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

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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

In clinical settings, medical professionals often use adult medical devices on children, even if that is not their intended purpose. Pediatric physicians rely on devices that have not been tested on children and are not FDA-approved for pediatric use when better alternatives are unavailable (Espinoza et al., 2022). This is referred to as "off-label" use. While pediatric patients differ from adults in physiology, neurodevelopment, disease presentation, diagnosis, and treatment, medical innovation is rarely tailored to their needs. In fact, although pediatrics accounts for a quarter of the population, the U.S. allocates less than 10% of all healthcare funding to this group (Espinoza, 2021). Consequently, pediatric medical device innovation lags 10 years behind adult devices (Hwang et al., 2014). This raises the questions: Are pediatric needs adequately prioritized in medical device innovation? And, if not, where can improvements be made to the system?

The array of medical devices used off-label in pediatrics is vast, including stents, infusion pumps, mechanical hearts, and rectal tubes. Due to various barriers in research and clinical trials involving children, adapting adult medical devices can improve efficiency in many cases (Jenkins et al., 2017). However, as senior vice president and chief information officer at Children's Health in Dallas, Pamela Arora, observes, "It's like trying to tailor an adult suit down to fit a small child—the idea may seem good, but in practical execution, it doesn't always work as well as intended" (qtd. in Stern, 2018). In my analysis of the prioritization of pediatrics in medical device innovation, I focus on one case study, an *overhead arm support* often used in interventional cardiology to position a patient's arms above their head for lateral X-rays during catheterization. In this case, there is only one commercially available device, which serves the function in adult populations; however, it is too large for children. Forcing the device to fit

smaller patients increases the risk of brachial plexus injuries, damaging the nerves that connect the spine and arm. As a result, pediatric cardiologists must create makeshift solutions. For my technical capstone project, my team is developing an adjustable pediatric version of the device to improve the current standard of care.

In this STS analysis, I investigate the network of relevant stakeholders for the overhead arm support device using the Actor-Network Theory (ANT) framework. By examining a combination of factors, including patient and physician needs, market size and financial incentives, clinical and technical challenges, regulatory hurdles, and ethical concerns, I argue that pediatric needs are not sufficiently prioritized in medical device innovation. This research also highlights the underlying reasons for the lack of prioritization and proposes changes to encourage stakeholders to innovate for children, including leveraging clinical real-world evidence.

Literature Review

Many pediatric healthcare professionals have voiced their frustrations with medical technology and techniques developed without consideration for their patients. Numerous published scholarly articles and reviews explore these shortcomings and investigate their causes; however, none specifically address the overhead arm support case. The sources I selected provide background on the need for pediatric medical devices and highlight incentives to prioritize innovation, which I apply to this case in my analysis.

The first source I selected is the article “Thinking Big for the Smallest Patients: Innovation in Pediatric Technology” by Gavin Stern (2018). This article recounts many of Stern’s conversations with various professionals working across a variety of pediatric sectors. For example, Stern quotes Kolaleh Eskandanian, PhD, vice president and chief innovation

officer at Children's National Health System in Washington, DC., as saying, “Jerry-rigging an adult device is the only way in many instances, but it's not preferable” (qtd. in Stern, 2018). In the case of modern mechanical hearts, this device is employed in adult patients awaiting or ineligible for heart transplants, prolonging their life. In pediatric patients, however, modern mechanical hearts cannot be built small enough and do not accommodate the different fluid dynamics. Instead, pediatrics must use a Berlin Heart, an older technology that causes stroke in about a quarter of cases (Stern, 2018). Stern explains many challenges with the off-label use of adult medical devices in pediatrics. Unfortunately, medical devices and their associated accessories are only scaled to the pediatric population after the adult device has been fully developed and matured. These limitations support my claim that pediatric needs are not sufficiently prioritized in medical device innovation, and Stern explains some of the reasons behind this.

Further navigating pediatric medical device innovation and its intricacies, Summer Duffy et al. (2024) reviewed 190 scholarly articles through the lens of regulatory, business, and technical incentives. In their article “The Challenges and Opportunities in Pediatric Medical Device Innovation: Monitoring Devices,” they explore the entire medical device product life cycle, from market incentives to anatomical challenges to conducting clinical trials to FDA incentive programs. They emphasize that clinical (medicine), commercial (business), technical (engineering), and strategic (entrepreneurship) needs must be fulfilled to bring a device to market successfully. This process requires a variety of key stakeholders, which I analyze through the lens of Actor-Network Theory. While the authors acknowledge that, “the ecosystem of device innovation has had a historic lack of incentives for pediatric development,” they also highlight some current incentive programs, such as the FDA’s Early Feasibility Studies (EFS) Program,

that seem promising (Duffy et al., 2024). This source serves as a basis for exploring the problem from the perspective of each stakeholder and determining how we can leverage current programs to improve the prioritization of pediatrics.

