INSIGHTS FOR RESPONSIBLE AND RAPID ADOPTION OF EMERGING MEDICAL TECHNOLOGIES

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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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A RISING NEED FOR EMERGING BIOMEDICAL SOLUTIONS

Increased financial and social investment in biomedical technologies following World War II revolutionized medical care in the U.S. and abroad. Pacemakers alone have lengthened the lives of millions of people since their introduction in the late-1950s and are currently supporting 600,000 new patients every year (Bains, Chatur, Ignaszewski, Ladhar, & Bennett, 2017, p. 23; Wood & Ellenbogen, 2002, p. 2136). With these successes, life-expectancy has risen and age-related diseases, such as stroke, heart disease, and cancer, have emerged as some of the defining clinical challenges of our time. The rising prevalence of these conditions and the permanent tissue damage they cause necessitates the development and diffusion of new biomedical solutions. Stem cells enable healing through direct replacement of lost cells, or through stimulating the body's natural regenerative processes. Therefore, implantable stem cell-based technologies offer the potential to functionally regenerate lost tissue, including neurons and cardiac muscle which are otherwise permanently lost following injury (L. Wei, Z. Wei, Jiang, Mohamad, & Yu, 2017, p. 50; Segers & Lee, 2008).

To date, only eighteen cell or gene therapies have been approved by the Food and Drug Administration ([FDA], 2020). With the enormous potential of stem cell-based implantable technologies, it is crucial to promote their development and eventual diffusion throughout the healthcare system. The closely coupled technical and STS projects both aim to support this goal.

A key limitation of stem cell-based therapies is rejection by a host's immune system. (Moshayedi & Carmichael, 2013, p. e23863-2). As a result, only cells harvested from the host are reliable for therapeutic use. To overcome this challenge, the technical project team has begun development of a device that uses micro-level fluid flow to encapsulate individual stem

cells in biocompatible polymers that hide the cells from the immune system. In the future, this device would allow for non-host cells to be stored in banks for later deployment, thus increasing accessibility and applicability of cell-based therapies.

Despite the meaningful contributions of technical research to the physical development of this technology, there is a societal hesitation to trust new therapies, especially those involving materials implanted into the body. The most obvious signs of this can be seen in the anti-vaccination movement where individuals follow discredited misinformation to erroneous conclusions (Matthews-King, 2018). Additionally, there are a plethora of regulatory, economic, and social factors that have historically influenced the diffusion of medical technology. This STS research aims to create a framework for the successful navigation of our socio-technical world based on insights gained from the history of medical device diffusion, mapped through an Actor-Network Theory lens (Baiocchi, Graizbord, & Rodríguez-Muñiz, 2013, p. 323). This analysis can be used to help emerging implantable or transplantable technologies achieve widespread acceptance.

The need for emerging stem cell-based therapeutics is clear and motivates the coupling of the technical and STS topics. Understanding and overcoming the challenges to development and diffusion, from both a technical and societal perspective, will help ensure efficient adoption of essential biomedical solutions.

SOCIO-TECHNICAL FACTORS INFLUENCE MEDICAL DEVICE DIFFUSION

Every emerging technology faces a network of socio-technical factors which have the potential to slow development and diffusion. This web of complications for new advanced medical technologies, such as implantable stem cells, is visualized in Figure 1 on page 3. To start, doctors often hesitate to accept innovative strategies for addressing old problems. In 2014,

