AN ACTOR-NETWORK ANALYSIS OF NEGLECTED STAKEHOLDERS IN THE DESIGN OF THE ENDOSCOPE

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By

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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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When evaluating the interrelationship between society and the engineer that lives within it, Law & Callon (1988) make the observation that engineers are "not just people who sit in drawing offices and design machines; they are also…social activists who design societies or social institutions to fit those machines" (p. 284). Given the close relationship between technology and the people that use it, engineers have a duty to serve as the intermediaries who are responsible for providing innovative designs that cater to a wide variety of stakeholders, due to the fact that society is made up of different actors with conflicting interests. Thus, what should be done when a medical technology reaches the hands of a 'neglected' user that the device was not properly designed for? The answer may appear simple at first: design a solution that better fits the criteria of the neglected user; however, when looking at the problem from the perspective of an actor network, a variety of factors and stakeholders need to be mobilized in order for a system to be changed.

The early motivation to address the problems associated with medical technology began with the technical project, which was conceived when the project team found, through shadowing physicians in the clinic, that many gastroenterologists often complained about pain in the left thumb while or after operating the endoscope. Upon further research, it became clear that a high volume of cases (Cohen et al., 2006, p. 967-968), as well as a lack of ergonomic design of the endoscope, was causing musculoskeletal overuse injuries in endoscopists (Byun et al., 2008). The prevalence of this issue is facilitated by the fact that the poor design of the endoscope has not changed since the 1980s (Shergill & McQuaid, 2019). Gastroenterology fellows are continuously being trained and assessed on their competency with the traditional endoscope, producing endoscopists every year who depend on the traditional endoscope to conduct endoscopy

(Sedlack, 2010). Furthermore, based on an interview with the technical team's medical advisor, physicians are also pressured by a prideful mentality to deal with the pain and carry on with their work (V. Sciortino & V. Seshadri, personal communication, December 6, 2019). When this systemic issue was brought to light, the team chose to address the problem by creating an auxiliary attachment device to the endoscope that would give physicians the option to relieve some of the musculoskeletal strain in their left thumbs while operating the device. The societal and technological concerns that led to this technical project are a result of inaction from and neglect of key stakeholders.

Tightly coupled with the technical project, the Science, Technology, and Society (STS) thesis seeks to illuminate the issues of stakeholder neglect by examining the network of actors surrounding the endoscope and identifying stakeholders that are negatively impacted by its design. In order to perform this analysis, Law & Callon's (1988) Actor-Network Theory (ANT) will be used to map out interactions between major stakeholders that are involved in the development and the usage of the medical technology. The STS topic will examine the roles of various actors involved with the endoscope and evaluate the situation in which the insertion of an engineer as a stakeholder can help mobilize the actors within the network to put forth better solutions.

THE ACTOR NETWORK OF THE ENDOSCOPE AND ITS NEGLECTED USERS

This paper will use Actor-Network Theory (ANT) to illustrate the intertwining network of technical and social factors that go into framing the development of the endoscope; however, the analysis will further examine the ways in which the network can overflow. This paper will evaluate the ways in which neglected stakeholders have the potential to redefine and reshape the network to address their unmet needs, but some may lack the capacity to do so. Engineers have the sociotechnical responsibility to identify these stakeholders who "may be silent or lack social power" in order to bring their needs to the forefront and address them as engineering problems (Benjamin Cohen et al., 2014, p. 10).

The concept of framing and overflowing within an actor network was first conceived by Callon (1998) and was used for the analysis of markets; however, this terminology was transposed by Jolivet & Heiskanen (2010) for analysis of project implementation. The analysis in this paper will apply this concept to the design of medical technology. According to Jolivet & Heiskanen (2010), framing refers to the process in which different actors within a network establish a consensus toward a common goal, while overflow occurs when stakeholders that were not initially "invited to the table invite themselves in order to start to carry out their own alternative scenario" (p. 6748). It is important to consider the actor network that was initially formed when the endoscope was first designed. Having this contextual framework will help underscore the importance of the neglected stakeholders and how they can disrupt the network to create an endoscopic technology that fits their requirements.

With this framework in mind, this analysis will consist of a case study on the traditional endoscope within a sociotechnical network. The case study will focus on mapping the roles of each actor that went into framing the medical technology's initial design and using the map to identify neglected stakeholders pushing for an alternative scenario. By using this methodology, this paper seeks to use this case study to not only illuminate the role of neglected stakeholders within the actor network but to also establish engineers as key actors in facilitating the sociotechnical disruption of the status quo.