Conceptual Framework

The STS framework best suited for exploring the prioritization of pediatrics in medical device innovation, particularly in the context of the overhead arm support case, is Actor-Network Theory (ANT). Bruno Latour is credited for his contribution to the creation of this theory, which describes how people and technologies are interconnected within complex networks (Latour, 2005). In ANT, both people and technology are actors that influence each other in a reciprocal relationship, shaping interactions within society. This theory emphasizes that the dynamic network of relationships within a system impacts the knowledge, power, and outcomes of that system. Kathrin Creswell et al. (2010) utilized ANT to analyze technological developments in healthcare, arguing that ANT is a useful tool for informing strategic decisions within such systems (Cresswell et al., 2010). ANT offers a holistic view of systems and reminds us to think critically about the influence technology has on our actions, especially as these technologies become more advanced.

Networks consist of key actors, technologies, and their interactions that are being analyzed. ANT is applicable to this case study because it views the problem from the perspective of key stakeholders, which are essential in the healthcare field. In the case of the overhead arm support actor-network, the actors will be categorized into user and provider social groups, with the technology at the center of the network. From the user perspective, I examine how this technology, and the lack of a pediatric counterpart, affects the operating healthcare professionals, the patient, and their guardians. From the provider perspective, I investigate why it has not been

a priority for engineers, investors, and regulatory agencies to originally design this technology for pediatric patients. By assessing the interactions between these groups and the technology, I identify where the power exists in the system and determine if pediatric needs are adequately prioritized. This is then used to identify where adjustments can be made to the network to improve pediatric prioritization for future designs.

Analysis

Actor Specification

The following analysis breaks down the key actors into user and provider social groups. The user group is divided further into subgroups of Pediatric Healthcare Providers, Pediatric Patients, and their Guardians. The Provider group is divided into subgroups of Medical Device Engineers, Investors, and Regulatory Agencies. The artifact at the center of my analysis is the overhead arm support medical device. I focus specifically on the lack of a pediatric alternative on the market, exploring why one should exist from the perspective of the users and why one does not yet exist from the perspective of the providers. Throughout this analysis, I rely on examples from each of the stakeholders to support my claim that pediatric care is not sufficiently prioritized in medical device innovation. An overall map of my actor-network is presented in Figure 1.

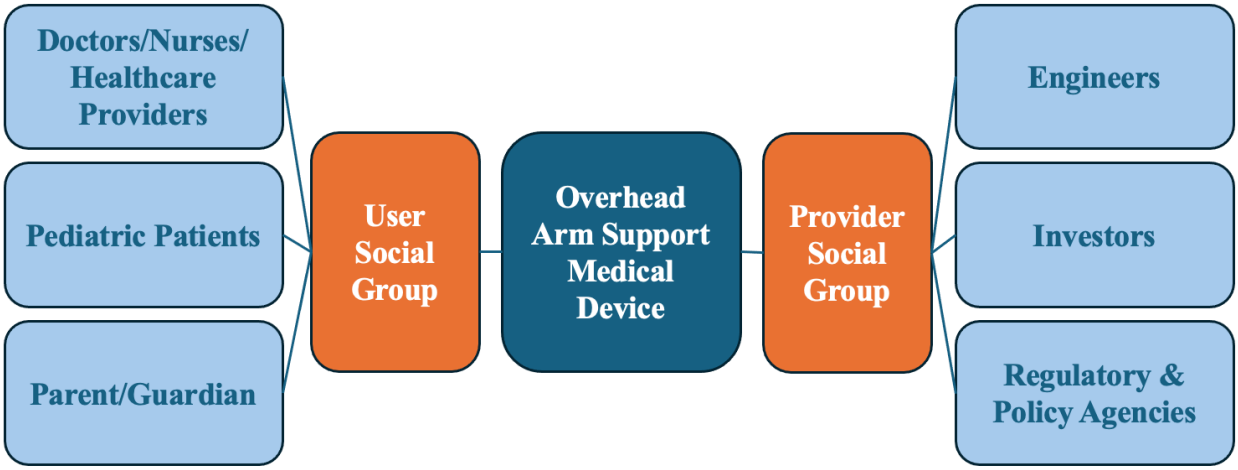

Figure 1. Outline of the Key Actors in the Case of the Overhead Arm Support Device

