

**The Accessibility of Uterine Fibroid Treatments for Understanding Sociotechnical
Setbacks for Focused Ultrasound Technology**

STS Research Paper
Presented to the Faculty of the
School of Engineering and Applied Science
University of Virginia

By

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April 12, 2023

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

What can you do when a painless treatment exists, but it sparkles out of reach? For the up to 75% of women who will be affected by uterine fibroids, this is a daily reality (Zimmermann et al., 2012). Uterine fibroids are benign uterine tumors that can cause heavy bleeding and debilitating pain. Most patients undergo invasive surgeries that can damage or remove their uterus and their ability to conceive forever – despite the fact that noninvasive focused ultrasound treatments have been Food-and-Drug-Administration (FDA)-approved since 2004 (FDA, 2004).

Current attributions of the underutilization of focused ultrasound treatments for uterine fibroid patients are technically oriented, centering on a lack of awareness of the relatively new technology, shortcomings in equipment design, and a lack of comprehensive post-operative outcome data. However, the awareness of focused ultrasound technology continues to grow as it gains news coverage such as via CNN headlines devoted to Charlottesville’s local nonprofit Focused Ultrasound Foundation. Additionally, from 2000-2022, the technology’s safety, efficacy, and publicity have advanced to treat 175,000 fibroid patients across the world (Broad et al., 2023). Technical shortcomings alone are not sufficient to explain the underutilization rates of focused ultrasound treatments for uterine fibroid patients and taking this view fails to consider the powerful non-technical factors that render a noninvasive treatment technology inaccessible.

Along with technical factors, we must consider provider and patient medical socioeconomics. To consider how these socioeconomics influence the accessibility of focused ultrasound technology for uterine fibroid patients, I will draw on the theory of technological momentum. Technological momentum is a Science, Technology, and Society (STS) theory that argues a new technology is shaped by society’s needs, while an old technology shapes society

(Johnson & Wetmore, 2009). In this framework, technologies contain reverse salients: components in the sociotechnical system that cause it to underperform in society (Johnson & Wetmore, 2009). With the theory of technological momentum, I argue that the underperformance of focused ultrasound treatments for uterine fibroid patients is due to socioeconomic reverse salients of provider workplace pressures and prohibitive treatment costs for patients. To corroborate my argument, I will use medical journal perspectives on focused ultrasound treatments for uterine fibroids, interviews of uterine fibroid patients from survey journals, and scholarly cost-benefit analyses on the socioeconomics of uterine fibroid treatment options.

LITERATURE REVIEW

There are several bodies of research on the diagnosis and treatment of uterine fibroids, a subset of which consider the relatively new technology of focused ultrasound as a treatment option. These analyses often take the form of large social surveys and attempt to quantify the treatment options chosen by uterine fibroid patients and their considerations prior to choosing. Technical research into improving focused ultrasound devices is performed separately in highly technical academic journals. While surveys provide valuable insight into the decisions being made by these patients and their stakeholder needs, and the technical analyses ensure that the treatment technology available to uterine fibroid patients are ever-improving, few analyses consider a both social and technical needs-based understanding of the use of focused ultrasound for uterine fibroids. By considering both technical and social needs as inter-connected rather than separate, I will show that focused ultrasound has strong potential for uterine fibroids treatment and it experiences underutilization when these needs are not considered as one sociotechnical system.

In previous literature, Riggan et al. (2021) importantly touch on the social needs met or not met by certain medical technologies used for uterine fibroid treatments, cataloging only 4 / 47 treatments of those surveyed as “minimally invasive” and recording patient interest in non-invasive options such as “Even if they were generally satisfied with their care, some women felt the range of currently available treatment options, including minimally invasive approaches, needed greater awareness among gynecology providers and patients.” However, the causes of the lack of provider awareness for minimally invasive treatment options that prevent uterine fibroid patients from accessing a greater range of treatment options are not discussed.

