THE IMPACT OF LEGISLATION ON THE MEDICAL DEVICE INDUSTRY

A Research Paper submitted to the Department of Engineering and Society
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By

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March 27, 2020

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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Over the past several years the demand for greater patient health care and treatment has grown tremendously especially within the medical device industry which is expected to reach $612.7 billion by 2025. However, the industry has key design and manufacturing issues as well as antiquated laws and regulations. The technical project aims to address a design issue, collaborating with the cardiovascular department at the University of Virginia Hospital. The lead garment is protective gear worn by medical teams during surgery procedures that require the use of radiation. While these garments provide adequate protection from the radiation, they weigh around 20 pounds posing significant ergonomic challenges to the medical health professionals who wear them. Therefore, the aim of the technical project was to create a novel hook brace that would ease the pain off of professionals' shoulders while still providing adequate protection and functionality. The project was undertaken in response to the decades old patents guiding the current design and ergonomic challenges and will be presented in a research style paper.

Along with physical medical devices, the realm of electronic medical devices through remote patient monitoring and health apps has grown tremendously. The concern for health data privacy and regulation has also grown given the decades old laws in place. Therefore, the loosely coupled STS research project aims to highlight the inadequacies of the legislations and regulations that currently guide the medical device industry. The research aims to prove that the patent and privacy laws established by the Food and Drug Administration and Health Insurance Portability and Accountability Act, which are over 25 years old are inadequate to guide the new remote patient monitoring systems used today. The project aims to prove that the Social Construction of Technology Model needs to be adopted through the means of education, security, and laws to allow for greater integration of the medical devices industry. The project will be presented in a research style paper.

HEALTHCARE CHALLENGES

The Medtech industry is growing and growing fast. By one report the industry is expected to grow at a rate of 5.6% worldwide from 2017 to 2024 reaching $595 billion (Kelly, 2018). The medical device industry is one of the up and coming markets that plans to bring out new and innovative technologies. However, much of the regulation and law that guides the usage and protection of medical devices and its data is severely outdated causing significant problems for not just patients but also physicians. New methods of surgery are being used however the protective equipment used by physicians has standards that are over two decades old and as the world becomes more digitalized there is a push for remote patient monitoring where a big issue lies in patient privacy and confidentiality. While the medical world is thriving with new discoveries, research, and technology it is still lagging behind with age old regulations and laws. This leads to the question of how these physicians could come into harm's way and how this new data and information can be misused. The first question relates to the technical project in how physicians use these medical devices and instruments and the second relates to how medical devices are used in the broader social context by patients.

DEVICES AND PATENTS

A major cause for the need for a new support for the technical project resides in the fact that the patent for the device is decades old. For the lead garment the patents were given in 1950 (Morris, 1950) and 1962 (Hollands, 1962) and the designs have not changed since. The laws that define the classification of these medical devices was created in 1976 and also have not been altered to reflect the changing times (U.S. Food and Drug Administration, 2020). During that

time there were many more male doctors than female ones and these patents reflect that, however given the recent rise in the number of females enrolling in medical school and matriculating into doctors there needs to be updated regulations and guidelines (Association of American Medical Colleges, 2017). There have been an increasing number of research studies being conducted on the ergonomic issues caused by medical devices and instruments such as lead garments, laparoscopic instrument handles, operating tables, etc. These devices in particular are affecting female surgeons and doctors more than male surgeons and doctors. In a study done of laparoscopic surgeons it was determined that those individuals with smaller hands, typically females, had more difficulty in operating these devices and had to get treated for health issues caused by the usage of these devices (Berguer & Hreljac, 2004). In a similar situation conducted in a 2014 study assessing pain in three different areas, it was shown that 21% of women experienced discomfort for hands compared to 3% of men, 77% of women experienced discomfort in the shoulder area compared to 27% of men, and 62% of women experienced discomfort in the neck area compared to 18% of men (Sutton et al., 2014). These studies highlight a glaring issue in the medical health field: the lack of accommodation and fixing of regulations in the new century leading to not just gender inequality issues but also ethical issues. A major part of this is because these devices and instruments were designed when only men were doctors, but given the recent social changes these laws and regulations need to change to provide for everyone. A major part of the problem arises in the way in which these designs are created and regulated, which is the Handoff Model (Carlson, 2009) as seen in Figure 1 below.

