ThirdEye: Providing a robust risk analysis system for AtheroSclerotic CardioVascular Disease (ASCVD)

An Interactive Qualifying Project Proposal submitted to the Faculty of WORCESTER POLYTECHNIC INSTITUTE in partial fulfillment of the requirements for the degree of Bachelor of Science

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WORCESTER POLYTECHNIC INSTITUTE

Abstract

This IQP addresses the problems in the US cardiovascular health industry, specific to the disease known as Coronary Artery Disease. Our goals are to conduct a thorough need analysis of the industry and gain a better understanding of why Coronary Artery Disease is the top killer in the US and costs to the tune of $200 billion. We executed this by identifying the age demographic that has unmet needs, getting expert knowledge on the disease and industry and coming up with hypotheses on integrating the power of artificial intelligence with the current medical system. We can summarize that the key needs are centered around cost, prevention, the nature of CAD and data collection. Our recommendation to address these needs is a risk-analysis system with A.I integration.

Acknowledgements

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Executive Summary

Introduction

ThirdEye is a project under the newly launched Foisie Sandbox Project Center developed by the Innovation & Entrepreneurship Department at WPI. The aim of this IQP was to study existing companies, potential needs and the current state of the market space that exists at the intersection of artificial intelligence and medicine to innovate and explore with the aim of developing a business model for an A.I assistant tool to aid the industry.

Project Goal

The goals of this project are to conduct a thorough need analysis of the cardiovascular health industry of the United States and gain a better understanding of why Coronary Artery Disease is the top killer in the US and costs to the tune of $200 billion.

Research Objectives

1. **Determination of value of Real-time monitoring system:** A real-time monitoring system for coronary artery disease would provide continual data to process. This continual collection is beneficial as it means a greater volume of data to be used for the risk-analysis system and a step towards preventive care. Such a system would naturally prove to be helpful for medical professionals but we need to know exactly how helpful it would be in order to tailor our idea.
2. **Examining reliability of data collected from wearable technology:** With so much technology around us, as well as the existence of the Internet of Things, a lot of useful data is generated simply by carrying out our daily work. This data generated depicts some properties of the human body. For instance, data generated by fitness trackers include heart rate, blood pressure, sleep analysis, and calorie intake and burning functions. Determining the source as well as the nature of data collected would guide us in recognizing how this data can be integrated with AI systems to solve problems with the respective body part. Thus, it is imperative to examine the reliability and consistency of data from wearable technology.
3. **Seeking target customers of proposed ideas:** It is critical to first validate our hypothesis about the problems from the people who are actually going to utilize our product. This includes answering questions such as should our technology be limited to patients, or should it be limited to doctors? If it is patients then what kind of patients should we target? Should we also target the family/guardians of patients?

Methodology

1. **I-Corps Program:** The WPI I-Corps lies under Foisie Business School, WPI which provides a support system to student or faculty teams who have a business idea addressing the elements of (Need-Approach-Benefit-Competition) NABC framework and has commercial potential. I-Corps focus on validating the needs assumed and discover a customer base which can benefit from our proposed solution. This revises the conventional flow of developing the tech in the lab, writing the business plan and then going out to implement it. Instead, it requires to focus on seeking input from real stakeholders, discover customers and validate the needs first and then develop the technology before entering the market.

2. **Interview Process:** We interviewed people who we believe will be impacted most by our product. Since our idea will be based around implementing the wonders of AI in the medical industry, we have identified cardiac doctors and other medical professionals as the participant base for this process. We gathered qualitative data from the interviews and performed analysis on the interview transcriptions through the use of qualitative coding.

Findings

1. **Pervasive and Slow Progressive nature of Coronary Artery Disease:** Coronary Artery Disease (CAD) starts developing around one's 20s, and is present throughout much of the lifetime. In the early stages of this disease, plaque (fatty streaks) starts depositing on the endothelial lining (interior lining) of coronary arteries. Deposition of more plaque leads to the formation of blockages in the coronary arteries which limits the blood flow to the heart. Due to this, heart muscles are deprived of oxygenated blood and they start to die. This also displays the irreversible nature of the disease. This might lead to heart attacks which is when the patient realizes about CAD progression after approaching a doctor.
2. **Nature of current treatment:** Currently, the cardiac health industry is more treatment based and less preventive based. It is also patient driven in terms of data collection. When a patient approaches a doctor after going through a cardiac event, that is the time when the presence of CAD is first observed and hence treated. Before the treatment phase, there was a preventive phase, where the progression of this disease could have been controlled. But during this phase, there may have been a lack of communication between the patient and the medical body due to the patient being unaware of the disease within them. Patients are advised to visit the doctor on a weekly or a bi-weekly basis and are asked questions about having symptoms related to heart attack such as chest pain and bleeding problems. It is most likely the case that patients will not have detailed knowledge of the condition plaguing them and so the responses that doctors

collect will be subjective and variably reliable. We also found that lack of medical compliance is an unfortunate aspect of the current treatment process. There are a lot of cases of reduced compliance since it cannot be realistically monitored by doctors and causes significant hurdles.

3. **Risk:** The risk factors associated with CAD are the patient's blood pressure, cholesterol, age, gender and smoking habits. These factors are then used to calculate the patient's ten year risk score of CAD. Some other risk factors are obesity level, environmental factors and hypertension. These other risk factors are currently not taken in account for risk score calculation. When the current ASCVD risk algorithms are applied to analyze risk score, some patients may receive an incorrect low risk score. The implications of this are that the patients may actually be at a much greater risk level and subsequently don't receive the level of medical care they require. Computed Tomography (CT) scans are used to check the risk score's accuracy but are very expensive. The risk of all these groups is determined by these existing inaccurate risk calculators. So this shows that there is a need to improve the efficiency of the current risk calculators used to make accurate predictive diagnosis for heart risk.
4. **Costs:** The cardiac health industry is more treatment based and a lot of costs driven from these systems are not spent on preventing the disease, but on treatments. Due to the irreversible nature of CAD, patients keep coming back to hospitals in need of more treatments to keep themselves alive. This imposes extra burdens on the healthcare systems and creates the need to reduce cardiac readmissions as increased readmission rates endangers the federal funding that these hospitals receive. This also adds up to the burden of extra costs driven out of the system and thus, costs of the treatment phase is a big concern for the cardiac health industry.The need arises from this is that the majority of cardiac systems need to be shifted to being for prevention rather than treatment.
5. **EMR integration:** The final theme of problems that we identified was within electronic medical records (EMRs). EMRs represent the natural evolution of recording from paper charts and graphs to electronic means. EMR systems at healthcare institutions are usually unique to the institution and record what they deem important. As such, there is an absence of a nationally integrated EMR system. This has negative consequences in the form of additional expenses and time wasted by both doctors and patients. The core need that emerges from the findings we made regarding EMRs is for better integration. EMRs need to be better integrated across hospitals and even within them. A doctor's diagnosis should be automatically included in the patient's EMR, as should the patient's risk score and category.

Conclusion & Recommendations

1. **Need:** The needs that we have identified revolve around the nature of the disease itself, data collection techniques and flow of cash driven in a healthcare institute. These factors combine and make the CAD a number one killer in the U.S. and give rise to an opportunity to provide the optimal solution to mitigate this issue. Due to the reach and

disease's slow progressive nature, the formation of plaque becomes extreme due to certain lifestyle and environmental factors. Multiple irregularities in the medical system adds to this issue. Medical system being patient-driven, decision-making on snapshot-like data, risk calculators being inefficient, and the system itself being treatment based rather than preventative. These flaws cause more and more delay to start the patient's treatment and ignores the chances to prevent the disease.

2. **ThirdEye's Solution:** Our solution is a web application technology providing a more robust ASCVD (AtheroSclerotic CVD) risk analysis management system that targets patients of age group 40-75 and are at "borderline" or "intermediate" risk of having a heart attack due to CAD. This risk analysis system will utilize concepts of AI for an increased number of factors and more frequent data capturing techniques such as monitoring of facial characteristics, EKG, blood pressure, cholesterol level, environmental factors and lifestyle factors. Conclusions from this technology will be integrated with the Electronic Medical Records of patients, which will be accessible across all the healthcare institutions who have adopted this tech. The technology will also have a built-in alerting system. If the conclusions drawn by the AI are that the patient requires immediate medical attention, it will alert the hospital nearest to the patient based on their location and instruct them to head there.

Authorship

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Background	Kushal Gandhi	Suryansh Goyal	Akul Agarwal
Methodology	Suryansh Goyal	Akul Agarwal	Kushal Gandhi
Findings	Akul Agarwal	Kushal Gandhi	Suryansh Goyal
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Appendix B	Suryansh Goyal	-	Akul Agarwal, Kushal Gandhi

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Chapter 1 - Introduction

ThirdEye is a project under the newly launched Foisie Sandbox Project Center developed by the Innovation & Entrepreneurship Department at WPI. The Foisie Sandbox Project Center can be likened to an incubator-like environment for student projects. It also allows for the opportunity of earning academic credits while pursuing their business idea. We grasped the opportunity of this project center in order to form a business plan bridging the gaps and solving irregularities in the current cardiovascular medical industry. The aim of this IQP was to study existing companies and the current state of the market space that exists at the intersection of artificial intelligence and medicine to innovate and explore with the aim of developing a business model for an A.I assistant tool to aid the industry. While researching and analyzing opportunities in the cardiac industry to form a business plan in the IQP, our goal is to extend this project to an MQP level where we will enter the prototyping phase and begin making the minimum viable product, launching the product and entering the real market.

We have studied multiple design thinking and business tools in order to formulate a business plan and carry out need assessment such as NABC framework and business model canvas. Through our background research in ID2050, it was pretty clear that there is a need in the cardiovascular industry given the flow of massive costs and significant death toll. We utilised the method of customer discovery which we learned from the National Science Foundation Innovation-Corps at WPI to “get out of the building” and talk to individuals who are going to pay for the idea as well as end users. We formed a customer base and divided it into multiple segments of different values. For example, doctors care about the lives of their patients while the management team cares about the costs of the healthcare institution and how to keep them as low as possible without hurting it. We then interviewed the customers to carry out the need assessment within the CVD medical industry. We determined the scope of the need assessment to be very broad initially as we were uncertain what to choose within the cardiovascular industry. As our project continued, the scope narrowed and we found CAD specifically to focus on.

CAD is a pervasive disease that starts developing with the formation of fatty streaks, known as plaque, in the endothelial lining of the coronary arteries. This process starts around the age of 20 and has an onset period of decades (Coronary artery disease, n.d.). Certain environmental and lifestyle factors can speed up this accumulation of plaque. Excessive deposition of plaque causes obstruction of crucial oxygenated blood from the lungs to the heart, a condition known as atherosclerosis (Coronary artery disease, n.d.). This deprives the heart muscles of oxygen and they start to die. Since the heart muscles cannot be grown back, the damage done to the heart is irreversible and can lead to a greater occurrence rate of events such as heart attacks. Currently, the risk factors associated with CAD are age, gender, race, systolic/diastolic blood pressure, total and HDL cholesterol, smoking habits and diabetic history(Coronary artery disease, n.d.). The two major methods that the US cardiac industry currently uses for the diagnosis of CAD for presented individuals are risk analysis using risk

factors and Computed Tomography (CT) scans. The contemporary medication-based treatments for CAD are Antiplatelet Therapy, Lipid Lowering Therapy, Blood Pressure control and Statin Therapy. The non-medication-based treatments include heart catheterizations and interventions such as placing stents in the coronary arteries. The switch between medication-based and non-medication-based treatment for patients is associated with their risk score, a concept that will be explained in greater detail, further in the report.