Aninye and Laitner (2021) expand on this research, considering that multiple social setbacks exist for focused ultrasound treatments for uterine fibroids, noting that “Because this is a new treatment, many providers do not know enough about it to offer this option, and MRg-FUS is not always covered by health insurance.” While this research notes possible causes for the sociotechnical setbacks to focused ultrasound treatments that began to be discussed by Riggan et al. (2021), the social setbacks are not explored in depth and neither are the effects of each social setback on the accessibility of focused ultrasound treatments for uterine fibroids.

The current body of research into focused ultrasound treatments for uterine fibroids notes social and technological setbacks to the adoption of the new technology without producing a clear understanding of how these setbacks interact to reduce the accessibility of focused ultrasound for uterine fibroids. This paper will not only describe social setbacks for the technology from both the provider and patient stakeholders, but also use the STS analysis framework of technological momentum to explain how each of these setbacks individually and collectively reduce the accessibility of focused ultrasound for uterine fibroid treatments.

CONCEPTUAL FRAMEWORK

To frame my argument, I will draw on the STS concept of technological momentum. The theory draws on the concept of physical momentum: it is difficult to influence the motion of a large, established object, while the motion of a small object is more easily influenced by the world around it. Technological momentum was developed by Thomas Hughes, a historian of technology who grew dissatisfied with both technological and social determinism theories of the role of technology in society from need to fruition (Johnson & Wetmore, 2009). Technological momentum combines the best of both theories and argues that when a technology, which is called a sociotechnical system in this framework, is early in its development, society has the most power to shape it (Johnson & Wetmore, 2009). As the sociotechnical system grows and gains more social momentum, the system exerts more influence over society and is more resistant to change (Johnson & Wetmore, 2009). Importantly, the framework also includes the concept of reverse salients: components in the system that fall behind others during complex change and cause the system to underperform (Johnson & Wetmore, 2009). In this analysis, I will identify and explain multiple reverse salients on the patient and provider side of focused ultrasound technology for uterine fibroid treatment that must be considered in order to understand the underutilization of this treatment method.

ANALYSIS

To understand the slow adoption of focused ultrasound technology for uterine fibroid treatments, we must consider it as a sociotechnical system with components and challenges spanning both realms. There are several under-illuminated socioeconomic reverse salients, aspects of the technology that fail to meet social needs and slow its utilization, faced by both providers and patients, the two ultimate groups whose needs must be met by any new medical technology. The following paragraphs detail the reverse salients on both the provider side, in the

form of a pressure to conform to the standard of care and a lack of workplace resources, and the patient side, in the form of insurance barriers and prohibitive costs.

Providers Experience Workplace Pressures

In order to understand the underutilization of focused ultrasound treatments for uterine fibroids, we must consider the social problems providers face. I argue the most significant needs faced by providers for uterine fibroid patients are the pressure to conform to the standard of care and a lack of resources and that the insufficient meeting of these needs by focused ultrasound functions as a reverse salient slowing its prescription rates.

Pressure to Conform to the Standard of Care

Providers take an oath to do no harm to their patients, which can manifest as conforming to a historical standard of care and functions as a reverse salient lowering recommendation rates for new technologies. Hysterectomy is the standard of care for uterine fibroid patients, with up to 80% of U.S. uterine fibroid patients receiving a recommendation from their provider (Tan et al., 2014). The high rate of hysterectomy recommendation is largely because *sans* uterus, uterine fibroids do not exist: symptoms are no longer present and will not recur. Where there is a current standard of care for a disease, as there is with hysterectomy for uterine fibroid patients, Hughes's theory of technological momentum argues that the momentum of that established medical technology is so great that the technology shapes how we approach the underlying problem of uterine fibroids. For uterine fibroid patients, this is observed as a provider appreciation of the permanent nature of hysterectomy for symptom relief, to the extent that uterine fibroids are still the leading cause of hysterectomy in the U.S. (Borah et al., 2013). Note that other diseases, like cancer, may require a hysterectomy for treatment but these procedures are eclipsed by the number of hysterectomies performed for uterine fibroid patients, whose needs

could be met noninvasively. By redefining a successful uterine fibroid treatment by the high-momentum hysterectomy standard of care, the problem of uterine fibroids is now approached with the intent of conferring total symptom relief and no recurrence. Though hysterectomy has gained technological momentum by successfully meeting providers' need to relieve their patient's symptoms, its momentum is so great that it suppresses new potential technologies. Similarly to an object with high momentum, a technology that meets a societal need becomes very difficult to change unless there is an improvement significant enough to facilitate the entrance of a new technology. New technologies which do not meet these total symptom reduction goals of treatment, in medical practice that is already characterized by cautious technological utilization to do no harm, experience severely delayed adoption.

