ANALYZING CARDIAC MEDICAL DEVICE FAILURES WITH A MACHINE LEARNING APPROACH

By

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ABSTRACT

Background: Cardiovascular disease is a prominent burden on modern day society. A wide variety of medical devices have been necessary in the treatment and therapy of disease that affect the cardiovascular system. Despite the ubiquitous nature of these devices, limited research exists regarding patient safety and device failure. The US Food and Drug Administration collects medical device data but the problem codes assigned to events as well as data integrity are problematic means of understanding the device failures and patient outcomes.

Methods: Supervised machine learning and data filtering methods were used to create tags and identify cardiac medical device failures that were related to: migration, extrusion and expulsion between 1997 and 2017. The results were then used to analyze patient outcomes.

Results: Approximately 20% to 21% of cardiac devices were identified from the base dataset, and of that .69% pertained to migrations, extrusions and expulsions. When evaluating results of cardiac and non-cardiac devices, injury was the most frequently occurring adverse outcome of the three failures. Death was an uncommon outcome in cardiac and non-cardiac failures, resulting in low percentages. Statistical significance between cardiac and non-cardiac injury was found. The problem codes associated with records as well as names for devices were unreliable within the realm of this research.

Conclusions: Cardiac medical devices account for approximately 20% to 21% of overall medical device events reported to the FDA each year. The risk of injury for medical device failures are high, and data would be more useful for research if accessible and accurate.

ACKNOWLEDGEMENTS

I began my educational journey in 2005, when I was simply unsure about how to approach this thing called "life." I enrolled in courses and discovered a passion for learning and a commitment to complete what I start. Back then, I had little idea where the road will lead, but I knew deep within that I would be ok, if I just continued ahead on the path. So, I pressed forward. The road has been a difficult one-full of personal disappointments, sacrifices and epiphanies about who I am as a person and what I can truly offer the world. But, here I am, nearing the completion and the only way I can describe this feeling now is "bittersweet."

I am grateful for my dissertation committee in providing guidance, feedback and patience during this part of my academic journey. I appreciated the honest and helpful advice that kept my aspirations and plans grounded while in this program. I have been empowered and confident in conducting research regardless of where my career takes me. I have connected with other students also enrolled in the Biomedical Informatics program that have offered words of hope, encouragement and perspective

A very special thanks to my husband, parents, and extended family for providing support as I worked on this project. There were days in which I personally felt I was unable to be the attentive wife and daughter-in law I wanted to be, yet I was allowed the space to focus on this endeavor. Having your unwavering support was priceless and I will always remember the kindness and love that you have shown me. I would also like to acknowledge James Lenglade, the man whom raised me until losing his battle with lung cancer in 1988. Thank you for being a true father to me.

To my husband and best friend Mike,

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Chapter I

I. INTRODUCTION

1.1 Statement

Medical devices, which are also referred to as medical technology, consists of a wide range of applications and potential usages. This large domain plays a very important role in the delivery of healthcare to patients. It consists of instruments, machines or apparatuses that aid in various aspects of healthcare such as, but not limited to: prevention, diagnosis, treatment, therapy, monitoring, correction or management of a disease or illness.

Although medical devices are immensely useful in healthcare, they are not without risk of failure. For medical devices that are implanted into the body, the risk of expulsion, extrusion or migration remains and can vary depending upon the device, medical condition and past medical history of the patient, as well as timing of the procedure to implant the device and the placement of the device. When a device migrates within the body, is exposed in anyway, or is expelled from the body, there is potential that this failure causes harm to the patient. A device manufacturer would need to know this and determine if this device is safe for use by the public. There was a point in history in which the use of certain medical devices carried a very high risk to patients, coupled with

less regulation. In our current age, there is improved technology overall, which includes computing that aids in data collection and tracking, which results in improved processes to ensure the device is safe for public use and mandatory federal oversight.

There is a lack of existing medical device safety research outside treatment relating to select areas. This research would like to address device expulsion, extrusion and migration relating specifically to cardiac devices. What is the frequency of these failures in cardiac medical devices? How harmful are these failures to patients? These questions were addressed in research.

1.2 Background

Exploratory research was first conducted to examine if our initial questions have been answered or if there is currently existing data and/or research that addresses them. The goal is to locate research that addresses medical device expulsion, extrusion and migration in cardiac devices. After review of existing literature and resources it is determined that the current body of research does not adequately answer the proposed questions. There is an abundance of research related to intrauterine devices (IUDs) expulsion and migration, but greatly lacking when related to other types of medical devices. There is a public Food and Drug Administration dataset that appears to have a comprehensive amount of information that should be useful in this research.

In our research, we have found Manufacturer and User Facility Database (MAUDE), answers our initial questions regarding cardiac devices. This database consists of data regarding adverse events involving medical devices, and is part of Food and Drug Administration's requirement to provide surveillance for device malfunctions, injuries or deaths. The database contains downloadable information relating to each reported event,

device involved, pertinent patient information, and narrative text. The MAUDE database has been used in other research and will be addressed in the Literature Review of this research.[1]

The amount of data, robustness, as well as the data organization made it a very appealing and viable option for analysis. Data between years 1997 and 2017 will be utilized in this research to understand the problem domain over a period of time. Upon examination of the data, specific hypotheses were formed, which inspired research into the area. In the following sections, preliminary research approaches will be discussed in further detail.

1.2.1 Exploratory Research

1.2.1.1. Data

The MAUDE data files were downloaded from Food and Drug Administration's website on March 3rd, 2019. The datasets were imported using Python 3.7 within a Jupyter environment. Jupyter is an open-source web application that promotes ease of sharing code and visualizations. This environment was chosen due to the ease of viewing code and visualizations over the project's evolution. Below are the datasets that have been imported for further analysis.

Dataset	**Entails**	**Count of Records**
deviceproblemcodes	List of all problem codes to classify device failures.	939
mdrfoiThru2018	Master list of all events of failures from 1991 to 2018.	7,174,549
mdrfoiChange	Changes to master list event reports.	153,802

foidevproblem	The crosswalk to map problem codes to device failures.	4,801,575
Foidevthru1997	Device data pertaining to failures to 1997.	136,359
Foidev1998	Device data pertaining to failures for 1998.	63,440
Foidev1999	Device data pertaining to failures for 1999.	52,880
Foidev2000	Device data pertaining to failures for 2000.	52,965
Foidev2001	Device data pertaining to failures for 2001.	58,067
Foidev2002	Device data pertaining to failures for 2002.	65,808
Foidev2003	Device data pertaining to failures for 2003.	66,952
Foidev2004	Device data pertaining to failures for 2004.	57,045
Foidev2005	Device data pertaining to failures for 2005.	93,413
Foidev2006	Device data pertaining to failures for 2006.	133,789
Foidev2007	Device data pertaining to failures for 2007.	149,334
Foidev2008	Device data pertaining to failures for 2008.	163,545
Foidev2009	Device data pertaining to failures for 2009.	218,727
Foidev2010	Device data pertaining to failures for 2010.	335,190
Foidev2011	Device data pertaining to failures for 2011.	416,047
Foidev2012	Device data pertaining to failures for 2012.	521,049
Foidev2013	Device data pertaining to failures for 2013.	639,922
Foidev2014	Device data pertaining to failures for 2014.	864,887
Foidev2015	Device data pertaining to failures for 2015.	965,466
Foidev2016	Device data pertaining to failures for 2016.	870,910
Foidev2017	Device data pertaining to failures for 2017.	941,114

foitext1997	Text data on failures for year 1997.	91,008
foitext1998	Text data on failures for year 1998.	68,315
foitext1999	Text data on failures for year 1999.	51,118
foitext2000	Text data on failures for 2000.	52.624
foitext2001	Text data on failures for 2001.	57,985
foitext2002	Text data on failures for 2002.	64,858
foitext2003	Text data on failures for 2003.	66,240
foitext2004	Text data on failures for 2004.	56,116
foitext2005	Text data on failures for 2005.	95,043
foitext2006	Text data on failures for 2006.	177,413
foitext2007	Text data on failures for 2007.	232,626
foitext2008	Text data on failures for 2008.	264,965
foitext2009	Text data on failures for 2009.	387,875
foitext2010	Text data on failures for 2010.	697,250
foitext2011	Text data on failures for 2011.	971,968
foitext2012	Text data on failures for 2012.	1,252,909
foitext2013	Text data on failures for 2013.	1,562,584
foitext2014	Text data on failures for 2014.	1,987,842
foitext2015	Text data on failures for 2015.	2,305,931
foitext2016	Text data on failures for 2016.	2,239,516
foitext2017	Text data on failures for 2017.	2,301,104
foitextChange	Changes and updates to text data files.	350,313
patientThru2018	Patient base file of reported outcomes	7,824,299

	associated with device events through 2018.	
patientChange	Changes and updates to patient base file	153,818

Table 1: Imported MAUDE datasets into Jupyter environment

1.2.1.2 Overall Device Events

There is a total of 7,174,549 records in the Master Record table by year, starting in 1991. Interestingly enough, the reported events have steadily increased every year. The earliest stages of reported events were very low, so this dataset may not be fully representative of the amount of device failures.

Year	Events
1991	15
1992	3,098
1993	4,408
1994	11,272
1995	9,758
1996	32,789
1997	77,691
1998	61,652
1999	52,909
2000	52,570

Year	Events
2001	58,391
2002	69,349
2003	75,971
2004	81,268
2005	98,874
2006	119,513
2007	171,020
2008	193,221
2009	239,974
2010	291,568

Year	Events
2011	410,694
2012	452,552
2013	577,463
2014	635,952
2015	704,106
2016	755,692
2017	903,826
2018	1,028,953
Total	**7,174,549**

Table 2: Total Reported Events by Year

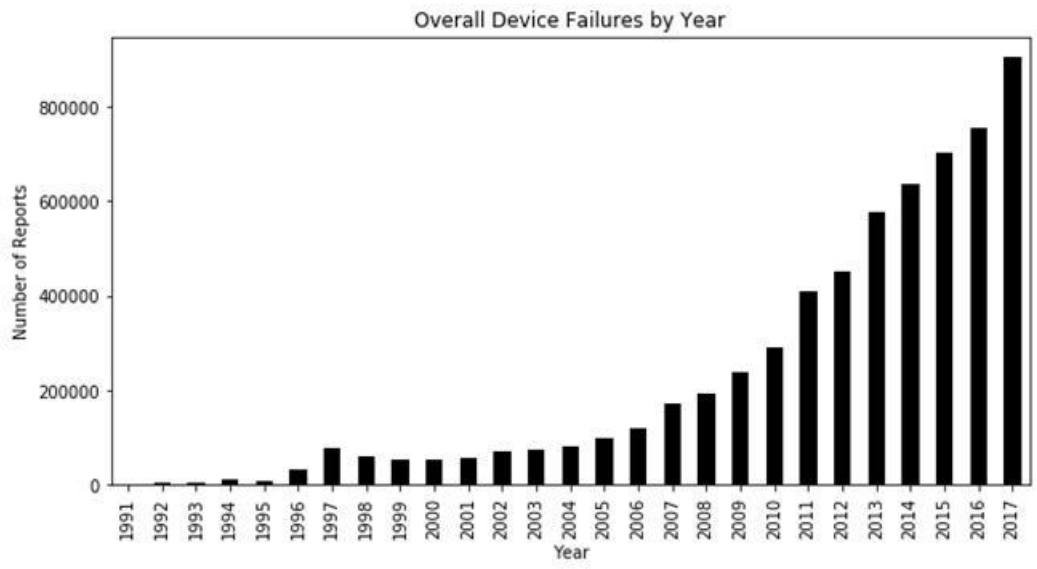

Figure 1: Overall Device Failures by Year

The years of interest for this project are 1997 through 2017, totaling a span of twenty years. During this time period there were 6,084,256 reported events. The theory in choosing this timeframe is this span of time is comprehensive and expansive to produce a statistically significant result as well as providing enough data points for building a robust machine learning model.

Year	Events
1997	77,691
1998	61,652
1999	52,909
2000	52,570
2001	58,391
2002	69,349
2003	75,971
2004	81,268
2005	98,874
2006	119,513
2007	171,020

Year	Events
2008	193,221
2009	239,974
2010	291,568
2011	410,694
2012	452,552
2013	577,463
2014	635,952
2015	704,106
2016	755,692
2017	903,826
Total	**6,084,256**

Table 3: Reported Events by Year Project Subset

1.2.1.3 Cardiac Specific Device Events

In reviewing the data, there are 939 problem codes. Two codes relate to general migration - 1395 and 1203, two describes expulsion-1395 and 2933. Interestingly enough, there are four problem codes to describe extrusion: 2934, 2979, 2618 and 2154. Problem 1203 refers to the migration of electrodes, and is relevant to this research given that cardiac devices routinely involves electrodes for cardiac monitoring.