The overhead arm support device that positions a patient's arms above their head during a lateral X-ray, as shown in Figure 2, is a Class I medical device. Medical devices are categorized into classes based on the level of risk they pose to a patient, with Class I being the least risky. My analysis both discusses this case study and generalizes the findings to include higher-class devices. As such, the case of the overhead arm support serves as a vehicle to highlight broader limitations within the medical device life cycle that impede pediatric device innovation.

Figure 2. Commercially Available Adult Overhead Arm Support (Adept Medical, 2022)

User Social Group vs Overhead Arm Support

Interactions between the user subgroups and the overhead arm support device prove that pediatric needs are insufficiently prioritized in medical device innovation. Pediatric healthcare professionals, pediatric patients, and guardians of pediatric patients all adapt to the current adult-centric system and would benefit from pediatric-specific devices. To support this claim, I analyze each of the user subgroups and their relation to the overhead arm support, as well as explore how these interactions can be generalized to other medical devices.

Pediatric Healthcare Professionals, including doctors and nurses, are responsible for jerry-rigging adult medical devices to fit their patients or creating make-shift solutions when modifying the original is not possible. In pediatric interventional cardiology, 60% of patients are exposed to "off-label," or "physician-directed," uses of various adult medical devices during

catheterization (Sutherell et al., 2010). When working on my capstone project, my team observed our advisor and pediatric interventional cardiologist, Dr. Shorofsky, perform a catheterization procedure on an 8-month-old patient. Dr. Shorofsky explained that there are no alternative overhead arm support devices on the market that properly hold a child's arms above their head. Instead, he must use a variety of readily available materials to balance the patient's arms, including rolled-up towels and foam blocks. While observing this procedure, the nurses had to reposition the patient three times within 45 minutes. While the pediatric cardiologists at UVA Health deal with this distraction daily, there are likely hundreds of other doctors and nurses experiencing a similar issue elsewhere. Maybe another doctor has already come up with a better make-shift solution or also has a group of undergraduates creating an innovative design for their capstone. However, without communication among these groups or motivation to make the solutions commercially available, others may never hear of these alternatives. Not having pediatric-specific devices is often inconvenient for healthcare professionals when there are other tasks to perform.

Pediatric Patients are constantly exposed to off-label use of adult medical devices, and they typically bear the brunt of this unideal circumstance. In the case of the overhead arm support, they risk brachial plexus injury if their arms are not positioned properly above their head. This occurs when the group of nerves that connect the spine, shoulder, arm, and head are stretched, squeezed, or torn (Mayo Clinic, 2024). Since the patient is under general anesthesia, if the make-shift solution of towels and foam blocks shifts or falls, their arms may be jolted down, increasing the risk of injury. In addition, if their doctor tries to fit them into the adult device, their arms could be stretched awkwardly while they are unable to communicate if the positioning

is uncomfortable. Children deserve healthcare that is tailored to their needs and should not be expected to shape-shift to meet the needs of the technology.

Parents/Guardians of Pediatric Patients typically do not interact with the overhead arm support device since it is used during procedures after the child has separated from their family. However, parents trust that healthcare professionals have access to the best tools to treat their children. As previously discussed, this is not always the case. When parents trust their child's care, they communicate and collaborate effectively, leading to informed choices and better care (Nobile & Drotar, 2003*).* If the make-shift arm support falls during catheterization, this trust may be compromised, and they deserve more dependable solutions.

Generalizing these actor interactions to higher-risk medical devices emphasizes the critical need for pediatric-specific designs. The risk that pediatric healthcare professionals cause harm is far greater when using Class II or Class III devices off-label. Regardless, 78% of balloon dilations performed in pediatric cardiology involve off-label use of adult devices (Sutherell et al., 2010). Other examples of higher-risk adult medical devices used on children include pacemakers and rectal tubes. In these situations, the level of discomfort is more significant for the patient, and they risk worse health outcomes (Stern, 2018). Furthermore, many parents and guardians must use medical devices at home. If a device requires specific adjustments for pediatric patients, this increases the responsibility and inconvenience for caregivers. Overall, as Gavin Stern states, "In healthcare, we sometimes get complacent with 'it is what it is.' But we need to make big changes to make the patient experience better" (Stern, 2018). The user actor interactions demonstrate that pediatrics is inadequately prioritized in medical devices, and they deserve better.

