Latent Dysfunctions in Device Innovation: An STS Perspective on Equity and Access

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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

Access to essential medical devices remains a critical issue, particularly for marginalized communities facing racial and socioeconomic disparities. While medical technology has advanced, its benefits are not equitably distributed.

Many low-income and minority patients encounter systemic barriers such as high costs, limited insurance coverage, and inadequate hospital resources. Addressing these disparities through low-cost production, innovative device design, and hospital integration is essential for fostering equitable healthcare access.

Research has highlighted disparities in medical device access, with non-Hispanic Black and Hispanic patients facing higher barriers than non-Hispanic White patients. Additionally, pre-market testing often excludes diverse populations, limiting device effectiveness across different demographics (Kadakia et al., 2023). While studies have explored affordability challenges, few have combined cost-effective production with hospital integration, leaving gaps in scalable solutions that can be implemented across healthcare settings.

Inequitable access to medical devices worsens health disparities, leading to untreated conditions, preventable complications, and rising healthcare costs. This research explores strategies for developing affordable, user-friendly devices that integrate seamlessly into hospital environments. By addressing financial and infrastructural barriers, it aims to provide strategies to improve patient outcomes and reduce disparities, ensuring that healthcare technology benefits all populations rather than being restricted to those with greater financial resources.

The primary objective of this research is to investigate how equitable access to medical devices can be improved by addressing the social, institutional, and contextual factors that limit their effectiveness. Rather than focusing solely on cost or technical performance, this work explores how medical devices can be designed, tested, and deployed in ways that reflect the

realities of underserved populations. Key questions include: How can developers ensure that devices function effectively across diverse clinical environments? What role do social and cultural contexts play in shaping device usability and trust? And how can stakeholders, such as patients, caregivers, and frontline health workers, be meaningfully involved in the development process to ensure devices truly meet community needs?

Rather than treating material costs, design strategies, and interoperability issues as isolated concerns, this research uses them to uncover broader systemic factors driving inequity in medical technology. Advancements in 3D printing (creating objects layer by layer), modular design (using interchangeable components), and IoT-based integration (connecting devices via the Internet) are considered for their potential to improve access, but only when paired with attention to social and infrastructural realities. For instance, a 3D-printed prosthetic may be low-cost, but without local repair capacity or patient trust, its impact is limited. These examples help illustrate how technological innovation must be embedded within the contexts in which care is delivered to be effective.

This research contributes an analysis that views affordability and hospital integration not as isolated technical challenges, but as interconnected elements of a broader social context. It highlights that successful medical innovation requires alignment with the cultural, infrastructural, and institutional realities of those it intends to serve in addition to performance and affordability. Devices that are inexpensive to produce but fail in under-resourced settings due to maintenance demands, lack of staff training, or mistrust among patients ultimately do little to reduce disparities. In this context, equity is not just an ethical imperative but a practical requirement for effectiveness.

The research emphasizes the need for early and ongoing stakeholder engagement, real-world testing environments, and institutional accountability in the development of medical devices. Design principles centered around equity, such as involving patients, providers, and community health workers in the design process, and testing devices in varied clinical settings, are recognized as essential strategies. Additionally, efforts to diversify engineering teams and integrate social awareness into biomedical education are key to addressing the root causes of exclusion. By reframing equity as a measure of innovation rather than a barrier to it, this research calls for a shift in how success is defined in healthcare technology: not just in terms of innovation, but in who benefits from it.

Methodology

This research uses a qualitative research approach to investigate disparities in access to medical devices, focusing on affordability, usability, and hospital integration. Given the complicated interaction of socioeconomic and systemic factors, a qualitative methodology offers the best means to pinpoint and understand the influences and factors affecting medical device accessibility. By relying exclusively on secondary data analysis, this research incorporates insights from peer-reviewed journal articles, policy reports, and case studies. These sources were selected to highlight cost-effective medical device production, healthcare infrastructure integration, and the socio-economic barriers hindering equitable healthcare technology access. The four primary articles examined provide valuable perspectives on disparities in biomedical engineering education, systemic biases in healthcare technology, and innovative strategies for improving healthcare equity.