Device Problem Code	**Problem Description**
1203	Electrode(s), migration of
1395	Migration or Expulsion of Device
2154	Implant extrusion
2618	Extrusion, impending
2933	Expulsion
2934	Extrusion
2979	Material Protrusion/Extrusion

Table 4: Problem Codes Associated with Migration, Expulsion and Extrusion

Within the problem codes mapping dataset crosswalk (foidevproblem), we have identified an initial set that are direct matches with the identified seven problem codes to validate if there are records associated with the codes. After cleaning and pre-processing the data, we were able to produce a combined dataset between several records that identified the number of cardiac records that pertain to the problem codes of interest. We have examined these values as a whole and by year.

Problem Code	Within Cardiac Records
1395	2,956
2933	4
2934	7
2979	89
2618	0
2154	2
1203	6

Table 5: Total Cardiac Device Failures of Interest by Code

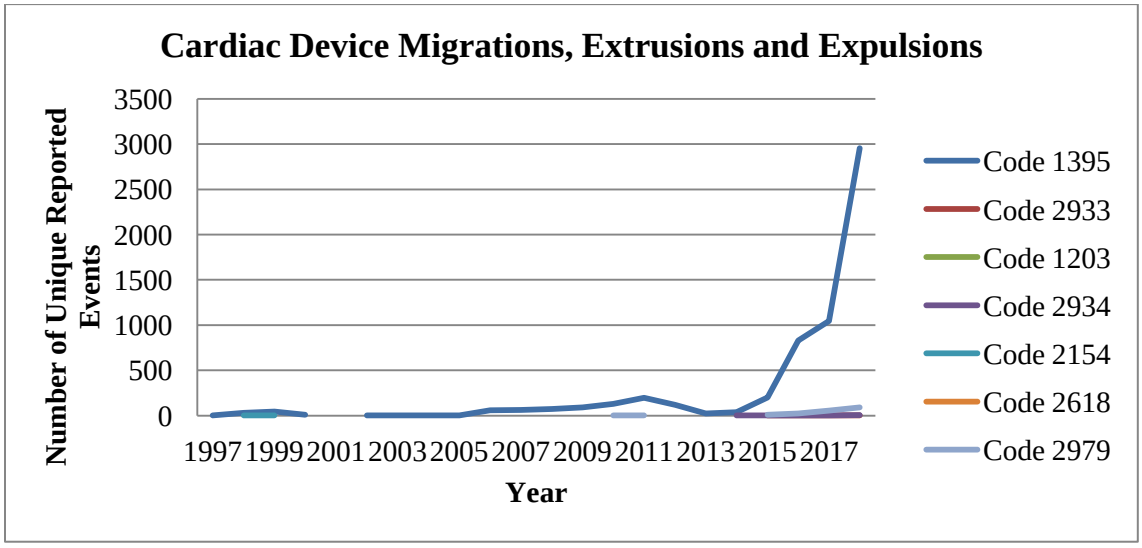

Figure 2: Cardiac Device Migrations, Extrusions and Expulsions by Year

Count of Migration, Extrusion and Expulsion Events by Year							
Year	**Code 1395**	**Code 2933**	**Code 1203**	**Code 2934**	**Code 2154**	**Code 2618**	**Code 2979**
1997	1		1				
1998	30				1		
1999	43				1		
2000	11						
2001			1				
2002	1						
2003	1						
2004	3						
2005	3		1				
2006	58						
2007	61		2				
2008	72						
2009	92		1				
2010	128						1
2011	198						1
2012	119						
2013	23						1
2014	37			1			
2015	200	1		1			8
2016	831	1		2			22
2017	1044	2		3			56
Total	**2,956**	**4**	**6**	**7**	**2**	**0**	**89**

Table 6: Cardiac Device Migration, Expulsions and Extrusions by Year by Code

The distribution between the seven codes by year are highly asymmetrical, due to a lack of reporting. Code 1395 has a far higher number of reported events after 2005. It is difficult to determine if there was a trend with the cardiac device failures, given the sporadic nature in the number of failures. It is interesting to note, that were no reports

found for code 2618. Also, there were no reported events for code 2933 and 2934 prior to 2014. It is very likely that problem codes 2933(expulsion), 2934 and 2618 (extrusion), were newly added codes according to documentation. Equally interesting, is that at the start of reporting there were few reports of failures in general, but towards the end of the period of interest (years 2016 and 2017), reported the highest number of cardiac related migrations, extrusions and expulsions than prior years. This reflects a loose pattern in the overall number of device failures and is likely that reporting and data initiatives greatly improved over time, which thus captured a higher number of failures.

Year	**Cardiac Events**	**Cardiac Migrations, Expulsions and Expulsions**
1997	131	2
1998	4,349	31
1999	5,480	44
2000	4,369	11
2001	1,734	1
2002	1,750	1
2003	1,499	1
2004	2,095	3
2005	2,222	4
2006	9,475	58
2007	12,029	63
2008	12,298	72
2009	16,558	93
2010	20,870	129
2011	24,201	199
2012	12,513	119
2013	3,366	24
2014	12,041	38
2015	22,670	210
2016	53,580	856
2017	94,727	1,105
Total	**317,957**	**3,064**

Table 7: Comparison of Overall Cardiac Device Failures and Cardiac Migration Extrusion and Expulsion Failures by Year

Year	Total Events	Cardiac Expulsions, Migrations and Extrusions
1997	77,691	2
1998	61,652	31
1999	52,909	44
2000	52,570	11
2001	58,391	1
2002	69,349	1
2003	75,971	1
2004	81,268	3
2005	98,874	4
2006	119,513	58
2007	171,020	63
2008	193,221	72
2009	239,974	93
2010	291,568	129
2011	410,694	199
2012	452,552	119
2013	577,463	24
2014	635,952	38
2015	704,106	210
2016	755,692	856
2017	903,826	1,105
Total	**6,084,256**	**3,064**

Table 8: Comparison of Overall Medical Device Failures and Cardiac Migration and Expulsion Failures by Year

Within total device failures as well as total cardiac device failures, cardiac migrations, extrusions and expulsions account for a small percentage of the data. Of the total 317,957 unique cardiac device failures reported from 1997 to 2017, just 1%, or 3,064 were cardiac migrations, extrusions or expulsions. In reviewing the overall 6,084,256 device failures for the time period of interest, only .05%, are the failures of interest. Given these low percentages of reported expulsion, extrusion and migration events, there are concerns regarding the reliability and accuracy of actual failures. Given that cardiac devices account for 5% of all device failures, the result is unexpected. There is a chance that there are truly low reported events with expulsions, extrusions and migrations, but that will be tested with further research.

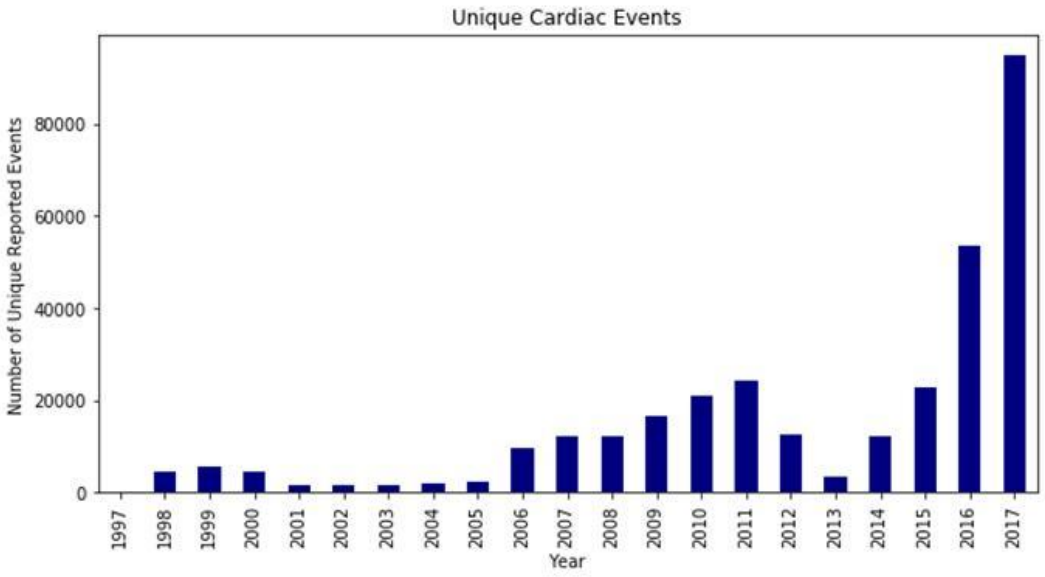

Figure 3: Overall Cardiac Device Failures by Year

1.2.1.4 The Healthcare Cost and Utilization Project (HCUP)

The Healthcare Cost and Utilization Project (HCUP) is a collection of health-related databases and tools through a partnership sponsored by the Agency for Healthcare Research and Quality (AHRQ) .[2] This system provides longitudinal hospital care data and information from across the United States. Using this database, we researched hospitalizations and discharges from 1997 through 2014, using specific ICD-9 CM codes that would be representative of the types of failures of interest. The purpose is to compare MAUDE cardiac device results with another source for validation.

ICD-9 CM	Description
996.00	Mechanical complication of unspecified cardiac device, implant and graft
996.01	Mechanical complication due to cardiac pacemaker (electrode)
996.02	Mechanical complication due to heart valve prosthesis
996.03	Mechanical complication due to coronary bypass graft
996.04	Mechanical complication of automatic implantable cardiac defibrillator
996.09	Other mechanical complication of cardiac device, implant, and graft
996.1	Mechanical complication of other vascular device, implant, and graft
996.72	Other complications due to other cardiac device, implant, and graft
996.74	Other complications due to other vascular device, implant and graft

Table 9: HCUP ICD-9 Codes Associated with Cardiac Implant Malfunctions

In reviewing data from HCUP, there have been a consistent number of cardiac device malfunctions each year, resulting in more than 1 million discharges. From 2001 to 2003 there was an increase in cases, then there was a decrease in 2004. After that point the number of cases found consistency. The results from HCUP far exceed our initial MAUDE cardiac device figures. HCUP data follows a reasonable, consistent pattern, while initial MAUDE results do not follow a similar pattern.

Year	**Cardiac Device Malfunction Discharges**
1997	71,081
1998	69,754
1999	70,026
2000	80,295
2001	103,131
2002	108,167
2003	109,992
2004	92,760
2005	91,086
2006	99,521
2007	90,809
2008	99,504
2009	97,405
2010	88,923
2011	92,324
2012	90,340
2013	84,950
2014	82,480
Total	**1,622,548**

Table 10: HCUP Cardiac Device Malfunction Discharges by Year

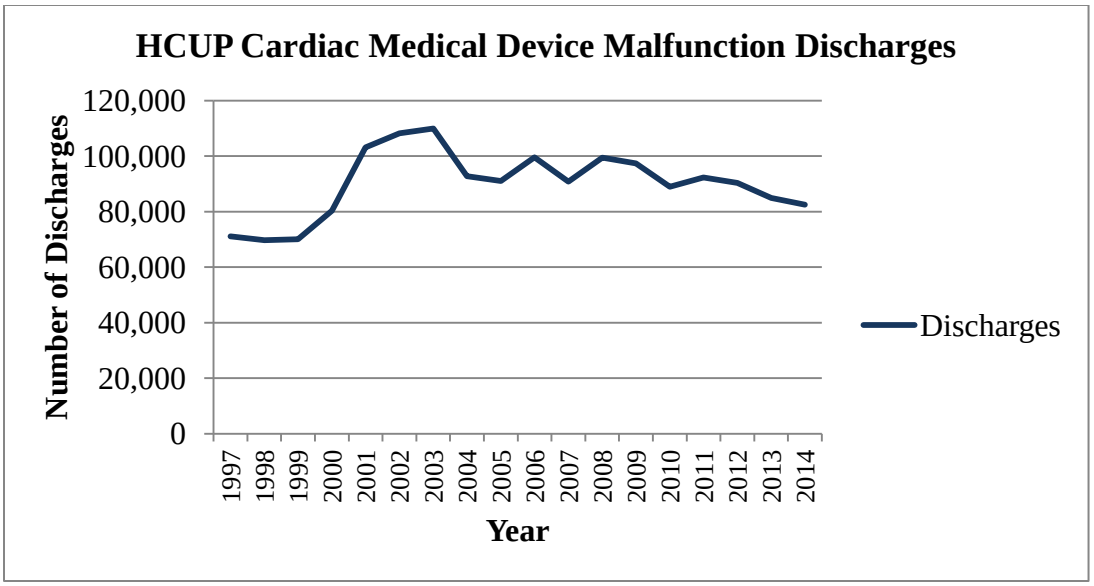

Figure 4: HCUP Cardiac Device Malfunction Discharges by Year

1.3 Initial Findings

The initial research regarding MAUDE datasets has rendered concerns about using the provided problem device codes. Using the designated codes alone has proven to be unreliable, due to the remarkably low reported number of records despite the high number of overall failures. From years 1997 to 2017, there have been an overall 6,084,256 total reported device failures, and of those 317,957 were cardiac device failures. Of those cardiac failures, 1% have been noted to be expulsions, extrusions or migrations based on the codes that pertain to the specific failures. Cardiac device migrations, extrusions and expulsions account for only .05% of the total device failures, which is unexpected due to the size of the dataset and initial assumptions. Although device failures overall have seen steady increases, cardiac devices have not followed an obvious pattern. When researching HCUP data hospitalizations and discharges, there were more than 1 million records related to cardiac device complications, which far exceeds the initial results from MAUDE. From HCUP there were a consistent number of

cases from our sample from 1997 through 2014. Concerning MAUDE, there were several years in which data was not present, or in very low numbers. Given the overall distribution of the dataset, it is surprising to observe years in which there was a lack of reported failures that is consistent among seven distinct problem device codes.