The US cardiac industry, on an annual basis, spends an average of $108 billion on the treatment of CAD patients. This whopping sum is expected to become even larger by 2030, where it will swell to 4 times the amount, $800 billion. The average number of people who die due to cardiovascular diseases is around 800,000 in the past decade and the numbers are growing(Tahra Johnson, 2015). So the big question arises: Despite the advancements in the US cardiac health industry, what are the reasons for the loss of so many lives and money? This question establishes our research space and paves the way for finding out the gaps in the cardiac health industry that are the primary causes of these large numbers.

Chapter 2 - Background

2.1 Artificial Intelligence

2.1.1 What is AI?

Artificial intelligence is any program or technique used to carry out a task which would require human-like intelligence. The first instance of artificial intelligence was brought into being by Alan Turing near the start of WWII, when he questioned if machines could think.“The field of artificial intelligence, or AI, is concerned with not just understanding but also building intelligent entities—machines that can compute how to act effectively and safely in a wide variety of novel situations”(pg. 1 Stuart Russell & Peter Norvig, 2009). At the moment A.I comprises a vast number of subfields such as general learning, perception and reasoning. Its umbrella also houses specific pursuits like playing chess, autonomous driving or diagnosing diseases. Many misidentify A.I. as built solely upon the concepts of computer science but the foundation of A.I. goes beyond that. The foundation of A.I. consists of multiple specialized fields like philosophy, psychology, mathematics, neuroscience, economics, computer engineering, control theory, cybernetics and linguistics.

The construction of any A.I program could have multiple approaches. One could think of building an A.I. tech that imitates a physical entity (humans, animals and nature) to achieve its level of task-solving abilities and intelligence while another could argue that the power of A.I is not limited by what already exists. For example, the innovation of artificial flight was successfully achieved when scientists stopped imitating birds and focused on the underlying principles of intelligence and concepts of aerodynamics. By following this theme of Human vs. Rational, there are a total of four approaches on how one can design any A.I tech: Acting humanly, Acting rationally, Thinking Humanly, Thinking Rationally (pg.2 Stuart Russell & Peter Norvig, 2009).

The main focus of the field of A.I. has been to achieve full human-like intelligence and the extended field of machine learning and deep learning has been focusing on building human-like brain models for decision making and accomplishing predictive tasks. But with great power comes great responsibility. If enough advances are made, there will exist situations where the potential of this technology can be abused and threaten human safety. Some instances would be development of lethal autonomous weapons, biased decision making and safety-critical applications.

2.1.2 Applications of A.I

We currently stand on the precipice of a technological revolution that will bring about a radical change to our lives. This generation is blessed to be a part of an ongoing phase shift; as

the integration of AI in our lifestyle is maturing day by day and in doing so, preparing us for the fourth industrial revolution: “The Age of AI”.

And so the big question arises: where should such a mighty innovation be deployed, to get the best out of it? In the not too distant future we will witness fully autonomous cars capable of transporting humans, finance carried out automatically, The ongoing innovations at Tesla are a testimony to this claim. Another big example is the development of the AI agent, “DeepBlue”, to test how the intelligence of A.I can be improved. In 1997, DeepBlue defeated Garry Kasparov in a classical chess game which marked the first defeat of a reigning world chess champion by a non-human. Additionally, companies such as Amazon, Netflix, Spotify, YouTube and others have harnessed the power of A.I. and machine learning to develop customized recommendation systems based on a user’s past habits. All in all, AI proves to be a critical tool in our daily lives and is used in every other industry today ranging from economics to military & defence (See figure 1,2 and 3).

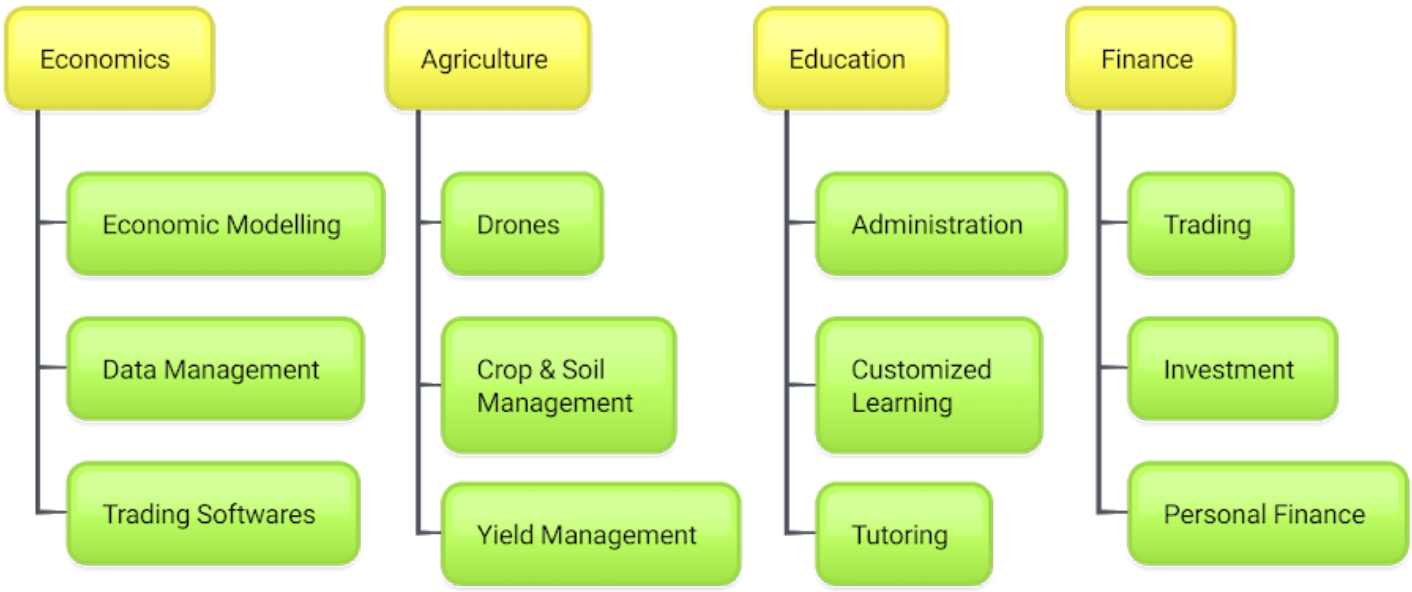

Figure 1: Applications of AI (Part 1)

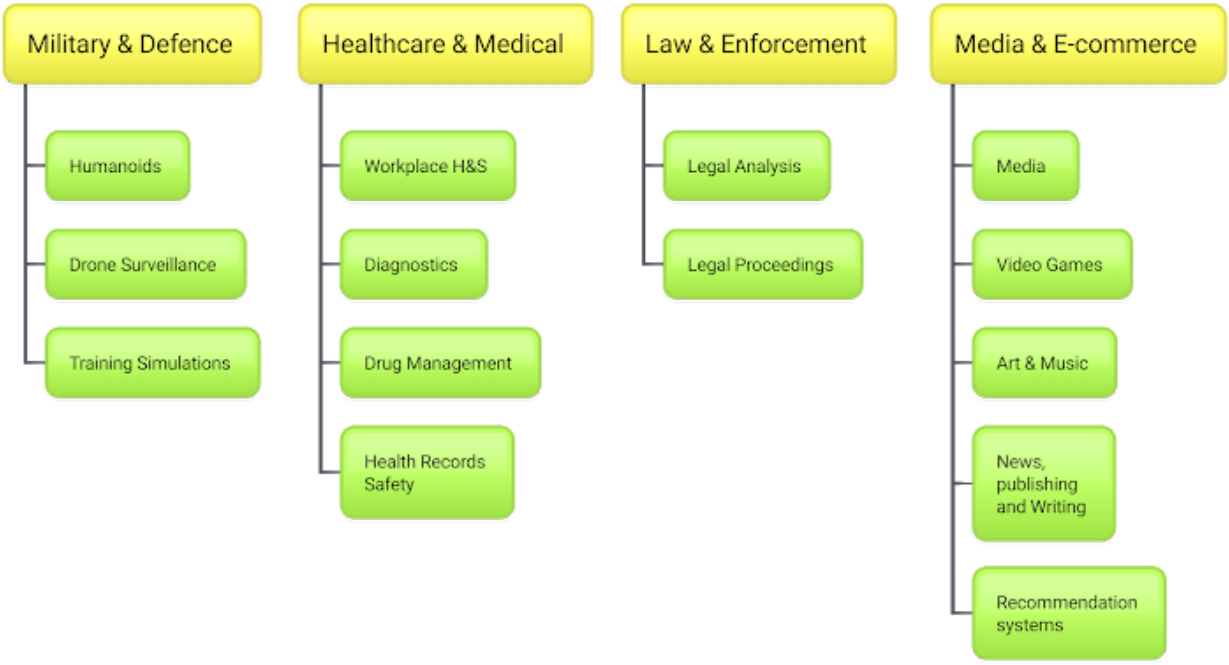

Figure 2: Applications of AI (Part 2)

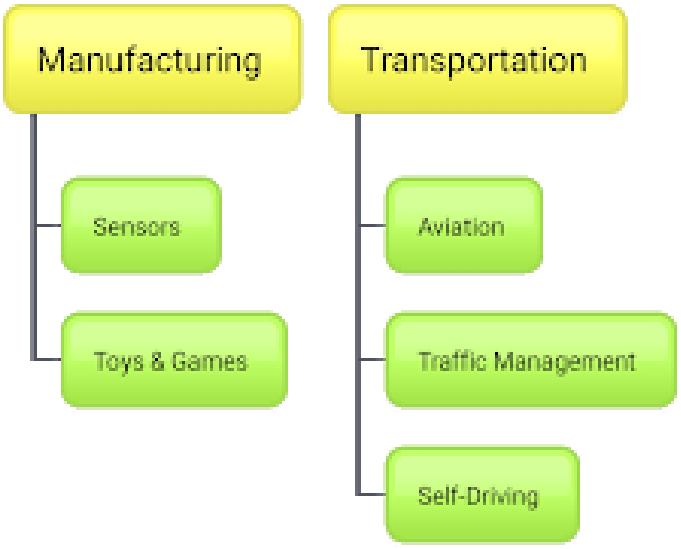

Figure 3: Applications of AI (Part 3)

Up till now we have talked about some of the major applications of A.I in general industries. One such specific industry where A.I is currently upending norms is in the Medical Sciences.

2.2 Medical Sciences and AI

2.2.1 Applications

We've spoken previously of how A.I is used in other industries and fields. Now, it's time to dive into how A.I has intersected with the medical industry and the resulting progress that has been made. Tasks of the medical industry are often repetitive, require massive data crunching and an extremely low margin of error. Add all these requirements up and A.I presents itself as the immediate solution. Here is something that can repeat tasks thousands of times without losing precision and simultaneously refine its process with each iteration. Some of the most novel ways A.I has been used for the medical sciences is data coalition and analysis, disease prediction, drug recommendation & assisting doctors with surgery.