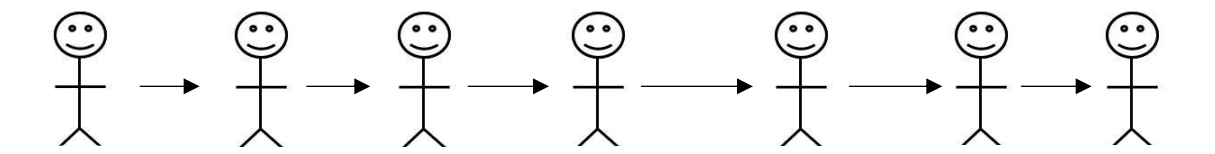

Figure 1. Handoff Model. Model that shows how medical devices were created and how laws are made for them. (Adapted by Rohni Awasthi (2020) from B. Carlson, 2009).

Currently, the process of designing, obtaining approval, and using medical devices is very linear. These devices are being created and manufactured by engineers from patents that are decades old and are then being handed off to the physicians and regulators to be used and assessed. There is no input from the physicians which is very problematic as this does not allow for the best possible device. The lack of accurate laws and regulations is hindering advancement for physicians in the medical device world.

DIGITALIZED MEDICAL DEVICE DATA

Over the past several years, the Internet of Medical Things (IoMT) has been on the rise. As the world becomes more digitized there is an increased demand and awareness for data and everything that comes with it. The purpose of IoMT is to provide greater healthcare and patient care to all individuals. Deloitte, a major consulting firm with a growing healthcare presence with the Center for Health Solutions released a major report in 2018 about Medtech and the Internet of Medical Things, stating:

> "The IoMT brings together the digital and physical worlds to improve the speed and accuracy of diagnosis and treatments, and monitor and modify patient behavior and health status in real time. It also improves health care organizations' operational productivity and effectiveness by streamlining clinical processes, information, and work flows" (Deloitte Centre for Health Solutions, 2018, p. 8).

The IoMT is connected to millions of medical devices that collect data to provide healthcare through online computer networks. By one account it was determined that there are about 3.7 million medical devices in use that are connected to patients to allow doctors to monitor their

conditions either remotely or in person allowing them to collect all sorts of data on the patient (Marr, 2018). This market is expected to grow vastly in the next couple of years with predictions indicating that the Internet of Things healthcare market is expected to reach $136.8 billion worldwide by 2021 (Marr, 2018). The IoMT will especially help the elderly. By providing remote care, doctors and physicians can give real time care and can monitor patients at all times to ensure they stay healthy and safe. The benefits of IoMT can be seen in Figure 2.

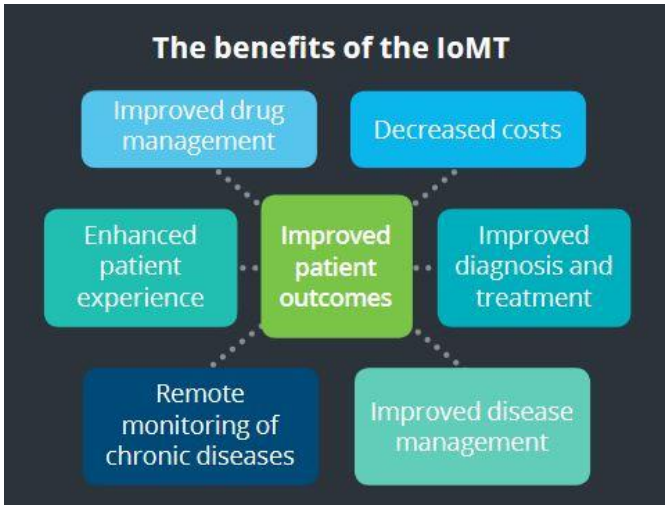

Figure 2. Benefits of IoMT. The end goal of IoMT is to improve patient care for all. (Deloitte Centre for Health Solutions, 2018, p. 6)