Issues regarding MAUDE problem device coding has suggested that the data may be susceptible to human issues that ultimately lead to a lack of reporting. The MAUDE reporting datasets consists of a mixture of voluntary, user facility, and manufacturer reports. The rigor and process involved in obtaining the data is unknown. Due to the issues regarding the MAUDE problem codes, we will not be able to use them as a reliable classification method of cardiac devices and failures. Unfortunately, there is not a reliable and accurate method of answering initial research questions that exists at this time. However, we have been able to identify another method for the identification and classification of devices that should render favorable results.

In addition to the MAUDE datasets that have been useful in mapping to problem codes, such as device and master events, MAUDE also has available textual files that accompany failures. Upon further examination these textual files, which are specified by each year in which the event occurred, contains useful information regarding events in a narrative format. To further explore the text files, we chose to perform a simple keyword and phrase search to describe migration, extrusion and expulsion. In performing these searches within the column that contains the textual event information, we were able to identify approximately 5,646 events in which there was a cardiac device migration, extrusion or expulsion. This is more than 2,500 devices that were not identified prior.

Based on the promising results and valuable information captured, we will proceed with utilizing the MAUDE textual column as the means to classify cardiac devices extrusions, migrations and expulsions. First, we will identify cardiac devices as done initially with MAUDE device files based on generic device information. Generic device information describes the type of device as a high level means of classification. Next, the goal is to classify migrations, extrusions and expulsions with the textual files in two categories A: a cardiac device migration, extrusion or expulsion, and B: not a cardiac device migration, extrusion or expulsion. After that point, based on the results obtained, it will be likely to answer the proposed research hypotheses.

1.4 Hypotheses

Based upon findings within preliminary research, in addition to the initial research goals, we have identified the following research hypotheses:

I. In the initial research, only a very small percentage of overall device failures are related to cardiac expulsions, migrations and extrusions (.05%). Based upon the lack of reporting and years in which data is unavailable, our assumptions have led us to believe that these results are inaccurate. Our expectation is that a larger percentage of cardiac device failures should include these failures.

II. Cardiac devices are implanted to a relatively high degree in the United States, and based upon the provided data, there has been an increase in general device failures with a strong upward trend, each year. According to the data obtained from HCUP, a consistent number of hospitalizations are related to cardiac device malfunctions each year. Based upon this

information, we expect to identify more cardiac devices than the current 5% we have identified.

III. Cardiac device implantation is considered major surgery, with serious complications if the device malfunctions or fails. Having the device migrate to another area, become partially or fully exposed, or is expelled from the original location may have fatal outcomes for the patient. We hypothesize patient outcomes related to cardiac migrations, extrusions and expulsions to be largely fatal.

1.5 Relevance of Study

This research is relevant and necessary within the greater scientific and medical community due to these key reasons:

There is limited data regarding medical device failures as a whole. From there, there is an even further limited amount of research regarding specific cardiac device failures. Performing research such as this, will aid others while creating a standard for future research about devices. The hope is that this will spur initiatives in creating structure around medical data and information in general that is accurate and reliable. That may mean mandatory reporting requirements from device manufacturers and clinical facilities. Having data that is openly available and structured will allow for more knowledge transfer and analysis to share with the larger community.

Using machine learning and natural language processing in the realm and health and patient outcomes will be useful for not only the scientific and medical community, but for society. Machine learning allows to analyze large amounts of records and make inferences from it, far more than what a human can analyze in the same amount of time.

Clinicians can be able to utilize this information to aid them in decision-making and providing more effective care to patients by being able to understand a problem on a larger scale. In using machine learning, can segue into other approaches that will be useful in understanding health. This research will be a step towards being able to help patients on a larger scale and being able to improve health and lives.

Chapter II

II. LITERATURE REVIEW

2.1 Introduction

Medical devices include a large range and variety of instruments that have a specific purpose relating to health. The United States Food and Drug Administration (FDA) defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: [3]

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)." [3]

The Food and Drug Administration is responsible for ensuring the safety and efficacy of drugs. After the Federal Food Drug and Cosmetics Act of 1976, the responsibility of the Food and Drug Administration was expanded to also include medical devices.[4] During this time, the Federal Food and Drug Administration created a classification system for medical devices based upon their risk of injury to the public. The devices' classification will determine the regulatory process involved in approving the device for the public. Below is the classification system regarding medical devices:

Class	**Risk**
Class I	Low risk of injury or illness. Requires the least number of regulatory requirements.
Class II	Moderate risk of injury or illness. Requires a more rigorous regulatory process than Class I devices, and must demonstrate they will perform as expected.
Class III	High risk of illness or injury. Requires the highest level of pre-market approval required by the FDA, requiring sufficient scientific evidence of safety and efficacy.

Table 11: Medical Device Classification [6]

In order to approve a medical device to be used by the public requires a lengthy process and can represent a succession of iterations of precious devices.[5] There are currently three processes to obtain FDA marketing approval for medical devices. There is a large percentage of Class I devices that qualify for "exempt" status in which the device does not need a proof of safety or efficacy, and can forgo the standard process. However, the manufacturer is required to register their establishment and list their devices with the FDA.[6] The three basic processes are outlines below:

Process	**Description**
Premarket Notification [510(k)]	This submission is required to for any new device in which there is not a presence of a similar device to prove safety and efficacy.
Premarket Approval (PMA)	This application is required of Class III devices to demonstrate safety and efficacy.
Humanitarian Device Exemption (HDE)	This is a marketing application for a Humanitarian Use Device (HUD). "A HUD is defined as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year."

Table 12: FDA Medical Device Approval Processes [6]

A cardiovascular device, or cardiac device, is a medical device that is used to treat diseases and conditions related to the cardiovascular system. The cardiovascular system is composed of the heart and the circulatory system. The goal of the cardiovascular system is to transport oxygen and nutrients to cells while circulating blood throughout the body. Cardiac devices are available in a variety of platforms and apparatuses, and are available to be worn on the outside of the body, as well as implanted in the body. It is important to understand the underlying issue of why patients will require cardiac devices, and the disease or condition they are intended to treat.

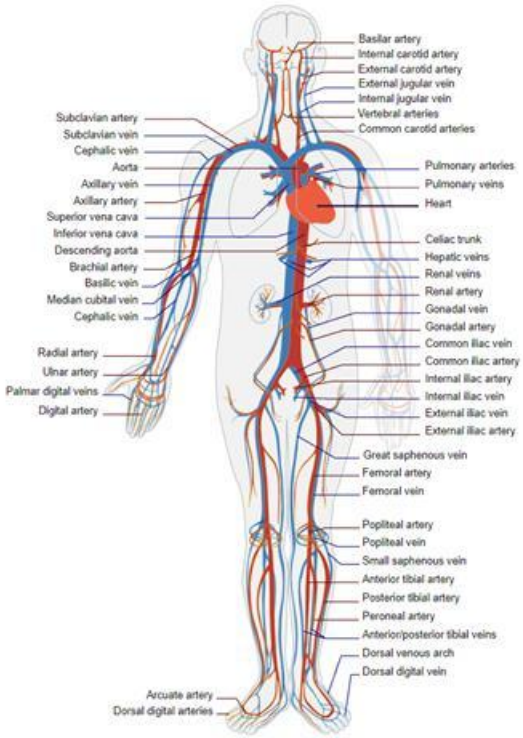

Figure 5: Depiction of The Cardiovascular System [7]

2.2 The Heart

The human heart is one of the first organs to develop and is an essential organ. Weighing at roughly 7 to 13 ounces, the function of the heart is to collect blood from the

body's tissues and pump blood to the lungs.[8] From the lungs the heart pumps blood out to the body. The heart is composed of cardiac muscle and myocardium (muscular heart tissue), and consists of four chambers, which contracts in a steady rhythm know as a heartbeat. The two upper chambers of the heart, can be viewed as the receiving chambers and are the atria, separated into the left and right atrium. The two lower chambers, can be viewed as the pumping chambers, are the left and right ventricles.[9] The division of the right and left side of the heart is to prevent contamination of blood. Deoxygenated blood is collected in the right side of the heart, while oxygenated blood is collected in the left. The heart also consists of four valves that allows blood flow: tricuspid, mitral, pulmonary and aortic.[8,9] The purpose of these valves is to maintain a one-way flow of blood.

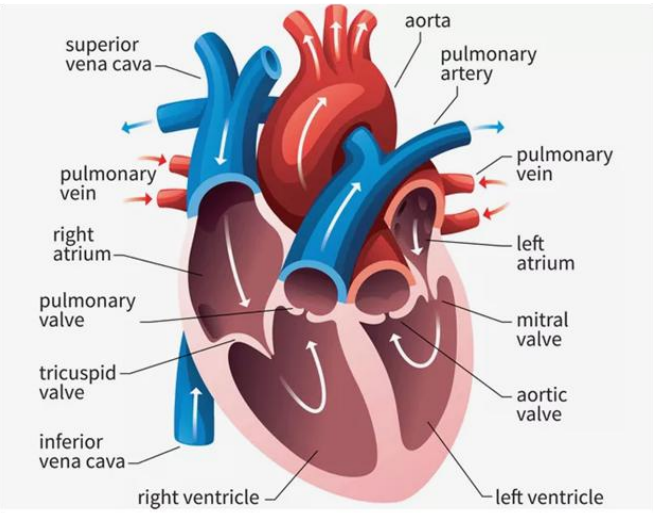

Figure 6: Depiction of Blood Flow to and From the Human Heart [10]

Blood is collected from the tissues through two large veins- the superior vena cava (head, neck and upper limbs), and the inferior vena cava (lower limbs and truck). The deoxygenated blood received from these veins are collected in the right atrium. The blood then exits the right atrium through the tricuspid valve, entering the right ventricle, where

the blood exits through the pulmonary valve. From that point, the blood then enters the pulmonary artery, where the blood is directed to the right and left lungs.[8,9] Oxygenated blood returns from the lungs through the pulmonary veins and enters the left atrium. The blood exits the left atrium through the mitral valve where it enters the left ventricle. At this time, the blood exits the left ventricle through the aortic valve, entering the aortic arch, then the aorta. The purpose of the aorta; the largest artery in the human body, is to distribute oxygenated blood to the rest of the body.

Blood is supplied to the heart by its own vascular system, called coronary circulation. Coronary arteries supply blood to the myocardium (muscular heart tissue) and epicardium (tissue surrounding the heart). In this process, blood flows from the heart through the coronary arteries, and returns back to the heart through cardiac veins. There are eight coronary arteries in the heart: right coronary artery, sinoatrial nodal artery, right marginal artery, posterior descending artery, left coronary artery, left circumflex artery, left marginal artery and left anterior descending artery. Coronary arteries are considered to be end arteries in which they supply blood without overlap from other arteries. A blockage in one of these arteries translates to ischemic damage. There are three major systems of cardiac veins- tributaries of the coronary sinus, anterior cardiac veins and atrial cardiac veins. The coronary sinus is the largest vein of the heart and is a collection of veins that form the sinus: great cardiac vein, middle cardiac vein, small cardiac vein, posterior vein of left ventricle, oblique vein of left atrium, right marginal vein and left marginal vein.