Provider Social Group vs Overhead Arm Support

The interactions between the provider subgroups and the overhead arm support device artifact continue to support my claim that pediatric needs are not sufficiently prioritized in medical device innovation. Engineers, investors, and regulatory agencies all face certain hurdles that limit their support of pediatric-specific medical device designs. These stakeholder circumstances also explore why shortcomings exist in the network and where they can be minimized.

Engineers face many technical challenges when designing for pediatric patients. For example, children's arms grow dramatically between being born and turning twenty-two years old, so one fixed overhead arm support device will not accommodate the whole age group. Further, two children of the same age may have different sized arms based on their sex and development. My capstone team is designing a pediatric version of the overhead arm support that has four extension points, making the device adjustable for patients of all sizes. One constraint the device must accommodate is the forearm length of the patient, which typically ranges from 8.57 cm to 25.4 cm (Edmond et al., 2020). Additionally, we considered arm circumference ranges, upper arm length ranges, arm weight ranges, etc., which take much longer to design than building one standard size. Children also endure many physiological changes throughout development causing many diseases to present differently, posing additional challenges for higher-class medical devices (Dimitri et al., 2021). Overall, the variability in this age group makes designing for pediatrics very technically difficult for engineers.

Investors encounter a smaller market size within pediatrics, limiting the potential return on investments. Medical device innovation is a business-driven ecosystem, and when the market potential is limited, there lacks an incentive for investing in pediatric devices (Duffy et al.,

2024). Although medical devices are a $156 billion industry in the United States, only about 1 in every 20 hospitals in the U.S. are children's hospitals, demonstrating their smaller share in the market (Espinoza et al., 2022; Stern, 2018). This is particularly significant given that the estimated cost to develop and commercialize a low- to moderate-risk device, such as the overhead arm support, is $31 million (Espinoza et al., 2022). When venture capitalists and angel investors are hesitant to back these ventures due to market risk, companies often rely on government grants for research and development. However, the National Institute of Health (NIH) allocates less than 12% of its budget to pediatric research (Espinoza, 2021). Additionally, pediatric care is typically reimbursed at lower rates, further reducing the returns (Catenaccio et al., 2021). The smaller market size, lack of funding, and lower reimbursement rates ultimately discourage investors and entrepreneurs from pursuing pediatric medical device innovation.

Regulatory Agencies and Policymakers work to ensure that drugs and medical devices brought to market are safe and effective. The approval process for medical devices is managed by the Center for Devices and Radiological Health (CDRH) within the FDA. This center classifies the devices and determines the type of approval required, such as a 510(k) for lower-class devices or PMA for higher-class devices (Espinoza et al., 2022). Class I devices, like the overhead arm support, undergo less extensive clinical testing than higher-class devices. In 2021, 25% of PMA applications approved by the FDA were tested for pediatric use. Although the other 75% of devices are also used to treat and diagnose diseases and conditions in children, they were not tested for safety or efficacy in this population (FDA, 2021). Hence, when physicians use adult devices for indications outside of their labeled uses, it introduces considerable uncertainty. Unfortunately, including children in clinical trials presents significant challenges, as there are ethical concerns surrounding consent, fewer potential participants in each age group, and higher

study and development costs (Field et al., 2004). Due to these difficulties and the length of the approval process, fewer pediatric devices are approved by regulatory agencies.

User Social Group + Provider Social Group

As explored through the actor-network, the lack of prioritization of pediatrics in medical device innovation negatively impacts the user group. Healthcare professionals are inconvenienced and challenged, pediatric patients are at risk of injury, and their parents/guardians may lose trust in the healthcare system or face difficulties when treating their child at home. On the other hand, the provider group lacks incentives and motivation to prioritize pediatrics because of how the system is structured. Engineers face technical challenges, investors see lower returns on investment, and regulatory agencies often lack the time or resources to conduct extensive reviews for each device application. Communication and collaboration between the user and provider subgroups could lead to significant pediatric device advancements.