Though hysterectomy can confer total symptom relief, it does not meet all needs of uterine fibroids patients. One of the needs that a conformation to the current hysterectomy standard of care failed to meet is a non-invasive treatment option for uterine fibroids. In a 2012 survey, 51% of patients under 40 were concerned about their ability to bear children in their treatment options, and 84% of patients under 40 indicated having a non-surgical option was important to them (Borah et al., 2013). The higher percentage of concern over non-invasive options suggest that the potential to conceive and the non-invasive nature of the treatment should be considered independently, circumventing a traditional view that non-invasive options like focused ultrasound are only important for the subset of patients who wish to still conceive. As it involves the surgical removal of the uterus, a hysterectomy recommendation by definition will always fail to meet both of these patient preferences. As such, there is the potential for new technologies, such as focused ultrasound, to stop the technical momentum of hysterectomies and gain its own technological momentum by uniquely addressing non-invasive treatment

preferences of patients. However, the provider pressure to produce a quantifiable best outcome reduces the perceived importance of patient needs outside of maximally effective symptom relief. The adoption rate of focused ultrasound for the treatment of uterine fibroids relies on not only the continued improvement of the technological efficacy itself but also the social agreement of the important needs to be met by a treatment among patients and providers.

Lack of Workplace Resources

Providers experience a lack of resources, specifically uterine fibroid expertise and time to spend with a patient, that function as a reverse salients to reduce the prescription rate of focused ultrasound treatments to eligible patients. Many patients report feeling that their providers did not fully consider the patient's individual experience before providing treatment recommendations, providing quotes to surveyors such as "I've yet to run into a doctor that I felt like they cared enough to know what's causing this, or tried to help me... I feel like because of my case being so severe, that they're just used to treating the one and two, or three or four, and it's just—what's the word—like a fast food restaurant" (Riggan et al., 2021). This patient's experience highlights the psychological harm, in addition to the physical pain accompanying non-invasive treatment options, endured when a provider's resource pressures result in a non-individualized treatment plan. It is understandable that not every provider will have expertise in uterine fibroid management. However, by not referring patients to educational resources or other providers with specific areas of knowledge, a lack of diverse options from providers ensures patients will not be exposed to, or likely even aware of, minimally invasive treatment options. Without an expert understanding of their disease pathology, the reverse salient of the providers' lack of expertise becomes a hindrance to the accessibility of focused ultrasound technology for uterine fibroids patients.

Even if providers are able to direct patients to new technologies, such as focused ultrasound, that allow minimally invasive uterine fibroid treatments, the time to implement the young technologies can be another major barrier to their utilization. The journal of Radiology of the Radiological Society of North America lists that “Use of MR-guided FUS therapy is limited by the time required to perform quality assurance, synchronize the ultrasound transducer and MR imaging scanner coordinates, create a treatment plan, acquire the MR images, perform each acoustic ablation (termed sonication), allow for cooling of the technology, and reposition the treatment focal spot” and that the actual ultrasound treatment time ranged from 3-5 hours in a 2008 study (Silberzweig et al., 2016). There is no doubt that this is a large procedure time commitment for providers and requires an additional time investment of special training. As hysterectomy requires less pre-planning time and mechanical expertise, focused ultrasound technology must keep improving its technological efficiency and intuitiveness for technicians to reduce the time of treatment before it gains sociotechnical momentum sufficient to outpace hysterectomies in time considerations.

