Developing a Novel Probe-Body Interface for an Ultrasound

The Challenges of Creating Pediatric Innovations

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By
Emma Stiglitz

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Technical Team Members:
Andrew Porter

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

Dr. Masahiro Morikawa, Department of Family Medicine

Rider W. Foley, Department of Engineering and Society

Introduction

Medical imaging technology plays a vital role in providing care for individuals. These technologies are able to produce images of internal structures in the body to help diagnose, monitor, or treat medical conditions (FDA, 2018). Advancements in medical imaging allow physicians to provide better treatments as higher quality images allow for earlier intervention and superior patient care. One improvement through the years is ultrasound. Ultrasounds are a safe, non-invasive imaging modality that uses high frequency sound waves (see Appendix A). The devices have a probe attachment with a layer of piezoelectric crystals that vibrate when voltage is applied (Ashish, 2016). These vibrations produce sound waves at frequency over 20KHz, greater than human hearing, that travels beneath the skin and reflects back towards to probe upon impacting tissue boundaries in the body (Ashish, 2016). The reflection is used to create a two-dimensional image (Ashish, 2016).

It produces real-time images and is used in a wide variety of specialties including obstetric, emergency, abdominal, and cardiac examination (Salmon et al., 2015). One of the notable advancements of the technology is the size and the cost. The technology is traditionally a cart reliant system that is bulky, takes up space, and can be tedious to move around to perform procedures (Falkowski et al., 2020). However, after the Gulf War in 1994, the military developed a portable model called a Point of Care Ultrasound (POCUS) to diagnose and treat serious injuries in the field (Kuttler, 2018). The POCUS is not just a better portable option, it is also more affordable. The starting price for a POCUS is around $2000, whereas the equipment for a cart-based ultrasound is typically over $100,000 (Falkowski et al., 2020).

POCUS is a critical on the spot decision making tool that can help patients. It has been proposed as an alternative to the stethoscope as it provides more accurate information and is not reliant on the auditory capabilities of the physician (Istrail, 2020). Instead of making assumptions based on audible feedback, the POCUS allows for clinicians to visually observe internal organs in real time. The technology has failed to be adopted by internal medicine specialists, despite its proven effectiveness. Internal medicine specialists, internists, treat patients admitted to the hospital and check on each patient's condition daily (Brennan, 2021). At the moment, POCUS is time-inefficient which is a barrier for internists as it would require spending too much time with one patient during rounds. This is partially due to the fact that the technology requires a medium to be placed between the ultrasound and patients' skin (Sippel et al., 2011). Ultrasound gel is highly effective, but tedious to apply and remove. This technical project seeks to develop a reusable, non-messy, and cost-effective medium that can be used with a POCUS as a replacement for the stethoscope during internal medicine rounds.

A Novel Medium to Increase POCUS Efficiency

Ultrasounds require a gel be placed between the probe and skin to prevent distortions caused by air acting as a barrier for the sound waves due to the difference in the speed of sound through air, 331 meters per second, and human soft tissue, 1540 meters per second (B. Stern, 2021). Ultrasound gel is composed of water and propylene glycol, which create a sealant on the skin preventing air bubbles (Premier Diagnostic Services, 2014). Sound travels through water at a similar velocity to soft tissue, which creates an ideal medium (B. Stern, 2021). However, this gel is one of the main reasons why POCUS has not become standardized in medicine. It is a single-use product that requires reapplication and must be wiped off after each use (Arnold et al.,

2020). This creates a recurrent operations cost. Currently, there is no standard for how much gel is required to create an adequate image, only that the gel is applied in a large enough quantity to cover the surface area being imaged and thick enough for the probe to glide over skin. If more gel is applied to multiple locations on the skin, it increases the time required for cleanup. In a busy practice this time is better spent with other patients.

