of this thesis focus on improving pediatric care and imagining how we can consciously design with vulnerable populations in mind. I will complete it over the course of the 2024-25 school year, using a variety of research, design, and iteration phases. In this thesis prospectus, I outline both the technical and STS projects, exploring their methods and significance.

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In this technical project, we aim to build a device that positions a pediatric patient's arms above their head, moving them out of the way of a lateral X-ray during cardiac catheterization. Currently, a commercially available medical device exists that serves this function in adult populations; however, it is too large for children. If the device does not properly fit the length and width of the patient's arms, it can cause a brachial plexus injury, damaging the nerves that connect the spinal cord to the arm. Since the adult device most often does not fit the pediatric patients, doctors and nurses must create makeshift solutions. We observed our advisor, Dr. Michael Shorofsky, during a catheterization procedure on an 8-month-old patient to understand the current standard of care. He uses a combination of towels, foam blocks, and other readily available resources to position the patient's arm above their head while under general anesthesia. This setup frequently shifts while he is working on the catheterization, forcing the doctors and nurses to pause during the procedure to reposition the patient.

We have seen this inconvenience in the UVA Pediatric Catheterization Lab, and pediatric cardiologists across the country likely face similar challenges. Yet, it has not received priority in medical device innovation. In pediatric interventional cardiology, over 60% of patients are exposed to off-label uses of various adult medical devices during cardiac catheterizations (Sutherell, 2010). Our goal is to reduce this prevalence by prioritizing pediatrics in our device design. This technical project will answer the following research question: How can we design and build an adjustable arm positioning device that safely and effectively accommodates pediatric patients of various sizes? Answering this research question will save doctors and nurses time and

minimize the risk of brachial plexus injuries in patients. This device can be used in pediatric catheterization labs and may also be useful in other situations where lateral X-rays are necessary.

The purpose of this technical project is to construct a functional arm positioning device that can be adjusted for pediatric patients aged zero to twenty-one. Additionally, we will establish a testing protocol to verify the functionality and effectiveness of our design through multiple iterations. We must ensure that the device can extend according to the patient's forearm size, create a structure to raise the arms to the proper position, design a base that does not interfere with the anesthesiologist's or cardiologist's work, and use materials that will not show up on an X-ray. We will consult with pediatric cardiology providers throughout the design process, develop instructions for physicians, and test the device's functionality on potential patients.

We have already met with our advisor and other healthcare providers to discuss the constraints of the device and preliminary design ideas. The next few months will focus on CAD design and prototyping. Once we finalize a feasible design, we will 3D print the device. We hope to have a functioning device by March, after which we will begin testing it on pediatric patients in the UVA Health System's Cardiac Catheterization Laboratory.

CHILDREN ARE NOT SMALL ADULTS: PRIORITIZATION OF PEDIATRICS IN MEDICAL DEVICE INNOVATION

RESEARCH QUESTION

Few medical devices are designed specifically for pediatrics. Instead, health professionals adapt adult devices for off-label use or create makeshift solutions to meet pediatric needs. Although pediatrics account for a quarter of the population, the US allocates less than 10% of all healthcare funding to this population (Espinoza, 2021). The pharmaceutical and medical device

industries are both impacted by these limitations, with 67% of all medications administered in the pediatric intensive care unit (PICU) lacking FDA-approval for use in the pediatric setting (Sutherell, 2011). Although physicians can legally use marketed devices or drugs outside of their labelled use on patients, that does not make the situation ideal, and it introduces additional sources of error. In the STS portion of this thesis, I will answer the following research questions: Why are pediatric needs inadequately prioritized in medical device innovation? How does this oversight affect the quality of care in pediatrics? And where can improvements be made to the system?