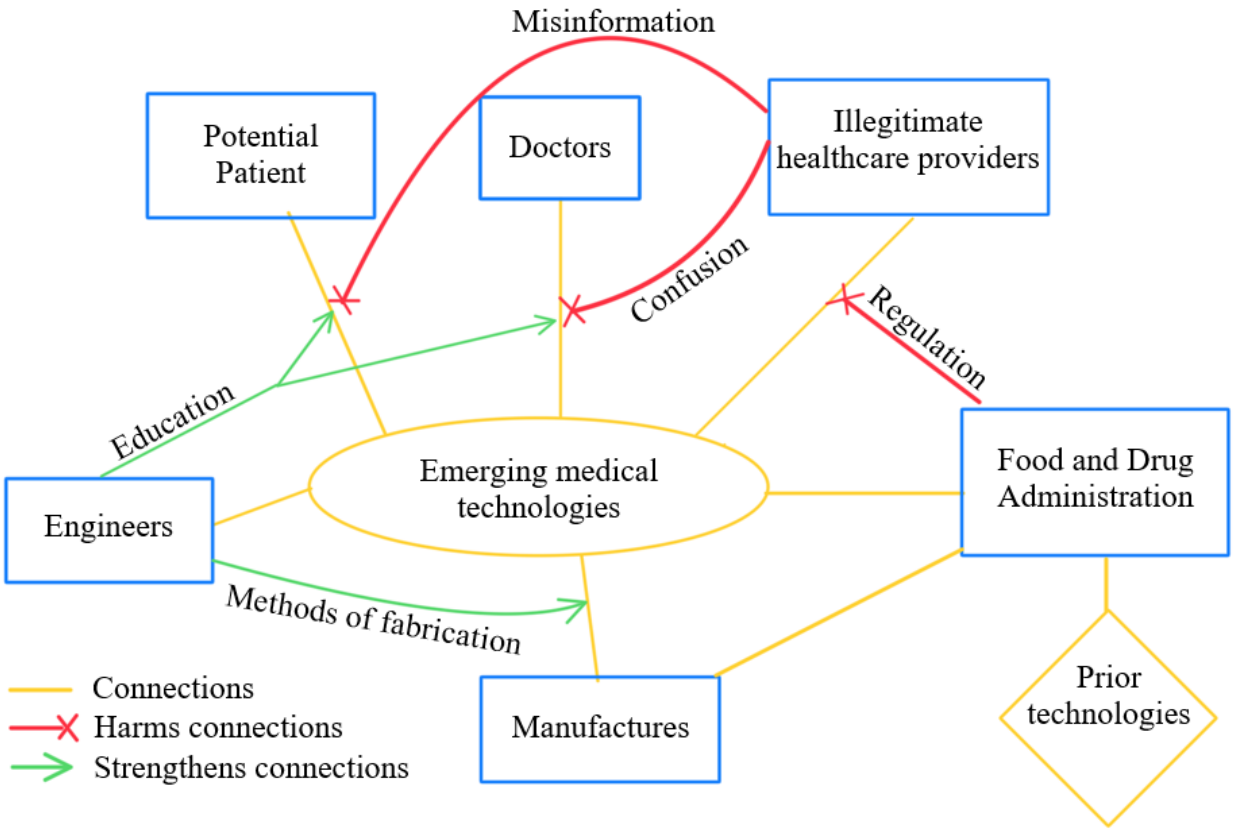

Figure 1: Modern socio-technical interactions surrounding emerging medical technologies: Various social groups interact with emerging medical technologies. Many of these groups interact with each other to either strengthen connections, denoted by green arrows, or harm connections, denoted by red arrows ending in a cross. (Created by Latvis, 2021).

Weiss et al. conducted a study which evaluated the efficacy of various diffusion of innovation models for medical device dissemination among medical professionals. It was found that the high burden of adoption and the need to make preemptive value judgments about the technology leads most doctors to resist incorporating new technology into their practice until persuaded by respectable colleagues (p. 041008-10). Further, it has proved difficult to regulate cell-based implants and other novel technologies. It is common to hear those in the biotechnology industry, or even academia, expressing how the current regulations can be outdated or overly cumbersome (Sharma, Blank, Patel, & Stein, 2013, p. 107-114). At the same time, the FDA (2019) has been forced to publish warnings against illegal, untested, and dangerous stem cell therapies being marketed to the public, as well as issue periodic recalls of previously approved products (p. 107-

114; Hern, 2017). Such mixed signals regarding the regulation and safety of emerging technologies then feed into a general anxiety felt by the potential patient population. Historically, these feeling can lead to the partial rejection of objectively safe and beneficial medical interventions. A contemporary example of this is the most recent anti-vaccination movement that grew rapidly when Andrew Wakefield published a study in 1998 containing falsified information, which he used to claim the combination measles, mumps, rubella vaccine caused autism and bowel disease. After further review, the original article was retracted for scientific fraud, but the damage was already done (Matthews-King, 2018). In the United States, twenty-seven states have seen reductions in childhood vaccination rates (Pilkington, 2019). These factors relating to doctors and patients are relatively unique to the biomedical field, but more common social influences, such as levels of financial investment and manufacturability, also shape the development and diffusion of medical technologies.