These sources were identified through an online search using academic databases such as PubMed, ScienceDirect, and IEEE Xplore. The selected articles come from journals specializing

in biomedical engineering, health technology policy, and healthcare disparities, ensuring a multidisciplinary perspective. The selection criteria for these sources prioritized research that examined financial constraints, geographical disparities, and technological biases in medical device design. Studies revealed that the cost of medical devices disproportionately affects low-income populations, with affordability and reimbursement policies playing critical roles in device adoption. Additionally, research on human-centered and equity-focused engineering emphasized the importance of stakeholder engagement to ensure that devices meet the needs of diverse populations and do not inadvertently exclude marginalized communities.

To guide the analysis, this research employs the concept of latent and manifest functions and dysfunctions. This framework helps distinguish between the intended (manifest) and unintended (latent) consequences of medical device policies and production strategies. Through this lens, the research evaluates both the explicit goals of healthcare innovation, such as affordability and efficiency, and the unforeseen consequences that may unintentionally reinforce inequities or create barriers for marginalized communities. A comparative analysis method was utilized to identify recurring patterns and gaps in the literature. This approach involved examining key themes related to disparities in medical device access, drawing comparisons between successful and unsuccessful attempts at reducing these disparities, and assessing how biomedical engineering innovations can contribute to more equitable healthcare solutions.

Additionally, this study integrates the principles of Responsible Research and Innovation (RRI). Designing for social good necessitates that engineers are able to anticipate future challenges, remain reflexive, embrace inclusivity, and respond to evolving social realities. By incorporating RRI into the analysis, this research ensures that proposed medical device solutions align with ethical considerations, stakeholder needs, and long-term societal impact. Emphasizing

a proactive problem-solving approach, RRI fosters an inclusive development process that prioritizes equitable healthcare access.

The decision to rely on secondary data analysis was driven by the broad scope of the issue and the wealth of existing research on medical device accessibility. This approach enables a comprehensive review of prior studies without the logistical challenges of new data collection. However, certain limitations must be acknowledged. Some perspectives, such as direct patient experiences, may not be fully represented in the available literature. Additionally, findings may not be universally applicable due to variations in healthcare systems across different regions.

Despite these constraints, the comparative approach employed in this research provides a detailed evaluation of cost-effective medical device design and healthcare integration strategies. Ultimately, the research contributes to a deeper understanding of how technological and policy-driven interventions can be refined to enhance equitable access to medical devices. By leveraging engineering innovations such as adaptive design, cost-efficient manufacturing techniques, and smart technology integration, disparities in healthcare access can be systematically reduced, ensuring that medical advancements benefit all populations regardless of socioeconomic status.

Analysis and Results

This research brings together key voices in biomedical engineering, ethics, and health policy to better understand why disparities in access to medical devices persist, even as technological innovation advances. Using a framework rooted in Science, Technology, and Society (STS) theory, primarily the concepts of manifest and latent functions, this analysis sheds light on how the intentions behind medical device innovation often fail to account for real-world challenges. Although many devices are designed with affordability in mind, affordability alone

does not guarantee accessibility to populations in need. To address these shortcomings, this research also integrates the principles of Responsible Research and Innovation (RRI), emphasizing the importance of anticipation, reflexivity, and inclusive stakeholder engagement in guiding ethical and socially responsive design decisions.

Production methods such as 3D printing, which builds structures layer by layer from digital models, and modular design, which assembles devices from interchangeable units, can lower device costs. However, if those devices are introduced into settings without trained staff, reliable electricity, or maintenance infrastructure, they remain out of reach for many of the communities they were intended to help. These unintended consequences, or latent dysfunctions, underscore a recurring theme across the literature: device innovation that does not consider the context in which the devices will be used can reinforce, rather than reduce, systemic inequities (Lanier et al., 2022; Rodriguez et al., 2023).