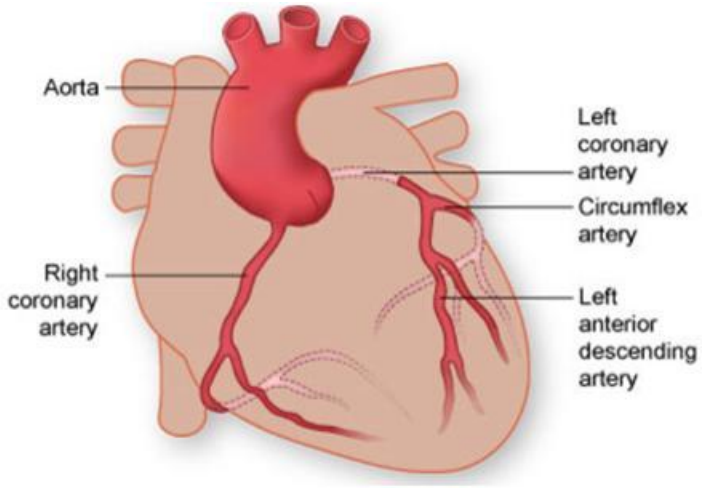

Figure 7: Depiction of Coronary Circulation [11]

2.2.1 Cardiovascular Diseases

Heart disease and cardiovascular disease is often used interchangeably, but cardiovascular disease refers to the numerous conditions that affect the heart, arteries, veins, and capillaries, while heart disease refers to conditions that affect the heart and its functioning. It is important to note, all heart diseases are cardiovascular diseases, but not all cardiovascular diseases are heart diseases.[12]

Cardiovascular disease is the global leading cause of death. In the United States, cardiovascular disease affects 1 in 4 people. The most common disease is coronary heart disease (CHD), and is also known as coronary artery disease (CAD), and is caused by the accumulation of plaque buildup within the coronary arteries. This buildup, is referred to as atherosclerosis, and causes the arteries to narrow, thus decreasing blood flow to the heart.[13] This decrease in blood flow may cause a wide array of symptoms and a blockage can ultimately cause a heart attack, or myocardial infarction.[14]

Another term, which is often used interchangeably to atherosclerosis, is arteriosclerosis. Arteriosclerosis specifically refers to the hardening and thickening of

the arterial walls, ultimately restricting blood flow to the heart and/or other organs. Atherosclerosis is a form of Arteriosclerosis, and both conditions can exist simultaneously. At times, Arteriosclerosis can develop into atherosclerosis, since the two conditions are closely related.[15]

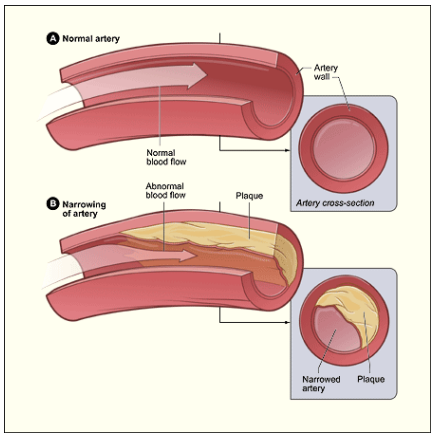

Figure 8: Depiction of Atherosclerosis [13]

The site of the plaque buildup will determine the type of heart disease. For instance, Peripheral artery disease is atherosclerosis of the arteries that provide blood flow to the extremities such as the arms and legs. Reduced blood flow or blockage to these areas may result in various symptoms including but not limited to: numbness, pain, and infections in the extremities.[16] Severe peripheral artery disease that has not been treated can have serious complications such as critical limb ischemia. Critical limb ischemia is defined as tissue loss/gangrene, impaired blood flow and claudication due to peripheral artery disease being present.[17,18,19]

Carotid artery disease is atherosclerosis of the arteries located in the neck (carotid arteries) that provide blood flow to the brain. Decreased blood flow or a blockage may result in stroke.[20]There are three classifications of strokes. Ischemic strokes account for

the majority of strokes and this is the blockage of the arteries that supply blood to the brain. A hemorrhagic stroke is due to a leak or rupture of an artery in the brain. A transient ischemic attack (TIA) is a temporary blockage of blood to the brain, and typically lasts less than 5 minutes. A transient ischemic attack is an indication of a future stroke.[21]

Myocardial Infarction is also known as a heart attack and occurs due to impaired blood flow to the heart.[20] A sudden blockage can be due to a blood clot that has formed in a coronary artery that has been narrowed due to the presence of atherosclerosis. Myocardial infarction can occur without the presence of a blood clot as well, given the demand for oxygen cannot be met with the current supply. A common cause of myocardial infarction is atherosclerosis, and the risk factors for both conditions are nearly identical.

Atrial Fibrillation is a condition that describes irregular heartbeat causing the chambers of the heart to beat differently from one another. This irregularity causes the lower chambers of the heart to not fill entirely or pump enough blood to the lungs and body. The lower chamber of the heart may pool with blood which potentially leads to clotting, stroke or other heart-related conditions that have serious complications if left untreated.[22] Heart arrhythmia is a condition when the heart beats irregularly. This irregularity includes tachycardia (heart beats too rapidly), and bradycardia (heart beats too slowly). Complications may include heart failure, which describes the heart's inability to work efficiently and meet the demands of the body.

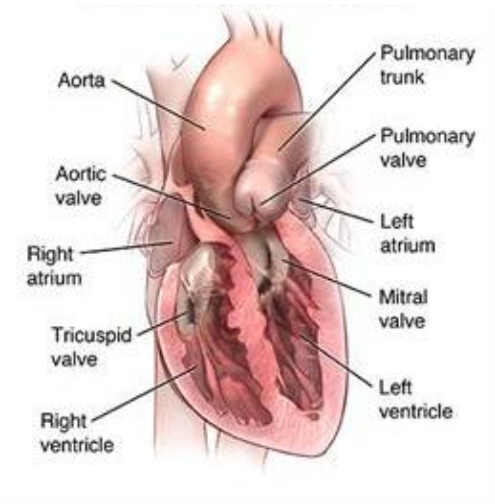

Figure 9: Depiction of The Human Heart [23]

As mentioned above, heart failure is defined as the heart failing to work efficiently. In other words, the heart fails to pump enough blood to meet the demands of the body. Heart failure can affect the left side of the heart, right side, or potentially both. Left sided heart failure involves the left heart ventricle failing to pump enough blood for the body. Right sided heart failure involves the right ventricle failing to pump enough blood for the body and the accumulation of blood in the veins which causes swelling in the body. Biventricular heart failure is defined as both sides of the heart being affected.[24,25]

Congestive heart failure (CHF), is often used interchangeably as heart failure, but The American Heart Association defines congestive heart failure as the heart's inability to pump blood to meet the demands of the body and additionally, "when the heart does not circulate blood normally, the kidneys receive less blood and filter less fluid out of the circulation into the urine. The extra fluid in the circulation builds up in the lungs, the liver, around the eyes, and sometimes in the legs. "This is called fluid "congestion" and for this reason doctors call this congestive heart failure." [26]

Heart valve disease is defined as one or more valves in the heart are not functioning properly. The human heart has four valves: aortic, tricuspid, pulmonary and mitral.[27] Regurgitation occurs when the heart valve does not completely close and blood flows back into the heart. This over time can cause thickening of the left ventricle due to overworking to remove the excess blood and may result in fluid buildup in the lungs. Stenosis occurs when the valve becomes thickened and can restrict or limit blood flow causing a gradual thickening of the heart.

2.2.2 Cardiac Medical Devices

Cardiac disease has at times required surgical intervention and the placement of a medical device. There are various types of devices that address disease and provides therapeutic benefit. Below are examples of cardiac devices that exist today and what they are meant to treat:

Cardiac Device	**Therapeutic Benefit**
Left Ventricular Assist Device	Aids the pumping ability of the heart-eliminating the need for a heart transplant.
Coronary Stent	Widens the artery increasing adequate blood flow to heart, usually performed after a balloon angioplasty.
Pacemaker	Aids in regulating heart rhythm.
Biventricular Pacemaker	Corrects contractions of lower left ventricle.
Implantable Cardioverter Defibrillator (ICD)	Detects heart rhythm and sends a shock to correct rhythm when necessary.
Implantable Cardiac Loop Recorder	Records heart's rhythm to determine source of irregular events.
Cardiac Monitor	Monitors heart activity.
Artificial Valve	Replaces heart valve after dysfunction/disease.
Left Atrial Appendance Closure	Effective for patients with atrial fibrillation to prevent blood clots entering the bloodstream to cause a stroke.

Table 13: Cardiac Devices and Therapeutic Benefit [28,29,30]

2.2.2.1 Coronary Stents

Coronary angioplasty, also called a percutaneous angioplasty, is a procedure to widen restricted arteries. During this procedure, a balloon tipped catheter that is designed to inflate, is inserted into the patient's arm or leg locating the artery. The inflated balloon will to push plaque against the artery's walls to widen the path for blood flow. It is likely that during this procedure, a device called a stent will be placed inside the artery. A stent acts as a prop or structure to keep the artery widened to maintain blood flow. There are stents that have a drug coating on them, called drug eluting stents and are designed to slowly release a drug to deter the formation of scar tissue within the artery.[31,32]

2.2.2.2 Pacemakers

A pacemaker is a device that is placed in the chest or abdomen to control abnormal heart rhythms, or arrhythmias. This device is typically placed after an initial procedure to address the heart's abnormality. Pacemakers monitor heartbeat, and will send electrical signals to the heart to speed or slow down the heart rate depending on the condition. A pacemaker is also useful in ensuring the chambers of the heart are pumping normally as well normal ventricle contraction.[33,34]

2.2.2.3 Left Atrial Appendage Closure Device

A left atrial appendance closure is a procedure performed to seal this area if there is risk of developing blood clots and subsequently suffering a stroke. This procedure is recommended for patients that do not have a valve disease and are unable to take Coumadin, which is a blood thinning prescription. A left atrial appendance closure device is inserted similarly to a stent, and then a narrow tube guides the device to left atrial

appendage of the heart. A relatively new device called the Watchman is giving patients an alternative to life-long medication use.[35,36]

2.2.2.4 Implantable Cardioverter Defibrillator (ICD)

An implantable cardioverter defibrillator (ICD) is a small device that is implanted into the chest to detect deadly arrhythmias and restore heart beat if and when the heart stops, known as cardiac arrest.[37] This device is a recommended option for patients that have survived a prior cardiac arrest, the presence of a condition that causes unpredictable heart rhythms, poor heart functioning and/or sarcoidosis, which is a condition that causes the growth of granulomas (cluster of cells or localized inflammation). An implantable cardioverter defibrillator can be a necessary life saving device. This device will send shocks to the heart to restore normal heart rhythm, or a high energy shock to restore functioning if necessary. Many Implantable cardioverter defibrillators can also act as a pacemaker and monitor the heart.[38,39]

2.2.2.5 Left Ventricular Assist Device (LVAD)

Patients that have experienced heart failure, may have a left ventricular assist device (LVAD) implanted onto their hearts. This device is a mechanical pump that is designed to assist the left ventricle of the heart to pump blood to the body.[40,41,42] It consists of the pump, an outside battery, controller and line to control the pump. This treatment can eliminate the need for a heart transplant for some patients. Other times, a left ventricular assist device is a viable replacement as a patient awaits a heart transplant, in this case this is known as bridge-to-transplantation. Destination therapy is the term for the type of therapy that will benefit patients long term from the use of this device. These patients are not eligible for a heart transplant.[42,43]

2.2.2.6 Heart Valve Surgery

Heart valve surgery encompasses procedures to repair or replace one or more heart valves after being affected by disease or dysfunction. Heart valve repair involves repairing the current valve so that it functions normally, such as covering perforations in a valve, removing excess valve tissue, or separating valve flaps that have merged at some point. If the valve cannot be repaired, it can be replaced by either a mechanical valve or a biological tissue valve based upon the determination of best course of treatment, which varies by patient.[42] Mechanical valves are longer lasting than a tissue valves, however, they will require treatment of blood thinning medications to prevent the formation of blood clots. Biological tissue valves may or may not need blood thinning treatment.[43]

2.2.2.7 Cardiac Monitor

A cardiac monitor simply monitors and captures information regarding the heart rhythm of a patient. This is useful regarding events that may happen infrequently, and/or aid in the process of diagnosing a condition. A cardiac monitor can be implanted into the body or be worn outside the body.[44] The length of monitoring depends on the patient's specific symptoms or condition. A cardiac loop recorder is another type of cardiac monitor that allows for long term monitoring, up to three years.[45]

2.2.3 Cardiac Device Migration, Extrusion and Expulsion

The FDA defines migration as the undesired movement of the device from the original or intended source.[46] Expulsion of a medical device refers to the unintended movement of the device from inside the body to the outside. Extrusion refers to a device that is fully or partially exposed. After research regarding the unintended movement of cardiac devices, the term extrusion was more commonly referred to than expulsion. In cardiac devices,

that require leads or wires that attach to an organ such as the heart, complete expulsion from the body would be unlikely.

In medical devices such as intrauterine devices (IUDs), which are a method of birth control, complete expulsion is possible given that the device is placed inside the uterus, held in place by the frame of the device. There is a thin string that is attached to the device that extends outside of the vagina. The device may be expelled from the uterus for various reasons, or the string that is attached to the device may be unintentionally pulled, subsequently pulling the device out. In the case of a patient with a completely extruded pacemaker, it was noted that this failure is extremely rare and a potentially fatal complication.[47] In a similar case regarding a completely extruded defibrillator, the device migrated under the skin and eventually became exposed. The site of exposure had experienced rare skin erosion and due to an exposed device, infection became present which required treatment and removal of the device.[48]

Device migration is a serious complication of cardiac device implantation, and can lead to other serious complications requiring re-operation. Re-operation is an undesirable result as well as a risk factor in cardiac device implantation.[49] In device migrations, dislodgement with leads (wires that attach to the device for functionality), is likely which poses an additional risk for complications. It has been noted there is a likely relationship between device migrations and infection.