Misdiagnosis and medical error account for a percentage of deaths worldwide. These often result from minute errors in medical histories, data or human error. An A.I by its very nature cannot make such errors and flaws and as such has returns like a lower diagnosis time and streamlined analysis of patient data and scans which are often unorganized. General Electric Company or GE, the tech conglomerate has a subdivision called GE Healthcare which has explored this application of A.I along with the University of California San Francisco. Their work has been focused towards lungs and their scans. The A.I parses through the scans hunting for scans which display pneumothorax and pinging positives as higher priority than the rest. They plan to refine these algorithms further and make them a part of their "Health Cloud" and smart imaging machines (General Electric & University of California, San Francisco, 2016).

GE's "Health Cloud" and fleet of smart imaging machines to be deployed around the globe are examples of another one of A.I's game-changing advantages to medicine. It will rely heavily on two key concepts: Internet of Things (IoT) and cloud computing (General Electric & University of California, San Francisco, 2016). Patient data is collected through the direct application of IoT with wearables, smartphones and social media, beamed to the cloud, where an A.I analyzes the data and makes findings available to doctors regardless of location. A doctor in Asia can access the files of a patient in Europe and provide a diagnosis. Given the data collection is occuring by utilizing IoT, the nature of the process is real-time, a monumental step. This implication means that the time between occurrence and diagnosis can be brought even closer to zero. This rapid data collection is also being utilized with smartphone apps to make systems that take in user input of symptoms and go through possible diagnosis, presenting the most likely one to the user and recommending a visit to the doctor if necessary.

A.I is also being utilized in another important field of medicine: drugs. Drug production systems and drug delivery systems both require massive amounts of time and money. By letting

A.I scan through data points, new hypotheses and possible functions regarding known compounds can be put forward for testing (Daley, 2019). With antibiotic immunity becoming a problem of increasing importance within the medical community, such an application will allow for rapid testing and production of effective, new drugs that get the job done, with overall lower costs in clinical trials. Further application of A.I will allow for the process to be tailored to the patient being treated and get the drugs that are the most biocompatible to them.

The above applications of A.I have also been focused on the so-called physicians side of medicine, which is concerned with administering medications to patients to alleviate their ailments. The other realm of medicine is the surgery side, where operating on the patient is required and invasive techniques are used (Daley, 2019). A.I is present in this sub-field as well, with surgeons conducting A.I assisted surgery through VR-enhanced robotics. The immediate advantages are machine preciseness, greater viewing capabilities for the doctor and the possibility of remote surgery.

2.3 Business Aspects

2.3.1 Market Need

There exist some diseases in the world, such as silent heart attacks, that have either no symptoms, minimal symptoms, or unrecognized symptoms. These abnormal symptom behaviours mean that there is a delay between symptoms being recognized and medical attention being sought. These delays lead to improper treatment and loss of lives. Further delays can arise from a sudden change in symptoms which can be misperceived as new symptoms when they were in fact old symptoms. Some people experience rapid onset of symptoms which appear “out of the blue”. These are all instances where the patient may be unaware of what’s going on in their body. These needs are what the patient most urgently needs. A second, parallel category of needs also exist which arise due to existing solutions falling short of being truly sound solutions. This falling short is why a thorough analysis of the competition is required.

2.3.2 Competition

2.3.2.1 Bio-beat:

Bio-Beat focuses mainly on the real-time remote monitoring of a patient by measuring vital signs and symptoms using wireless, non-invasive medical grade technology. Moreover, all Bio-beat devices such as portable monitors and smartwatches connect to the Bio-Beat application over an IoT and cloud technology making it possible for them to monitor these changes and keep track of a patient's progression. The foundation of the Bio-beat’s real-time monitoring system lies in their in-house designed PPG sensor.

Photoplethysmography or PPG is a very subtle and cheap method, mainly used to monitor heart rates. It is a sensor type that allows for the monitoring to be done with no invasive measures as the detector is applied to the skin and blood circulation measured accordingly. Along with heart rate, other important information is then further extracted from the PPG sensor such as heart rate estimation and pulse oximetry readings to run a diagnosis of the current state of the patient (Denisse Castaneda, Aibhlin Esparza, Mohammad Ghamari, Cinna Soltanpur, and Homer Nazeran, 2018). A wide range of parameters are measured by Bio-beat including remote monitoring of blood pressure, respiratory rate, pulse rate, heart rate variability, stroke volume, cardiac output, cardiac index, pulse pressure, systemic vascular resistance, mean arterial pressure.

2.3.2.4 Arterys:

Arterys is an online platform with a mission to enhance healthcare services by reducing “subjectivity and variability” in clinical diagnosis. The platform utilizes the combined power of Artificial Intelligence and cloud computing to perform medical diagnosis. This tool enables health care providers, all over the world, to collaborate and make the best possible diagnosis and treatment judgements for their patients. Arterys’ primary solution for cardiac imaging is based upon using 4D Flow technology to observe blood flow. Then they extended their solution for image processing for cancer, liver problems, lungs problems and chest problems (Arterys, n.d.).

2.3.2.5 Upgrade Labs:

Upgrade Labs utilizes technology to exponentially improve health of individuals at the cellular level. The aim of their solution is to upgrade the body via “Biohacking”, which is upgrading body functions through the use of technology and science. One of the solutions is the AI-powered Adaptive Bike, which provides the benefits of a “40 minute jog in 40 seconds”. This is accomplished by using an AI system which learns about the user’s body and conforms to provide the best work-out experience. Other solutions involve targeted techniques for enhancement or recovery of specific parts of the body in a controlled manner (Upgrade Labs, n.d.).

2.3.2.6 Tandem Diabetes Care:

Tandem Diabetes Care is a medical technology company which develops solutions for the treatment of diabetes and insulin infusion therapy. The latest development in the t:slim X2™ insulin pump. This device can be used as a standalone insulin pump as well as can be integrated with the Dexcom G6 continuous glucose monitoring (CGM) system. It uses two predictive insulin delivery technologies: Control-IQ Technology and Basal-IQ Technology. Control-IQ technology helps in adjusting insulin delivery to patients which helps in preventing highs and lows. Basal-IQ technology operates in the background without constant input and helps in reduction of the frequency and duration of low-glucose events by using a predictive algorithm (Tandem Diabetes Care,) n.d.).

2.3.2.7 Automatic Knee Osteoarthritis Diagnosis:

Knee osteoarthritis is one of the most common disorders that develops over the musculoskeletal system of the human body. Diagnosis for this disease was earlier conducted by only using plain radiographs and determining symptoms, which was a very subjective process. A new proposed computer-aided diagnosis method utilizes the “Deep Siamese Convolutional Neural Network” to score the severity of knee osteoarthritis with respect to the Kellgren-Lawrence grading scale. This new proposed method used data to train the AI model and then validate it on 3000 subjects, which were randomly selected. The results of this method yielded an average accuracy of 66.71% as compared to the diagnosis given by a committee of clinical experts. The method also produces “attention maps” which highlight the radiological features that affect the AI model’s decision (Aleksei Tiulpin, Jérôme Thevenot, Esa Rahtu, Petri Lehenkari, and Simo Saarakkala, 2018). It is believed that this AI powered method will be useful for clinical decision making and knee osteoarthritis research.

2.3.2.8 Plume App:

Plume Mobile Application mainly concentrates on detecting and tracking a person’s motion through Wi-Fi. This technology converts all the WiFi enabled devices present at home into nodes and develops a network of these nodes. With the existing hardware present in these devices, these nodes act as motion detectors which sense interruptions in Wi-Fi waves to accurately locate people, through their mobile phones, inside their homes and identify different levels of motion (Avery Lewis, 2020). This technology is not directly targeted towards medical sciences but can be used by medical professionals to remotely keep a track of real time motion of patients who can be affected by certain types of motion.

2.3.2.9 Alzheimer’s App:

It is primarily a mobile application which allows for early detection of Alzheimer's Disease. This solution is an easy and cheap early detection system and isn’t meant to compete with a medical lab detection method. The application uses a functionality which checks on a person’s gait (manner of walking) by utilizing sensors built in the phone. It records these movements of the user and then analyses the results. Walking patterns have been observed to be the “validated markers” of neurodegenerative diseases, like Alzheimer's disease (Chris Burns, 2019). Thus, this application makes up for a good early detection system which will help users in Alzheimer’s diagnosis.

2.3.3 Benefits of existing tools

The above tools & techniques represent a consortium of methods to utilize A.I in medicine. The core ideas of these intersections are constant monitoring, data that can be easily

shared and analyzed and personalization. These core ideas are also the greatest benefits of these technologies. Constant monitoring allows for peace of mind for a diabetic that their blood sugar isn't spiking or dipping in their sleep, a time that they can't dose. Personalization goes beyond being just an advantage of these systems, it is practically a requirement. No two users will be the same and to ensure that the best quality of care is given, the user's unique needs must be attended to. For example, a high BP patient will use the same Bio-Beats module as someone under observation for post-stroke treatment, yet what they need from the monitor will differ significantly. Finally, ensuring that data remains fluid and can be accessed from a variety of points means that medical professionals from around the world can collaborate on cases and that less processing power is required to run complex computations.

2.3.4 Shortcomings of these existing tools

The main shortcomings of using A.I in medical sciences arise from the same characteristics that give it such immense benefits. The very same principle of IoT that allows for doctors to work on cases all around the world represents a major risk for patients. Medical data is fast becoming a commodity to be bought and sold like all other forms of big data and unlike the other types, it doesn't change, meaning users are at risk for extortion (Jeremy Wagstaff, 2015). There is also an innate reliance on connectivity and significant resources for A.I which aren't freely available all around the globe. Oftentimes it can also be the case that a game-changing A.I is developed but consumer usage was not one of the design conditions and so it will never see application in the field.

2.3.5 Importance of studying competition

Competitors are entities who sell the same or similar product as a reference business or products which have congruent features and which target similar sets of problems and needs in the market. Considering our specific case, the closest competitors would be products which have features like IoT integration, cloud computation, real time analysis systems and simulations to study the cause and effects of diseases, with all of it powered by AI. Examples of said competitors would be web application startups such as Arterys, Biobeats, Tandem, Plume and an Alzeihmer's app.

It is critical to analyze the deficiencies in the current solutions provided by our competitors to understand the competitive advantage we can have over other startups in the market and to prevent our ousting. Also, a huge part of developing a business is experimenting through trial and error. Every different combination of customer needs and respective solutions is a different business idea in itself. Experimenting with these different combinations will produce different results. So if we study our competitors in detail, it can greatly benefit us as we can see
what works and what doesn't. This will result in us trying less combinations and reduce some of the trial and error.

Studying competitors can bring good knowledge about the saturation of the market and thus can help in narrowing down business ideas. Our project, for example, started off from the idea of how to use the power of A.I in the field of medical science. Since then we have formulated a number of hypotheses in multiple avenues and after studying competitors in those respectives fields, we discarded similar solutions and have realigned to developing something either which has never been touched upon before or improving upon an existing product. This procedure is helping us in becoming a customer centric project and at the same time guiding us to develop and narrow down our niche to set up an entry-exit barrier (Amy Biggart, 2018).