The research indicates that these disparities are not the result of insufficient technological advancement. Studies show that the number of medical device patents and innovations continues to climb, particularly in high-income countries like the United States (O'Cearbhaill et al., 2018; Organization, 2020). Despite this, gaps in access remain wide, especially among low-income, rural, and racially marginalized populations in these countries. A critical disconnect lies in how devices are designed and introduced. Equity-centered design principles stress the importance of involving patients and healthcare workers as early as possible in the development process, testing devices in diverse real-world environments, and understanding the broader social, political, and economic contexts that shape healthcare delivery (Harte et al., 2017; Rodriguez et al., 2023). When these steps are overlooked, devices may meet technical standards but fail in practice.

One of the clearest examples of this gap is the continued failure of pulse oximeters to accurately detect hypoxemia in Black patients. One study found that Black patients were significantly more likely than White patients to have occult hypoxemia, low oxygen levels not detected by pulse oximetry, which can cause severe health complications (Sjoding et al., 2020). This highlights systemic flaws in device design and testing processes. This problem is not a flaw in the basic science but a reflection of development and testing practices that did not sufficiently account for racial diversity. These failures emphasize how medical technologies can inadvertently perpetuate existing inequities when there is a lack of diversity on engineering teams and the heterogeneity of patient populations is overlooked. Research suggests that more emphasis needs to be placed on educating biomedical engineers and healthcare professionals on social determinants of health and structural inequities in order to address these systemic challenges more extensively (Vazquez, 2018; Vazquez et al., 2017).

Historically, the field of biomedical engineering has compartmentalized concerns like cost, usability, and hospital integration, treating them as separate design issues. However, these factors are deeply interconnected. A device that is affordable but unusable, or one that fits poorly into existing clinical environments, cannot be considered effective. Usability encompasses not only physical design but also the time, training, and institutional support needed for proper operation, all of which vary dramatically between healthcare settings. In lower-income hospitals, where biomedical technicians may be scarce, devices requiring frequent technical maintenance become impractical, regardless of their initial affordability (Harte et al., 2017; O'Cearbhaill et al., 2018). Even in well-resourced hospitals, successful adoption depends on how seamlessly new technologies integrate with existing practices (Rodriguez et al., 2023).

Systemic barriers often persist long after a device enters the market. Studies stress that a device's social and cultural acceptance plays a critical role in its success. Devices that are difficult to maintain, misunderstood by users, or mistrusted by patients fail to deliver meaningful improvements, no matter how technically sophisticated and medically effective they are. This reinforces that context is not an auxiliary consideration but the environment in which innovation either succeeds or fails. Without deliberate attention to the realities of diverse healthcare settings, even well-intentioned designs can end up exacerbating existing disparities (Kadakia et al., 2023; Rodriguez et al., 2023).

These findings align with long-standing patterns of healthcare inequality. Historically underserved communities are often the last to access new medical technologies, and even when devices are introduced, they do not meet and fulfill local needs. As Lanier et al. (2022) argue, this is not merely a distribution problem, but a fundamental design problem rooted in upstream decisions about who is included in research and development processes. A lack of diversity in research teams leads to blind spots in understanding user needs, which can ripple through product design, testing, and deployment. This dynamic also contributes to broader funding inequities, such as the underinvestment in diseases like sickle cell anemia compared to conditions that primarily affect wealthier or white populations (Organization, 2020).

However, there are signs of progress. Educational initiatives, such as those implemented at The City College of New York, demonstrate that engineering students are eager to address real-world inequities when given the tools to do so (Vazquez et al., 2017). Integrating health disparities content into biomedical engineering curricula has been shown to increase awareness and broaden students' approaches to problem-solving. Programs like the Meyerhoff Scholars

Program, which supports underrepresented students in STEM, further show how building diversity strengthens innovation capacity (Lanier et al., 2022).

From this analysis, it becomes clear that affordability, usability, and integration are deeply connected elements of equitable device development. Devices that are cheap to produce but impractical to operate in target settings fail to fulfill their promise. Innovation must be judged not only by technical sophistication but also by its practical effectiveness across diverse communities. Equity, therefore, is not an abstract ethical add-on; it is essential to functional success.