Some may argue that it is appropriate for providers to stick to providing patients with tried-and-true hysterectomy recommendations for their protection. While it is true that providers should not prescribe treatments they believe to be inappropriate for an individual’s disease, it has been shown that many uterine fibroid patients receive too little treatment option information in lieu of only recommending hysterectomy. Corona et al. (2014) note that “Among those who had alternative treatment [to hysterectomy], the majority had only 1 documented therapy, when >1 therapy may have resulted in adequate treatment” and go on to point out “These patterns of practice are unlikely to be consistent with guidelines from the ACOG [American Congress of Obstetricians and Gynecologists] that recommends the use of medical

rather than surgical therapy.” Corona et al. (2014) went on to show that when provided with a second medical opinion of a radiologist and gynecologist with expertise in uterine fibroids and a guaranteed 30 minutes for consultation, the rate of recommendation for hysterectomy plunged from up to 80% in the general U.S. to just 4.4% of patients in the study. When the reverse salient of a provider lack of resources alone were alleviated, non-invasive prescriptions skyrocketed. While hysterectomy should remain a treatment option for uterine fibroids, its high rate of recommendation has more to do with expertise and time deficits of providers than with being the best option for the patient every time. The reverse salient of a lack of resources, specifically expertise and time put into the recommendations of providers, lowers the rate of focused ultrasound treatment recommendations for uterine fibroid patients outside of treatment eligibility.

Providers make up a crucial group of stakeholders whose needs must be met by any medical technology prior to its adoption. In the case of focused ultrasound treatments for uterine fibroids, there are several provider needs which are not met by aspects of the sociotechnical system, which function as reverse salients slowing the adoption of focused ultrasound. The pressure providers face to conform to a standard of care and the lack of resources for them in the workplace together contribute to a lower rate of recommendation of focused ultrasound treatments than is warranted by the technological development stage itself. As patients need provider approval for treatment, these reverse salients preclude potentially highly-benefiting patients from accessing focused ultrasound treatment technology.

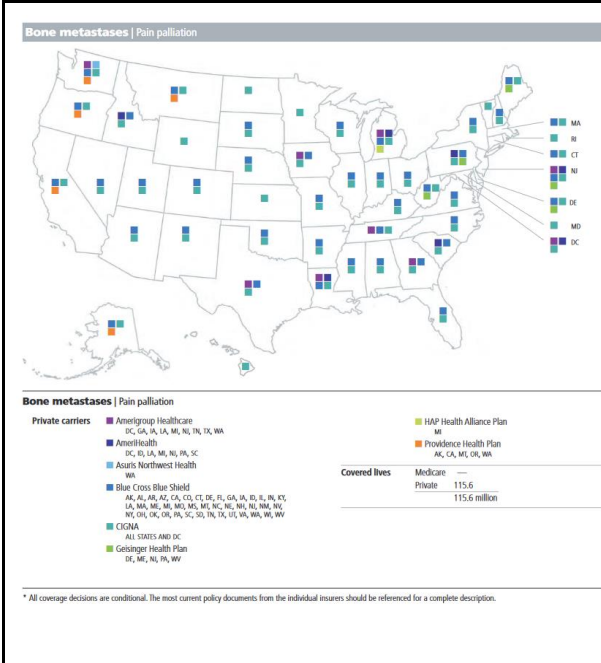
Patients Face Unaffordable Treatments

In order to fully understand the underutilization of focused ultrasound treatments for uterine fibroids, we must focus on the socioeconomic barriers to patients, one of the most

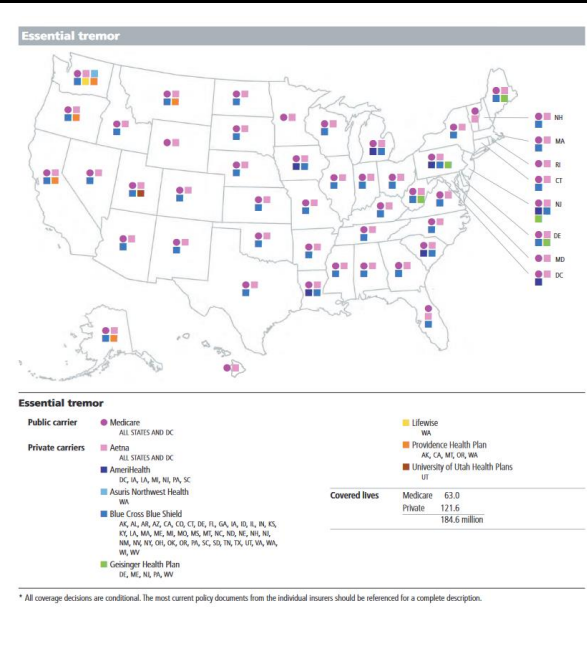
significant being the lack of insurance coverage and prohibitive out-of-pocket costs for the procedure. These economic barriers to patients serve as reverse salients to focused ultrasound accessibility by reducing the number of patients to the very few who are eligible for assistance or who can afford the treatment without significant financial assistance.