The complicated web seen in Figure 1 on page 3 is itself a simplified model. To fully appreciate and understand the dynamic influences over medical technology diffusion, the STS research took the form of a historical analysis where perspectives from physicians, nurses, engineers, and sociologists from various time periods were reviewed and synthesized into Actor-Network Theory models. Understanding how and where the challenges to medical device diffusion came about will reveal strategies for facilitating the dissemination of much needed emerging medical technologies.

LESSONS FROM THE HISTORY OF MEDICAL DEVICE DIFFUSION

Historical analysis of medical technology diffusion in the United States has led to the identification of numerous influences on this process. Among these, the two most important determinants appear to be the dynamics of societal values and the approval of the end-user.

SOCIETAL VALUES CHANGE OVER TIME

There are clear changes in societal values around medical technologies over the last century. During the economic and cultural boom in the United States following World War II, there was heavy investment, as well as enthusiasm for, biomedical solutions (Ginzberg, 1990). This stimulus led medical technologies to rapidly advance and integrate into American hospitals, and produced an attitude shift in the medical profession. The prevailing belief became that, to uphold the Hippocratic Oath, it was an imperative for physicians and clinicians to employ the most advanced screening and therapeutic methods in order to maximize patient outcomes, regardless of cost (Butter, 1993, p. 13). As a result, doctors sought institutions with access to cutting-edge equipment and, in a bid to attract talented medical workers, hospitals purchased that equipment, thus reinforcing the proliferation of new medical technologies. On the surface, these rapid advancements appear purely beneficial, however, the process came with growing consequences which slowly changed societal values around medicine.

The competition between hospitals led to the oversupply of out-of-date equipment, as well as the over-prescription of expensive procedures (Butter, 1993, p. 13; Greenspan et al., 1998). Additionally, the introduction of new technologies was not always done responsibly. For example, electric fetal monitors (EFMs) were introduced in the 1960s to monitor the status of the fetal heart rate and maternal contractions during labor (Butter, 1993, p. 23). The product was intended for high-risk pregnancies. However, as Irene Butters discussed in a 1993 *Journal of*

Social Issues article, a controversy surrounded the technology after the rate of cesarean births more than doubled in the decade following its introduction. Subsequent clinical trials of EFMs in the 1970s failed to show that the technology could outperform safer and less invasive older technologies (p. 24). This electronic monitoring device was not were not the only technology to enter the clinical setting without proper clinical testing in the decades following World War II. Many commonly used technologies, such as computed tomography (CT) and ultrasound, were similarly implemented before proper regulatory controls (Butter, 1993, p.24; Blume, 2013, p. 727). It was not until 1976 with the passage of the Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 that the Food and Drug Administration ([FDA], 2018) began regulating medical devices at all, largely in response to patient injuries caused by undertested devices. The passage of this law was indicative that the fallibility of medical technologies had seeped into the public consciousness.

In addition to the technology itself, its rapid introduction changed how patients interact with their doctors. Before this period of technological change, a patient could expect to meet with a single doctor who could explain their treatment prescriptions in a clear and concise manner. However, as the medical field was bombarded with new and increasingly complex medical innovations, this type of personal communication became more difficult. Medicine was compartmentalized to ensure new technology could be properly understood and applied by medical professionals, which led to patients being sent around hospitals to access specialized expertise instead of relying on a single physician (Butter, 1993, p. 20). This lack of personalized care, combined with the complex concepts surrounding the new technologies, also made it more difficult to adequately explain to patients the care they were receiving. Instead, many physicians relied on their authority as medical experts to convince patients of the necessity of treatments

(Butter, 1993, p. 21). Unsurprisingly, the reduction of personalized care and communication created feelings of lost autonomy in segments of the patient population, and this process persists in the present day. Robillard, Roskams-Edris, Kuzelkevic, and Illes (2014) conducted a survey on public acceptance of gene therapies, an emerging technology, and found that over 50% of those surveyed were "most concerned" that they would not have all the necessary information when considering medical applications of gene therapies (p. 744). High costs for the patient to receive advanced treatments bolsters these negative feelings into skepticism of the medical profession, and even medical science.