Device infections are associated with morbidity, mortality and increased hospital length of stay. Due to these factors, there is an increased cost associated with device infection.[50] Extraction of the device, proper medication therapy to treat the infection and subsequent device replacement resulted in a more favorable outcome for the patient.[51]

Not properly treating the prior infection and addressing the issues that lead to the initial infection, resulted in an infection relapse or another poor outcome.[51] Relapse is defined as the reoccurrence of the infection with a similar type of organism within one year of treatment of the initial infection.[51]

2.3 Machine Learning

2.3.1 Definition

The application of machine learning has grown exponentially within the past decade due to its potential benefits and uses. The field has progressed from curiosity to widespread practical and commercial use. Many applications and software have a predictive component, and machine learning is now the method of choice for development. One informal definition of machine learning as explained by Mathworks: "Machine learning is a data analytics technique that teaches computers to learn from experience."[52] Another definition of machine learning as explained by IBM is: "Machine learning is a form of artificial intelligence that enables a system to learn from data rather than through explicit programming."[53]

The effects of machine learning can be observed across a range of industries where data is a necessary tool for operation.[54] The concept of learning can be defined as the problem of improving a measure of performance when executing a task, through iterative experience. Experience refers to historical information that is available to the learner (machine learning algorithm), which is generally the form of data and made available for analysis. The goal of machine learning is to make accurate predictions using prior data or experience.[55] As an example, in the case of classifying undesirable unimportant emails (spam), the task is to assign "spam", or "not spam" to any given

email. The performance metric to improve is the accuracy in the spam classifier, and the training dataset will consist of prior emails that have already been classified appropriately.[54]

This research involves machine learning regarding medical devices, which is related to health. Machine learning within healthcare and biomedical communities has seen immense growth and the need for accurate analysis, early disease detection and patient care continues to grow along with population and advances in technology/data usage. Within clinical environments, there is now access to medical data from electronic health records (EHR), and the introduction of various telehealth and telematics paradigms, such as the collection of mobile users' data in real time.[56]

Machine learning is further understood by overarching learning classifications: supervised, unsupervised and semi-supervised. This research will also look to understand natural language processing, which is the ability of the algorithm to understand human language. This research will depend heavily upon textual fields to identify and classify cardiac medical devices.

2.3.2 Supervised Learning

In supervised learning, the learner receives a set of labeled data (known examples), as training input and makes predictions for all unseen data points. The spam detection problem discussed in the previous section is a classic example of supervised learning.[55] Supervised learning can be classified into two major types of problems: classification and regression. In classification, the goal is to predict a class label, which is a choice from presented groups.[57] In classification, at times the case is distinguishing between two classes which is known as binary classification. Classification problems can be compared

to yes/no questions such as, "cardiac device" or "not a cardiac device". In regression, the goal is to predict a value. An example of a regression problem, is to predict the value of a home based upon the square footage.[57] There are various algorithms that are common in supervised learning.

2.3.2.1 Decision Trees

A decision tree is a type of classifier that consist of a collection of decision nodes arranged in a tree structure. This particular algorithm is used in classification and regression problems. Each node is associated with a particular parameter, or a terminal node.[58] A terminal node is also referred to as a leaf. Decision trees are similar to if/else questions, then eventually leading to a decision.[57] Learning in a decision tree is the ability to arrive at the accurate answer, with the least number of if/else questions. A random forest is a collection of decision trees, where each tree is slightly different from one another. A collection of multiple machine learning models are called ensembles, and random forest is a common example.

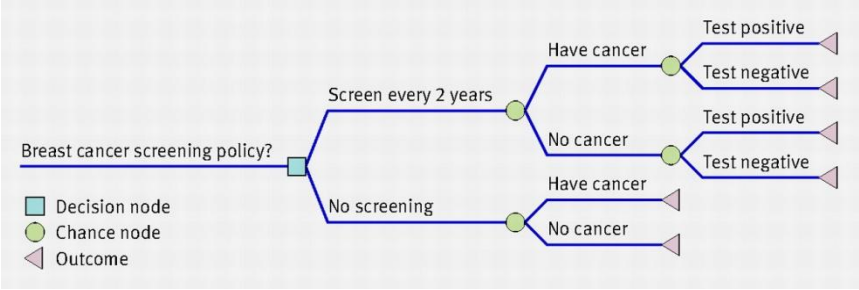

Figure 10: Decision Tree for Breast Cancer Screening Options [59]

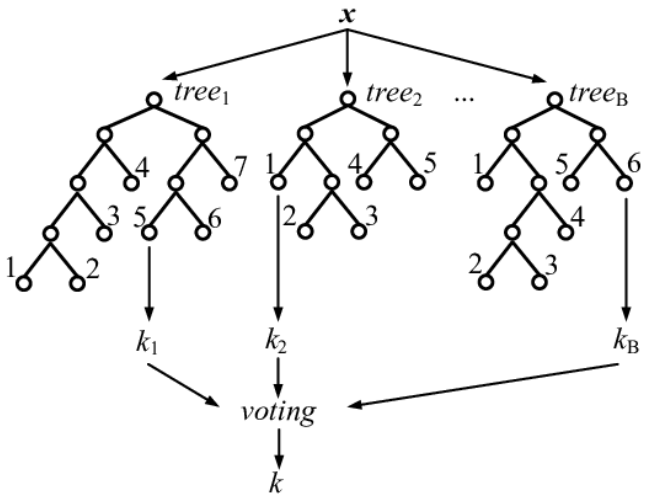

Figure 11: Random Forest [60]

2.3.2.2 Logistic Regression

Logistic regression is an appropriate algorithm when the dependent variable is dichotomous (binary). In contrast, linear regression describes when the dependent variable is continuous. Logistic and linear regression are commonly used for classification tasks. Logistic regression models the chance of an outcome based on individual characteristics.[61] The logarithm of chance will be modeled, given that outcome is ultimately an odds ratio. Below is the algorithm describing this:

$$\log\left(\frac{\pi}{1-\pi}\right) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots \beta_m x_m$$

Equation 1: Logistic Regression

Where π indicates the probability of an event and βi are the regression coefficients associated with the reference group and the xi explanatory variables. What is present is a

binary output variable (Y), and we are interested in modeling the conditional probability Pr(Y = 1|X = x) as a function of x; any unknown parameters in

the function are to be estimated by maximum likelihood. Below is the formal logistic regression equation.[62]

$$\log \frac{p(x)}{1-p(x)} = \beta_0 + x \cdot \beta$$

Equation 2: Formal Logistic Regression Equation

Solving for p results in this:

$$p(x; b, w) = \frac{e^{\beta_0 + x \cdot \beta}}{1 + e^{\beta_0 + x \cdot \beta}} = \frac{1}{1 + e^{-(\beta_0 + x \cdot \beta)}}$$

Equation 3: Solving for P in Logistic Regression

To minimize the error rate (misclassification), we should predict Y = 1 when $p \geq 0.5$ and Y = 0 when $p < 0.5$. This means estimating 1 whenever $\beta 0 + x \beta$ is non-negative, and 0. Ultimately, logistic regression results in a linear classifier.

2.3.2.3 Naive Bayes

Naive Bayes is a probabilistic classifier that originates from Bayes' Theorem. This particular algorithm has been a popular choice for text classification due to its simplicity, ease of use and efficiency. Bayes' Theorem gives the probability of a certain hypothesis, regarding the data. This method of thinking of an event is called diachronic interpretation. This refers to something that is happening over time; changing the probability of the hypotheses over time, as new data is seen.[63]

Bayes' Theorem is described as:

$$p(A|B) = \frac{p(A)\, p(B|A)}{p(B)}$$

Equation 4: Bayes' Theorem [63]

Three distribution models; Bernoulli, multinomial and Poisson models have been incorporated into the Bayesian framework. [64]

2.3.2.4 Support Vector Machines

Support Vector Machines (SVM) is a method for building a classifier. Its goal is to create a decision boundary between dichotomous classes that enables the prediction of labels from one or more feature vectors.[65] In this learning algorithm, only a subset of the training points matters for defining a decision boundary, or hyperplane.[66] These points that reside on the border between the boundaries are called support vectors. For the classification, the SVM finds a maximum margin hyperplane with normal vector w~ that divides the two classes. SVM can be applied to classification or regression problems. The following two figures illustrates this concept:

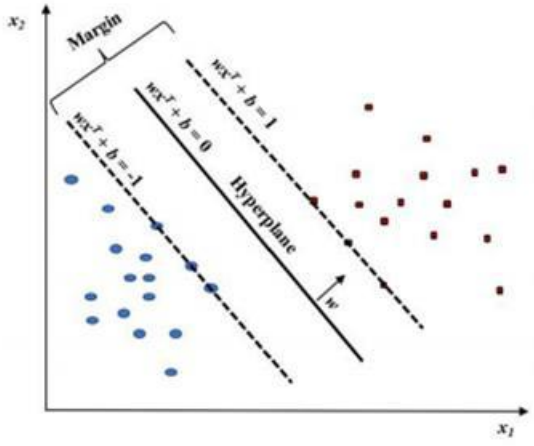

Figure 12: Linear SVM Model with Two Classes [65]

In a labeled dataset, the equation is as follows:

$$(x_1, y_1), ..., (x_n, y_n), x_i \in R^d \text{ and } y_i \in (-1, +1)$$

Equation 5: Support Vector Machines

Regarding this equation, x_i is a feature vector representation and y_i represents class label of a training compound i. The optimal hyperplane can then be defined as:

$$wx^T + b=0$$

Equation 6: Optimal Hyperplane

In this equation, w is the weight vector, x is the input feature vector, and b is the bias. The w and b would satisfy inequalities in the following training set:

$$wx_i^T + b \geq +1 \text{ if } y_i = 1 \; wx_i^T + b \leq -1 \text{ if } y_i = -1$$

Equation 7: Satisfying Inequalities in the Training Set

The objective of training an SVM model is to find the w and b in order for the hyperplane can separate the data and maximize the margin.[65, 66]

2.3.3 Unsupervised Learning

In unsupervised learning, the learner receives unlabeled data (unknown examples), as training input and makes predictions for all unseen data points. Since there are no labeled examples available, it can be difficult to quantitatively evaluate the performance of a

learner. Clustering and dimensionality reduction are example of unsupervised learning problems.[54] Unsupervised learning can be viewed as in a free-form manner being able to find patterns and structure from input data.[66] Two common algorithms within this realm are k-means clustering and principal component analysis.

2.3.3.1 Clustering

Clustering involves separation of the data into groups, aptly named clusters. Clustering algorithms assign a value to each data point indicating the cluster that the point belongs to.[67] K-means clustering is a commonly used clustering algorithm in data science. K-means accomplishes two things: finds the most optimal centroids by first (1) alternating between assigning data points to clusters based on the present centroids and (2) choosing centroids based on the current assignment of data points to clusters. The algorithm finishes its task when there are no longer changes or clusters to assign to. The following is a figure that visualizes assignment of cluster in k-means algorithm.[67]

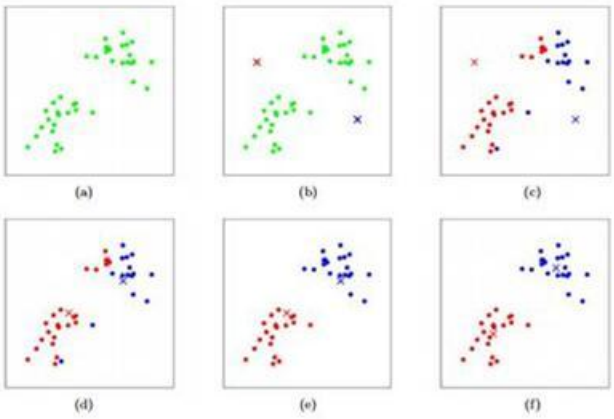

Figure 13: K-Means Algorithm [67]

In figure 13, the training data points are the dots, and cluster centroids are the crosses. Box (a) Is the original dataset. Box (b) Is the random initial cluster centroids. Boxes (c-f) are depictions of two iterations of k-means. In each iteration, each training example was

assigned to the nearest cluster (shown by "painting" the training examples the same color as the cluster centroid to which is assigned); then each cluster centroid was moved to the mean of the points assigned to it.[67]

2.3.3.2 Principal Component Analysis

Principal Component Analysis (PCA), is similar to k-means clustering in that it finds patterns without prior knowledge about whether the samples originate from the same group or distinctively different. [68] PCA reduces dimensions by projecting them to lower dimensions, aptly named principal components. The goal of this task is to find the best summary of data with the points, essentially minimizing the distance and variance identifying clusters of similarity.