As I outlined in the technical portion, physicians are forced to use makeshift solutions in a clinical setting due to the lack of a commercially available pediatric arm positioning device. In one case study, healthcare professionals positioned an 8-month-old's arms during catheterization using multiple rolled up towels. Throughout the procedure, the nurses had to continuously reposition the patient, distracting them from other roles. This could result in injury because the patient is under general anesthesia and cannot support their arms when the structure fails. In addition to makeshift solutions, many examples of "off-label" use of adult devices in pediatrics elevate risks, worsen quality of care, or inconvenience physicians and nurses. In an interview, Erin Reilly, a PICU nurse, shared several cases of this she has encountered. One case includes nurses using adult rectal tubes on small children, causing severe discomfort. In another case, many buildings with automated external defibrillator (AED) kits only have adult sized pads, increasing the risk of children being treated improperly with the larger pads. Lastly, most drug dosages are pre-measured for adult patients, so nurses must adjust those doses based on a child's weight, which constantly adds extra steps for pediatric healthcare providers. Some limitations to pediatric medical device innovation are unavoidable, but it is important to analyze where we can make improvements to ensure a high standard of care.

ACTOR-NETWORK THEORY & RELEVANT SOCIAL GROUPS

To determine where there are faults in the system and where we can make improvements, I will analyze the prioritization of pediatrics in medical device innovation through the Actor-Network Theory (ANT) framework. Kathrin Cresswell and colleagues describe how ANT can effectively apply to technology in healthcare (Cresswell, Worth, & Sheikh, 2010). I will use this framework to identify the key stakeholders, or actors, in the system and show how they interact with the technologies, or artifacts. In this case, medical devices designed or adapted to children are the key artifacts. The main actors in this system include the user and the provider social groups (Figure 1). I will break the user group down into doctors/nurses/other healthcare providers, pediatric patients, and parents/guardians. The specific social group using the device may depend on the context it is employed in. I will break the provider group down into engineers, investors, and policy makers. The providers play a key role in deciding which medical devices are available on the market. The users determine how they utilize those devices and what adjustments need to be made for their optimization.

By using the Actor-Network Theory, I can analyze the impact of pediatric medical devices on each group. Doctors and nurses continuously adapt their methods to use the commercially available devices, which requires additional training and steps in their processes. Pediatric patients and their parents/guardians suffer from the lack of standardization in the practice, facing worse quality of care and worse insurance coverage. Engineers experience technical challenges since children change so quickly and include a wide variety of patients. They also deal with regulatory challenges in getting pediatric devices approved with limited clinical data. Investors provide limited funding to pediatric medical devices due to a lack of market incentive. Policy makers and regulatory institutes face intense pressure in a rapidly changing industry. I will investigate these

social groups to determine where we can adjust the system to prioritize pediatrics. All these stakeholders play a crucial role in the care pediatric patients receive, and these children deserve the same quality of care as adults.

