The Effect of Access to Insurance on the Diffusion of Innovation Model

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

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Spring 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

When I was shadowing a doctor in the Labor and Delivery department, I saw a lot of cesarean sections (c-sections). During the fifth or sixth c-section, I noticed that this time, they were using a device I had never seen before. The doctor explained that it was a device used to open up the incision more to allow better access, like the metal retractors used before, but this one also helped protect against infection since it included a plastic sheath. He said that he had his residents who perform the operation practice with both the plastic device and metal retractors because some people might not be able to afford the single-use device, and he wants them to remain skilled in both methods. As I continued shadowing physicians in this and other departments, I started to notice that one of the first things doctors check when helping patients was whether or not they have insurance. Based on this criterion, they adjust the course of treatment accordingly: the less insured patients were often given worse care because they cannot afford the better technology, drugs, and other treatments.

In the United States, new drugs and medical technologies must go through rigorous trials overseen by the Food and Drug Administration (FDA) that occur in multiple steps over many years. Drug testing occurs in four phases. The first phase consists of less than eighty healthy participants who have the technology tested on them to test for safety purposes. Phase II recruits a few hundred people for whom the drug is intended for, and it tests for efficacy. In Phase III, several thousand participants similar to those in Phase II test the new drug so researchers can develop an understanding of the side effects and confirm the efficacy. The final phase follows along as the drug is distributed commercially to confirm safety on a larger scale (*The Basics*, 2015).

Medical devices are regulated in a slightly different way by the FDA. sorted into three categories, with Class III being seen as the most dangerous, such as hip replacement pieces, and Class I being unlikely to cause harm, such as latex gloves. According to the FDA's website, newly developed devices are first tested in laboratories and often on animals, then tested on humans, and finally reviewed carefully by the FDA to determine whether the benefits of the device outweigh the potential dangers of using it (Office of the Commissioner, 2018). These lengthy processes were developed to tightly regulate the medical innovations. Unfortunately, many people without access to insurance will not be able to afford these potentially lifesaving innovations due to the high costs that come along with them.

There are several notable trends of people who do not have access to health insurance in the United States. For instance, families with no members who earn a wage are over three times more likely to be uninsured than families that have two full time wage earners. Lower income families and individuals also have much higher rates of being uninsured. Other trends include education level, age, marital status, immigration status, race, and ethnicity (Institute of Medicine, 2001). There are specific sets of people who tend to be more frequently denied access to medical care, drugs, and medical technology due to their ability to afford it.

In this paper, I am arguing that the diffusion of medical innovation in the United States differs from the typical Diffusion of Innovation framework because it is unevenly distributed among people based on insurance coverage throughout the entire process of medical technology diffusion, potentially resulting in physician skill decay. I do this by first outlining literature on ways in which we see technology being diffused in the United States, how medical schools are adapting teaching methods as new technologies continue to be produced, and how physicians need to continue practicing with technologies to maintain skill-based knowledge to prevent skill

decay. I then analyze studies on the demographics of participants in clinical trials to compare insurance statuses to the phase of clinical trials and whether they are being tested for safety or efficacy. I also analyze the potential of physician skill decay by determining factors that might make it occur. Finally, I develop a proposed model for Diffusion of Innovation specifically for medical innovation in the United States by emphasizing the different treatment methods based on insurance statuses.

Literature Review

There is a constant demand for newer and better technologies in the medical field to make procedures possible, easier, faster, less painful, and much more. With more technological innovation and more demand for this new, more effective technology, people with better health insurance are able to continue having access to the best and newest technology, while those with worse or no insurance only have access to a restricted set of medical technology (Neumann & Weinstein, 1991). Oftentimes, technologies that can be afforded by people with worse or no insurance are those that are reusable. Correlated with these trends are statistics of worse health outcomes among uninsured people (Wilper et al., 2009).

Maternal healthcare is one area of medicine that demonstrates this trend. Maternal mortality was shown to significantly decrease in states following Medicaid expansion compared to those that did not allow this expansion to occur (Eliason, 2020). An international meeting among a group of specialists in the first of maternal health compiled a list of technological fixes that could greatly help in reducing the five most common causes of maternal mortality around the world. The only problem is that the communities struggling with maternal mortality often don’t have access to the technology (Tsu, 2005). This pattern is not unique to maternal

healthcare. For those who do have access to technological solutions for illness or injury, physicians or other specialists are often required to become skilled at operating the technologies.