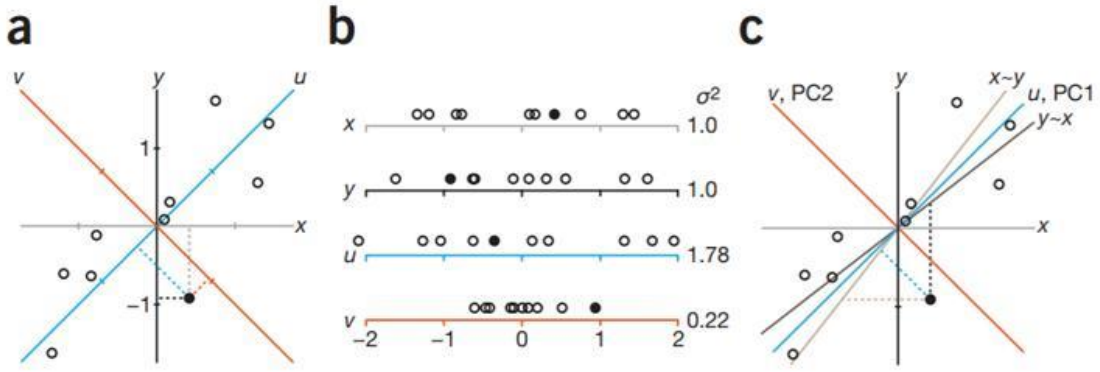

Figure 14: PCA Dimensionality Reduction [68]

In Figure 14, (a) represents projection along a path, which is illustrated with the solid point, (b) represents the projections of points (a) onto a line, (c) the subsequent minimizing of the distances between points. [68]

2.3.4 Reinforcement Learning

This algorithm involves the concept that the training example does not contain the target output, but contains potential output with a measure of the value of that particular output.[64] In other words, the learner is not given the answer, but given choices, and must discover through learning what action provides the greatest reward.[69] A famous example in reinforcement learning is regarding the computer program AlphaGo, a Google creation, that beat a human professional Go player. Go is an ancient East Asian game, thought to have originated in China, that requires skill and strategy and has many possible positions for victory. AlphaGo's first match was against a reigning champion, named Fan Hui, and next was against the 18-time Go champion Lee Se-dol.

2.3.5 Natural Language Processing

Natural language processing (NLP), allows the computer to learn human language. Computational linguistics, and NLP are synonymous as it relates to the subfield of artificial intelligence dedicated to using computational techniques to learn, understand, and produce human language content.[70] Natural languages contain large diverse vocabularies, words with various meanings and speakers with accents. Humans make linguistic errors in writing and speaking, leaving things to be ambiguous and mispronunciations. The skillful of use of language is what makes humans unique. Given the importance of language as well as the complexity of it, is why NLP research is so important. This method of data processing can be useful in healthcare and the medical field in which there are robust text and narrative fields that are typically underutilized. As in our particular research, the textual fields will be utilized in MAUDE to gain more insight about the device failure and the effects on the patient. In a preliminary analysis,

the textual fields revealed information not found in other fields. Traditional NLP has relied upon rule-based processing, which was found to be very labor-intensive due to the necessary constant maintenance as the context and language changes.[71] In modern methods, SVM, Naive Bayes and Convolutional Neural Network (CNNs) algorithms are used to identify and classify text, where the model learn directly from sets of text.

2.3.6 Gradient Descent

In machine learning gradient descent is described as optimization algorithms to adjust parameters with the purpose of finding the minimum of the cost function.[72] In gradient descent, there is a local minimum and a global minimum. A local minimum is the smallest value of the cost function, usually within a particular range, whereas a global minimum spans the entire domain of the function. The cost function also known as the loss function, measures how well the parameters are performing on the training dataset. This function allows the algorithm to minimize the error. The gradient is a vector that directs to the steepest descent, with the length dependent upon the steepness of the gradient. Gradient descent identifies the optimal value and adjusts iteratively.

$$b = a - \partial \nabla F(a)$$

Equation 8: Gradient Descent

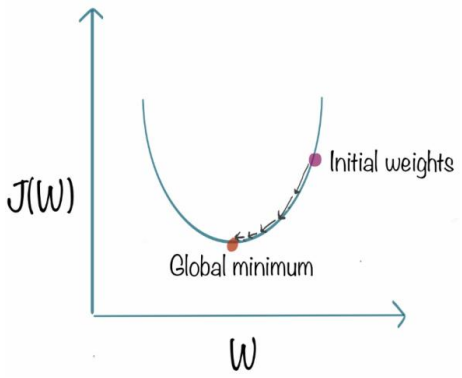

Figure 15: Gradient Descent [72]

2.3.7 Deep Learning

Deep learning is a subset of machine learning that has been inspired by the structure of the human brain. This structure is referred to as an artificial neural network. The fundamental building blocks of deep learning is the perceptron-which refers to a single neuron in a neural network. We live in a data-centric society with far easier access to data. Deep learning algorithms are massively parallelizable and benefits from our modern GPU architecture. Building and deploying deep learning algorithms have become rather simple for the general public, with a worldwide community willing to share methods and information.

Traditional machine learning algorithms typically have defined sets of data, and they work to extract these features as part of their pipeline. Deep learning takes traditional machine learning a step further and learns directly from the data, instead of being hand-engineered from the data professional. Hand-engineering took considerable domain expertise to design the feature extractor that would be able to detect or classify patterns.[73] Deep learning represents a hierarchal model capable of various levels of abstraction. Deep learning has rendered promising results regarding natural language processing, in areas such as topic classification, sentiment analysis and in the translation of languages.[73]

Forward propagation is how the data is “fed” or input through this single unit. This process is the method in which predictions are made.

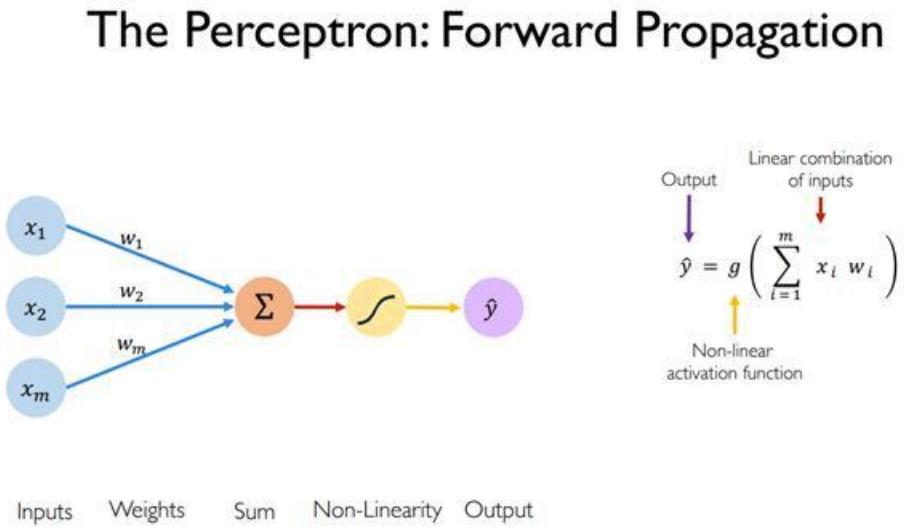

Figure 16: The Perceptron [74]

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A set of inputs are defined X_1 through X_m and multiply each input by corresponding weight 0 through $0_{m,}$ take the weighted combinations of all inputs, sum them and pass through a nonlinear activation function which then produces output ŷ. Bias allows the activation function to shift in some way and is represented by $0_{0.}$ The bias allows the model to find the best fit in the data. The activation function is represented by g and is always nonlinear. Activation functions introduce nonlinearities into the network, establishing flexibility for a wider variety of boundaries. Using a linear function with nonlinear data, the resulting output will only be linear. This can lead to data points being misclassified. There are different types of activation functions to consider. The sigmoid function is the commonly used to produce probability outputs.

$$\phi(x) = \frac{1}{1+e^{-x}}$$

Equation 9: Sigmoid Function

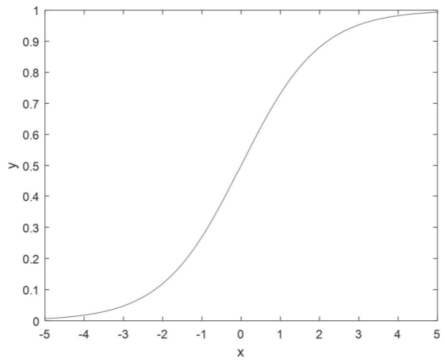

Figure 17: Sigmoid Function [75]

$$\phi(x) = \tanh(x) = \frac{e^{x} - e^{-x}}{e^{x} + e^{-x}}$$

Equation 10: Hyperbolic Tangent

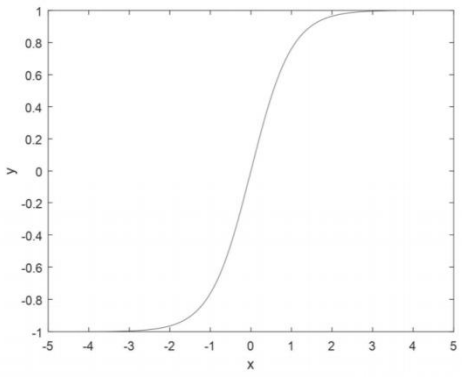

Figure 18: Hyperbolic Tangent [75]

$$\phi(x) = \max(0, x)$$

Equation 11: ReLU

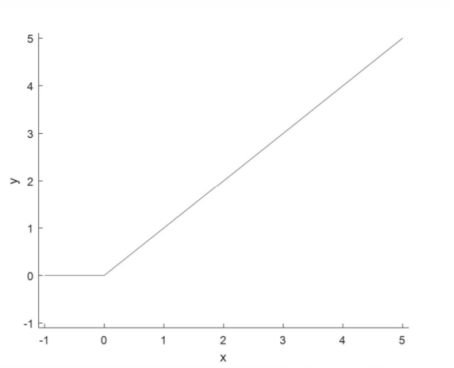

Figure 19: Rectified Linear Unit (ReLU) [75]

In order to train neural networks, stochastic gradient descent is widely used. Previously gradient descent was described as an algorithm to find the minimum in the loss function. Stochastic gradient descent is a variation of gradient descent in which the gradient is computed using a single training example. This method is computationally less expensive than traditional gradient descent which computes gradient for each data point. However, one issue is that stochastic gradient descent can be "noisy", consisting of irrelevant data points, and may not be representative of the true gradient.[73] A solution to this issue is to use "mini batches" or smaller segments of the data, and compute average gradient across data points and to use those as estimates of the true gradient. This method parallelizes computation and achieves significant speed allowing for faster training. Another benefit is larger learning rates and smoother convergence. The mini batch method can render overall favorable results over stochastic gradient descent.

Backpropagation is the tool gradient descent uses to calculate the loss in the loss function. Once there are outputs generated from the forward propagation process, the loss then gets calculated for said output. Then gradient descent updates the weights with the purpose of minimizing loss. This is in a sense working "backward" through the network to find these values. Backpropagation are the partial derivatives of the error function with respect to individual weights in the network to use in gradient descent. Backpropagation applies the chain rule through all possible paths in network.

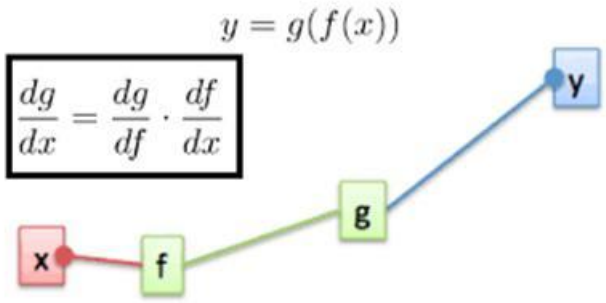

Figure 20: Chain Rule [76]

As mentioned previously, sigmoid functions have been popular activation functions due to their ability to produce easily understandable outputs between zero and one. Outputs are not zero centered, which can make gradient of weights either positive or negative. If a local gradient is small, it can lead to vanishing gradients, which occurs the more layers that are added to the neural network and as the gradients of the loss function approaches zero. Hyperbolic tangent functions produce a zero centered output between one and negative one. This function can also suffer from vanishing gradients. Rectified linear units (ReLU), produces an output that is less than zero when X is zero, and linear with a slope of one when X is greater than zero. ReLU learns faster and more efficiently

and avoids vanishing gradient problem. Because of this, ReLU is becoming a popular choice for neural networks.

A single layer neural network, is a shallow, one-layer deep network. The hidden layers are not directly observable. A deep neural network is to stack fully connected layers and the weights between layers. The underlying building block remains the perception. Multi-output perceptions describe every node being connected to every node in another layer.

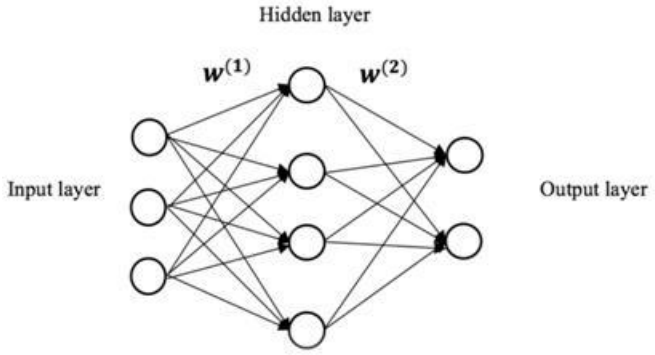

Figure 21: Single Layer Neural Network [77]

2.3.7.1 Convolutional Neural Networks

Convolutional Neural Networks (CNN), have been used primarily for image processing, but has shown promise in other data analysis. This is a neural network designed to process data that are in array format.[73] CNNs are comprised of hidden layers and pooling layers. The hidden layers, called convolutional layers, can receive input, transforms the input, and then output to the next layer. Units in a convolutional layer are organized in feature maps, connected to local patches in the feature maps of the previous layers a set of weights called a filter bank.[73] Within each convolutional layer, this is where specification of filters are determined.