Geographic Reimbursement “Dark Spots”

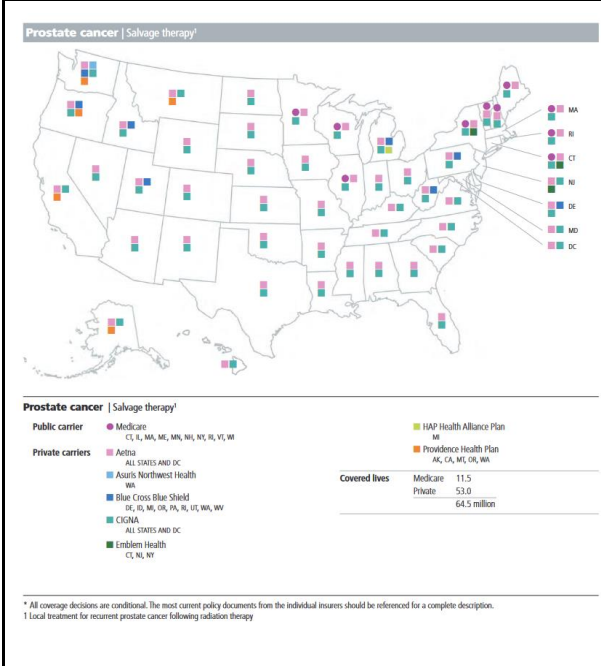
A lack of reimbursement for focused ultrasound treatments functions as a reverse salient for focused ultrasound treatments by greatly reducing the number of potential patients who can receive financial assistance for the treatment. In the United States, there are 5 FDA-approved use indications for focused ultrasound treatments, as shown in **Figure 1** (Broad et al., 2023). Of these 5 use indications, all are either reimbursed in all 50 states or include government age-based coverage under Medicare – except for the uterine fibroids use case, which is reimbursed in only 7 states under 1 private insurer (Broad et al., 2023). Uterine fibroids patients are uniquely poorly reimbursed among focused ultrasound use cases, proving that focused ultrasound itself is not prohibitively difficult to reimburse. As focused ultrasound is a young technology, treatment is usually carried out at designated centers, to which patients already have to manage their own travel. On top of the patient symptom-related pain, there is added the significant time- and money-consuming management of their travel to care locations, and on top of this, there is the management of determining whether and how they can receive any reimbursement of the treatment with their insurer and in their home state. Reimbursement dark spots significantly complicate access to the focused ultrasound treatments, serving as a reverse salient barring access to patients without the ability to invest much greater effort than is required in more established treatment paths, such as hysterectomies, in managing their treatment course.