2.3.6 Entry/Exit Barrier

Early stage startups can be differentiated into two main categories: First Movers and Fast Followers. First mover startups are the ones who research and develop a product or service in a virgin market. They also have to invest gargantuan capital to develop the needed solution and carry out heavy testing and optimization before launch. On the other hand, fast followers are the type of startups which study their competitors and focus more on what they can provide better. Fast followers have a clear advantage in that they can abandon already tested solutions and leverage off the research that has already been done by their competitors. Both of these categories leave room for opportunities to newcomers. To avoid this situation; two widely used techniques by early stage startups are to create barriers to entry and exit.

Entry barriers describe the various factors that prevent an early phase startup from getting outcompeted by preventing growth of other newcomers in the same business sector. Some of the factors are high investment costs, closed source tech, patenting proprietary tech, and government intervention leading to legal hurdles (Adam Hayes, 2020).

Similar to creating an entry barrier, an exit barrier is a stratagem of introducing obstacles or hindrances that prevent a startup or even mature companies from exiting the market after the already sunk costs due to entry barriers. Exit barriers usually include investment in highly specialised assets with deprecating value, which if the company wishes to sell or relocate will result in customer loss. These sort of barriers come into play if a company is incurring a loss in their business and will prevent their exit and further increase their level of loss (Will Kenton, 2019).

2.3.7 Revenue Generation Models

2.3.7.1 B2B lead conversions

As part of this model, businesses rely upon lead generation which helps to draw new customers. Lead generation comprises of people who are interested in a business's product/service and contact them directly or indirectly. Businesses convert these leads into

customers. This happens when they develop a client-server relationship with the leads. This can happen by sending them regular emails about the product, offering them free services and information, and finally encouraging them to convert into paying customers. Most of the time, conversion of lead generations into long-term customers turns out to be beneficial for any product or service. They essentially help in generating more revenue for a longer period of time as they have been established as long term customers.This long-term relationship also ensures stability for the company. Sometimes, there can be cases when the lead generation might turn down the offer to become paying customers. Thus, the B2B lead strategy of a company should be solid in order to attract the leads effectively. Some of the useful techniques for lead generation are using social media strategically, Content Marketing, distribution of “free tools”, and using market automation (Jeremy Smith, 2019).

2.3.7.2 Subscription-Based Model

This model first emerged in the 17th century. It has been widely adopted as it is simple and benefits both businesses and customers. This model generates revenue by requiring customers to pay a subscription fee for the products or services they are using. The fee is processed at regular intervals and aids in establishing a long-term relationship between businesses and customers. This model is best suited for a specific type of companies which provide access to products such as videos and books and services such as insurance and. The subscription-based model follows a five-step cycle which includes acquiring customers, delivering high-quality service, making use of opportunities to upsell or cross-sell, retaining current users, and repeating the cycle. Additionally, this model could help develop a sustainable long-term revenue system which helps in cutting down on extra expenses for finding new customers (Patrick Campbell, 2020).

2.3.7.3 Advertisement-Based Model

This model is frequently adopted by businesses for their websites. Key advertising features such as Clickthrough Rate (CTR) and Cost-Per-Click (CPC) are used to analyze the behavior of the audience and track website advertising revenue. CTR is defined as the ratio of clicks on an online advertisement to the number of people who view it. Higher CTR values indicate effective advertisements which attract customers to the advertiser’s landing page. Display advertisements (a type of online advertisements) interfere with the user experience and appear annoying sometimes. They are also susceptible to advertisement blockers. Native advertisements are the ones which fit easily with the background website content and so provide a more engaging experience for the viewers. Native advertisements have a higher CTR and they generate more revenue. A low CTR is not a good sign and can be increased effectively through customer personalization and audience segmentation. CPC is the amount of money spent by advertisers during customer clicks on their online advertisement (Amanda Walgrove, 2020).

2.3.8 Business Canvas Model

Business canvas model is a tool used by startups to understand and list different aspects of the idea which allows them to describe, design, challenge, invent and pivot the initial business idea to a solid problem statement after iterating and refining through multiple versions of it (Mark Hemmer, 2016) (See Figure 4).

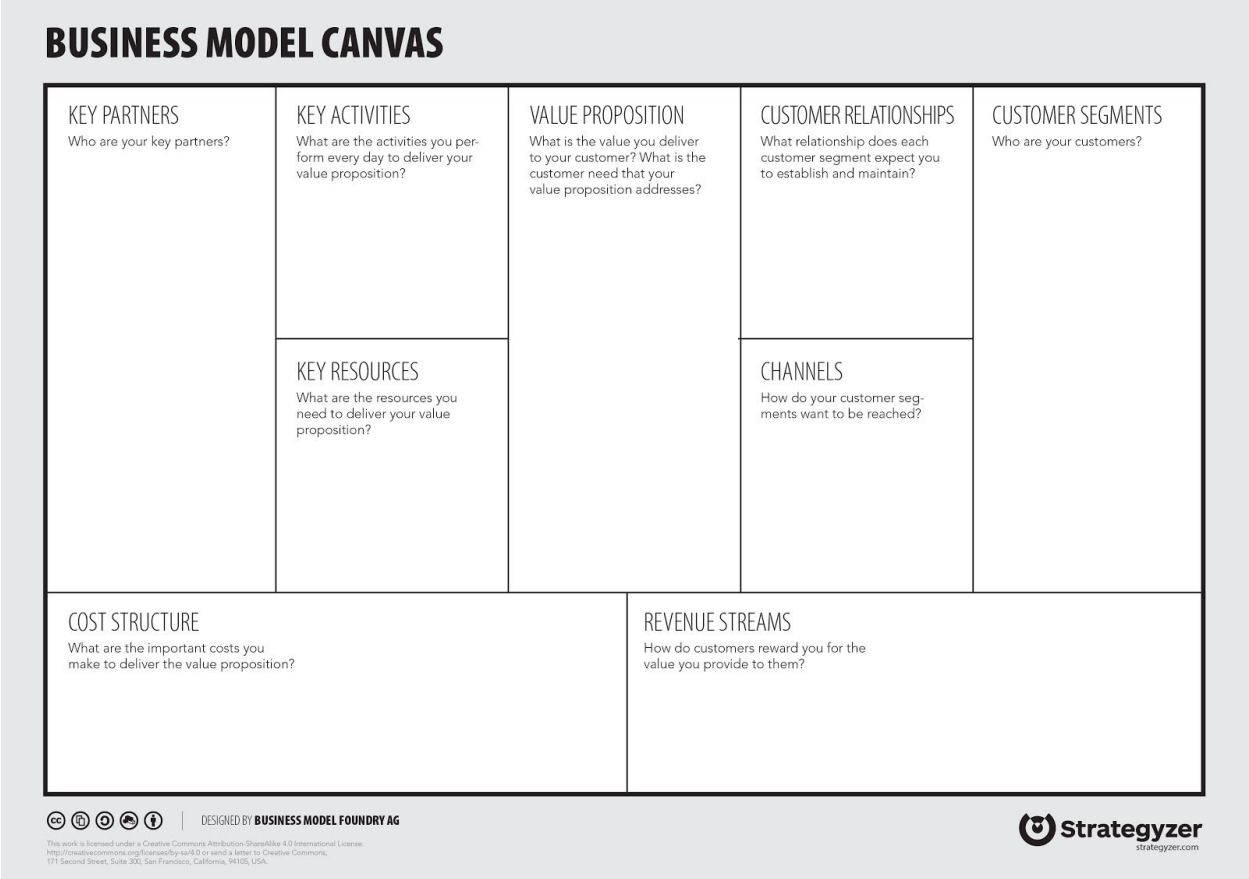

Figure 4: Business Model Canvas

Customer Segments: It is a strategy to break down the target customer base into various groups of individuals based on similarities such as demographics, geographics and psychographics.

Value Proposition: This brick acts as the most basic and functioning unit to any business idea. Value Proposition consists of a problem statement that targets the practical needs of a target set of individuals and how the proposed solution adds value to the market by fulfilling the needs of the customers.

Channels: This column helps to analyze the different forms of avenues through which the product will come into contact and distributed within the customers. If worked thoroughly on this segment of business model, then a suitable marketing plan can be developed for the sales cycle.

Customer Relationships: This block helps understand the relationship businesses share with their customers and how their business idea will interact with the end-users. Some examples of different modes to relate to customers would be in person, online, third party contractors, and social events.

Revenue Streams: Revenue streams are different paths through which a company gains profit. From concept to a launch, these streams help to convert the defined value proposition into a financial benefit (Mike Ebinum., 2016).

Key Activities: The Key Activities of any business idea are the operations or actions that the organization will initiate to attain the value proposition and fulfil the needs of the customers.

Key Resources: These are the resources which are practically needed to undertake the key activities of our business idea.

Key Partners: Every early stage venture needs support from external entities to survive in the markets. Key partners are a gist of other companies, parties or organizations needed by businesses to attain their key activities and satisfy the customer chain.

Cost Structure: This cell in the business model canvas defines the cost architecture to operate the business and keep the venture running.

2.3.9 Target Customers

A target market is a set of audiences which share similarities in terms of needs and solutions that a company's product or service hopes to serve. There are a number of factors which decide the formation of a customer base such as demographics, geographics, psychographics and certain lifestyle preferences. Generally following the temptation to become too general and targeting everyone is the most common failure which young startups do and in turn prove to be expensive and sometimes dangerous (Michael Kaleikini, 2009). Target customers are very critical to an early stage startup as they help in solidifying the value proposition and validating the needs assumed during the need assessment phase. Also, young startups have low budgets to carry out marketing and are limited with resources to reach out to larger crowds in comparison to companies with high capital who can cater their solution to everyone who might be a potential customer.

To create a specific target base, we will indulge in a process of customer discovery where we will interview a group of professionals in their respective fields. We will further discuss the importance of having a target customer base and procedure of Customer Discovery in our methodology chapter which would mainly focus on confirming our hypothesis and validating customer needs.

2.3.10 Team Dynamics

Team dynamics is an important business aspect for startups. Good exhibition of team dynamics will help a startup to achieve its objectives with better quality and efficacy. Mostly, startup companies have a single founder but to achieve the desired objectives at an incredible rate, it is a dire need to engage with one or more co-founders. With bringing more people onboard, the team dynamics in startups should be given more importance. Team dynamics facilitate the development of teammates into valuable assets for the company. This is because the “social relationships” between teammates can either promote or demote their individual talents and excellence. Interpersonal skills which involve communicating effectively help in building positive relationships amongst teammates. Negative team dynamics establish a “toxic working environment” and might cause failure for startups. Some of the examples of unhealthy team dynamics include: jealousy, internal competition, backstabbing, regular unhealthy conflicts, and much more.