Internists currently use stethoscopes, a disc shaped device that is able to amplify the internal sounds of the body, as a quick check to asses a patient's condition (Kaye, 2019). During daily rounds, the physicians will use the stethoscope to determine if the patient's treatment plan requires adjustment. Internists would benefit greatly from the implementation of POCUS as they use knowledge of the internal organs and systems of the body to diagnose and treat a variety of illnesses (Brennan, 2021). Although, the stethoscope is efficient, it is not always accurate. One study on the detection of pulmonary edema, a fluid buildup in the lungs that indicates congestive heart failure, found that the stethoscope detected fluid in 4 out of 10 cases, while the POCUS was able to detect it in 97% of cases (Istrail, 2020). The POCUS is a more accurate device and just as portable, but the current gel requirement is problematic.

This project has two objectives. The first is to determine how POCUS interacts with materials and create a protocol for image analysis. The second, the focus of this section, is to design a material. Several design specifications have been identified to consider the material successful. The first is to develop a material that has a high elastic modulus that can mold to the different areas of the patient's body. The medium must also produce an image of comparable quality to the current gel. The gel and POCUS must be able to be used in all the same areas as the stethoscope and take approximately the same amount of time, 5 to 7 minutes. Also, the medium must be able to withstand disinfection in between patients using 70% isopropyl alcohol.

Additionally, the product will be interacting with human skin and must comply with the biological standards for medical devices (ISO 10993-1).

The current material approach is to develop a polyacrylamide (PAM) and alginate double network (DN) hydrogel. A hydrogel is a type of polymeric material that cross-links hydrophilic polymers to create a network able to hold water without losing its structure (Chai et al., 2017). The water content creates an ideal medium for ultrasound as sound waves can pass unobstructed. Traditional hydrogels are liable to tear due to weak mechanical properties; however, the DN fabrication retain their elasticity, high water content, and have increased mechanical properties (Ping Gong, 2010). These hydrogels are made by creating two separate polymer networks. One acts as a skeleton that gives the material a strong base, while the other is more ductile and gives it its elasticity (Ping Gong, 2010). The two networks coexist together to create a strong shape without compromising its other properties (Ping Gong, 2010). PAM and alginate were chosen as this type of hydrogel has been extensively studied and has not been used for this application. A hydrogel is a better alternative to the current gel because it has predetermined dimensions and it is reusable. It can easily be placed and reapplied to various locations on the body and it is non-messy. This creates a more time efficient procedure as it is easier to move between areas of the body and eliminates the delay from clean-up. Moreover, it is more cost-efficient to use a single product than multiple gel applications.

The Human and Social Dimensions of Pediatric Innovations

While the team's technical work is focused on designing an ultrasound medium that increases POCUS efficiency, this paper will also explore the unmet medical needs and solutions in the pediatric population. In the United States, the pediatric population, children ages 0 to 18,

represents approximately one quarter of the total population (Espinoza, 2021). Yet, less than 10% of all health care funding is for this population (Espinoza, 2021). The lack of innovation has consequences as children with certain conditions have no device options, a poor selection, or physicians must modify adult devices for off-label use with no safety or efficacy data (Sutherell et al., 2010). There is more diversity of illness in children, so conditions manifest differently (G. Stern, 2018). An example of this is Congenital Heart Defects (CHD), which is a type of abnormality that affects the structure of the heart and the way it works (G. Stern, 2018). These children often require major reconstructive surgery to repair the defect (G. Stern, 2018). Current CHD treatment is adult devices that have been altered to fit pediatric patients. This technology is prone to infection, blood clotting, and calcification especially as the devices are adapted to smaller patients (Shoji & Shinoka, 2018). In addition, this technology cannot grow with the child. As a result, children must undergo many surgeries to continually replace it.

In addition, illness can manifest differently in children versus adults. Inflammatory bowel disease (IBD) is a condition that results in chronic inflammation of the GI tract (Kelsen & Baldassano, 2008). Research has found significant differences between the two populations that require different approaches to treatment and management. Crohn's disease is a type of IBD that impacts a person's ability to absorb nutrients (Kelsen & Baldassano, 2008). In children it can impact their normal growth and development, so early intervention is important (Kelsen & Baldassano, 2008). Another challenge is that the market for pediatric technology (therapeutics and devices) is so small that companies face a low investment return for anything they create (G. Stern, 2018).