Tacit knowledge is the knowledge someone obtains and maintains through practice, and might be difficult to obtain merely through reading or explanation. Physicians need to continue to practice tacit knowledge in order to maintain it. Examples of common tacit knowledge important to doctors might include using a piece of technology, performing an operation, or performing a physical examination. It is the responsibility of both the physician and the healthcare system to ensure skill competency is maintained for the sake of the patient. This can be done in several ways including retraining, practicing, and specializing (Santen et al., 2020). Following long periods of not practicing medicine and maintaining tacit knowledge, skill decay has been shown to occur. The most significant and recent example was seen over the COVID-19 pandemic. Particularly, surgical and anesthesia residents reported a diminishing of technical skill – often learned as tacit knowledge. (Nofi et al., 2022).

Once medical technology is available to the public and starts to be more commonly used among physicians, medical students need to learn how to use it. Medical school education is evolving by requiring more practical and technical skills to be learned. As new technologies and increased digitization are making their way into medicine, medical school education needs to be humanistic, adaptable, and continue to incorporate patient exposure (Han et al., 2019). A case study of Singapore suggests that skills with new technologies should be taught alongside core medical skills (Zainal et al., 2022). It's important for future doctors to learn about new technologies and remain skilled at old treatment methods, but there's also the concern of requiring too much to be learned, thus potentially making medical students less skilled at more techniques rather than more skilled at fewer.

My analysis of technology accessibility and its effects draws on the Diffusion of Innovation STS framework, which helped me understand some of the social factors responsible for the ways in which new technologies are dispersed. This framework outlines how new technologies are being adopted by people over time. It includes categories of people from innovators to laggards and tries to identify each group's motivation for adopting the technology when they do. Innovators are the very first people to adopt a new technology, followed by early adopters, the early and late majorities, and finally the laggards (Singer, 2016). The Diffusion of Innovation framework in healthcare tends to vary because physicians can be especially skeptical about trying new technologies (Cain & Mittman, 2002). I use this framework to analyze how the different levels of diffusion of medical innovation among people with different health insurance statuses contribute to inequity in medicine.

The existing research lacks a correlation between different, but related, areas of research. While there is research that examines extenuating circumstances that cause physician skill decay, like the COVID-19 pandemic, there is little research into how the continuously increasing number of effective medical technology might play a role in skill decay. In this instance, a physician would not completely step away from medicine for a significant amount of time, but instead lose skill by continuously performing a task using a certain technology and not practicing without that technology. In the following analysis, I consider factors like physician skill and clinical trials to propose my own, altered model of Diffusion of Innovation for medical technologies by focusing on the effects of insurance coverage.

Methods

I gathered secondary sources, primarily academic journal articles that focus on the relationships between technology, physician skill decay, and insurance status. By doing this I

construct a sort of timeline and map through which technology is approved and distributed, as well as the implications of the key steps. I focus on STS and sociological studies done after 2000 so that the information is somewhat recent. Some papers taken from before 2000 were be evaluated to ensure the information is still recent enough to be relevant. Building my argument in this way allows me to create an alteration to the Diffusion of Innovation framework for medical technology by attempting to generalize medical technology diffusion. This means my research is abstract so that I can apply it to different fields of medicine rather than focusing on just one.

Analysis

People with worse or no insurance coverage participate more in early-stage drug clinical trials and human tests for technology due to monetary incentives. Throughout history there are instances of medical experiments being tested predominantly on people who have less power in society. Following the horrific events of the Holocaust, the Nuremberg Code put rules into place to emphasize the need for consent in medical experiments done on people (Bhatt, 2010). While this well-recognized Code is still important, it still does not take into account people who might be compelled to enter clinical trials for compensation. Participants in the United States involved in early FDA drug and device safety testing are notoriously underpaid (Dresser, 2009; Lamkin & Elliott, 2018). This leads to people who need the money more and have time to spare to sign up for potentially dangerous trials that are used to test for the safety of medical products. Unemployed people especially are most likely to participate due to having more time to be able to allocate to these studies (Kalbaugh et al., 2021). This research goes to show that there is a group of people who are being taken advantage of to ensure the safety of medical devices.