Respecting the rights of oneself and teammates is necessary. This happens by not accepting any mistreatment against oneself or other teammates. Approaching these issues in a calm and professional way is a key part in managing and resolving internal conflicts. Remaining active while listening to others in meetings, is another major expectation from all members of the team. “Good listeners make strong startup leaders” (Ron Flavin, 2019). Open and clear communication between teammates is critical to ensure healthy team dynamics. Merely, assuming other people’s opinions, without talking to them about it, might prove to be dangerous. In the times of conflicts, “always criticize the behavior and not the person” (Ron Flavin, 2019). This allows to maintain positive group dynamics in startups. Another important point is to plan to manage conflicts and disagreements, since they are inevitable. Establishing a “conflict resolution framework”, before the rise of a conflict, will help the team to thrive through it and resolve it. Hence, establishing healthy team dynamics involves a lot of planning and effort from the members of the team.

Every person in the team is a leader in themselves, have strengths and weaknesses, and know how to get things done at their own respective levels, which discards the burden of micromanaging everyone. "Talent wins games, but teamwork and intelligence win championships." – Michael Jordan.

2.3.11 Funding Sources

Funding is a component to keep the startup flowing. A team can go through a number of iterations to develop a solid business model but when it comes to enter the market and execute the developed plans, funding is necessary. Funding covers the licensing, patenting, marketing, product optimization and testing, and hiring the necessary talents. Employees must receive appropriate payments on specific dates throughout the month. It takes months and sometimes a couple of years to achieve stability within the customer base to generate revenue and a company can go through a lot of ups and downs in its initial days without earning a profit. Thus, it is important to have a specific base amount of funds within the company to pay the employees on time.

Going off of a very basic source, fundings on a university level for a team of students can be a direct and easy source. Every other university has student led organizations or a department with a network of alumni who are successful entrepreneurs in their respective fields. This could be a starting point to pitch the idea and convince faculties or alumni to invest in the business model. Inter-collegiate pitch competitions or innovation encounters could be another major source of funding on university level.

Other forms of funding could be long term borrowings and short term finances. Selling the company's shares and borrowing long term finances is suitable for expanding new facilities or launching the company, whereas to look after payroll, inventory management, and unexpected expenses, and assuming if the company is in operation; short term finances are advisable. Short term financing can easily be achieved by approaching banking institutions as their forte is offering quick and easy credit lines that can be swiftly repaid. Additionally, their extensive consultancy services aid a venture in times of uncertainty.
(Devra Gartenstein, 2018).

Incubators or accelerators could be another spot to look after for funding in early days of execution. As the importance of incubation has increased for business startups, such incubation centers have appeared all around the globe at a blistering pace. These communal spaces offer an environment unlike any other as there is a constant audience to use as a scratchboard, gain input from and develop networks. These centers are also increasingly connecting with educational centers to impart the importance they teach to impressionable minds.

2.3.12 Legal Challenges

When starting a small business, people often go through a plethora of legal challenges which might disrupt the flow of impact it might have in society to make the world a better place. Licensing is one of the most common legal challenges that small businesses encounter. It should be farsighted to ensure that the business is in accordance with the local government's requirements and lies within all regulatory rules (Amy Jones, 2019). Failure to do so can result

in payment of unnecessary fees which could have been easily avoided. Licensing also includes having an appropriate patent for the technology which may vary according to the field of technology and its utility and its target use.

Lawsuits are another form of legal challenges most often faced by small scale startups. Especially for tech startups which aim to improve the lifestyle of humans and have to do with human interactions, are vulnerable to legal actions from another party, even if the organization has not done anything wrong. The team has to be extremely careful in terms of what it says and what it does as it can be counted as a misstep by the rival group used as an excuse to sue the startup. Therefore, it is very essential to have a corporate attorney and a legal structure within the firm when the project reaches the market entry phase.

Infringements related to misuse of one's brand, trademark and name of the firm is one more legal threat a startup can confront. Protection of intellectual property is an actual need for a company before it is too late to prevent others from earning a profit based off of our hard work. Sometimes, startups with restricted fundings skip this step to avoid investing money in legal procedures which results in unnecessary headaches in the future if the business takes off. If a larger company happens to use one's name, brand, or patent, it could lead to court proceedings and demand huge financial commitments. Larger companies have enough capital to fight the corporate battle, but the one to suffer is small scale startups whose name or work has been used. This demonstrates the vitality of getting paperwork completed in an ordered fashion through the US Patent & Trademark Office as well as the Library of Congress before any substantial impact is made. (Amy Jones, 2019).

2.4 Social Implications

In the above sections, we learned how the field of Artificial Intelligence is amalgamated with medical sciences to produce solutions that will drive a healthy society. Current AI powered solutions are touching the society at large. Thus, cultivating acceptance of Artificial Intelligence based applications into our society is important. Let us explore the specific societal issues related with the use of AI. These consist of legislation, interpretability and explainability, privacy and anonymity, and ethics and fairness.

2.4.1 Legislation

Ever since the dawn of civilization, human beings have been standardized by the framework of legislation. Within academics, advances and research in AI didn't have any legal issues. But the minute applications of AI step out into the society, their impact on people will have legal concerns which need to be dealt with. The European Union directive for General Data Protection Regulation (GDPR) has mandated that citizens reserve the right to demand a thorough explanation of any and all decisions made by "automated or artificially intelligent algorithmic systems". The connotations of GDPR for the use of AI in medical sciences and healthcare draws that any AI-based medical decision support system (MDSS) that explicitly

provides a (semi)automated decision on a patient such as diagnosis, prognosis or treatment consultations, will necessarily involve a medical expert who will be monitoring the MDSS as a “data controller” for it. This legislation (mandatory for countries under the European Union) requires that the medical expert using the AI technologies must be able to explain the reasoning for specific medical decisions made to any human being affected by it. Thus it is crucial that A.I based technologies are always used in an advisory or supplemental role with their intelligence being efficiently harnessed by the experienced healthcare providers. (Vellido, 2019).

2.4.2 Interpretability and Explainability

Human beings have the inbuilt ability for natural language processing which plays a communicative role. And since AI has been conceived as an attempt to mimic the intelligence of the human brain, it should also have this feature of natural language processing. A requirement to achieve interpretability is that it is ensured that every AI model can be explained. Currently, there is a lack of interpretability as expressed by AI technologies. In medicine, if a machine learning (ML)-based MDSS cannot make comprehensible decisions, then medical experts won't be able to trust these technologies and thus, will have to make the decisions by utilizing human intelligence. Hence, AI- based technologies are useless until they conform to guidelines of medical sciences. Sometimes MDSS are often perceived by healthcare providers as a burden in their daily schedule, when they conflict with these guidelines. Thus, there needs to be much work done in order to integrate knowledge of medical experts and the AI models to achieve interpretability and explainability (Vellido, 2019).

2.4.3 Privacy and Anonymity

In the current world, data privacy and anonymity have developed as big social concerns especially in healthcare systems. The current use of EHRs (Electronic Health Records) deepens these concerns, since sensitive data of patients are digitally uploaded to networked systems with different layers of security. There has been a less initiative in policy development involving privacy concerns lifted by the EHR system. AI also features privacy-preserving algorithms. The disruptive element of privacy and anonymity in terms of AI and ML applications in medicine is the intervention of IT companies in the medical field such as Google’s DeepMind and the emergence of AI-based start-ups that are medically oriented.This reinforces the need for the most stringent of protection measures when transerfing sensitive medical data on a large scale between public and private entities. (Vellido, 2019).

2.4.4 Ethics and Fairness

Ethics is one of the aspects that provides the foundations for the regulation of societies. The ethical issues related to AI involve the decisions made by the human brain that controls these AI technologies for a given application. Ethics is also a core concern in medical sciences. It is clear that humans are the sole identifiers of ethical and moral quandaries when they arise.

Thus philosophy, one of the core components of A.I becomes even more important for the medical experts who use AI tools in medical practices. In terms of fairness, it's quite controversial to pick and imbibe the right and ethical form of fairness in AI systems as in human society as well, it is difficult and controversial to decide upon the best form of fairness. Sometimes the lack of fairness in AI systems may appear due to generation of biased data based on gender, ethnicity, sexuality or disability etc. Integration of “fairness constraints” is important in order to diminish these biases (Vellido, 2019).

2.5 Problem Statement

To study existing companies and the current state of the market space that exists at the intersection of artificial intelligence and medicine to innovate and explore with the aim of developing a business model for an A.I assistant tool to aid the industry.

Chapter 3 - Methodology

3.1 Research Objectives

The goals of this project are to conduct a thorough need analysis of the cardiovascular health industry of the United States and gain a better understanding of why Coronary Artery Disease is the top killer in the US and costs to the tune of $200 billion. To accomplish these ideals we will need:

1. **To determine if the real-time monitoring system will add any value to the existing market space**
    - **a.** Monitoring which in Phase will be more valuable?
        - **i.** Before the patient is diagnosed with disease (Phase 1)
        - **ii.** After the patient is diagnosed with disease (Phase 2)
2. **To check if the data collected from wearable technology such as smartwatches and mobile phones be used to make sound inferences about the human body**
    - **a.** What kind of data can we collect from wearable tech users?
    - **b.** How reliable is the wearable tech data? Can there be a link between wearable tech data and data generated from superior forms of diagnosis (MRI/CT/Ultrasound/laser retina scan, etc)?
3. **To determine the target customers of the idea**
    - **a.** Should it be doctors or/and patients?
    - **b.** What should be the factors on which our target audience will be based on?

3.1.1 Objective 1: Determination of value of Real-time monitoring system

To define the value for our project, we decided to look at our primary aim. This aim being the act of catching the root of ill health at a stage where it is recognizable and the time saved compared to if a cause was found later at a critical stage of the condition. For example if our idea allows for a professional to make a diagnosis that a patient is exhibiting signs of the beginnings of a chronic disease 5 years earlier than if the patient had gone and been told the reach was extensive. That 5 years of extra attention being provided by all parties involved and careful, considered analysis of parameters is the conceptual value we hope to provide.

Current RTM systems are based primarily on the volume of sensors that can be packed into wearables and phones, which are the vector for the concept. The larger system is known as “Telemedicine” and is especially advantageous as it allows for the healthcare to be patient-oriented rather than facility-oriented. These wearable-based systems are an example of one of two types of telemedicine; Store and forward. The other is live communication. Both doctor and patient must be in the picture for live communication systems. Live communication systems are faster than store and forward but integration of A.I to store and forward would allow for the gap to be bridged. The value of this procedure would be the rough 7 billions smartphone users (Priyanka Kakria, N. K. Tripathi and Peerapong Kitipawang, 2015) . Those most benefited

would be the users without internet numbering a whopping 3 and a half billion as the phones would be still able to transmit crucial data with Bluetooth. This crucial data boils down to the measurements taken by the sensors such as heart rate, body temperature, blood pressure, oxygen rate and physical activity conducted (Priyanka Kakria, N. K. Tripathi and Peerapong Kitipawang, 2015) . The heart of this operation, the sensors themselves are also making leaps and bounds in terms of cost, accuracy, durability and ease of usage. RTM systems are actively used in asthamatic, cardiovascular and neurological disease management programs. Security is always a concern when it comes to electronic matters but such lengths have been taken to each such concerns such as expert recommendations throughout the process. RTMs are comprised of cascading levels. At the base are the sensors and the phone they are housed in. Sandwiched in the middle is the interface that displays this information from the phone. Finally is the network link that moves the data to the cloud in the form of Structured Query Language (Priyanka Kakria, N. K. Tripathi and Peerapong Kitipawang, 2015).