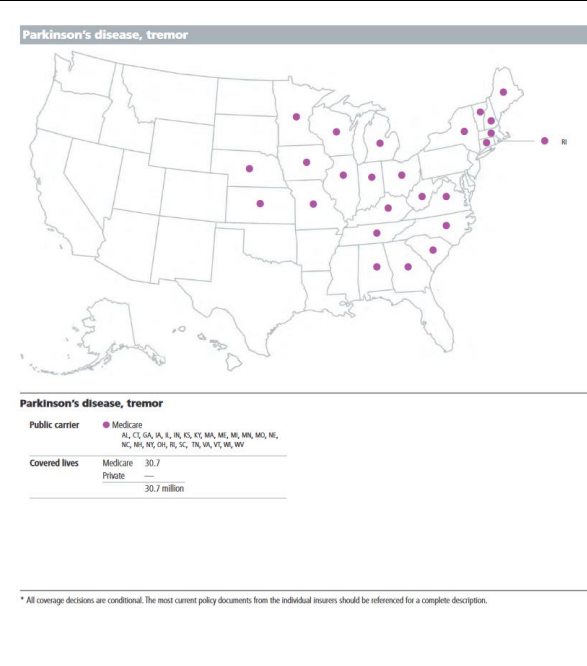
Bone Metastases



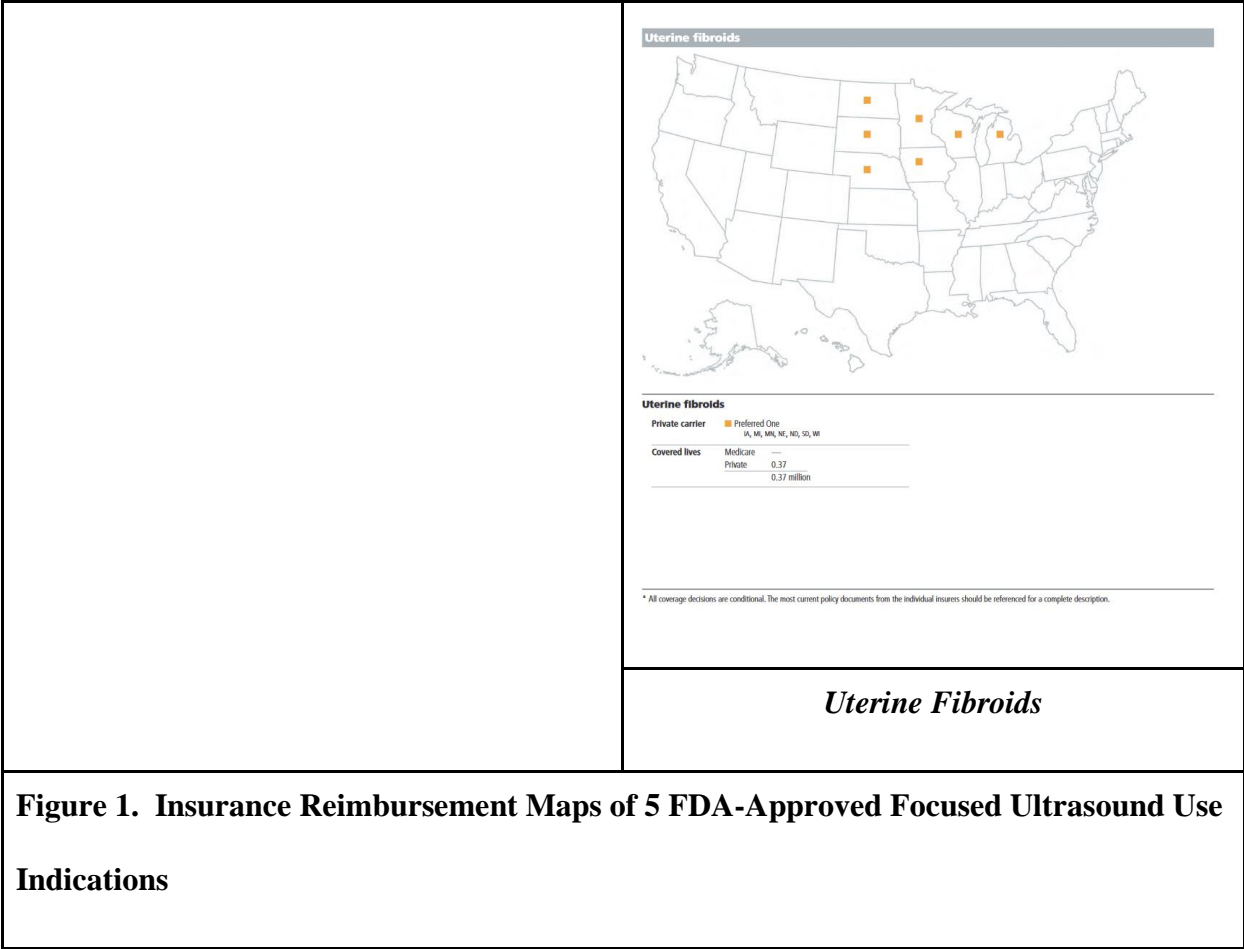
Essential Tremor



Prostate Cancer



Parkinson's Disease



The limited reimbursement of the focused ultrasound treatment for uterine fibroids reduces the number of potential patients who can receive assistance affording the treatment to only approximately 185,000 women in the United States (Broad et al., 2023). Using the U.S. female population in 2020 (Google Data Commons, 2022) and a conservative estimate of 7% prevalence (Zimmermann et al., 2012) of uterine fibroids, there are approximately 11,540,000 women with uterine fibroids in the United States right now with no ability to receive insurance reimbursement for a focused ultrasound treatment for their condition. As such, I argue that focused ultrasound is severely underutilized as a uterine fibroid treatment because its reimbursement is inaccessible to the vast majority of patients. Because the implementation of focused ultrasound treatments for uterine fibroids is failing to meet large groups of women in

their current locations and with their current insurers, this reverse salient is severely hindering the technology's adoption by turning away eligible patients.

Prohibitive Out-of-Pocket Costs

The out-of-pocket cost for a focused ultrasound treatment for uterine fibroids is prohibitively high, and in conjunction with poor reimbursement, functions as a reverse salient by reducing treatment accessibility for uninsured patients to the few who can afford the out-of-pocket cost. The problem of spotty geographic reimbursement options grows when calculating the average patient cost of a focused ultrasound treatment for uterine fibroids, which a 2009 estimate places at \$27,300, all of which would be paid out of pocket by a patient who had no insurance reimbursement for the procedure (O'Sullivan et al., 2009). For comparison, the patient cost of a hysterectomy is \$19,800 (O'Sullivan et al., 2009), but with insurance reimbursement, can reduce down to 10% of that, at \$1,870 on average for a total hysterectomy with Medicare (U.S. Centers for Medicare and Medicaid Services, n.d.). In practice, given a choice between an \$1,870 hysterectomy and a \$27,300 focused ultrasound treatment, affording the focused ultrasound treatment is barely within the realm of choice for many women, regardless of whether it is otherwise their preferred treatment. The economic barrier to accessing the focused ultrasound treatment serves as a final sealing reverse salient that hinders the adoption of the technology.