The rising cost of healthcare was also a product of the societal drive for advanced biomedical solutions in the post-World War II era which pushed out lower cost alternative treatments. The availability of more advanced technologies made the recommendation of inferior treatments an ethical violation in the eyes of the typical physician (Butter, 1993, p. 13). This thought process is still common today and is reinforced by the threat of malpractice claims against physicians that fail to liberally employ any potentially useful imaging modalities or advanced treatment options. For example, it has been suggested that reusing pacemakers from deceased owners could be an affordable alternative to a new pacemaker for lower income families, especially those in developing countries. It has even been shown that the practice is safe when high standards of cleaning are met (Nava et al., 2013). However, the idea is still generally frowned upon in medical communities and is even illegal in some countries (FDA, 1995). This technological imperative also drove the medicalization of natural processes like child birth and dying "of old age," making each an enormously expensive event (Butter, 1993, p. 19). Children are no longer born inexpensively at home with the aid of midwives. Instead, they are born in hospitals under careful monitoring by electronics and doctors. In many areas, the use of non-

nurse midwives instead of medical professions has even been legally challenged, reflecting the cultural shifts after World War II (Butter, 1993, p. 20).

The rapidly growing cost of healthcare eventually caught the attention of policymakers. The Congressional Office of Technology Assessment carried out a series of studies in the late 1970s to identify how healthcare costs could be controlled and how the diffusion of medical technology could be best regulated (Blume, 2013, p. 727). The insights gained from these studies and subsequent investigations produced new policy tools and guidelines which entered the societal consciousness. Of these, the ideas of evidence-based medicine (EBM) and health technological assessment (HTA) became particularly influential.

The idea of EBM contends that, prior to adopting new medical technologies, efficacy must first be quantitatively demonstrated through randomized clinical trials (Blume, 2013, p. 272). This idea developed in response to the aforementioned practice of adopting undertested and potentially dangerous technologies, such as EFMs. The implications of this new standard for medical devices were mainly positive for the health of society. The ideas associated with EBM led to the passage of the Medical Device Amendments in 1976 which expanded the oversight capabilities of the FDA (2018), providing new patient protections through basic assurances that medical devices were efficacious and safe. With this change, the amount of trust a patient must give to an individual doctor is reduced since any medical device they use must have been vetted by an independent agency. While these strict standards defend the safety and autonomy of patients, the process makes development of new technologies more costly and time consuming.

The focus of HTA is on the holistic application of medical technologies and encourages taking into account the economic, social, and ethical implications of innovations, rather than simply the medical efficacy (Blume, 2013, p. 727). This idea can be understood as a response to

the rising cost of healthcare and desires to make medicine more democratic for patients. Encouraged by this broad reassessment of the values surrounding medical innovation, patient advocacy groups have grown in prominence (Blume, 2013, p. 728). The general critique these groups levy is that medical decisions are being made on the basis of professional knowledge in a hierarchical manner that disregards the autonomy of the patients themselves. Many of these groups are made of people with a common medical condition and contend that their lived experiences constitute a type of experienced-based expertise that should be taken into account in the medical decision-making process around their ailment (Blume, 2013, p. 728).

A modern example can be seen with autism spectrum disorder, where conventional cure-focused efforts are being challenged by groups like the Autism Rights Movement which advocates instead for promoting acceptance of neurological differences (Jaarsma & Welin, 2012, p. 21). Many such groups have succeeded in making their voices heard both publicly and within medical committees that determine the direction of new technology and provisions relevant to them. Thus, the shifts in societal values throughout the late 1970s expanded the voices of marginalized groups and promoted patient autonomy through the partial democratization of medicine. The shifting perspectives on what medicine is and how devices should be regulated, exemplified by EBM and HTA, had profound impacts on the interactions between the medical community and the rest of society. However, these changes did not produce exclusively positive outcomes.

For instance, it has become progressively more difficult to convince underinformed patients to accept objectively beneficial care. As previously discussed, the rapid adoption of new medical technologies in the post-World War II era had the effects of lowering patient involvement in decision making and substantially increasing the cost of healthcare. Together,

these influences primed people to become untrusting of medicine and medical advances they are unfamiliar with. Now that ideas such as EBM and HTA normalized questioning the institution of medicine and diluted the authority of professional knowledge, the door has opened for more medical skepticism. This process is exemplified by the prevalence of anti-mask individuals seen during the COVID-19 pandemic. Reasons for being a part of this demographic vary, but common themes are not trusting medical science or professionals and fears of lost personal autonomy that come with top-down mandates.