3.1.2 Objective 2: Examining reliability of data collected from wearable technology

Wearable technology is starting to become incorporated to a much greater degree in our daily lives. With so much technology around us, as well as the existence of the Internet of Things, a lot of useful data is generated simply by carrying out our business. This data generated depicts some properties of the human body. For instance, data generated by fitness trackers include heart rate, blood pressure, sleep analysis, and calorie intake and burning functions. Determining the source as well as the nature of data collected would guide us in recognizing how this data can be integrated with AI systems to solve problems with the respective body part. Comparing data from wearable technology and data from medical diagnostics techniques and relating the accuracy of the former with respect to the latter might also help to establish correlations between them. These correlations can be modelled and can be used to strengthen the inferences that we can make from wearable tech data.

To achieve this objective, it is important to examine the above-mentioned qualities of wearable tech data. Is the data collected from wearable tech reliable and consistent enough to make sound inferences about the human body? If so, how do we test it’s reliability and consistency? Can we combine the power of AI and wearable tech data to generate a new diagnostic field? These are some of the questions which will help us to examine the nature of wearable tech data. It is also important to comprehend the answer to these questions before diving deep into this area. Therefore, we have decided to conduct interviews with doctors and other medical professionals who can help us to critically analyze and arrive at the right conclusions about wearable tech data. For more details about this, please see the attached Appendix B: Interview guide for Customers.

3.1.3 Objective 3: Seeking target customers of proposed ideas

As we have covered before, identifying “target customers” is an important business aspect. This can be realized by understanding the need of “Customer Discovery Process”. In 1991, Motorola and a global partnership of 18 companies founded Iridium. It was a startup which proposed to develop a global mobile telephone system and claimed that it would work “anywhere on Earth” from submarines in the oceans, to the remote mountain peaks of the Himalayas, to the deserts of Africa where no cell towers existed. While constructing this business plan and ignoring customer needs, the company started prototyping and investing heavy capital into resources such as buying 15 rockets from the US, China and Russia and launching 72 private satellites into orbit of Earth. After 7 years of intense prototyping, Iridium cell phones made its first call, but 9 months after this, the company got bankrupt. What went wrong? In the era where smartphones existed, Iridium handsets were the size of a lunchbox and weighed as heavy as a brick. In these 7 years of execution from concept to a launch, innovations in the mobile phone industry proceeded in a flash. By that time, there were very few places on Earth where cell phone coverage didn’t exist. Moreover, due to use of costly resources such as rockets and satellites, the price of each handset was $3000 and each call cost $7 per minute. Due to the expensive nature of this project, the Iridium’s potential market shrunk everyday. Thus, Iridium became the world’s biggest startup gamble as it didn’t focus on 4 key questions (Steve Blank & Bob Dorf, 2012):

1. Have we identified a problem a customer wants to see solved?
2. Does our product solve this customer’s problem?
3. If so, do we have a viable and profitable business model?
4. Have we learned enough to go out and sell?

Learning from this example, it is critical to first validate the hypothesis from the people who are actually going to use it and then execute the business plan considering the practical needs of the customers (Steve Blank & Bob Dorf, 2012). Since the initial theory of implementing a real time monitoring system for progressive diseases lies at the junction of A.I. and medical sciences, marking the territory of the consumer base can sometimes become delusional. Should our technology be limited to patients, or should it be limited to only doctors, since they are the ones to be alerted, or should it be extended to both the parties? It depends on various attributes such as disease we are focusing on or factors that determine unhealthy lifestyle which can lead to certain diseases. If we decide to go disease-specific, then drawing the boundary within a specific set of patients at a certain stage of that disease and doctors in that field sounds an appropriate consumer base. If the disease is age specific, then guardians of that age group might be our customers as well. For example, if our tech targets SIDS (Sudden infant death syndrome), then the target customer base might include pediatric pulmonologists, parents, infants themselves and insurance companies. On the other hand, if we decide to mechanise our tech to keep a track of the general lifestyle of people, then factors regulating the formation of customer base might be based on demographics, age group or genetics and family history.

Hence, to investigate thoroughly and get practical insights on the best possible target group for our tech, we intend to indulge in the customer discovery process through the I-Corp program. We will conduct multiple interviews with medical experts themselves to confirm the theory and get other useful data. For more details about this, please see the attached Appendix A:I-Corps Program and Appendix B: Customer Discovery Process.

Chapter 4 - Findings

Using the proposed customer methodology of I-Corps, we have interviewed 9 medical professionals as part of the Customer Discovery process. This process required us to carry out a need assessment for our project. We have analyzed the transcripts we made of our interviews using the **N**eed-**A**pproach-**B**enefit-**C**ompetition (NABC) framework and developed findings from that analysis. We then further refined the needs into different themes to find repetitive problems in the industry, or a sequential pattern to understand the scenario from different stakeholder's perspectives, such as doctors, management of the healthcare institutions and patients themselves.

We started off with the top 4 diseases which have the highest impact on the U.S. medical industry: Coronary Artery Disease, Myocardial Infarction, Sudden Infant Death syndrome and hypertension in pregnant women. To narrow down to one specific disease, we ran down an analysis using certain metrics such as average number of cases, accessibility to resources, mortality rate, average cost spent and future increment rate.

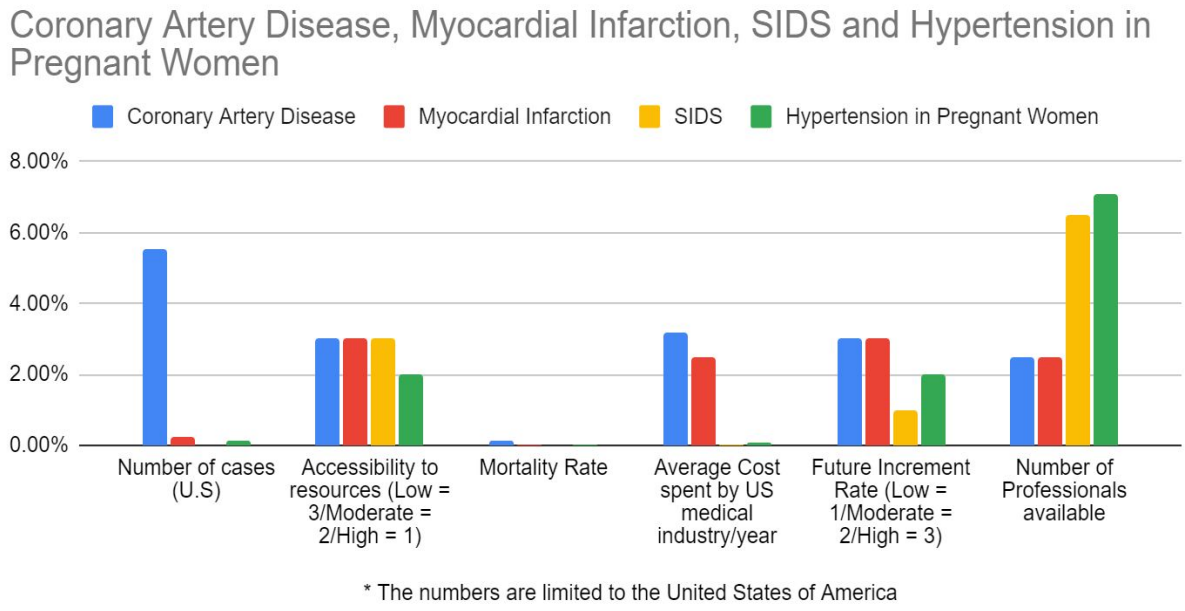

Figure 5: Impact analysis for top 4 killer diseases in the U.S.

After assigning the weights to these different metrics, we calculated an impact score and the following graph (See *figure 5* and *figure 6*) shows the result of our analysis.

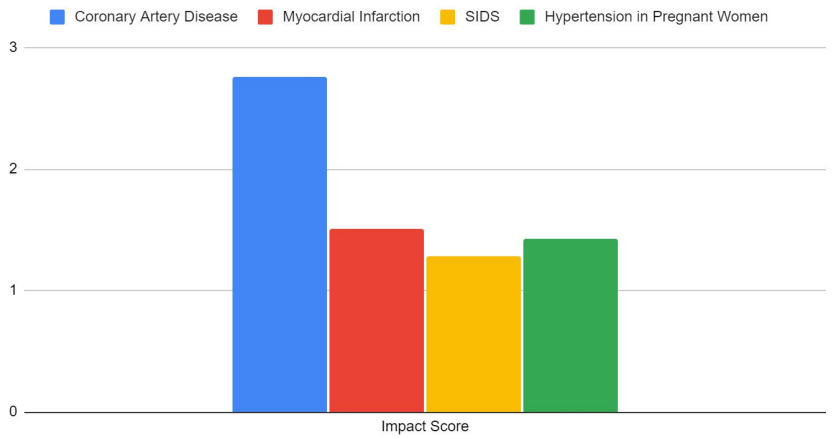

Figure 6: Impact score for top 4 killer diseases in the U.S.

With this, the themes of the findings that we have identified are:

- Pervasive and Progressive nature of CAD
- Nature of treatment
- Risk
- Costs
- EMR/EHR integration and interconnection

The summation of our key findings is that the current data collection and diagnosis method leaves a lot to be desired, the current patient-driven system of treatment is proving unsatisfactory for both doctors and patients and that the nature of CAD makes it a very tricky disease, with regards to detecting, treating and living with.

4.1 Theme 1: Pervasive and Slow Progressive nature of CAD

As time has progressed, human lifestyle habits have drastically changed. Where once a majority of our nutrition was derived from fresh produce and meats, it is now slowly coming more from processed and fast foods. Similarly where once occupations required significant movement and physical activity, desk jobs and working from home have become the norm. In this manner, our food and exercise habits have taken a turn for the worse and the effect can be seen on our cardiac health.

Coronary Artery Disease (CAD) starts developing at an early age, usually around one's 20s, and is present throughout much of the lifetime. In the early stages of this disease, plaque (fatty streaks) starts depositing on the endothelial lining (interior lining) of coronary arteries. During this time no relevant preventive actions are taken and there is deposition of more and more plaque which leads to the formation of blockages in the coronary arteries. This limits the blood flow to the heart and the disease reaches an obstructive phase. During the obstructive phase, heart muscles are deprived of oxygenated blood and they start to die. This also displays the irreversible nature of the disease. Once the heart muscles are deprived of oxygen, they will never recover to the condition they were in prior to deprivation. This might lead to heart attacks which is when the patient realizes about CAD progression after approaching a doctor.

Thus, this disease is present for a very long time before any signs or symptoms appear and the cardiac health industry addresses this issue only when the symptoms occur, which is a long time after the disease has already started.

The location of the obstruction within the coronary artery is also significant as it influences where the blood flow gets off. If blood flow is restricted in the upper region of the heart, the person will experience neck/shoulder pain. This pain is often misperceived as regular fatigue and “wear and tear” kind of pain, solved by taking a few painkillers. Similarly, if there is a lack of blood flow in the lower parts of the heart, the patient may shrug off the resulting stomach pain, attributing it to indigestion or some other minor issue. This unfortunate misperceiving can mean that the patient remains unaware of their CAD condition.