Several strategies emerge from this analysis. First, medical devices should be tested across a range of real-world settings, including under-resourced hospitals and clinics (Kadakia et al., 2023; Rodriguez et al., 2023). Second, stakeholder engagement must be standard practice. Patients, healthcare workers, community leaders, and administrators should be involved from the earliest stages of development, not merely consulted after designs are finalized. Third, regulatory and funding agencies should implement formal equity evaluation criteria. These tools would help assess whether new technologies address the needs of underserved populations, are maintainable in various settings, and were developed with diverse perspectives at the table (Lanier et al., 2022; Sege & Laraque-Arena, n.d.).

Beyond these immediate strategies, a broader cultural shift is needed. Equity must be reframed as a fundamental measure of innovation itself. Technologies like telemedicine and AI-driven diagnostics hold great potential but also risk deepening inequities if not designed inclusively. When context is overlooked, even well-intentioned technologies can lead to latent dysfunctions, unintended and often invisible consequences that undermine their effectiveness. From an STS perspective, this disconnect between manifest intentions and real-world outcomes

reveals how technical artifacts are shaped by, and in turn reinforce, existing social systems. True success, therefore, must be defined not by the volume of innovations, but by their reach, inclusivity, and practical impact across diverse communities.

The findings of this research also highlight the relevance of Responsible Research and Innovation (RRI) as a guiding framework for advancing equitable healthcare technologies. Many of the issues identified, such as context-blind design, exclusion of marginalized users, and latent dysfunctions, reflect a lack of anticipation and reflexivity in the innovation process. RRI provides a model for addressing these shortcomings by encouraging engineers and developers to proactively consider the social consequences of their work, remain attentive to stakeholder needs, and adapt to emerging ethical and cultural concerns. By aligning with the values of anticipation, inclusion, and responsiveness, RRI helps shift the focus of innovation from purely technical performance to long-term societal impact. Integrating RRI into the development process would not only mitigate the latent dysfunctions observed in current device deployment but also foster a culture of design that views equity as central to success, rather than peripheral.

Reflecting on the research, it is clear that the original focus on affordability as the primary barrier to access was too narrow. The deeper issues lie in design practices, representation, and systemic integration. Those excluded from the design and deployment of new technologies are often those who stand to benefit most. Although this exclusion is systemic, it is not inevitable. It can be changed through intentional, inclusive practices that acknowledge the broader sociotechnical landscape in which devices are developed and used.

The key insight is that equity must be embedded from the very beginning of the engineering process, not treated as an afterthought. Engineering solutions are only as strong as the questions they seek to answer, and those questions must be informed by the lived realities of

diverse communities. In alignment with STS theory, this means recognizing that technological systems are not neutral, they are inherently shaped by values, priorities, and institutional power. Encouragingly, examples from education, research, and policy show that change is not only possible but already underway. The next step is to scale these efforts, incorporate them into the mainstream, and ensure that success is measured not just by innovation itself, but by the range of lives it meaningfully touches.

Conclusion

This research set out to explore the structural and systemic barriers that contribute to disparities in access to medical devices, with a particular focus on affordability, usability, and hospital integration. Through an analysis rooted in STS theory and employing a qualitative analysis of peer-reviewed studies, policy analyses, and engineering literature, the findings reveal a nuanced but urgent reality: while medical device affordability is often considered the greatest barrier to access, it is only one piece of a far more complex puzzle. The key takeaway is that innovations in medical technology frequently overlook the real-world contexts in which they are implemented. Even when design principles and manufacturing methods are utilized to make medical devices low-cost and technically advanced, they can still fail if they are not usable, maintainable, or trusted in the communities they are meant to serve.

This study highlights the significant gap between technological innovation and practical accessibility. Though methods like 3D printing and modular design can reduce production costs, these cost savings do not automatically translate into accessibility for underserved populations. In settings lacking reliable electricity, trained personnel, or infrastructure for maintenance, even the most affordable devices remain inaccessible. This disconnection between technical possibility and real-world functionality emphasizes the importance of designing with context in

mind. It also reinforces the need for equity-centered design strategies that prioritize the experiences of end users and stakeholders from the very beginning of the development process.