Substantial shifts in societal values have clearly altered the landscape that a medical device must navigate to obtain acceptance in society. Understanding how our society arrived at our values provides lessons for how to gain public acceptance. The insights also allow for identification of actors and their dynamic influences over time. However, to fully reconstruct the actor-networks, especially in more complex modern times, it is necessary to understand the finer stabilizing social connections that ultimately allow the diffusion of technologies.

THE IMPORTANCE OF THE END-USER

The development of technology does not occur in a vacuum. Instead, it is informed by the social network interactions within the society. Similarly, the efficacy of a new medical technology alone is not necessarily sufficient to ensure it will be accepted in the clinical setting. This is especially true in the post-1970s era where public enthusiasm and the technological imperative no longer drive the adoption of innovations to the same extent. Three case studies illustrate the importance of understanding the social interactions involved in the use of emerging medical technologies.

In 1975, the first computed tomography (CT) scanner was marketed to hospitals (Alexander & Gunderman, 2010, p. 780). Three years later, seventeen separate companies had

developed to supply this technology and two-hundred scanners had been installed (ImPACT, 2013, “clinical acceptance and early commercial development”). Stuart Blume (2013) pointed out that the swift dissemination of this technology seemed less dependent on patient needs, and more focused on attracting talented physicians, stating: “Even if the earliest adopters of a new device were principally concerned by its possible benefits for patient care (and by the opportunity to study those benefits), gradually, adoption came to reflect the search for legitimacy within the set of comparable institutions” (p. 727). This process is reflective of the lingering pre-1970s attitudes towards medical technology, where the drive among medical professionals to apply the most cutting-edge technology motivated hospitals to invest in emerging treatments. Implicit in this style of adoption is the dependance on the physician’s preferences. Since pre-1970s values did not place emphasis on patient autonomy, the doctors can be viewed as end-users which stabilize the diffusion network. Without physician support, there would be no drive to adopt expensive CT scanners.

A technology that was more recently integrated into the medical field is radio frequency identification (RFID), which uses radio emitting microchips to track objects and people. Although this is not necessarily a medical device, the story of its diffusion into Australian Hospitals offers important insights, as chronicled by Chandana Unnithan (2014) in her Digital Health and Public Health Informatics dissertation. In hospitals, the RFID technology offers clear and obvious benefits, such as facilitating the tracking of patients around the hospital and maintaining organization of expensive equipment in large facilities. However, through the 2000s and early 2010s, efforts to integrate the technology into Australian hospitals faced variable success. To understand why, Unnithan investigated two case hospitals, one that faced consistent problems adopting the technology and one that did not, using an Actor Network Theory lens.

Unnithan found that the most important influence on the success of RFID integration was the manner in which the technology was introduced (p. 281). When the autonomy of the end-user is respected and maintained, the community facilitates the diffusion of the technology within their system. In the problem case, decisions regarding how and where the RFID would be used were made without the input of nurses, the primary end-users. As a result, the nurses felt the technology was an unnecessary disruption of their workflow and experienced consistent problems working with the technology. By contrast, the more successful hospital emphasized the inclusion of nurses in negotiating and carrying out the implementation of RFID. This maintained the control of the nurses over their workflow and allowed the technology to be seen as an aid, rather than an imposition. Since the nurses were happy with the technology, they enforced usage and convinced doctors, staff, and nurses from other departments to adopt the technology (Unnithan, 2014, pp. 284–287). Therefore, the key to stabilizing the network of technological diffusion was maintaining the autonomy of the end user, the nurses. With their support, diffusion with a medical community occurs naturally.