4.2 Theme 2: Nature of the treatment

Currently, the cardiac health industry is more treatment based and less preventive based. It is also patient driven in terms of data collection. When a patient approaches a doctor after going through a cardiac event, that is the time when the presence of CAD is first observed. Since at this stage the heart muscles of the patient have already been damaged, there is no way that the patient can be relieved of CAD, since CAD causes an irreversible change to the organ. This also marks the period of time when the treatment for CAD will start. Before the treatment phase, there was a preventive phase, where the progression of this disease could have been controlled. But during this phase, there may have been a lack of communication between the patient and the medical body due to the patient being unaware of the disease within them. Thus, the opportunity to prevent the disease is missed and now the patient has to undergo the treatment phase. This whole situation is repeated on a thousand fold scale throughout the US on a daily basis, illustrating how CAD is treated through treatment rather than prevention in the US.

During the treatment phase, patients are advised to visit the doctor on a weekly or a bi-weekly basis and are asked questions about having symptoms related to heart attack such as chest pain and bleeding problems. The nature of these questions means that the patient’s word is what is considered for the doctor’s diagnosis. It is more than likely that the patient isn’t of a medical background and so will not have a thorough understanding of the disease and what is expected of them. Hence, the data is extremely subjective and often variably reliable. And since a huge portion of the doctor’s strategy in terms of testing, treatment and management depends on the patient’s reported data, the treatment phase is often not as efficient and effective as it could be.

Another facet of the patient-driven system is compliance. Medical compliance is the extent to which a patient cooperates with their medical professional and follows their instructions on treatment. Regularly taking their medication and following a prescribed exercise plan would be displaying diligent medical compliance but regularly failing to show up to appointments and disregarding medication plans would be displaying poor compliance. There are a lot of cases of reduced compliance since it cannot be realistically monitored by doctors.

A lot of people don’t get their body parameters such as body weight, BP, cholesterol etc., checked on a regular basis. This causes the risk of low risk CAD patients to develop into high

risk levels without their being aware of it. So reminding people to visit a doctor regularly and getting their body parameters checked is a need. Another need is to make patients understand what CVD risk level they stand at and what could be the consequences if they do not improve their lifestyle and adhere to instructions given by their doctors. Because improving their lifestyle and behaviour towards the instructions given to them can change their risk category. There is a need to improve medical diagnostics at home in order to monitor the information of factors such as blood pressure, cholesterol level, exposure to smoke or smog or pollution, blood sugar level for diabetics, etc., on a daily basis to better understand their risk.

Improving medical compliance is critical because it contributes to a high mortality rate. For example, it is very important to comply with the antiplatelet drug regime after placing a coronary stent in the patient's heart. Another example is, if a patient has poorly controlled hypertension, which is a critical reason to get angina. There is a huge need to confirm the patient's compliance with the prescribed medicines and also continuously monitoring risk factors. An additional necessity is to communicate the data gathered about compliance and other monitoring parameters back to the physician, so they can have a clear picture of the patient's health.

4.3 Theme 3: Risk

Consider a person going about their life, when they suddenly experience severe pain in their torso, either in the shoulder and neck region or the upper stomach. Once the initial shock has passed, the person may decide to go to a Primary Care Physician (PCP) to get some sort of explanation as to why the pain occurred. The first part of the appointment will most likely be the PCP questioning the patient on their general health and recording the responses. Some things that would most likely be covered under the questioning would be the patient's blood pressure, cholesterol, age, gender and smoking habits. These are the patient's risk factors, which are indicators of their chance of developing a cardiac disease. These factors are then used to calculate the patient's ten year risk score of CAD. The factors are not always concrete indicators of the presence of CAD but are crucial to take nonetheless. Some other risk factors are obesity level, environmental factors and hypertension. These other risk factors are currently less frequently employed in risk score calculation due to the focus on genetic factors. It is an oversight to ignore these factors because the rapid change in death toll due to CAD cannot be attributed simply to genetics. Environmental factors play a huge role in the progression of CAD and their observation and control is crucial.

Currently, the risk calculators utilized are AtheroSclerotic CardioVascular Disease (ASCVD) risk calculators and take into account the above-mentioned traditional risk factors. When the current ASCVD risk algorithms are applied to analyze risk of heart attack, some patients may receive an incorrect low risk score. The implications of this are that the patients may actually be at a much greater risk level and subsequently don't receive the level of medical care they require. Computed Tomography (CT) scans are used as a way of checking the score's accuracy and confirming the extent of blockage within the patient's heart. Almost half of the population around the age of 40 and above, are at a significant risk of atherosclerotic disease. Some of them, from an early age, show early signs of this disease. The risk of all these groups

is determined by these existing inaccurate risk calculators. ASCVD risk calculators are mostly used for patients within the age range of 40-75. This same age range is the one that has the most significant risk of atherosclerosis and by being forced to rely on these inefficient calculators, a considerable population is at risk. So this shows that there is a need to improve the efficiency of the current risk calculators used to make accurate predictive diagnosis for heart risk.

Another important aspect of risk factors is frequency of data collection. Usually, patients are instructed to check-in with their doctor on either a weekly or bi-weekly basis. The frequency of data collection is very subjective as it also depends upon the severity of the case of the patient and can range from weekly to monthly. These check-ins are therefore at intervals and provide discrete data for risk analysis. This snapshot data is then collated and converted to an estimated continuous data sample. This raises the problem that doctors are forced to make decisions based upon this snapshot data, which is less accurate than continuous data. Additionally, the time difference between the collection of data and a decision being made on it means that the patient's condition will continue to imperceptibly grow worse and further irreversible damage will continue to occur. From this, we concluded that there is a strong need for continual monitoring of risk factors, in order to have the most up-to-date assessment of the patient's health and ensure that they receive the treatment they need at the optimal time.

4.4 Theme 4: Costs

Since the cardiac health industry is more treatment based, a lot of costs driven from these systems are not spent on preventing the disease, but on keeping the patients alive with interventions and medications. Due to this, patients keep coming back to hospitals in need of more and more interventions, additional therapists, other devices or supplements, and sometimes even new hearts to keep themselves alive.

This imposes extra burdens on the healthcare systems and creates the need to reduce cardiac readmissions. Healthcare institutions receive some amount of federal funding. There is a limit set by the government on the total number of patients to be readmitted within a 30 day period for cardiac events. Upon exceeding this limit, the federal funding may be retaken or negated/penalized. This also adds up to the burden of extra costs driven out of the system and thus, costs of the treatment phase is a big concern for the cardiac health industry.

The need that our interviews and analysis uncovered with respect to the costs of the cardiac industry is that the majority of them need to be shifted to being for prevention rather than treatment. It is not realistic to imagine that treatment costs can be brought down to a complete zero, but they can be minimized by shifting expenditure towards programs promoting regular checkups, exercise schedules, nutritious diets and other such measures.

4.5 Theme 5: EMR integration and interconnection

The final theme of problems that we identified was electronic medical records (EMRs). EMRs represent the natural evolution of recording from paper charts and graphs to electronic means. EMR systems at healthcare institutions are usually unique to the institution and record

what they deem important. As such, there is an absence of a nationally integrated EMR system. This has negative consequences in the form of additional expenses and time wasted by both doctors and patients. An example would be a patient going to Hospital A for a CAT scan. A week later, the patient is rushed to Hospital B and they require a CAT scan of the patient. Although the patient had the CAT scan done a week ago, it is more than likely that Hospital B will tell the patient to get it done again and bill them for it. The reason behind this is that arranging for the scan, or a copy of it, to be transported to Hospital B is deemed a waste of resources.

The core need that emerges from the findings we made regarding EMRs is better integration. EMRs need to be better integrated across hospitals and even within them. A doctor's diagnosis should be automatically included in the patient's EMR, as should the patient's risk score and category.

Chapter 5 - Conclusion and Recommendations

From this theme identification of needs we can summarize that the key needs of the cardiovascular industry are centered around cost, treatment, the nature of CAD and data collection. Cardiovascular diseases as a whole and specifically Coronary Artery Diseases are the leading cause of death in the US. They can be reduced to formation of plaque in the inner lining of blood vessels. This formation of plaque occurs in almost everyone, as early as age 20. Certain lifestyle habits and environmental factors can speed up this formation and even take it to the point of blockages in coronary arteries. The current US medical system focuses much more on treatment rather than prevention of CVD. Certain obstacles that the current system cannot hurdle are the slow progressive nature of the disease, a long onset time of symptoms, inefficient risk calculators, a reliance on snapshot data collection techniques, and patient-driven monitoring systems. CAD is an irreversible condition and will only get worse with time. Our solution to these hurdles is a technology that will make the diagnostic system preventative in nature by integrating solid risk analysis with remote data capturing techniques.

5.1 ThirdEye's Solution

Our solution is a web application technology providing a more robust ASCVD (AtheroSclerotic CVD) risk analysis management system that targets patients of age group 40-75 and are at "borderline" or "intermediate" risk of having a heart attack due to CAD. This risk analysis system will utilize concepts of AI for an increased number of factors and more frequent data capturing techniques such as monitoring of facial characteristics, EKG, blood pressure, cholesterol level, environmental factors and lifestyle factors. Conclusions from this technology will be integrated with the Electronic Medical Records of patients, which will be accessible across all the healthcare institutions who have adopted this tech. The technology will also have a built-in alerting system. If the conclusions drawn by the AI are that the patient requires immediate medical attention, it will alert the hospital nearest to the patient based on their location and instruct them to head there.

5.2 Value Proposition

Based on the solution that we are recommending, here is a brief overview of how each feature of our solution will address relevant problems identified with the cardiac health industry. The benefits are also mapped with each solution feature:

Physical manifestations of CAD include pain in the upper torso. If a patient approaches a doctor with symptoms or conditions like angina or chest pain, they utilize their ASCVD risk calculators and estimate a 10 year heart condition risk level. Depending upon the score, they categorize patients: low, borderline, intermediate and high risk. These calculators have a 50% probability of being correct.

We think we can develop a more accurate ASCVD risk analysis management system. This accuracy will come from it accounting for more risk factors than traditional ASCVD risk calculators. Along with traditional risk factors such as age, sex, race, medical history (Heart

attacks, diabetes etc), blood pressure (systolic and diastolic), smoking, total cholestrol, HDL cholestrol, some of the additional risk factors that the new system will consider are facial patterns, environmental factors (pollution exposure, extremes to noise and temperature), lifestyle factors, and possibly EKG.

Also, the current diagnosis system for atherosclerosis is based on weekly or bi-weekly check-ins with doctors. This is snapshot data capturing and will not yield a continuous progression, which is necessary to see if the patient's condition is worsening or relieving. Given its nature, this method is also likely to further increase a patient's heart damage, an irreversible occurrence.

Our tech focuses on continuously capturing data rather than converting snapshot data to continuous form. This can be done by using remote and portable forms of sensor based technology such as smartwatches and mobile phones to capture risk factors. This has the added benefit of saving time to classify the patient's health and take necessary actions.

We think that the age group of 40-75 are at higher risk of having their CAD progress to atherosclerosis than other groups. Patients who have established CAD and are in the "borderline" or "intermediate" risk category can benefit from our system and we can prevent them from going to higher risk levels where greater measures and interventions are required.