DISRUPTION OF AN UNCHANGING CYCLE OF INACTION

The Need for an Ergonomic Solution

Current endoscopes often require the physician to use their left thumb and forearm muscles to exert and sustain forces on a system of dials to control and maintain the position of the scope during a procedure. The current design allows the physician to deflect the distal end of the scope so that the tortuous bends of the gastrointestinal tract can be navigated (K. Chang, personal communication, September 25, 2019). The repetitive abduction and extension of the left thumb often leads to De Quervain’s tenosynovitis which, in a study conducted by Byun et al., (2008), affected 49 out of the 55 (89.1%) endoscopists surveyed. As shown in Figure 1, characterization of this injury typically involves a painful inflammation of two tendons that run between the thumb and the wrist: the abductor pollicis longus (APL) and the extensor pollicis brevis (EPB) ("De Quervain’s tenosynovitis", n.d.).

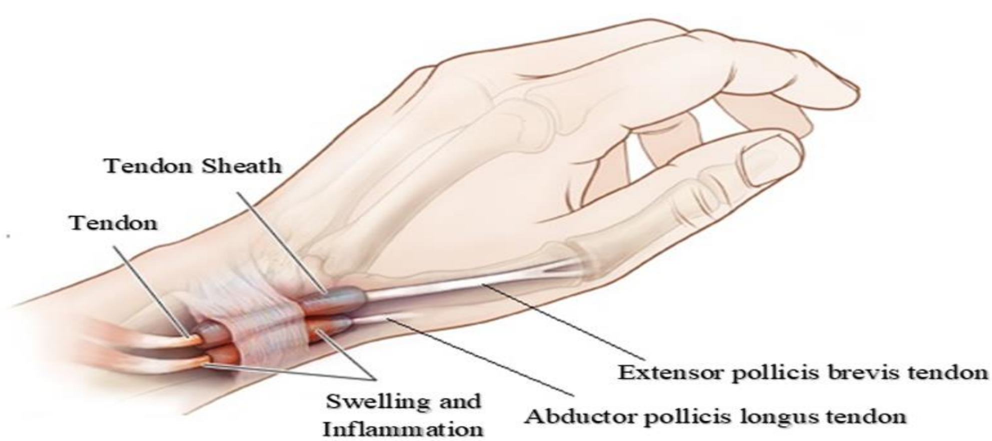

Figure 1: De Quervain’s Tenosynovitis. This figure visualizes the swelling and inflammation of the extensor pollicis brevis and abductor pollicis longus tendons involved in De Quervain’s tenosynovitis. (Adapted by Kevin Chang from Ryan Glover, 2018).

Despite the high prevalence of injury caused by operating the device, Shergill & McQuaid (2019) have noted the design of the modern endoscope has remained relatively unchanged since the 1980s. In order to understand why little about the endoscope's design has changed, the following analysis will examine the actors in Figure 2 which maps out the various stakeholders who play a role in maintaining the status quo.