People with better insurance coverage are more likely to participate in efficacy and side effect focused clinical trials for drugs. Studies show that people of a higher income participate more in later phase clinical trials for drugs (Unger et al., 2013). As mentioned earlier, people who make a higher income are more likely to be insured than people with a lower income (Institute of Medicine, 2001). These phases occurred after drug safety has already been tested and testing is now done for efficacy and side effect detection. Diffusion of innovation during clinical trials is different than when it is diffused later for commercial use. This evidence suggests that the innovative drugs and technology are at first given to lower income people to ensure the new drugs or technology are safe. In the case of drugs, once the safety is confirmed, efficacy is tested primarily on people with insurance, who predominantly fall into overrepresented groups. When drug efficacy and side effect testing are not done on a diverse range of people, broad and sometimes inaccurate conclusions can be drawn about the drug.

Contrary to the trend of people with worse insurance participating in earlier clinical trials, there are some notable instances in drug development and diffusion where instead people with better insurance or higher socioeconomic status participate more in these early clinical trials. Cancer drugs are a common type of drug that causes this change in trend to occur (Unger et al., 2016). This is because for most cancer drugs, healthy individuals do not need to be used for Phase I since the drugs can cause them harm. Instead, patients for whom exhaustive efforts have been made to treat their cancer and whose cancer has progressed to the later stages (Corr et al., 2020). In these cases, safety is still being tested, but it is worth the risk for the participants to try a new treatment since many others have failed. These circumstances are different from when healthy individuals complete clinical trials for compensation because unlike the sick individuals,

the only thing the healthy participants have to gain is a little more money from the experiment rather than a potential cure to their illness.

Physician skill decay can occur as a result of innovation as some physicians turn to exclusively using the newer technology. The ever-increasing number of medical technologies needing to be learned by physicians might lead to worsening of tacit knowledge, practical knowledge, and bedside manner. Studies show that overreliance on diagnostic tools has contributed to a degradation of diagnostic skill using simple and classic techniques like physical examination (Datta, 2021). These new and more innovative diagnostic tests cost money, which not all patients might be able to afford. A less insured patient who might not be able to afford these tests might need a physician to instead assess them directly as a diagnostic tool as opposed to running tests they may be accustomed to. Verghese et al.'s (2015**)** study suggests that performing a physical exam after having lost some skill due to diagnostic tests could contribute to results such as a misdiagnosis, a delayed diagnosis, or an unnecessary exposure to radiation. This isn't just a phenomenon that occurs with diagnostic tools. Just like with long sabbaticals, when physicians don't practice a skill for an extended period of time after being exposed to a new technology, their tacit knowledge of the older treatment or procedural method may degrade over time. This might have implications on patients if the doctors suddenly need to use the older technology, like if a patient has worse or no insurance coverage and can't afford a new technology for an emergency procedure. This could result in worse care or treatment provided by the physician.

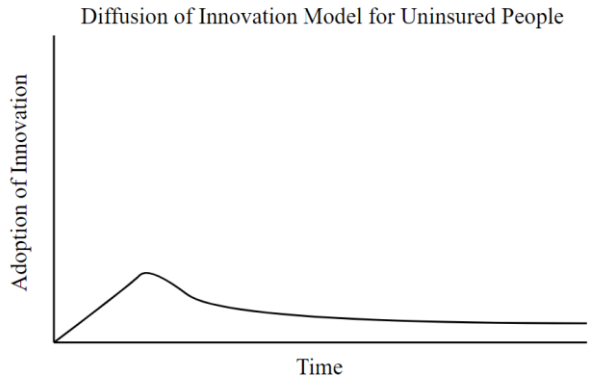
However, part of the problem is that technologies are not being diffused to areas with people of a lower socioeconomic status or worse insurance coverage. Although there are instances of uninsured people being denied access to technology in healthcare, it doesn't seem

like skill decay in physicians is currently a widespread problem since physicians who normally treat people in areas with a high population of uninsured people also don't have access to the technology. Still, the potential of skill decay in physicians who do have access to the technology could be currently having implications on people in ways that have not yet been proposed. As the future of medicine in the United States progresses and evolves, skill decay in physicians due to technology could have increasingly large implications. For instance, if a natural disaster prevents a physician from accessing the disposable technology they are accustomed to, they might be forced to use the older, reusable technology that they have not practiced with for some time. Or maybe physicians who choose to move to different areas in the United States will be expected to be skilled at performing a procedure using a particular piece of technology or having a more widespread skillset.