This study underscores the importance of integrating cost-efficiency with human-centered usability and hospital compatibility. The examination of secondary sources and comparative case studies reveals that true accessibility goes beyond design and manufacturing innovations. It involves inclusive development practices, diverse testing protocols, and meaningful stakeholder involvement. By exploring the intersection of affordability, equity, and functionality, this research contributes to a broader understanding of how medical devices can be designed not just to treat, but to transform systems of care for historically marginalized communities.

The significance of these findings is applicable to multiple domains, such as biomedical engineering, health policy, education, and institutional practice. For engineers, the research suggests that for a medical device to be considered successful, it should not only meet performance standards, but also be practical in low-resource environments, interoperable within different hospital infrastructures, and adaptable to cultural and social contexts. For policymakers and funding institutions, there is a pressing need to support initiatives that evaluate the equity potential of new devices. For educators, the research supports efforts to integrate equity-focused frameworks into biomedical engineering curriculum, preparing students to think beyond simply just technical challenges, and engage with ethical, social, and cultural aspects of design.

Importantly, this research does not assert that existing innovations are inherently flawed. Instead, it points out the consequences of neglecting context, diversity, and inclusivity. As demonstrated through the analysis of cases like the pulse oximeter's racial bias in clinical performance, the issue lies in systematic exclusion in testing and validation processes, revealing

how racial and socioeconomic inequities can be embedded within the very tools intended to improve health outcomes. Addressing these issues requires structural change, not simply better products, but better processes for creating them.

Nevertheless, the research acknowledges certain limitations. The study relied exclusively on secondary data, meaning that insights are derived from existing literature rather than firsthand research. While this approach allowed for an analysis that was comprehensive and utilized sources from various disciplines, it also means that certain voices, particularly patients directly affected by inaccessible technology, may not be fully represented. Additionally, because the research draws from a broad array of healthcare systems and contexts, some findings may not be generalizable across all regions or clinical environments. Variability in healthcare infrastructure and cultural attitudes toward technology all have an influence over the applicability of the recommendations presented.

Another limitation stems from the evolving nature of medical technology. As new devices and digital health tools emerge, such as telehealth and AI diagnostics, additional disparities may arise that this study does not fully capture. For instance, while this research discusses device integration in clinical environments, such as hospitals, the growing trend of home-based care introduces new questions about device literacy and internet access in low-resource areas. These developments suggest that the field must remain responsive and iterative, with ongoing research required to keep pace with technological shifts and evolving community needs.

Despite these limitations, this research offers a compelling argument for reimagining what equitable innovation in medical technology looks like. It suggests that equity is not a result of affordability or technical efficiency, but a foundational design parameter. This reframing

opens the door to more intentional and responsive innovation that actively seeks to reduce disparities rather than inadvertently reinforce them. Furthermore, by applying STS theory to biomedical engineering challenges, the research demonstrates the power of interdisciplinary perspectives being used to uncover hidden dysfunctions and propose actionable alternatives.

Looking ahead, several directions for future research and practice emerge. There is a need for empirical studies that center the voices of patients, caregivers, and healthcare workers in underserved communities, to better understand how they interact with and experience medical devices. Design teams should also explore design processes where community members are not merely consulted but serve as active collaborators in the innovation process. In addition, regulatory bodies could develop formal equity impact assessments, similar to environmental impact reports, to evaluate how proposed technologies might affect various population groups.

In conclusion, this research underscores the idea that the value of a medical device is not measured solely by how it performs in controlled settings, but by how well it meets the needs of the people it is intended to serve. A device that works only for well-resourced hospitals or homogeneous populations fall short of its potential. True innovation in healthcare demands inclusivity as a design imperative, not an afterthought. By embedding equity from ideation to medical device development, we move closer to a future where healthcare technology is not a driver of division, but a bridge toward justice.

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