Ultimately, the end goal is to have better patient care and a greater overall healthcare system that benefits all. The IoMT allows all aspects of the American healthcare system to become interconnected. While this interconnectedness provides a lot of benefits it also causes a lot of problems about privacy and data security. Many Americans are concerned about their data and having all this data in the cloud leads to a lot of room for possibility for abuse.

Much of the data involved in the IoMT comes from remote patient monitoring.

"Remote patient monitoring (RPM) is a healthcare delivery method that uses technology to monitor patient health outside of a traditional clinical setting. RPM refers to the specific technology used to electronically transmit information between patients and physicians, and it is just one delivery system within the broader telehealth industry" (Dolan, 2019)

This new RPM system includes stationary medical devices, implanted medical devices and wearable external medical devices. These devices can include any type of medical devices from apps that remind diabetes patients to take insulin to digital blood pressure cuffs, all while

allowing patients to send their information to physicians immediately who are able to monitor the disease (Dolan, 2019).While this new shift toward remote monitoring are important, they have the potential to cause a lot of issues especially in the sense of data security and privacy.

PRIVACY AND LEGISLTAION

Americans, in particular are very concerned about their data and what is done with it. In a study conducted in 2019 by the Pew Research Center it was shown that 79% of Americans are concerned about how companies use their data and 64% are worried with how the government uses their data (Auxier et al., 2019). The same study established that 81% deemed that the potential risks of the government collecting their data outweighs the benefits and approximately 59% lack understanding of how this data is used (Auxier et al., 2019). Many Americans are critical about how their data is used and perceived and, in a world, moving toward IoMT these data protection concerns are only going to increase especially given the lack of accurate and correct protections.

Currently, health data in the United States is protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). When this was introduced it changed the game in how patient health data was protected. However, the current problem with this law is that it is 24 years old and does not account for all of the new technology that has been created since that time. It was created in 1996 before the IoMT was prominent and given all of these new fitness and health apps that are in a sense considered medical devices this could cause a lot of problems. Once again, the laws and regulations in the medical world are causing problems for advancement. The major problem with HIPAA is that it is more about health care data than health data and focuses on who has the data rather than what kind of data it is (Chen, 2019). For

example, the wearable technology mentioned as remote patient monitoring devices can include wristwatches or blood pressure monitoring devices that are connected to apps or other information gathering sites. The problem with this is that the data collected by these health apps are not protected by HIPAA (Chen, 2019). People are entering data in these apps, tracking various health conditions unaware that this is considered a medical device in latent terms and that their data is unprotected and collected and being used in ways they may not understand. There are also problems in the data that is not collected by these health apps. According to HIPAA, as long as the information has been de-identified the information and data can still be sold, so even if people do not participate in using these health apps their data can still be given away without their consent. The major problem with HIPAA is that it has many loopholes and is over 20 years old thereby not addressing all of the technical needs that it is supposed to. Because of this, the data has a huge probability of being breached and abused, either being sold or used for identity theft or cyberstalking.

Given these preconditions and potential for abuse many Americans are concerned with how their data is tracked and they have every right to do so. In 2019, a data breach occurred at the American Medical Collection Agency, through which a total of 24,390,307 records have been exposed (HIPAA Journal, 2019). Many people's health information as well as credit/debit card numbers, Social Security numbers, physician names, health insurance information, and names among other personal identification information has been exposed (HIPAA Journal, 2019). A major problem was in determining that a breach had occurred and that so many people had been affected and then notifying these individuals that they have been affected. This is only one of the concerns that arises with a world turning to more digitalized methods and the IoMT.