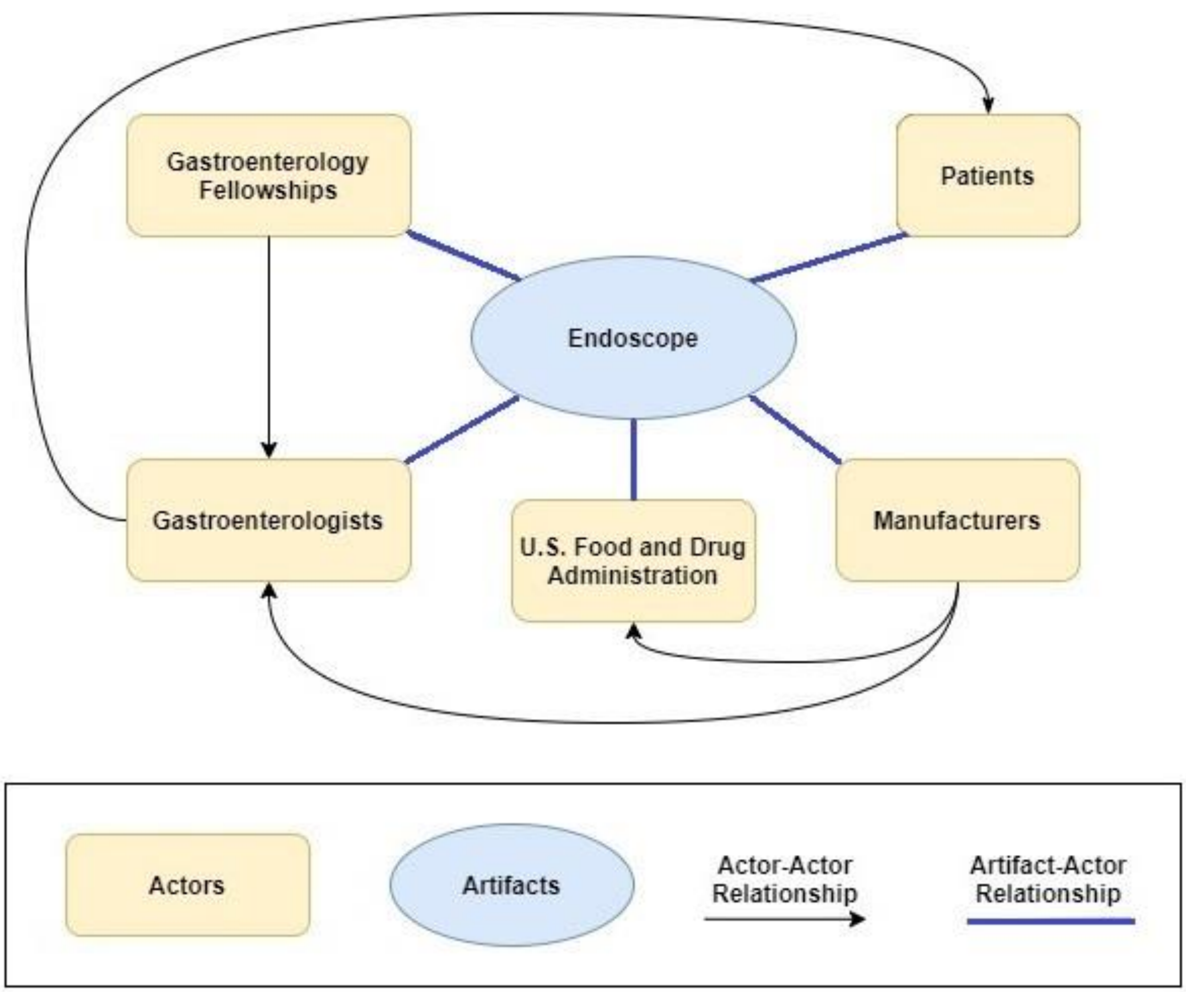

Figure 2: Framing the Actor Network of the Modern Endoscope. All actors in this diagram share a relationship with the endoscope. The arrows describe a directional relationship between the actors, depicting the way in which they interact within the initial framework of the system. (Created by Kevin Chang, 2020).

Framing the Perpetual Cycle of Inaction

According to Study.com (2020), the final step to becoming a gastroenterologist is through the completion of a fellowship program ("How to become a gastroenterologist", 2020), where physicians are trained to be competent in a variety of endoscopic procedures that align with the requirements of the Accreditation Council for Graduate Medical Education (ACGME) (2019). Gastroenterology fellows are trained with and their competencies evaluated through their use of the traditional endoscope (Sedlack, 2010). In one study, Gómez, & Wallace, (2013) estimated that most endoscopists typically achieve competency after an average of 275 colonoscopies, which is a number that may take a couple years to acquire (p. 659). Due to the extensive training that goes into learning how to use the endoscope, it is likely that skilled gastroenterologists would be reluctant to exchange years of experience and training for the sake of learning a new system, even if the new system could potentially decrease their risk of musculoskeletal injury. In a personal discussion about this issue, Dr. Dushant Uppal, the medical advisor for the technical project, stated that gastroenterologists are also burdened by a sense of pride and often feel pressured to keep quiet about their pain and manage their symptoms in private (V. Sciortino & V. Seshadri, personal communication, December 6, 2019).

All of these factors combined create a feedback loop that keeps the design of the modern endoscope in a state of paralysis. Most gastroenterologists trained to be competent with the modern endoscope will continue to rely on those skills instead of going through more years of training to be competent with a novel device. The lack of a collective outcry from physicians demanding a more ergonomic endoscope, driven by a sense of pride in the practice, gives manufacturers little incentive to produce a different device. As a result, fellowships only have the traditional endoscope available to them to train new gastroenterologists, allowing the cycle to continue.

