Ethics in Medical Devices

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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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Introduction

Ethics not only asks the question of what is good or bad but also delves into understanding the reasons why something is right or wrong. While ethical questions should be asked in everyday life, they are especially relevant in the medical device field. A medical device is an instrument, apparatus, or another similar or related article that intended use is for a medical purposes (Medical Devices, n.d.). Today there arean estimated 2 million different kinds of medical devices worldwide that can be categorized intomore than 7000 generic device groups (Medical Devices, n.d.). Because of how many medical devices are out there, and the fact that these devices greatly impact the patients' health directly there needs to be ethics incorporated. While new innovations have led to more lives saved it is important to consider the possible consequences that may arise with rapid advancements laden with ethical dilemmas. These dilemmas will be further reviewed later in the paper in the form of looking deeper into the designs of certain medical devices and the relations that come out of them.

Background

Medical devices can date back to at least 1816 when the first stethoscope was made by French physician Rene Laennec (Sakula, 1981). Though the design of the stethoscope was essentially a wooden tube with, and the earpiece attached the true beauty lies withing the design process. Laennec observed two children sending sounds to each other using an extended piece of wood and a pin. One child would scratch the pin on one end, while the other child would place their ear on the opposing end to detect an amplified sound of the pin scratching (Roguin, 2006).

Laennec would subsequently later have to diagnose a young woman with general symptoms of a heart disease, but the current practice at the time was immediate auscultation that did little of diagnostic assistance. This is where Laennec recalled the acoustic phenomenon and had tightly rolled a piece of paper and placed it over the patient's chest to hear her heartbeat clearly more so than just by ear. After this discovery of using mediate auscultation was better than immediate auscultation, he devoted years developing the first stethoscope made of wood to aid in diagnosis.

Without realizing Laennec had undergone the engineering design process a series of steps that are structured for engineers to followto solve a problem. The number of steps vary, but generally consist of: defining the problem, brainstorm/research, imagine solutions, develop a design, prototype, test/evaluate and finally improve (What Is the Engineering Design Process?, n.d.). Laennec identified a clinical problem of immediate auscultation giving little help then later brainstormed and developed a solution based on his observations. He developed various prototypes of his wooden stethoscope varying their length and diameter of the hole testing them until he ultimately settled on a finalized design (Roguin, 2006). With his invention he authored books of physical examination of the chest with methods that are used to this day.

The engineering design process remains an effective tool to employ to solve a problem, but it can be improved further when designing with the user in mind. Established by the Belmont Report there are four principles of biomedical ethics: beneficence, nonmaleficence, respect for autonomy, and justice (Bird, 1989). Beneficence is kindness with a strong connotation of doing good to others which can be defined as aiming to do good for patients. Nonmaleficence represent the obligation of a physician to cause no harm to the patient and the identical thing goes for designing medical devices. The respect for autonomy is acknowledging patients' to rights to

make their own decisions and be transparent informing them of potential risks that come with medical devices. Finally, the last principle represents justice which is the quality of being fair to the patients. Having this patient-centered mentality and combining these four principles not only make a better product but a healthier patient.

Analysis

Incentive Spirometer

The incentive spirometer is a plastic, non-electrical device that patients regularly utilize to practice sufficiently expanding their lungs. The incentive spirometer has been used worldwide for managing a plethora of respiratory diseases. However, there is variability in lung function measurement across different categories. This had led to global standardization projects, which resulted in the outcome of 'race correction' also known as 'ethnic adjustment.' As the name suggests incentive spirometer operators would adjust the spirometer's settings based on the patients' race by asking the patient to self-identify or make their own judgment. In the United States spirometers have correction factors based on race with 10-15% for people labeled as 'Black' and 4-6% for people labeled 'Asian' (Pellegrino et al., 2005). These correction factors are also implemented in Europe and in Canada, the country implements a mix of international and local standards for lung function.