Another fear among Americans is the ability for this data to get out and be used to discriminate people for employment purposes. One such example of this can be seen from an internal Walmart memo that circulated in 2005. Walmart spends a lot for employee healthcare and one of the points discussed in this memo was how to reduce spending money on healthcare with a major recommendation being discouraging hiring people who were unhealthy or unwell (Greenhouse & Barbaro, 2005). This leads to major concerns over health care data collected by medical devices. Information shared between physicians and patients is usually private and not the same as information shared with employers. If the laws are not updated to help protect this data there could be unintended consequences especially in the terms of employment measures. If this data is not protected and given to employers, they could use it as a basis to fire or not hire individuals. This also connects back to the antiquated patents that guide medical devices. If the health of those physicians is collected and is seen that they are facing ergonomic challenges that could impact their work those physicians could be affected by being unemployed. In both cases these laws and regulations that are not updated are harming a whole realm of people.

SECURITY, LAWS, AND EDUCATION

The way in which to regulate the data collected via medical devices is 1) update the laws and regulations and close all loopholes, 2) provide for greater data protection and security, and 3) educate people in how to protect themselves and on how their data is being used as well as the engineers who create such devices. The major problems being caused at this time are due to the fact that all of the regulations that guide the usage of these devices as well as their data collection are decades old. The patents for some medical devices have not been altered since they have been introduced causing a lot of ergonomic challenges. A major problem in protecting health

data is the various loopholes that exist in HIPAA. These are caused mainly because HIPAA is over 20 years old and does not account for health apps or remote patient monitoring. In 2003 updates were made to HIPAA via the Privacy Rule which established national standards to protect patient medical records (U.S. Department of Health and Human Services, 2008). However, this rule does not apply to health apps, it only applies to health plans, health care clearing houses, and health care providers that conduct all transactions online (U.S. Department of Health and Human Services, 2008). Therefore, if a certain device requires monitoring via an app there is no guarantee it will be protected under this law allowing that patients data to be used without their permission. To provide the best healthcare and get the best patient outcome major revisions need to be conducted of HIPAA to reflect the current times and technologies that run it.

There also needs to be greater data protection and security. A large part of this can be done through data masking and encryption. A major study, presented in the *Journal of Big Data*, done of big data healthcare, stated that data masking and encryption can help prevent the abuse of this data. Data masking would allow sensitive information to be replaced by unidentifiable information so that private information such as social security, name, birthday, etc. are not able to be linked to a certain person or obtained (Abouelmehdi et al., 2018).

The second method is through encryption which is "an efficient means of preventing unauthorized access of sensitive data. Its solutions protect and maintain ownership of data throughout its lifecycle – from the data center to the endpoint (including mobile devices used by physicians, clinicians, and administrators) and into the cloud. Encryption is useful to avoid exposure to breaches such as packet sniffing and theft of storage devices" (Abouelmehdi et al., 2018, Pg.8).

By better protecting the data that is collected there is less chance of it being abused by hackers and employers to discriminate during hiring procedures. Legislation can also be altered by adopting some facets from the General Data Protection Regulation enacted by the European Union in 2018. This law gives more control to the people in who can see their data and places

limits on what organizations can do with their data (Burgess, 2020). Updating HIPAA with these measures could be extremely beneficial especially to people who are at great risk to be affected by these measures.

Finally, the effort in which to bring about change should be done through education. As mentioned before, many Americans do not understand the laws that guide their data and by educating them there will be less fear involved and greater understanding allowing them to bring about the necessary change needed for these data protection laws. If the people do not understand the laws that govern them it will be very difficult to bring about change. Education also needs to be provided in the creation of these medical devices. In this case it needs to be done by teaching empathy to engineering students. In one research study conducted looking at empathy in engineering, interviews of practicing engineers were conducted and was concluded that they did not believe that empathy and care was a factor they strived to achieve with their products (Strobel et al., 2013). One particular participant stated that while empathy was a good skill to have, they are not necessary to be a good engineer (Strobel et al., 2013). This creates great problems in designing medical devices seen through no change in patent laws. The idea of protecting the user is not being taken into account which is why these patent and design laws have not been changed in years. If empathy had been taken into account, perhaps female physicians would not be facing the impacts of ergonomic challenges. Empathy needs to be taken into account while designing these devices so to provide the greatest amount of benefit for the user of the device. Care ethics also needs to be taken into account when creating medical devices that generate and collect data. The engineers need to create these devices that are encrypted well and mask information well so that it is not abused. It is the duty of engineers to look out for the users of their devices even if the outcome will not affect them. Given that these could affect the