A few years later, Hurtado-de-Mendoza, Cabling, and Sheppard (2015) studied the public and academic perception of medical adherence technologies and reached similar conclusions. Their study was focused on perceptions of patient agency, particularly as it pertains to Digital Pills. The Digital Pill is an ingestible sensor which aims to monitor compliance with prescription regimens of oral medication by tracking time of ingestion and physiological data, then relaying it to an app. The data can be shared with the patient, doctors, nurses, or family members, at the discretion of the patient (p. 327). The prevailing academic thought around such technologies viewed their introduction as a removal of patient agency, conjuring ideas of “Big Brother” tracking your private habits. However, Hurtado-de-Mendoza, Cabling, and Sheppard argue that

these technologies can be viewed as empowering the users to maintain their own health and reinforcing their ability to remain autonomous (p. 333). The company producing Digital Pill has been successful with their product through encouraging this process of understanding. Even their motto "Powered by you" emphasizes this point (p. 329). In this case, as with RFID diffusion in Australian hospitals, maintaining feelings of autonomy among the end-users of the technology is essential for ensuring efficient medical technology diffusion. In all three cases, the networks that facilitated adoption of the new technologies were stabilized by the end-users, though the identity of this group changes over time and context. Having discussed the dynamics of societal values and the end-user's critical role in the diffusion of medical devices, actor-networks can be constructed to enable the identification of deeper connections.

VIEWING THE HISTORY THROUGH AN ACTOR-NETWORK THEORY LENS

Actor-Network Theory is a theoretical approach developed by Michel Callon, Bruno Latour, and John Law that is used to describe the bidirectional influences between society and technology (Baiocchi, Graizbord, & Rodríguez-Muñiz, 2013, p. 323). It does this by describing various human and non-human influencers called actors and actants, respectively, and organizing them into dynamic networks of interactions with one another (Fioravanti & Velho, 2010, p.2). The historical context presented in the previous sections conveys an understanding of which actors and actants changed over time and which remained constant. To visualize these changes, Figure 2 on page 14 compares viable network structures for the pre-1970s and post-1970s. Viewing both side-by-side emphasizes which influences are producing modern problems in the diffusion of medical technology, as well as highlight important actor-network connections to foster.