The history of racial and ethnic differences in lung capacity can be traced back to America's early years of slavery. It was written in Thomas Jefferson's Notes on the State of Virginia to justify slavery for the republic that "a difference of structure in the pulmonary apparatus." This remark on the difference in lung capacity between slaves and white colonists was to draw a clear line to separate and marginalize slaves from being seen as actual people (Wamsley & Chin-Yee, 2017). Jefferson's philosophy was carried on to the end of the United

States civil war when Benjamin Apthorp Gould lead a massive anthropometric survey of both black and white soldiers published in Investigations in the Military and Anthropological Statistics of American Soldiers (Gould, 1972). In his report, there was an entire chapter dedicated to describing the difference in lung capacity measured with a spirometer of these soldiers. Gould has reported that 'Blacks' have a lower lung capacity than 'Whites' with disregard for other factors that could have an impact such as height or age. Once more, the sole purpose for this is to cause a schism based on race and it's disheartening to read about this because these soldiers had fought together on the battlefield only to be discriminated against in the end.

For my capstone project of the gamified incentive spirometer, I want to make sure there is no 'race correction' and 'ethnic adjustment.' With ethics in mind design of the gamified incentive spirometer does not feature an indicator, which most current incentive spirometers on the market contain. This indicator is used to set a target goal for the patient, but this is where race correction factors can come into play. By removing the indicator in the gamified incentive spirometer design correction factors no longer exists. This would not cause a decrease in functionality because the numbers of the incentive spirometer indicator are arbitrary. The significant part of our gamified incentive spirometer is to increase patient adherence because what is the use of a medical device when the patient barely uses it at all. Having this patient-centered mentality when prototyping the gamified incentive spirometer allows for more inclusion for the use of the device without the stereotyping of the patients.

Artificial intelligence

Artificial intelligence is broadly defined as the science and engineering of producing intelligentmachines, especially computer programs according to the U.S. Food and Drug Administration (FDA) (Health, 2021). The history of artificial intelligence can be dated back to Allen Newell, Cliff Shaw, and Herbert Simon's Logic Theorist which was a program made to

mimic the problem-solving skills of a human, making it to be the first artificial intelligence program in 1956 (“The History of Artificial Intelligence,” 2017). From 1957-1974 there were setbacks due to a lack of computational power and funding, but then crucial breakthroughs occurred in the 1980s with the innovation of deep learning which allowed computers to learn using experience. Fast forward to today artificial intelligence is everywhere in multiple industries such as the healthcare industry. The following examples are of artificial intelligence in the healthcare systemdeveloped against COVID-19, which is prevalent today as new variants emerge. A software called COViage, is a prediction system that assesses hospitalized patients with COVID-19 who are at high-risk and need intubation (COViage, n.d.). Another example is the CLEWICU system that helps predict which COVID-19 patients in the ICU are at risk for respiratory failure or low blood pressure.

Artificial intelligence algorithms are trained by using massive datasets. Ostensibly, these datasets are diverse, and include a among a variety of populations so that they are not biased which can affect accuracy and reliability. However, these datasets are hard to compile due to their costs and the fragmentation of the healthcare system in the U.S. leading to potential errors. These limitations can lead to biases that can affect minority groups leading to improper or insufficient treatment (II, 2019). An example is an algorithm that was trained with data from the Framingham Heart Study, which was primarily data on white patients who had overestimated and underestimated cardiovascular disease risks in populations of races and ethnicities that are not white (Char et al., 2018). This also poses an ethical question about patient privacy because there are times that data for these datasets are collected and given to technology

companies without patients' knowledge. The act of giving away this information seems like a violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), but this only applies to "covered entities" and "business associates" (USA, 2021). Many artificial intelligence developers do not fall in either of these categories allowing them to collect data without HIPAA's requirements. However, in 2016, the Office for Civil Rights within the U.S. Department of Health and Human Services made guidance addressing the relationship between health applications and HIPAA (Rights (OCR), 2008). If the developer is only offering services directly to and collecting information for or on behalf of consumers and not for providers, health plan, or health care clearinghouse then they are not subjected to HIPAA. This is equally accuratefor developers that only use consumer-generated health data to develop artificial intelligence.