Endoscope manufacturers are stakeholders that also play a role in perpetuating the loop. Since the adoption of the first flexible video-endoscopes in the 1980s, manufacturers have continued to ignore the need for human-centered design by continuing the production of a “one-size-fits-all design” (Shergill & McQuaid, 2019, p. 967). In a study conducted by D. L. Cohen et al. (2008) on gastroenterology fellows, they found that of the gastroenterologists with a surgical glove size of 6.5 or smaller, 97.4% of them were female, and all of them felt that the endoscope was too large for their hands, impeding their ability to perform endoscopy. Smaller hands lead to a suboptimal grip, which results in a decreased ability to produce force (The Eastman Kodak Company, 2007). This problem is also exacerbated by significant differences in pinch and grip force generation abilities between men and women. According to one study, approximately 90% of females have a maximal pinch less than 95% of that for males (Leyk et al., 2007). The problem of the one-size-fits-all design became further apparent when the technical team was shadowing female gastroenterologists in the clinic at the University of Virginia. Two of the three female gastroenterologists the team spoke to confirmed that they had to compensate for smaller hands by occasionally operating the dials of the endoscope with two hands instead of one (V. Sciortino & V. Seshadri, personal communication, December 21, 2019).

According to Shergill & McQuaid (2019), current endoscope companies seem to be more interested in improving other qualities of the endoscope, such as optics, despite the growing concerns on the device’s ergonomic shortcomings (p. 967). For example, Olympus is currently one of the biggest endoscope manufacturers in the world, accounting for approximately 70% of the global endoscope market (Grand View Research, 2020). Founded in 1919, Olympus began as a domestic microscope manufacturer in Japan and expanded into the camera market by developing Zuiko photographic lenses in 1936 (Olympus, 2020c). Not until almost thirty years later in 1964 did Olympus launch their first gastroscope, breaking them into the endoscope market (Olympus, 2020d). By then, Olympus had already been an established optical manufacturer for decades; thus, it is apparent that they are more comfortable improving the optics of their products, staying close to their roots (Olympus, 2020a). This is further exemplified when taking into consideration that, in November 2002, Olympus unveiled the world's first High-Fidelity Display (HDTV) endoscopic system which improved the image quality of endoscopes and drastically increased the amount of information that could be seen on the screen (Olympus, 2020b).

Aside from improving imaging quality for better diagnosis, manufacturers like Olympus also appear to be more interested in developing devices to aid in more advanced endoscopic procedures, such as polyp resection. Boston Scientific (2020), another medical device company founded in 1979 that also specializes in gastroenterology products, produces a whole suite of endoscope accessories for diagnosis and polyp removal, such as their biopsy forceps (Boston Scientific, 2020c), single use snares for resection (Boston Scientific, 2020a), and rotatable retrieval devices to capture food boluses and foreign bodies (Boston Scientific, 2020d). As such, medical advances in gastroenterology are geared more toward the benefit of patient wellbeing, and less toward the health of the physicians using them.

Neglected Stakeholders and the Role of the Engineer

Up until this point, the way in which the endoscope actor network is framed suggests that gastroenterologists, including the subgroup of female practitioners, are the neglected stakeholders. Through the technical team's literature search (Byun et al., 2008; Shergill &

McQuaid, 2019) and personal investigations (V. Sciortino & V. Seshadri, personal communication, December 6, 2019, December 21, 2019), it is clear that the network sits in a state of debilitating complacency where physicians, despite their awareness of the ergonomic problem, remain resistant to change and would rather compensate and manage symptoms than demand action. Manufacturers also appear to be more invested in improving diagnosis and treatment with the endoscope rather than improving its ergonomics.

In this network where all the actors exist in a static paradigm where little is being done within the system to enact change toward an alternative scenario, overflow will not occur naturally without the action of a catalyst. By assuming the role of a catalyst, engineers must disrupt the actor network by accelerating changes to a medical device and putting forth novel designs, forcing overflow into the network.

Figure 3 (p. 10) diagrams an example of the behavior of the engineer once they enter the actor network of the endoscope, mobilizing other actors along the way. As shown, in order to address the ergonomic problem, engineers must operate within the actor network to identify the problem, design a solution, and then implement the technology. Problem identification synthesizes information about the issue gathered from physicians and researchers, while the design of a solution involves the technical work of putting forth a medical device. Some engineers have already successfully accomplished these first steps and have conducted studies on their novel device.