The provider subgroups have made some initial efforts to advance pediatric medical device innovation. The FDA has established programs that encourage pediatric device development, including the Pediatric Device Consortia, which funds grants to advance pediatric device development, and the Humanitarian Device Exemption (HDE), which provides a marketing pathway for devices that treat or diagnose diseases and conditions affecting less than 8,000 individuals in the U.S. per year. In 2016, the FDA also released a guidance document that helps companies determine how to leverage existing clinical data for extrapolation to pediatric uses, encouraging safe off-label use (FDA, 2021). Furthermore, some entrepreneurs and investors pursue pediatric medical ventures despite the challenges, often driven by personal connections to the cause or a genuine passion for improving children's health (Stern, 2018). In

my case, my capstone advisor is a pediatric cardiologist who dealt with repositioning his patients' arms overhead every day. This occurrence motivated him to organize a team to develop a pediatric version of the current device. Many engineers, like my capstone team, are passionate about children's health and are inspired to design for this vulnerable population, even when it may not offer the largest financial incentive. Programs that alleviate barriers for these dedicated providers are essential to supporting innovation.

The user subgroups have also taken steps to improve pediatric prioritization. Advocating for children's health has the potential to make a substantial impact, particularly because many entrepreneurs and engineers are motivated by a personal connection to the cause and a desire to drive change. Healthcare professionals can advocate for their patients by communicating daily off-label inconveniences that people would otherwise not notice. For instance, my capstone team would not have discovered the need for a pediatric overhead arm support device if our advisor had not identified the challenge and recruited a team to solve it. Additionally, when patients share their experiences, it raises awareness about their circumstances and fosters empathy among providers. Likewise, parents and guardians can share their family's background and needs to inspire providers to make a difference. Furthermore, many parents/guardians join the provider group when they are desperate for a solution for their child. This was the case for Ryan Shelton, CEO and founder of PhotoniCare, who developed a handheld imaging device to visualize the eardrum in the middle ear when his son was suffering from recurring ear infections (Stern, 2018). Advocating for meaningful change could motive more engineers, investors, and regulatory agencies to work toward a brighter future for children's health.

Progress is rarely instantaneous, so we should also consider ways to leverage the current system to drive advancements. Strengthening real-world evidence (RWE) is a promising method

to improving off-label use and informing physician decision-making when using devices not originally designed for pediatrics (Duffy et al., 2024). Valuable existing data, such as health records, clinical registries, and medical billing, could be utilized to make decisions in clinical and regulatory settings (Espinoza at al., 2022). This strategy may reduce the need for extensive clinical research, while still relying on data for informed decisions regarding device labeling and use in pediatrics (Lasky & Chakravarty, 2023). In the overhead arm support case, another health system may have already built a pediatric solution but chose not to commercialize it due to the insufficient market incentive. Better communication across health systems using electronic data ecosystems would help standardize these advancements, making them more widespread.

Conclusion

Children are not small adults. They do not just differ in size, but also physiology, disease presentation, neurodevelopment, etc. However, these differences are rarely recognized in medical device designs, and pediatric devices continue to lag 10 years behind (Hwang et al., 2015). This research is significant because it acknowledges the inadequate prioritization of pediatrics in medical device innovation and guides us toward making crucial changes to the system, ultimately benefiting all stakeholders, but especially children. I utilized Actor-Network Theory to examine key stakeholders and how they interact with the technology, which illustrates limitations within the system. The interactions between the user subgroups and the overhead arm support demonstrate that pediatric healthcare professionals are constantly adapting their practices and pediatric patients endure discomfort from off-label use. The interactions between the provider subgroups and the overhead arm support explain why pediatrics is not always prioritized, as there is an insufficient market incentive and many technical design challenges.

Better prioritization of pediatrics would improve efficiency for healthcare professionals and outcomes for patients, but providers need incentives for this change.

When courageous providers and persistent users unite, they create a powerful team capable of driving positive change. Current regulatory incentive programs and patient advocacy encourage investment in pediatric healthcare. Another way to prioritize pediatrics is by improving the confidence of off-label devices through strengthening real-world evidence and leveraging health data. Developing a system that helps stakeholders communicate across the network about current advancements in pediatric medicine may minimize innovation obstacles. It is time we adjust the system to create devices are tailored to meet the unique needs of children, instead of children tailoring themselves to meet the needs of their devices.

Word Count: 3817

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