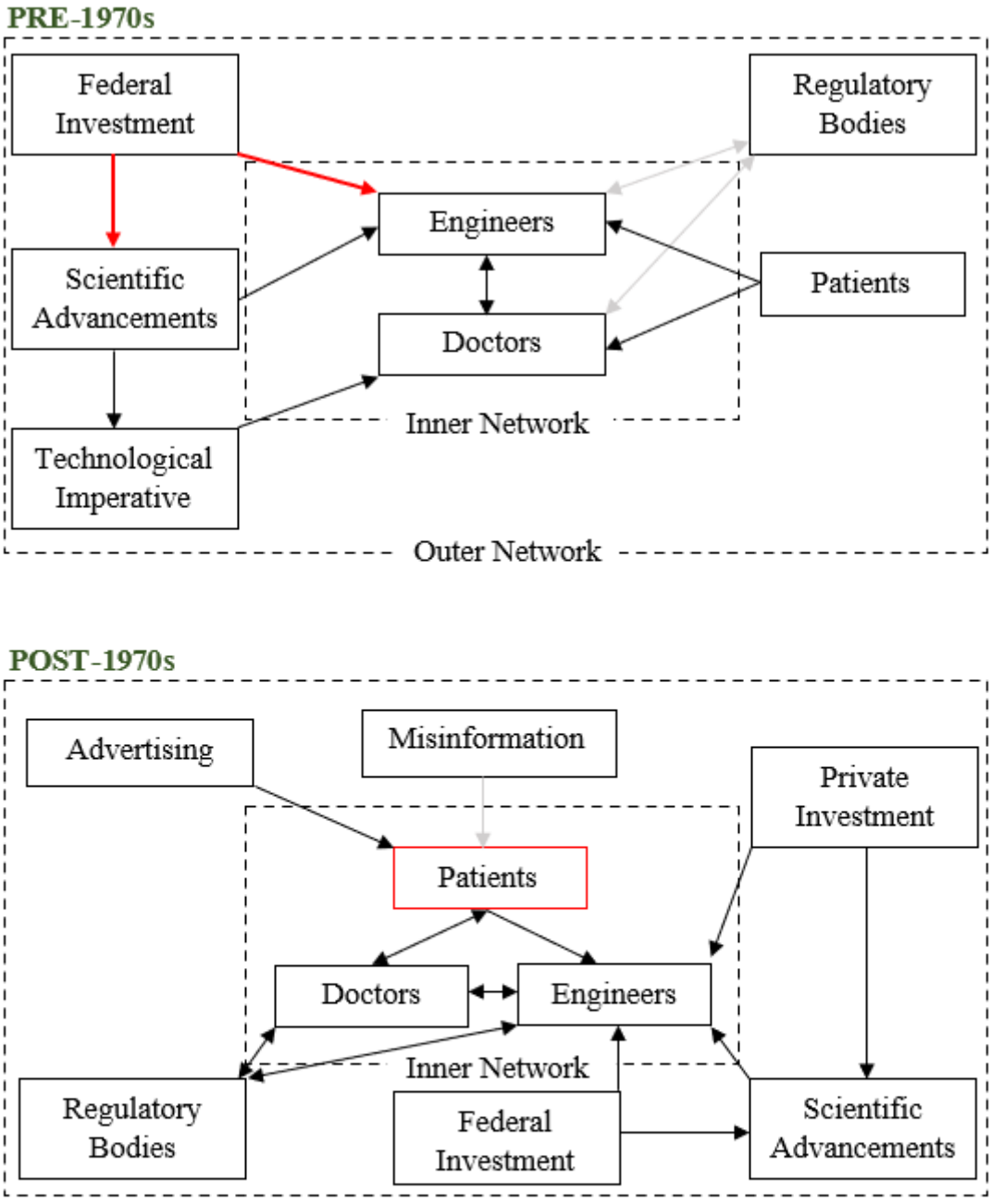

Figure 2: Medical technology Actor-Network Theory mappings over time: Each of the overall networks contains an inner network composed of actors that directly negotiate the diffusion of medical technologies. The larger global networks include peripheral actors and actants that do not directly determine the diffusion of the medical devices. (Adapted by Cole Latvis (2021) from Downing et al., 2018).

There are many ways actor-networks can be organized. For the purposes of mapping the connections around medical device diffusion, it is useful to divide the overall network into inner and outer sub-networks. The inner network, or negotiation space, represents those who directly

negotiate whether a technology diffuses and how. Actors and actants existing in the outer network indirectly affect the diffusion of the medical technology through one of the inner network members (Law and Callon, 1998, p.289).

In the pre-1970s, only engineers and doctors formed the inner network. The patients themselves did not behave as actors with decision-making capabilities. Instead, it was simply their aliments which acted as sources of inspiration and justification for introducing new technologies. As a result, the patient population found itself in the outer network in the pre-1970s era. The true motivators for innovation were federal investment, scientific advancements, prevailing culture within the medical community, and broader culture in the United States after World War II. These three driving forces, combined with the lack of regulatory oversight or societal obligations for patient involvement, meant new medical devices faced little challenge in their development and diffusion. The process was relatively cheap, easy to fund, and success was virtually guaranteed so long as a notable advance was made.

The unsustainable nature of the pre-1970s model for medical device diffusion led to rising healthcare costs and reduced personalization of medicine which produced feeling of lost patient autonomy, and eventually created a shift in societal values around medicine. These shifts, exemplified in the ideas of EBM and HTA, reduced the authority of individual medical professionals through the establishment of new standards for medical care and placed a new emphasis on the role of the patient in healthcare decisions. Now, for a diffusion network to be stable, the end-user and their autonomy must be respected. As the new keystone actor, patients have become powerful decision-makers and have entered the negotiation space around medical technologies. A downside of this development was that it enabled misinformation and advertisements to become greater influences on device diffusion because patients lack the

scientific expertise needed to properly parse the information. While the increase in regulatory oversight in the post-1970s era expanded consumer protections, it also slows the process for emerging medical devices to reach clinical usage.

These actor-networks, along with an understanding of their dynamics, provides insight into the conditions that facilitate modern emerging medical technology development and diffusion. Applying these considerations to much needed developments, such as implantable stem cell therapies and cell-based biomaterials, will help ensure these emerging technologies rapidly reach the clinic and save lives.