A published study by Rozeboom et al. (2015) was conducted in order to determine the feasibility of a device that allows for joystick guided colonoscopy. An endoscope is mounted onto a device that turns the dials of the endoscope according to the way a thumb operated joystick is positioned. The design of this device removes the forces imparted on the left hand entirely by reducing it down to the movement of an electronic joystick.

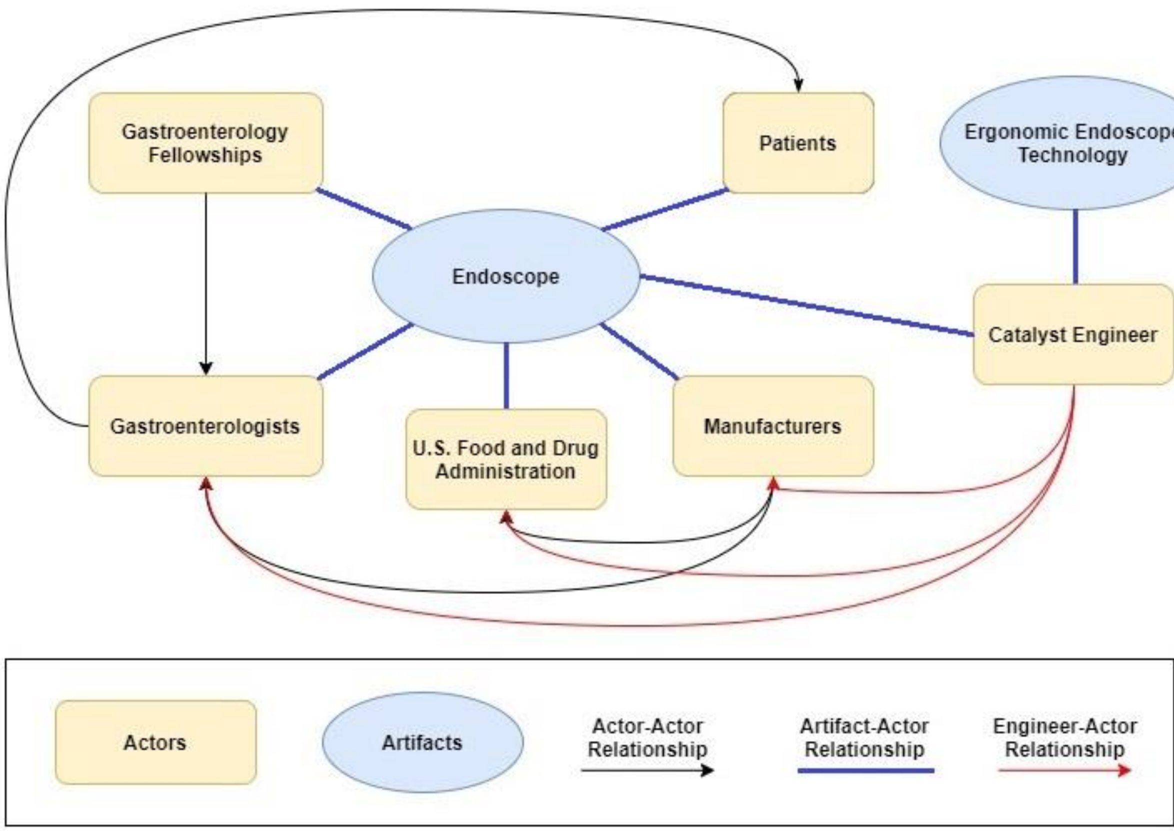

Figure 3: Engineers Overflow the Endoscope Actor Network. Building off of Figure 2 (p. 5), this diagram displays the addition of an engineer who serves as a catalyst in breaking the cycle of inaction. By interacting directly with manufacturers, the Food and Drug Administration, and gastroenterologists, engineers have the power to bring a new ergonomic endoscope technology to the forefront (Created by Kevin Chang, 2020).

A separate device developed by Vucelic et al. (2006), is a self-propelled endoscope that uses a pressure gradient within a system of two balloons to move the endoscope through a patient's colon. The device is integrated with a computer system which calculates and generates the necessary pressure gradient within the balloons. These projects are a testament to the growing recognition of the need for a better endoscope system, and engineers are the ones taking the lead.