The filters are the backbone to the layer, in which patterns are able to be detected from data. A filter can be described a matrix, with a determined number of rows and columns and the values within the matrix are initialized with random values. When the convolutional layer receives input, based upon the filter, the filter will "slide" over each set of pixels until it has viewed every block of data from the image, for example. The input plane receives data that are relatively normal sized and centered.[78] This process of moving over the data or sliding, is referred to as convolving, or a convolution operation. After the filter has convolved the entire input of data, there will be a new representation of the input, which will be made up the entire matrix of stored dot product returned from the filter.

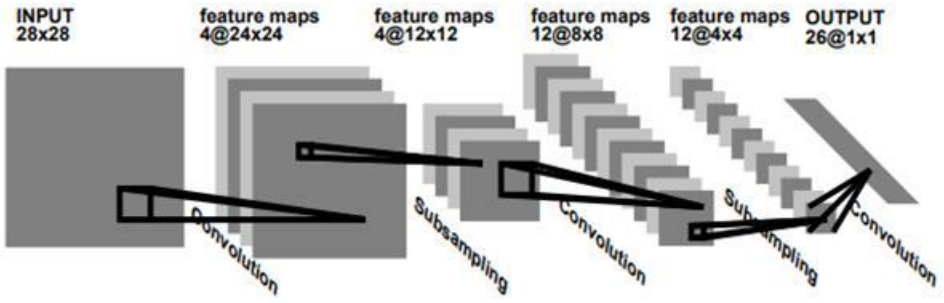

Figure 22: Convolutional Neural Network in Image Processing [78]

2.3.7.2 Recurrent Neural Networks

A Recurrent Neural Network (RNN), is the output becoming the input for the network. This is particularly useful for sequenced data, that varies in size, such as speech or audio. This neural network can be described as a linear map. Each step in the neural network is dependent upon the output the previous step's output.[79] RNNs have shown to be problematic during training due to backpropagated units grow or shrink during each time

step, so during several iterations, they may either explode or simply vanish.[73] In order to address this issue, Long Short Term Memory Model (LSTM), can be used which is a gating mechanism. This is used to maintain and update the states of the model outside of normal execution flow. Within an LTSM memory unit consists of an information cell, and three gates: keep gate, read gate and write gate. The write gate, or input gate is responsible for writing data into the memory cell. The read gate, also known as the output gate is responsible reading data from the information cell and sending that back to the RNN as input. The keep gate, also known as the forget gate, maintains or deletes data from the information cell. By manipulating these gates, an RNN can remember only what is useful. These functions are similar to a neuron in a neural network. They are multiplicative, sigmoid activated nodes. LTSM networks have proven to be more effective that RNNs when there are several layers at each step enabling for deeper recognition of data.

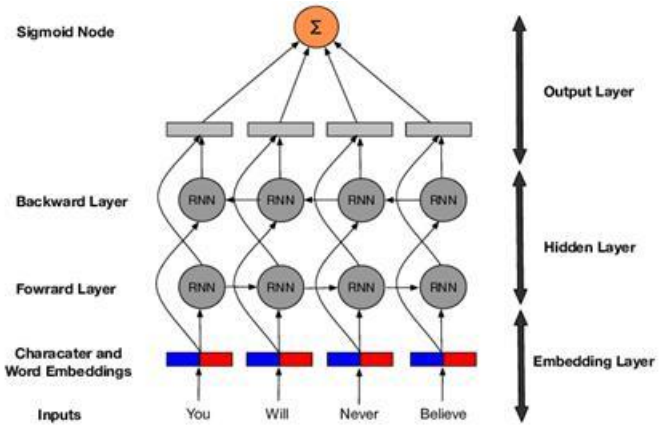

Figure 23: Recurrent Neural Network in Clickbait Detection [79]

Figure 22 conveys the RNN architecture used for the detection of clickbait, which are internet ads that are designed to gain the attention of the viewer and at times leading to

disingenuous websites. The architecture consists of an embedding layer, hidden layer and an output layer. The embedding layer transforms the word into embedded features that can be input into the hidden layer. The hidden layer is where the RNN resides, and the output layer is where the data learned from the RNN is passed through and classified as either "clickbait", or "not clickbait." [79]

Chapter III

III. METHODS

3.1 Introduction

There are three goals associated with this research:

Goal 1: To identify cardiac medical devices.

Goal 2: To identify cardiac device failures: expulsion, extrusion and migration.

Goal 3: To identify patient outcomes associated with device failures.

In order to identify cardiac medical devices, and subsequently classify the particular failures of interest within the 13 million records of narrative text, we have used a supervised machine learning method. Using the device failure reports contained in the Manufacturer and User Facility Device Experience (MAUDE) dataset, events were categorized into positive or negative classes, denoting records of interest versus records that are not of interest. The process of developing models began with algorithm and approach selection, then proceeded to model training and tuning, leading to evaluation of results. Results were evaluated through data visualization, statistical measures and manual reviews. Initial data preprocessing and exploratory analysis will be performed

within a Python Jupyter environment, and subsequent machine learning performed within a Microsoft Azure Machine Learning environment. This is an interactive, virtual environment designed to create and deploy machine learning models.

3.2 Identification

It was essential to address this research in various steps with two methods to evaluate model performance. Research Goals 1 through 3 was addressed by way of two approaches: first with a Naive Bayes classifier, and second with a Decision Tree classifier.

3.2.1 Classes

In order to classify the records for a model that is both simplistic and effective in nature, it was necessary to classify each report of cardiac medical device failures from MAUDE into a negative or positive class.

For identification of cardiac devices:

1. **Class One***: cardiac device*
2. **Class Two***: non-cardiac device*

For the identification of the three distinct failures, the identified cardiac devices were categorized into three classes:

Extrusion

1. **Class One***: extrusion*
2. **Class Two***: non-extrusion*

Expulsion

1. **Class One***: expulsion*
2. **Class Two***: non-expulsion*

Migration

1. **Class One***: migration*
2. **Class Two***: non-migration*

3.2.2 Data

Data for this research was obtained through the U.S. Food and Drug Administration's website, as described in section 1.2.1.1. The first step of this process was exploratory data analysis, in which the variables of interest were carefully analyzed for appropriateness for this research. The files were extracted as text files from the website and stored in a Jupyter environment for analysis. Data encompassing a twenty-year span (1997-2017) was of interest, reasoning being to find the most statistically significant result as possible and to observe device failures over a period of time. A twenty-year span of time would have the capacity to render reliable results, and given the size of the dataset, would not suffer from a lack of data. Lastly, a larger dataset would allow for more options in research approaches and a wider variety of machine learning algorithms.

Originally, four sets of files were joined to create the foundation file to be used for machine learning models and consisted of: device failure codes, narrative text files, master record of device failures and device information. Upon evaluation after merging these four datasets on a unique key, it was clear that incorporating the problem device codes of interest relating to device migration, extrusion and expulsion greatly limited the

foundational dataset. Given that it has been determined that the problem device codes are not a sufficient representation to the extent of failures, they were excluded after the initial exploratory analysis. Excluding these codes resulted in a dataset that represented the large breadth of the original master file and will be more representative of the true extent of cardiac medical device failures. There can be multiple text files associated with a record, resulting in a 1:M relationship. The following table represents a tabulation of unique key values as well as non-unique.

Unique MDR_REPORT_KEY			*Non-Unique MDR_REPORT_KEY*	
Year	**Count**		**Year**	**Count**
1997	74,769		1997	88,952
1998	60,123		1998	67,340
1999	50,985		1999	52,365
2000	50,761		2000	52,586
2001	57,180		2001	59,712
2002	67,728		2002	71,776
2003	73,205		2003	78,122
2004	78,034		2004	89,526
2005	97,233		2005	109,298
2006	117,571		2006	164,384
2007	158,166		2007	281,729
2008	174,180		2008	321,324
2009	217,779		2009	427,646
2010	280,022		2010	615,603
2011	410,388		2011	971,106

2012	451,624		2012	1,096,668
2013	576,720		2013	1,406,995
2014	632,178		2014	1,448,863
2015	698,810		2015	1,712,872
2016	755,005		2016	1,960,366
2017	898,961		2017	2,255,884
Total	**5,981,422**		**Total**	**13,333,117**

Table 14: Narrative Text Files

3.2.2.1 Data Fields

MAUDE files consist of pipe delimited values. Each record is associated with an MDR_REPORT_KEY, which is the unique key from which the records were joined upon across various datasets. In order to understand if an adverse event occurred, the ADVERSE_EVENT_FLAG specifies a value of either a "Y' for yes, or an "N" for no. In tracking outcomes such as a serious injury, malfunction or fatality, the EVENT_TYPE field was utilized. The caveat in using this value is that the REPORT_SOURCE_CODE must be an "M", the value for a manufacturer report. In order to classify each device, the GENERIC_NAME was used as a filter method. To determine the type of cardiac device failure, the contents in FOI_TEXT was most useful in this task. When the information about the type of device was unavailable within the generic name field, the contents in FOI_TEXT was meaningful in extracting that information.

Field	Entails
MDR_REPORT_KEY	Unique identifier for each record. This field was used as the unique key in order to associate records across datasets.
REPORT_SOURCE_CODE	Used to denote the source of the report.
REPORT_NUMBER	Report number for each record. A report number may be associated with more than one failure.
DATE_RECEIVED	Date report was received.
ADVERSE_EVENT_FLAG	This field indicates if an adverse event occurred. Y = Yes N = No U = Unknown * = No answer provided
EVENT_TYPE	This relates to the outcome. Only relevant for REPORT_SOURCE_TYPE =M. D = Death IN = Injury IL = Injury IJ = Injury M = Malfunction O = Other * = No answer provided
FOI_TEXT	Narrative text field containing information regarding the event.
GENERIC_NAME	The generic name of the device involved in the failure. This field will be used to classify the cardiac devices.

Table 15: MAUDE Fields

3.2.3 Textual Preprocessing

To prepare the fields for analysis, textual preprocessing was performed as an initial step. To simplify analysis, all fields were converted to strings. The fields that were denoted as text, were normalized as uppercase input. In textual analysis, when string fields have differing input (such as lower case and upper case), the input will be recognized as unique, even in the case of the word being identical-such as cardiac and

CARDIAC. Leading and trailing whitespaces were removed from FOI_TEXT and GENERIC_NAME, as well as special characters and punctuation by way of a python regular expression function.

As mentioned in section 3.2.2, there can be multiple textual records associated with one MDR_REPORT_KEY, resulting in a 1:M association. A single device can experience multiple events or failures, and of varying types. For purposes of developing a machine learning methodology that results in the best potential outcome, it is best practice to have one textual record to be associated with one unique key. This technique will be useful for the classifier to correctly identify the cardiac device, as well as determining the failures of interest: extrusion, expulsion and migration. If there are multiple textual records associated with one unique key, it may be difficult for the algorithm to determine the true nature of the device; as the algorithm will likely view each separate record as a unique event, rather than an identical device with a different failure type. In order to solve the issue, the textual files were concatenated into one record and joined on the corresponding unique key. This resulted in an extended textual column devoid of punctuation and a 1:1 association.

A list of more than 200 cardiac-related terms were used as reference in order to designate a subset of the data. In order to train a supervised learning classifier, the algorithm requires a set of labeled examples to learn from, in order to estimate labels for unseen data. These labeled examples consisted of both known cardiac devices, designated with a 1, as well as known non-cardiac devices, designated with a 0. In total, the subset consisted of 1,000,000 labeled examples-randomly selected non-cardiac and randomly selected cardiac designations. This value is approximately the equivalent to 18% of the

total number of records used in this research, after the data was normalized and combined in preparation for analysis, referenced in section 3.2.2, table 12. The reason why a larger number of records were selected for labeling is due to the necessity to include as much data as possible to return an acceptable result depending upon the data analysis approach. The records that were not used in the initial set will be used for validation.

Upon separating the data into two distinct groups, it was apparent there were differences between them. The sizes of the groups were unequal (there were more non-cardiac devices than cardiac). Analyzing the subsets in both partially and fully labeled devices, the differences remain that there were more non-cardiac devices present within the MAUDE dataset.

Cardiac Devices	Non-Cardiac Devices	**Total**
1,183,941	4,448,315	**5,632,256**

Table 16: MAUDE Cardiac and Non-Cardiac Device Counts

Cardiac Device Count (Unique)	Non-Cardiac Device Count (Unique)	**Total**
17,673	119,544	**137,217**

Table 17: MAUDE Cardiac and Non-Cardiac Unique Device Counts

Fully labeled cardiac devices account for more than 20% of the overall MAUDE dataset, with 80% belonging to non-cardiac devices. This outcome was to be expected. In reviewing unique device counts, there are fewer uniquely labeled cardiac devices than in the non-cardiac device group due to the popular usage of certain cardiac devices. Performing a manual review of the top 20 largest devices among both groups, the outcome was as expected, with that the most common devices were listed.