By implementing a new and more solid risk analysis system, we will be helping with preventing unnecessary interventions and reducing the number of specialists required for one patient. This will also reduce the rate of readmissions and the cost driven out of that healthcare institution.

Lastly, our system will also integrate the conclusions it makes with existing EMRs. This allows for up-to-date information that doctors can easily access across healthcare institutions. The system will also alert doctors if immediate action is required.

5.3 Next Steps

Based on the project's current stage, we have started to discuss our future steps and where we need to take this whole idea next. We plan for our project to shift gears and enter the prototyping phase. This will entail beginning the Engineering Design Process to design the minimum viable product along with rudimentary prototypes. The way we will develop these prototypes and MVP is by our tried and tested method of getting out of the building and considering what customer needs tie in with the larger problem and then acting on them. Along with the prototyping aspect, we will continue the customer discovery and validation process to further refine our business plan. While we work our way through our prototyping stage, we plan to participate in the Tech Advisors Network (TAN), hosted by Innovation & Entrepreneurship department, WPI. TAN is an incubator which provides advising and networking to projects who are about to enter the execution stage of their business plan. We plan to pitch our business plan to several mentors at the TAN roundtable event and ask for mentorship and guidance for execution of our business and we will be banking on having a refined business plan and a MVP (Minimum Viable Product) by that time.

We also plan to participate in WPI TinkerBox. WPI Tinkerbox provides seed funding upto $3000 for WPI student initiated innovation and entrepreneurship ideas. The funds will mainly be

utilized for multiple prototyping aspects such as hosting a server for databases, buying a domain for the website and collecting shadow data from different healthcare providers. This shadow data is what will be used to “train” the A.I and begin preparing it for actual usage. One of our interviewees gave us extremely helpful information on the matter and even offered to put us in touch with a few specialized data scientists at their facility to better learn the process.This is to be one of the more important parts of the future of our startup. Funds can also be utilized for marketing in the form of paid advertisements on social media such as Facebook and Instagram.

We also plan to carry forward this IQP as an MQP where we will continue prototyping the product and executing the business plan. It is our hope that we will be able to work the project to a level where we can execute some form of “launch” of our product as one of the core deliverables of the MQP.

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Appendix A: I-Corps Program

The I-Corps program was initiated by the National Science Foundation which uses experiential education to train research enthusiasts and achieve understanding about entrepreneurship, industry insights and starting a business. The I-Corps chapter at WPI lies under Foisie Business School, WPI which provides a support system to student or faculty teams who have a business idea addressing the elements of NABC framework and has commercial potential. I-Corps focus on validating the needs assumed and discover a customer base which can benefit from our proposed solution. This revises the conventional flow of developing the tech in the lab, writing the business plan and then going out to implement it. Instead, we are required to focus on seeking input from real stakeholders, discover customers and validate the needs first and then develop the tech to enter the market.

Customer discovery will include two phases. The first phase will analyze the customer's point of view on the problem and the customer's need to solve it. Is the problem assumed an actual need? The second phase will include presenting the full-fledged theory of solution to the customers for the first time. This phase will aim on extracting assurance whether the solution elegantly solves the problem to scale the product and grow the customer base. This forms a loop between customer search and customer validation. After each iteration of this loop, the team will be able to find new pivots and get more & more insight on the valuable needs of the people. As shown in figure 1, each pivot will be a refined version of the previous one and sometimes an entirely new field to explore in. The end condition to get out of this loop will be met once the team finds a solid value proposition addressing the filtered needs.

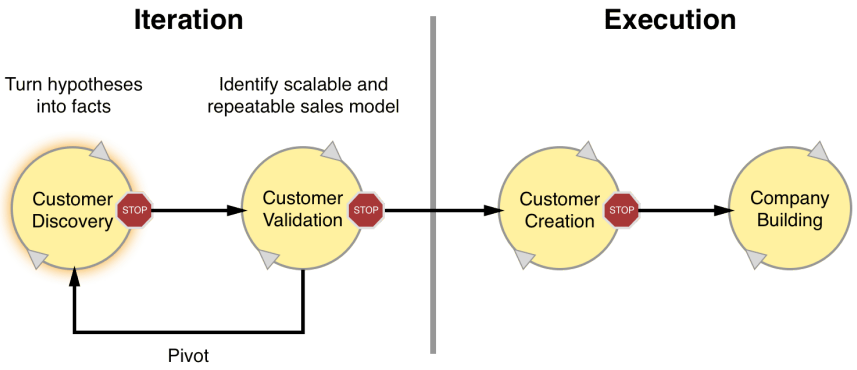

Figure 7: Customer Development Process

Four Steps of Customer Development Process (See Figure 7):

Customer Discovery: Seize the team's vision and turn it into a series of business model hypotheses which will then be used to gauge the customer reaction and converted into facts (either right or wrong).

Customer Validation: A verification if the business model is of a scalable nature. If the verification fails, a pivot is necessary, followed by a return to customer discovery.

At this point, the team should be ready with the solid value proposition

Customer Creation: Initiates the execution part. This builds the end-user needs and discovers sales channels to begin scaling the business.

Customer Building: Convert the startup into a company by applying various customer growth and retention techniques with a sole focus on existing business model (no pivoting required at this stage, only growth)

Format of I-Corps, WPI Program:

The team will begin to work on testable hypotheses under the NABC framework. What is the need among the society, what is the proposed solution/approach towards that problem, what benefit is the solution adding to the market, and what is the competitive alternative for the product? We will start identifying different stakeholders in the industry and the team will be responsible for conducting 30 interviews with those stakeholders. After every interview, we have to extract useful information that fits and shapes our project, analyze the pivots and explore deep into those pivots.

After each interview, the team will come away with deeper insight to the value of the team's idea. We may end up pivoting a lot as we start discovering the initial idea is not viable. At the end of the program, the team will be funded within $2,000-$3,000 range which must be used to travel to key customer locations or attend other forms of customer discovery events such as conferences or seminars.

Appendix B: Interview Process

Participants in this process

The people who we will be interviewing are the ones who, we believe, will be impacted most by our product. Since our idea will be based around implementing the wonders of AI in the medical industry, we have identified doctors and other medical professionals as the participant base for this process. But since most of our earlier research has been focussed over certain types of medical conditions, such as progressive diseases, as well as around certain parts of the human body, such as the heart, we have decided to interview medical professionals from the above mentioned relevant backgrounds. To brief more about this, we have selected certain fields within Cardiology:

1. General Cardiology
2. Interventionist Cardiology
3. Preventive Cardiology
4. Noninvasive Cardiology

We have identified relevant doctors, radiologists and professors affiliated with the Massachusetts College of Pharmacy and Health Sciences (MCPHS), University of Massachusetts Medical School, Mass General Hospital and the Tufts Hospital. A significant percentage of these personnel are also members of Harvard Medical School. We have decided to contact them via email. Through our email, we will describe our current hypothesis regarding solving real life problems through AI and then request them to interview with us. When we will get a response, we will immediately try to corroborate with the participants about their availability and set up an interview call over Zoom.

Interview Guide

Introduction: (Ask to RECORD)

Introduce names. We are currently undertaking a project as our IQP which focuses on the intersecting area of medical sciences and AI. Within the vast field of human conditions and diseases, we've focused our research on cardiovascular diseases such as Coronary Artery Disease, Myocardial Infarction, Hypertrophic Cardiomyopathy and Hypertension. According to our literature review, the American medical industry has to spend around $108 billion solely due to CAD per year and it is estimated to rise to $800 billion by 2030.

Goal: Need Assessment

Needs to Validate from previous Interviews:

1. **<u>Current Data collection:</u> Snapshot (discreet) vs Continuous and Subjective vs Objective:**
    a. Another problem is doctors are forced to make decisions based upon snapshot data, which is less accurate than the continuous (supposedly, perfect) data. Making decisions based on snapshot data also increases work for doctors as it increases the capital spent on organizing short follow up meetings.
    b. The reason why it is more work for doctors due to snapshot data is, to classify if the condition of the patient is worsening or relieving, doctors have to capture the data in different time periods (which is usually on weekly basis) in order to make it continuous which helps in understanding the nature of that data well. But this increases the time period between when the patient approaches and when the patient is properly diagnosed.
2. **<u>Preventive Needs:</u>** Current systems for cardiovascular diseases are treatment based and not preventative. A lot of costs driven from the hospital systems are not spent on preventing the disease, but on the treatment and keeping them alive with interventions and medications. Patients approach doctors very late and a lot of damage is already done to the heart (which is irreversible) and the heart is not functioning and pumping properly. This is called heart failure. Because of this, patients keep coming back to hospitals in need of more and more interventions, in need of additional therapists, sometimes new hearts, and other devices or supplements to keep themselves alive. This causes a lot of severe extra cost to the healthcare systems.

1. What does the current CAD symptom monitoring system in the industry look like?
    a. What are the common symptoms and their affiliated causes?
    b. What all types of diagnostic techniques are used?
        i. Technology?
    c. How reliable is this current system of monitoring and diagnosis?

2. If we plan to go with such a track of implementing a real time monitoring system for recording changes, who do you think will be our primary users? Will it be doctors or patients?

3. How do existing monitoring systems connect with the diagnosis for a presented patient? Following from that, how do you think we should approach the integration of our remote and real time monitoring system to this existing framework?
    a. According to your expertise, What sort of relationship users will share with this technology?
4. What are criterias upon which a patient should be admitted?
    a. Usually what are the types of procedures done when they are admitted? Invasive or non-invasive ones?
5. What are criterias upon which a patient should be readmitted?

6. What departments, teams and people are involved within a healthcare institution that make purchasing decisions and adopting new technologies?
7. Will the hospital buy a product just if it saves patient lives? Will healthcare institutions benefit from it? If not, what other incentives are the healthcare institutions currently looking for?

Towards the end of the interview, try to extract potential solutions based on:

- **AI + Data + IoT possible Solutions.**
- **Prevent lower risk patients to develop into higher risk patients.**

Finally,

1. What should we have asked you?
2. Who are some of the other professionals you suggest that we should contact regarding our hypotheses?

*Some of the questions can be tailored according to the person we are interviewing and the flow of the conversation

Data collected from the Interview process

Data is one of two main types: Quantitative or qualitative. The names partially give away what these data types are and what they mean. Quantitative data is data collected from the study's counting and measuring in terms of numbers (Devin Pickell, 2019). The data we collect is not going to be quantitative in nature.

Qualitative data on the other hand is not so methodic and linear. It is analogous to a liquid phase when compared to quantitative data. Qualitative data is expressed through terms, descriptors that describe the quality of the subject of the study (Devin Pickell, 2019). Relevant to our IQP, the quantitative data we will be collecting is the advice of the interviewees and possible paths that emerge from that. We plan to present the data in a more concise manner by transcription.

Given the unusual nature of the collected data, the analysis process is a little different than we initially expected. By transcribing the interviews, we can see particular threads or topics emerge more often than others and then move on accordingly. Topics that are expansive codes are ones that represent important answers to our hypotheses. From these hypotheses, we will be able to gain facts and maneuver accordingly.