Nonetheless, devices that intend to break into the endoscope industry can face a lot of obstacles with regulation as well as with established manufacturers. The government body that regulates all medical devices sold in the United States (U.S.) to assure safety and effectiveness is the U.S. Food and Drug Administration (FDA), (2018). Before a medical device can enter the market, the engineer must work with the FDA to pass through numerous regulations. The FDA requires the device to be classified, that a premarket application is submitted and that necessary feasibility, safety, or efficacy tests are conducted on the device (U.S. Food and Drug Administration, 2019a). Ensuring that a marketable, FDA approved product is available will legitimize the technology, allowing engineers to use the product as a concrete means of disrupting the system.

One of the largest obstacles to achieving meaningful change, as framed in the original actor network in Figure 2 (p. 5), is the endoscope manufacturing industry, responsible for supplying gastroenterologists with all the technology necessary for them to perform endoscopy. Their influence reaches a worldwide market involving an approximate $43 billion dollar industry (Wood, 2015). In order for engineers to attain access to the global market, it would be necessary for them to negotiate an acquisition or purchase of the intellectual property so that renowned companies can use their expansive influence to market the new technology to gastroenterologists. By mobilizing all these actors within the network, the engineer will be able to trigger an overflow, allowing for an alternative scenario that breaks the cycle inaction. As a result, physicians will no longer be neglected stakeholders and will have access to a more ergonomic endoscope technology.

THE POWER TO DISRUPT THE SYSTEM

Engineers are in a unique position in society to build bridges that connect the gaps between society and technology. In the words of Langdon Winner (1986), “what matters is not

[the] technology itself, but the social…system in which it is embedded" (p. 2). What Winner's words mean is apparent in the actor network surrounding the endoscope because it was clear to the gastroenterologists that the technology was not ergonomic, but a variety of social factors maintained by a system of fellowship programs, peers, and manufacturers smothered their will to push for change. Although gastroenterologists must take their share of responsibility for the perpetuation of the cycle of inaction, they as stakeholders are still neglected. As the situation stands today, little is being done about the ergonomic problem despite the fact that such a large percentage of gastroenterologists suffer from musculoskeletal injuries (Byun et al., 2008). If anything, manufacturers should take the responsibility in ensuring that the device is safe to use for not only the patients, but also for the gastroenterologists. The FDA requires that a recall of a medical device is necessary when the "medical device is defective, when it could be a risk to health," or both (U.S. Food and Drug Administration, 2019b, para. 2), and the considerations for risk should involve everyone, including the gastroenterologists.

According to the Code of Ethics for Engineers written by the National Society of Professional Engineers (NSPE) (2019), all professional engineers must "hold paramount the safety, health, and welfare of the public" (p. 1). When it comes to medical technology, maintaining the health of the public is often considered to refer to the betterment of patient wellbeing; thus, the physicians that use them are often not considered (Healthcare Business & Technology, n.d.). Nonetheless, poor ergonomics will often turn physicians into patients themselves, accounting for $15 billion to $20 billion dollars in job related injuries every year (Sara Berg, 2019). When it has been identified that a growing health problem is resulting from a lack of ergonomic design, engineers must draw from their professional code of ethics and strive for a better solution.

The Actor-Network Theory (ANT) analysis conducted in this document can be applied to various other medical technologies that also involve neglected stakeholders (Law & Callon, 1988). One medical technology that can be further examined is a voice recognition software that is used by attending emergency physicians to transcribe verbal notes about patients. One study found that when incorrect transcriptions were made by the software, 15% of the errors miscommunicated critical points of information regarding a patient's health (Goss et al., 2016); furthermore, another study reported that a significantly higher rate of transcription errors were caused when the software was transcribing the voice of a woman than a man (Rodger & Pendharkar, 2007). Criado-Perez (2019) attributes this problem to the misrepresentation of women in data, which, in this case, created a technology that was incapable of properly detecting a woman's voice. In this situation, with women serving as the neglected stakeholders, engineers must again play a role in disrupting the network to improve the voice recognition system so that female voices can be more easily detected by the device.

Further research into other medical technologies can help support the thesis that engineers play an important role in disrupting a static network, mobilizing actors to put forth better technology for society. Although doing so is easier said than done, engineers should still take on the sociotechnical responsibility to seek out networks that are stuck in a cycle of inaction and provide an alternative scenario that is more favorable to its neglected stakeholders. Not all stakeholders have the power to demand technological change; however, all engineers at least have the power to try.

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