employment future of many people. By educating the general public as well as creators of these medical devices great change can be brought about in the rules, regulations, and laws that guide these instruments.

This can be accomplished with an interconnectedness with all aspects and at every levels of the medical device industry through the Social Construction of Technology Model (Carlson, 200) seen below in Figure 3. This model allows everyone to be involved in the process of designing, using, and regulating these devices. The medical device industry is in the center because it can be affected by all the other stakeholders to create the best possible device that will provide the greatest benefit to the user.

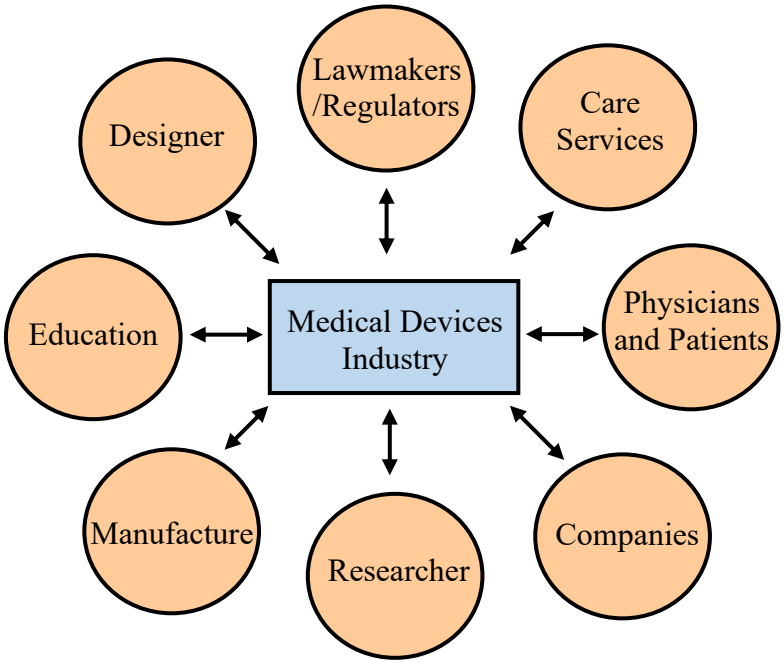

Figure 3. Social Construction of Technology Model. This system of designing, implementing, and managing medical devices and its data should be adopted as it allows every stakeholder to have a say in what goes into the industry. (Adapted by Rohni Awasthi (2020) from B. Carlson, 2009).

Without this interconnectedness the medical devices industry would not be able to progress in the means it needs to. Also, by letting these problems persist creates a lot of ethical issues and complications. By having a model in which everyone is involved feedback is gained at every step of the way to provide the best possible outcome for everyone involved with the device.

CONCLUSION: AN INTERDEPENDENT WORLD

The interconnectedness of laws and technology has never been a more important issue as it is today. With new technological discoveries being made each day these technologies have far surpassed the realm of what past laws could dictate. The use of remote medical devices puts the U.S. population at risk everyday without the accurate legislation to guide it. This data has a possibility to be abused or could set a precedent to be abused if it is not regulated. Introducing new legislation, providing effective security measures, and education all serve as important assets to come up with an effective solution. Education will call for greater empathy in designing these devices leading to the greatest beneficial impact for all users while new legislation will help cement the new effective security measures that are needed. Now more than ever it is important for government and technology to work together to provide for the safety and security of all its citizens.

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