I propose an altered Diffusion of Innovation model. One previous model depicts the Diffusion of Innovation in the medical field as an S-curve, like the typical non-medical representation (Singer, 2016), with an especially high initial hesitance to begin initial adoption of technology (Cain & Mittman, 2002). I argue that instead, there are two different models for diffusion of innovation based on groups with better or worse insurance coverages. While it is possible to keep this new model of Diffusion of Innovation as one, I feel as though this ignores the severe effects that insurance coverage in the United States have on diffusion and access to innovative technologies and drugs.

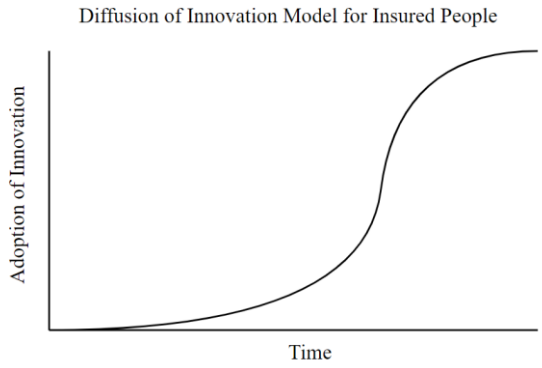
The first model I propose is the one that represents people who have worse or no insurance coverage. Medical innovations are at first available in very small quantities during the safety stages of clinical trials for both drugs and devices. Access is lost once the innovations go on the market and they can no longer be afforded. For drugs, access is mostly lost as the clinical

trials transition from Phase I to Phase II. As seen below, this would appear as a small bump in innovation diffusion at the beginning of a device's or drug's history and a relatively low, flat line continuing on after the device has been made available to the public. Overall, this represents the lack of access people with worse or no insurance have to new technologies and medicines from their introduction to if it becomes a standard in medical care.



The second model I describe represents people with better insurance coverage. In this model, technology is diffused more slowly to this group in the beginning than the first model since people in this category tend to make up higher income levels and socioeconomic statuses and rely much less on the compensation from these initial trials. After the device makes it to the market, it is likely that there would be an initial hesitancy still to adopt new technologies in a medical setting like as Cain and Mittman predicted (Cain & Mittman, 2002). If a technology begins to be used and is found to be effective, the adoption would likely increase dramatically among the group physicians caring for well insured people. As seen below, I propose that innovative, effective technology and drugs would diffuse to well insured people in the shape of an S-curve that begins after an extended initial slow growth phase during which the technology or drug is still being tested for safety. With a new technology reaching its peak adoption in the medical community, older, less effective technologies designed for the same purpose might

begin to be phased out of usage. It is in these areas that adopt the new technology that physician skill decay becomes a possibility.



Conclusion

New medical inventions being passed through different groups of people based on how safe science believes the technology to be and how much they can afford it can lead to potentially harmful outcomes both directly and indirectly, such as in physician skill decay. In the example of technology in maternal health, insurance coverage and thus technology access are believed to curb the high rates of maternal mortality in the United States. Inequitable access to these technologies, however, might be increasing these rates even more due to physicians losing the skill of performing procedures using older forms of technology. The FDA plays a major role in its method of regulating initial safety tests of devices, and could try to find ways to make earlier and later stages more equitable by looking at them as two separate issues that require two separate solutions. Companies who design devices could also make more of an effort to create cheaper and more readily reusable technology, which would make innovation more accessible to more people.

Research building off these ideas could focus on how safety net hospitals are dealing or adapting to limited diffusion of innovation, and how they should manage diffusion of innovation in order to ensure physicians in their hospitals remain skilled at older techniques in case they lose access to this technology. This area of research would also benefit from more quantitative studies of physician skill decay to determine what types of technology might cause this, and what skills might be more susceptible to decay, if any. Furthermore, a more comprehensive study could be done to determine the income, employment, insurance, and socioeconomic statuses of participants in different phases of clinical trials for both drugs and devices. Compiling this data could open a window into how significant this problem is in our society and help us determine steps to remedy it.

By working towards a solution to the problems of inequitable Diffusion of Innovation and its implications, medical technology could be used to help everyone regardless of their socioeconomic status or insurance level. This has the potential of helping thousands of people who don't have access to potentially lifesaving technology around the world. Furthermore, considering the intertwined issues of medical innovation diffusion, required education of the technology, and skill maintenance of physicians might be able to help us determine a system that avoids bringing too many unnecessary devices into the medical field, and instead focus on building more generalizable, necessary, and lifesaving technology.

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