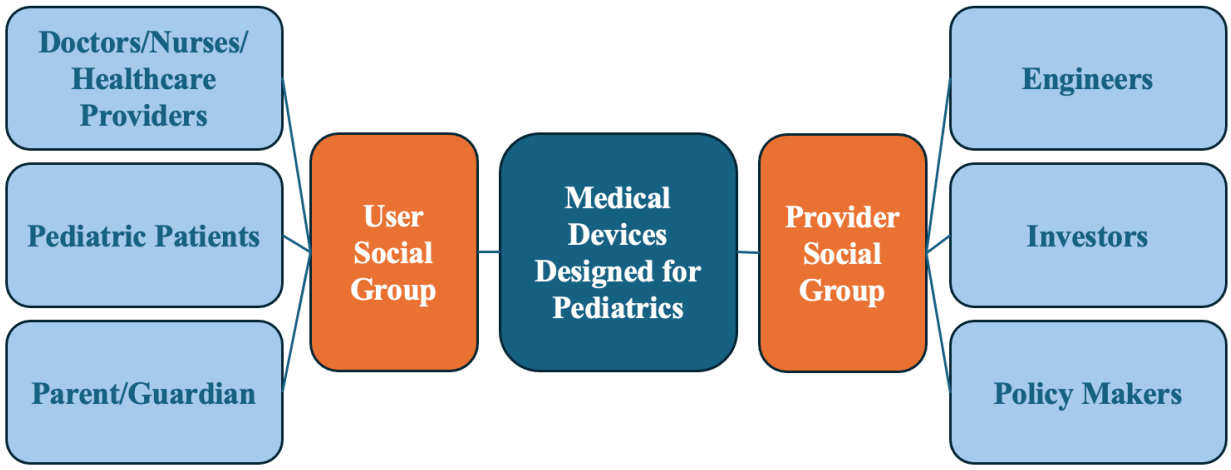

Figure 1: Pediatric Medical Devices Actor-Network Theory Diagram

METHODS & TIMELINE

I will focus my research efforts on case studies like that of the pediatric arm positioning device in our technical project by interviewing doctors, nurses, and patients who experience a lack of prioritization firsthand. I will use ethnography as the primary method of research because Georgia Black and colleagues argue that ethnography successfully supports healthcare improvement research on vulnerable populations (Black et al., 2021). Secondary, I will find, read, and synthesize previous literature using history methods. Through this research, I will apply the Actor-Network Theory to offer new perspectives on the current state of medicine and how we can improve the system to serve disadvantaged groups, particularly pediatrics.

In preliminary interviews this fall, Dr. Michael Shorofsky and Erin Reilly, BSN, shared their experiences of using adult devices and makeshift solutions in pediatrics. In the next three months, I will conduct more interviews with healthcare providers at UVA Health and INOVA

Health. I will also perform research on FDA pediatric guidances, pediatric medical device review processes, pediatric medical device market size, and investor activities. In March 2025, I will compile this information from my STS research to answer the key research questions using ANT.

KEY TEXTS

Cresswell, K. M., Worth, A., & Sheikh, A. (2010). Actor-Network Theory and its role in understanding the implementation of information technology developments in healthcare. *BMC Medical Informatics and Decision Making*, *10*(1), 67. https://doi.org/10.1186/1472-6947-10-67

Kathrin Cresswell, Allison Worth, and Aziz Sheikh explore Actor-Network Theory (ANT) and how it can be applied to understand the implementation of information technology in healthcare. They discuss the characteristics of the Actor-Network Theory approach and, "how different realities are experienced and enacted by different actors." They specifically use ANT in conjunction with ethnography methods, and the main argument is how that combination can, "focus data collection and inform strategic decisions." This source is important to my project because it will be used to navigate the ANT framework and apply it to the technology of pediatric medical devices using ethnography methods.

Hwang, T. J., Kesselheim, A. S., & Bourgeois, F. T. (2014). Postmarketing Trials and Pediatric Device Approvals. *Pediatrics*, *133*(5), e1197. https://doi.org/10.1542/peds.2013-3348

Thomas Hwang, Aaron Kesselheim, and Florence Bourgeois analyze clinical trial evidence regarding pediatric device applications. They studied class 3 devices approved for therapeutic use in children between 2008 and 2011 to analyze their clinical trial conditions. For most of these devices, it was found that the devices were approved using trials with participants >18 years old. Only 3 of the 25 approved devices studied required pediatrics

in their trials. Hwang, Kesselheim, and Bourgeois, expose that few pediatric medical devices are tested on children, questioning their safety and efficacy. This will be helpful to my project when exploring why there is a lack of pediatric patients in device trials.

Klassen, Terry P, Lisa Hartling, Jonathan C Craig, and Martin Offringa. "Children Are Not Just Small Adults: The Urgent Need for High-Quality Trial Evidence in Children." *PLoS Medicine* 5, no. 8 (2008): e172. https://doi.org/10.1371/journal.pmed.0050172.

Terry Klassen, Lisa Hartling, Jonathan Craig, and Martin Offringa explore how the safety and efficacy profile for adults and children are very different, which should affect the use of medical devices on these patient populations in a clinical setting. They explore historical challenges and then focus in on an Epilepsy case study. They also give suggestions of where in the system improvements can be made to ensure pediatric care is safe and effective. This source will help me answer the research question: Where can improvements be made to the system?