Even though developers sometimes do not need to follow HIPAA requirements, it is still unethical to gather this information without informing the user/patient. Anonymizing patient data is not the sole solution because data need to be representative of many populations (How FDA Regulates Artificial Intelligence in Medical Products, n.d.). If anonymizing were to happen, then and dataset demographics were unknown there can be bias in the artificial intelligence program just like in the algorithm of the cardio disease risk. To help overcome this problem when collecting data, it must be transparent to the patient what kind of data is getting collected from them and for what purposes. The FDA is also regulating artificial intelligence to ensure that it is ethical, safe, and effective for patients. The FDA treats artificial intelligence medical products as medical devices categorizing them into three classes where the higher the class the more regulation is made (Health, 2021). Class, I devices are ones that contain minimal risk usually software that displays reading like a heart monitor. Class II devices pose moderate to high risk that typically includes software that analyzes medical images. Lastly, Class III devices are ones

that have the highest which include products that are life-supporting, life-sustaining, or implants. Having the FDA regulate artificial intelligence as medical devices is crucial to ensure that ethics are followed.

Doctor Bribing

It is no secret that drug and medical device companies have been paying doctors a kickback for pushing their drugs or product. This has been going on for years even dating back to 2013 when one doctor the name of Jon W. Draud earned about $1 million dollars by promoting a drug through promotional talks for it (Ornstein, n.d.). In a report from 2014 to 2018, drug and medical device companies have spent $2.2 billion dollars essentially bribing doctors to promote their products (Jones, n.d.). This sort of corruption is terrible and affects the well-being of patients which could increase costs for the patient when they get prescribed medicine or medical devices that they don't need. This perpetuates lower-quality care and grows the already current inequalities in health and medicine. A notable example of bribery is with the medical equipment company called Olympus Corp. which specialized in endoscopes in 2016. The company had violated the Anti-Kickback Statute, which prohibits payments to induce purchases paid for by federal health care programs (Anti-Kickback Statute and Physician Self-Referral Laws (Stark Laws), n.d.). They were fined $646 million dollars for making unlawful payouts to physicians and hospitals in the U.S. and Latin America (Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in the United States and Latin America, 2016). Another example is a medical device company called Fresenius Medical Care that paid approximately $30 million dollars worth of bribes to doctors and public health officials in 17 countries (Fresenius Medical Fined $231M in Bribery Probe, 2019). The company is the world's largest dialysis equipment provider and violated the Foreign Corrupt Practices Act from 2009 to 2016. Fresenius subsequently settled on a $231 million dollar settlement.

This unethical practice of bribing doctors and other health care officials needs to be addressed. There have been state laws that passed legislation in California that restricts pharmaceutical and medical companies from giving gifts and incentives ("California Senate Passes Ban on 'Gifts' to Physicians," n.d.). The U.S. Department of Health and Human Services and Department of Justice have also been a big part in stopping unethical bribing of these companies have done through fines and imposing guidelines. Not only do these companies need to be punished there needs to be penalization for physicians breaking moral codes and taking these bribes. The medical profession is a noble one treating people is selfless task and bioethics should be upheld to stand against corrupt practices such as bribery for overall more adequate healthcare (Chattopadhyay, 2013).

Future Directions

The purpose of this paper is to highlight how ethics are an important factor in medical device's design and use. This paper demonstrates the potential to be used in future research when delving into medical devices and how ethics can and should be incorporated. This can be employed in clinical settings since that is where medical devices are primarily used. It is critical that ethics remain in the minds of healthcare professionals so that morals can be upheld leading to better care.

Conclusion

Medical devices' sole purpose in society should be to help propel healthcare forward to prevent, diagnose, and rehabilitate diseases in the most efficient and safest way possible. They function as an extension of healthcare workers to improve patients' health. Having a patient-

centered mindset throughout the design process leads to better products leading to healthier patients. Examples that I used where ethics are rooted include incentive spirometers, artificial intelligence, and doctors' relationship with medical device companies. For incentive spirometers, I discussed its roots were based in racism and eugenics, but I argue that this can be modified and improved upon by keeping a patient-centered design in mind. In artificial intelligence in healthcare, I argue that developers need to be ethical when designing these programs so as to not invade the privacy of the patient by being transparent. Finally, I argue that doctors need to uphold their morals of putting their patients first and not being swayed by the lucrative opportunity that these medical companies might provide. Moreover, medical companies that do incentives must be penalized for bribing doctors to promote their product or at the very least to make it known that they are paying doctors to push their product. Ethics are the moral principles that society upholds, so it won't fall into ruin ethics should apply to medical products to maintain the safety of the patients.

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