The Social Construction of Technology (SCOT) explores the idea that technological development is influenced by social groups and their present needs (Pinch & Bijker, 1984). The

theory examines how technology can impact the world and how individuals give meaning to technology, which influences its design and purpose (Pinch & Bijker, 1984). Through the lens of interpretive flexibility, this theory can be used to examine how social groups can influence the progress of pediatric innovation (Ulucanlar et al., 2013). In the case of a bioengineered trachea (used in a compassionate care case for a young child), the technology was framed as lifesaving by its innovators and physicians because the patient had run out of other viable options (Gardner et al., 2017). Despite the fact that the technology is high risk and far from implementation in the general population, the framing of the technology as a low-risk option in the future becomes a justification for further research (Gardner et al., 2017). This is especially relevant as it illustrates how the adoption and dissemination of a technology is dependent on the advocacy by various stakeholders. The pediatric population is one that cannot advocate for its own needs properly, so it becomes essential that other groups, like physicians and family members, become involved in the narrative to promote change. SCOT helps explain the problem space and the relevant stakeholders as well as how to find a solution.

The iterative sociotechnical analysis (ISTA) is a framework focused on understanding the complexity of interactions between technology and the existing socio-technical systems in order to properly understand user needs and adapt technology as needed (Harrison et al., 2007). It explores the unintended consequences that technology can have. There are four elements of Harrison's theory including: examining the actual use of technology, the impact of technology in a technical and physical setting, how users reinterpret the technology in their social space, and the interactions between the social and technical system (Harrison et al., 2007). This theory is essential for understanding the problem as it explores why current solutions are problematic. An example is the off-label use of devices for pediatrics. Adult devices are designed, tested, and

marketed based on the assumption they will be used in the adult population (Sutherell et al., 2010). However, when these devices are adapted for pediatric patients, it results in an increased risk of mechanical failure as the devices are being utilized in an environment they weren't designed for (Sutherell et al., 2010). The lack of options in the pediatric space has led to physicians branching out in order to find technologies that can have a meaningful impact on individual patients exposing the unintended consequences of a lack of pediatric innovation.

Research Question and Methods

The research question being explored in this paper is: what are the current challenges that prevent the creation of medical innovations for the pediatric population and how can these be overcome? Pediatric patients represent one quarter of all healthcare needs; yet, off-label adult medical devices are commonly used (Espinoza, 2021; Sutherell et al., 2010). Despite the pediatric population facing the same maladies as the adult population, there is a distinct lack of innovations made specifically for these smaller patients. This can be detrimental to their care as they are at risk for more complications and the possibility that no treatment exists. There is a need to understand this problem space and why this remains an unmet need in order to begin understanding how to overcome this challenge.

This paper will be exploring the topic with two different case studies. The first is the lack of medical devices to treat congenital heart disease (CHD) in patients over the age of one. This case study will be analyzed using interviews with cardiologists who treat CHD to understand what challenges they currently face, how they are addressed, and what future solutions they advocate for. This data will be used with Harrison's theory to understand the unintended consequences from this lack of innovation as well as how potential solutions can be

implemented. A historical analysis of legislation impacting the regulatory pathways for pediatric devices will be used as well. Data will be compiled from FDA reports, like the annual pre-market device approval reports, and compared to relevant legislative actions. This information will be used to create a timeline to understand how tedious it is for pediatric technology to succeed. SCOT will be used to understand how the advocacy of social groups impacted these regulations.

The second case study will focus on therapeutics for IBD. Interviews with 3 to 5 pediatric gastroenterologists will be conducted with the same parameters as described above. The responses will be compared to understand the common problems and any ideas for solutions. In addition, a historical analysis will be used to create a comparative timeline. The timeline will compare how the disease manifests and progresses in an adult versus a child over a period of 20 years. This will include an extensive literature review to understand medication each population has access to, track the onset of symptoms, treatment options (surgeries or drugs) and chances of remission. This data on the disease progression and how it is handled will be analyzed to understand how the severity can differ between the two populations. Harrison's theory will be used to analyze how the extensive roadblocks in pediatric medicine may be unintentionally worsening the outcome of the condition while SCOT will explore the role various groups play in managing or treating the condition.