Stern, Gavin. "Thinking Big for the Smallest Patients: Innovation in Pediatric Technology." (2018). https://doi.org/10.2345/0899-8205-52.4.260.

Gavin Stern recounts conversations with multiple healthcare providers and engineers who discuss the challenges that come with "off-label" adult medical device use. He outlines multiple cases of such medical devices and how they negatively affect pediatric patient care. Stern also explores the financial challenges with promoting pediatric device innovation because the market is smaller. This source will be used to understand the frustrations felt in the pediatric field and will help generate questions for interviewing healthcare professionals. These case studies will be especially important in understanding different social groups in the ANT framework.

REFERENCES

Black, G. B., Van Os, S., Machen, S., & Fulop, N. J. (2021). Ethnographic research as an evolving method for supporting healthcare improvement skills: A scoping review. *BMC Medical Research Methodology*, *21*(1), 274. https://doi.org/10.1186/s12874-021-01466-9

Cresswell, K. M., Worth, A., & Sheikh, A. (2010). Actor-Network Theory and its role in understanding the implementation of information technology developments in healthcare. *BMC Medical Informatics and Decision Making*, *10*(1), 67. https://doi.org/10.1186/1472-6947-10-67

Dimitri, P., Pignataro, V., Lupo, M., Bonifazi, D., Henke, M., Musazzi, U. M., Ernst, F., Minghetti, P., Redaelli, D. F., Antimisiaris, S. G., Migliaccio, G., Bonifazi, F., Marciani, L., Courtenay, A. J., Denora, N., & Lopedota, A. (2021). Medical Device Development for Children and Young People—Reviewing the Challenges and Opportunities. *Pharmaceutics*, *13*(12), 2178. https://doi.org/10.3390/pharmaceutics13122178

Espinoza, Juan C. "The Scarcity of Approved Pediatric High-Risk Medical Devices." *JAMA Network Open* 4, no. 6 (2021): e2112760. https://doi.org/10.1001/jamanetworkopen.2021.12760.

Espinoza, J., Shah, P., Nagendra, G., Bar-Cohen, Y., & Richmond, F. (2022). Pediatric Medical Device Development and Regulation: Current State, Barriers, and Opportunities. *Pediatrics*, *149*(5), e2021053390. https://doi.org/10.1542/peds.2021-053390

FDA. (2024). Pediatric and Perinatal Devices Program: Research of Pediatric and Perinatal Devices. *FDA*. https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/pediatric-and-perinatal-devices-program-research-pediatric-and-perinatal-devices

Hwang, T. J., Kesselheim, A. S., & Bourgeois, F. T. (2014). Postmarketing Trials and Pediatric Device Approvals. *Pediatrics*, *133*(5), e1197. https://doi.org/10.1542/peds.2013-3348

Jenkins, Kathy, et al. (2017). "Off-Label Use of Medical Devices in Children | Pediatrics | American Academy of Pediatrics." https://publications.aap.org/pediatrics/article/139/1/e20163439/52002/Off-Label-Use-of-Medical-Devices-in-Children?autologincheck=redirected.

Klassen, Terry P, Lisa Hartling, Jonathan C Craig, and Martin Offringa. "Children Are Not Just Small Adults: The Urgent Need for High-Quality Trial Evidence in Children." *PLoS Medicine* 5, no. 8 (2008): e172. https://doi.org/10.1371/journal.pmed.0050172.

Stern, Gavin. "Thinking Big for the Smallest Patients: Innovation in Pediatric Technology." (2018). https://doi.org/10.2345/0899-8205-52.4.260.

Sutherell, J. "Off-Label Use of Medical Devices in Pediatric Interventional Cardiology: Prerogative or Necessity?" *Interventional Cardiology* 3, no. 5 (2011): 549–58.

Sutherell, J. S., Hirsch, R., & Beekman, R. H., III. (2010). Pediatric Interventional Cardiology in the United States is Dependent on the Off-label Use of Medical Devices. *Congenital Heart Disease*, *5*(1), 2–7. https://doi.org/10.1111/j.1747-0803.2009.00364.x