When fewer focused ultrasound treatments are performed for uterine fibroid management, not only are women who would like to receive the treatment prohibited, but a cycle of inaccessibility begins. Fewer focused ultrasound treatments for uterine fibroids creates a lack of long-term supporting evidence for the efficacy and safety of the treatment. When there is a lack of long-term supporting safety and efficacy evidence for a treatment, few providers will

present it as a treatment option, and fewer provider requests for reimbursement for the procedures means there will be less pressure on insurers to reimburse the procedure. Each of the patient-facing reverse salients to the use of focused ultrasound for uterine fibroid treatment combine to hinder a noninvasive new technology for alleviating a common and often severe women's health condition.

CONCLUSION

The inaccessibility of focused ultrasound treatments for uterine fibroid patients is a complex issue fraught with both technical and sociological setbacks. To fully understand the reason focused ultrasound technology is underutilized for uterine fibroid treatments, we must move beyond detailing technical shortcomings. The technical safety and efficacy of focused ultrasound continues to advance and cannot explain the underutilization of treatments for uterine fibroid patients alone. Understanding focused ultrasound treatment accessibility means we must understand the sociological reverse salients, system aspects that have not kept pace with technical advancement. On the part of providers, the main reverse salients are the pressure to conform to the standard of care and a lack of resources, and on the part of patients, they are a lack of financial support options including geographic reimbursement barriers and prohibitive out-of-pocket treatment costs.

Using the conceptual framework of technological momentum, it is possible to refine focused ultrasound technology to make it better suit the needs of the providers and patients in the broader commercial medical system and accelerate focused ultrasound technology out of research labs and into the lives of women in need.

word count: 3670 (goal 3000-3750)

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