Conclusion

POCUS has been demonstrated to be a more accurate tool for diagnosing and monitoring the patient's condition compared to a stethoscope. Visuals of the body's internal structures are more accurate than relying on inferences of the patient's condition from audible noises. However, the current gel required to produce clear images is a barrier to the routine use of POCUS as it is

tedious to apply and remove for each use of the transducer on the skin. A new material interface would improve patient care as it would increase the accessibility to a convenient medical imaging technology.

There is currently a lack of innovation in pediatric medicine. This is due to variability of disease in children as well as the small disease population, which prevents technologies from being profitable. This is detrimental as adult technology must be adapted for a new function without proper regulation. This puts children at higher risk for complications and it is much more challenging to provide care. The first step towards promoting change is to understand why it is a problem and where the challenges are, so viable solutions can be developed.

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Appendix A

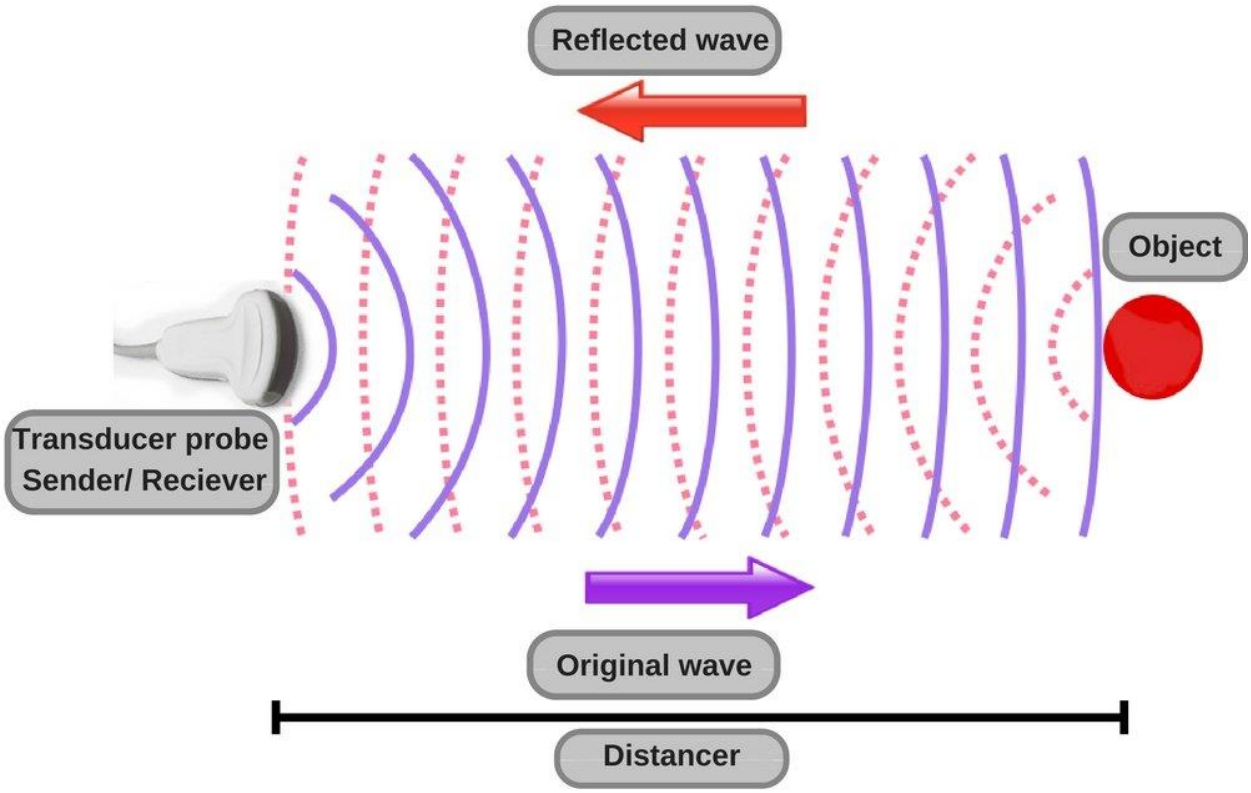

Fig.1. The above image illustrates a sound wave leaving the probe and travelling some distance towards an object. When it impacts the object, a wave is reflected back and picked up by the probe (Ashish, 2016).