RECOMMENDATIONS FOR EMERGING MEDICAL TECHNOLOGIES

Three primary recommendations can be made for emerging medical technologies based on the preceding Actor-Network Theory analysis. The first is to adequately engage all members of the negotiation space, and particularly the end-users of the technology. Their feedback early in development can guide the form of new products such that they can be easily accepted by society. In the past, it was possible to bypass the thoughts of patients as the doctors enjoyed a greater degree of implicit authority. The use of medical devices was thought of as an act, by the doctor, onto the patient. Thus, medical professionals were the end-users of medical technology in societal perceptions. This is in contrast to the modern post-1970s era where the application of medical technologies is often seen as a patient's decision to receive a service which is simply offered by doctors. In this way, the end-user and primary decision-maker is now typically the patient. This is not to say that the engineers and doctors have no control. They are still considered members of the negotiation space because of their specific expertise and roles in the development and diffusion process. Engineers apply their training to construct effective devices and therapies, while doctors communicate patient needs to engineers based on both their own

medical expertise and interactions with patients. However, in both cases, what solutions are pursued and how needs are defined has become increasingly a product of patient input. Just as conversion therapies, and their associated technologies, have been rejected following activism by the LGBTQ+ community, so will any emerging medical technology which fails to take into account the autonomy and values of the potential patient population.

The emphasis of patient input in medical technology diffusion carries with it the need to maintain a public perception that elicits feelings of individual self-determination. Both poor advertising and misinformation can stand in the way of this goal. Stem cell therapies are already facing misinformation threats from unscrupulous actors advertising fraudulent and potentially dangerous stem cell treatments (Vigdor, 2021). This phenomenon may obfuscate the safety and trustworthiness of legitimate treatments in the future. The anxiousness around stem cell technologies can then hamper their adoption in the clinic as patients do not feel they are capable of making an informed decision for their health. To prevent this patient-driven rejection of otherwise revolutionary emerging technologies, it is important to construct robust connections with the potential patient population. For injectable stem cell-based therapies, this could mean sending easy-to-understand pamphlets to those at risk of stroke or heart attacks. Alternatively, or in conjunction, public service announcements providing accurate information about the technology could be aired during television programming mainly watched by those over the age of 60. In these messages, the ability for the individual to maintain decision-making power over their own health must be emphasized. This recommendation will ensure the end-user feels they are able to make the autonomous decision to accept the emerging technology as part of their healthcare.

Alongside patients, the cultural shift during the 1970s also saw a rise in the influence of regulatory agencies over medical devices. Now, with the 1976 Medical Device Amendments to the Food, Drug, and Cosmetics Act, strict and standardized procedures need to be followed to legally market a medical product (Food and Drug Administration [FDA], 2018). Even for products that are technically exempt from this regulation, lacking approval raises immediate questions around the legitimacy of the product's efficacy and safety. However, as Sharma, Blank, Patel, and Stein (2013) and many others note, regulatory standards may be difficult to navigate and, at times, feel poorly constructed. Without proper communication between engineers and regulators, the complex and novel nature of emerging biomedical technologies has the potential to lead to variably overbearing or inadequate standards. On either end, problems emerge. Overbearing regulations slow the development process and disincentivize investment, while inadequate standards threaten the safety of the public. Ideal standards are subjective and difficult to set, but they can be approached by contacting the FDA early and often throughout the development process. Companies of all sizes can arrange meetings with FDA representatives at the onset of new projects to collaboratively develop outlines for experimentation to demonstrate safety and efficacy. If the product is especially novel or controversial, additionally contacting policymakers can ensure that new regulations help, rather than hinder, development of the new technology. Based on the historical analysis presented in this STS reseach, adhering to the three recommendations–engaging the end-user, educating the public in a manner which emphasizes patient autonomy, and establishing early and continual connections with regulatory bodies–will aid emerging medical devices in reaching clinical relevance.

While the conclusions drawn from the presented historical analysis are valuable, it is important to understand limitations of the methodology used in this analysis. Actor Network

Theory is a powerful tool for understanding the dynamics of socio-technical systems over time, but their everchanging nature means the conditions that derive the recommendations of this research are also subject to change with time. As the temporal gap increases between the writing of this text and the modern date, it becomes progressively more important to employ a critical mind when evaluating to what degree the advice is still applicable. This research can serve as a basis for developing updated models if the connections within the actor-network shift. Despite this limitation, the recommendations of this research provide generalizable guidance for medical device diffusion. Applying these principles to emerging medical technologies, such as the encapsulated stem cells of the technical project, can facilitate a speedy development and diffusion process in order to enhance the standard of living for our most vulnerable citizens.

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