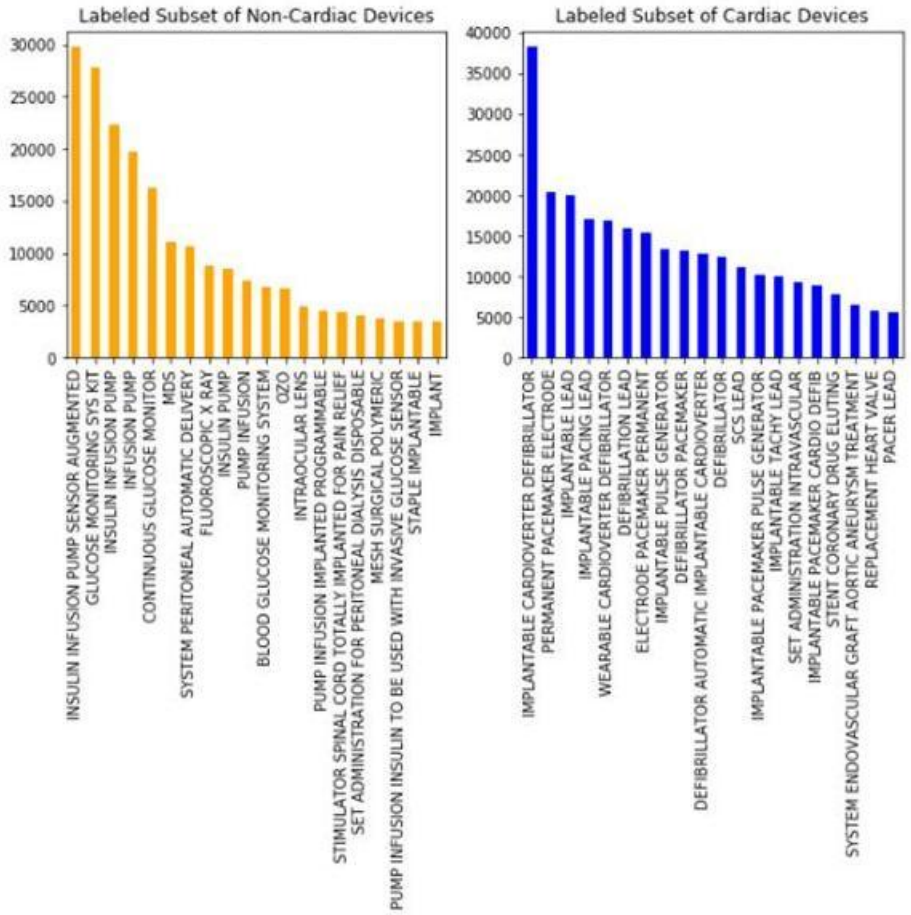

Figure 24: Labeled Device Groups

3.2.4 Classifier

In selecting a classifier, several different algorithms were considered to determine their performance in their ability to identify cardiac devices. We took an experimental process approach to observe various models' output, and ultimately chose the model with the best performance.

Naive Bayes

This algorithm was chosen as the baseline model due to its simplicity, and prior examples of uses for textual analysis. The Naive Bayes classifier is based on the assumption that all features are independent of one another.[80] This algorithm, based upon Bayes' Rule, is a conditional probability model based upon X to predict the variable Y. To revisit the section 2.3.2.3, Bayes' Theorem stipulates that:

$$\Pr(X = x|Y = y) = \frac{\Pr(\mathrm{Y} = \mathrm{y}|\mathrm{X} = \mathrm{x})\Pr(\mathrm{X} = \mathrm{x})}{\mathrm{dx}\Pr(\mathrm{Y} = \mathrm{y})}$$

Equation 12: Bayes' Rule

Decision Trees

Decision trees, can be useful in textual and sentiment analysis, with many examples of this particular type of analysis. This algorithm was chosen due to its simplicity and ability to work with textual data of this format. As mentioned in section 2.3.2.1, this algorithm is similar to if/else questions, leading to a decision. In this case, there are two classes: a positive cardiac device, and a negative non-cardiac device. Based upon the textual column, the algorithm would arrive at the correct option.

3.2.5 Bias

Bias is an important aspect in machine learning. A model is said to have low bias when it predicts well on the training data. High bias is when the model does poorly on the training data, which is known as underfitting. High bias is also known as high variance, which describes the variance of error of the model due to sensitivity in small variations in the dataset. When a model underfits, it can be attributed to the model being too simplistic

for the data, or the features chosen for the model are not appropriate. Overfitting, on the other hand, is due to the classifier learning the training data very well, but is simply memorizing rather than learning, thus predicting poorly on the test data set, which leads to poor predictions. An overfitting model can be attributed to a model that is too complex for the data, or there are too many features in comparison to the number of training examples.

3.2.6 Training Data Generation

Feature engineering is the process of converting data into numeric elements. In order to classify the devices and failures, a numeric value needed to be assigned to them as a labeling method for the algorithm to recognize. It was imperative to first be mindful of the questions this research was looking to answer and to choose features that would be most appropriate. We are looking for a variable to be stored in X, which is the input variable, which will be used to predict Y. In this case, the text columns, GENERIC_NAME and FOI_TEXT are the inputs, and the Y will be created and either a 0 or 1 will be stored as the output. The 0 or 1 represents either positive or negative-cardiac device or non-cardiac device, or failure of interest, or not the failure of interest. This relationship can be described mathematically as:

$$Y = f(X)$$

Equation 13: Learning a Function

The algorithm will learn the relationship between the X and Y and apply that relationship to classify unseen data. So, we should be able to input into the algorithm devices not before mentioned and it should fairly accurately predict whether it is a cardiac device or

not. Similar result for a migration, expulsion or extrusion case. The features that were most appropriate in this work was:

Classification of Devices:

X: GENERIC_NAME

Y: 0, 1

Classification of Migration, Expulsion and Extrusion Failures:

X: FOI_TEXT

Y: 0,1

Training data is imperative for the model to learn patterns from the data. The model did not have appropriate labeled examples, therefore, they needed to be generated. To revisit section 3.2.3, GENERIC_NAME is the column in which the common device name was stored. Using the common name of the device and comparing it against a 200+ list of cardiac terms, the device was labeled with a 1 (positive class), or 0 (negative class). An empty column named CARDIAC was created to store the value. Any device name that did not meet the list of cardiac terms, were deemed as non-cardiac and stored in a separate dataframe. The python code below demonstrates the method in which labeling was conducted.

```
cardiac_set=twenty_years[twenty_years['GENERIC_NAME'].str.contains('|'.join(terms_list))==True]

#select a random sample of 500,000 records, label as 1
cardiac= cardiac_set.sample(n=500000, random_state=0) #Does not produce additional random set when running the data
cardiac['CARDIAC'] = '1'

non_cardiac_set=twenty_years[twenty_years['GENERIC_NAME'].str.contains('|'.join(terms_list))==False]

#select a random sample of 500,000 records, label as 0
non_cardiac= non_cardiac_set.sample(n=500000, random_state=0) #Does not produce additional random set when running the data
non_cardiac['CARDIAC'] = '0'
```

Figure 25: Python Code for Labeling Cardiac Devices

349,166 null value of GENERIC_NAME records were omitted from the base dataset, which left a remaining count of 5,632,256 records for analysis. In total, 18% of the overall data was labeled with a 1 or 0, at 1,000,000 records. The unlabeled device records are for the purpose of testing and validation.

A similar method was employed for labeling the three types of device failures: expulsion, extrusion and migration. FOI_TEXT contained narrative text that was key to the type of failures that occurred during that particular event. Three empty columns were created in order to store the positive and negative class of 0 or 1 pertaining to each failure. Using a string pattern match, those records that were positive matches were classified as belonging to that failure. The failures were split into cardiac and non-cardiac groups for better understanding of the data. Below are examples of the code used to identify and label migration failures as well as the end result.

```
migrate=cardiac[cardiac['FOI_TEXT'].str.contains('MIGRATED|DID MIGRATE|MIGRATION|MIGRATING', na=False)]
non_cardiac_migrate=non_cardiac[non_cardiac['FOI_TEXT'].str.contains('MIGRATED|DID MIGRATE|MIGRATION|MIGRATING', na=False)]
migrate['MIGRATION']='1'
migrate[['EXPULSION','EXTRUSION']]='0'
non_cardiac_migrate['MIGRATION']='1'
non_cardiac_migrate[['EXPULSION', 'EXTRUSION']]='0'
```

Figure 26: Python Code for Labeling Migration Failures

FOI_TEXT	GENERIC_NAME	CARDIAC	MIGRATION	EXPULSION	EXTRUSION
DEVICE 1 OF 2 REFERENCE MFR REPORT 1627487 201...	SCS LEAD	1	1	0	0

Figure 27: Labeled Migration Example

Labeling the three specific failures rendered different results from labeling the types of devices. There was a total of 14,486 records that belonged to the three groups. However, when analyzing the failures pertaining specifically to cardiac devices greatly reduced the subset to 8,851 records. The number of records for expulsion were especially low; with 267 preliminary identified records, which will be challenging for a machine learning algorithm.

The normalized datasets were extracted from python in the form of text files and imported to a Microsoft Azure Machine Learning environment.

1. Training/Testing

The training and testing dataset contained the 1,000,000 labeled device records for the classifier-500,000 positive and 500,000 negative as well as 4,632,256 unlabeled records.

2. Failures

The Failures dataset contained 14,486 labeled examples using narrative text to identify cardiac device migration, expulsion and extrusion.

3.2.6.1 Feature Extraction

Both the Naive Bayes and Decision Tree Analysis models relied upon tokenization and vectorization in order to normalize and transform the text into features for use by the

algorithms. Tokenization is the process in which the text can be separated into smaller pieces of information so that the machine learning can identify the input. Vectorization converts text in a document to a matrix. In the Microsoft Azure environment, this was represented by Preprocess Text step.

3.2.6.2 Pipeline

The Naive Bayes model was first established with a pipeline. The purpose of a pipeline is an organized set of steps to train a machine learning model. First was an instantiated Naive Bayes algorithm, expressed as MultinomialNB() in python. This step simply takes a class and creates an object that can be used.

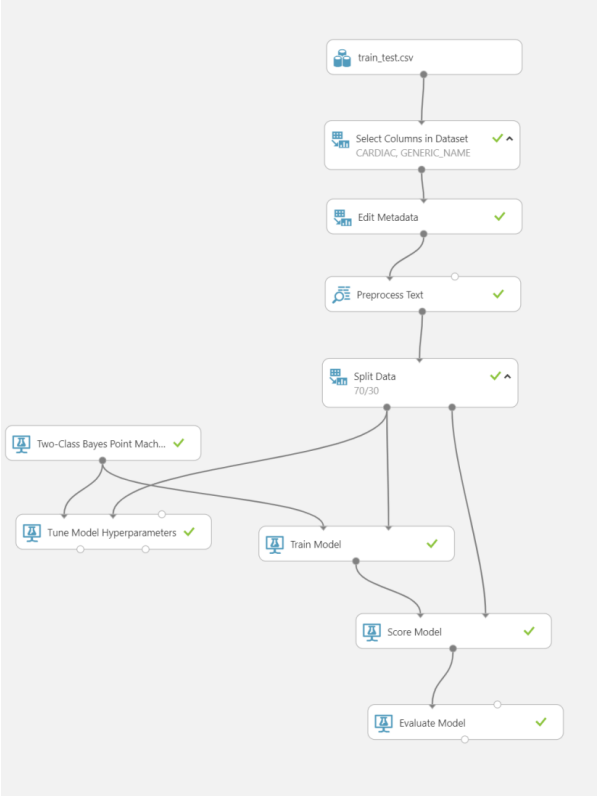

Figure 28: Microsoft Naive Bayes Machine Learning Model

3.2.7 Model Training

The Naive Bayes algorithm was used as the initial model for classification of devices and failures. A decision tree model was the validation model. The main data was split into training and testing sets, at 70% training (3,942,579 records), and 30% testing (1,689,677 records). The failures dataset followed a similar method, with a 70% training (10,140 records) and 30% testing ratio (4,346 records).

3.2.8 Hyperparameter Tuning

Hyperparameter tuning was completed once the initial model had been developed and the results observed. This step is to further optimize the model and improve its performance. This step is always necessary when creating machine learning algorithms.

3.2.9. Model Scoring

The Classification Summary Report is produced after the machine learning model has been trained, and as a means to assess the model. Each element of the report is explored below.

Precision

Precision is the ratio of correct positive predictions in relation to the overall number of predictions. [81]

$$Precision = \frac{True\ Positive}{True\ Positive + False\ Positive}$$

Equation 14: Precision

Recall

Recall is the ratio of correct positive predictions to the overall positive examples available within the data.[81]

$$Recall = \frac{True\ Positive}{True\ Positive + False\ Negative}$$

Equation 15: Recall

F1-score

In statistical analysis this score represents the overall measure of a model's accuracy, that is a combination of precision and recall. This measure is what is usually referenced in assessing the performance of a machine learning model, but it is not meant to be the sole point of assessment.

$$F1 = 2 * \frac{Precision * Recall}{Precision + Recall}$$

Equation 16: F1 Score

Accuracy

Accuracy is defined as the number of correctly classified examples in relation to the total number of examples.

$$Accuracy = \frac{True\ Positive + True\ Negative}{True\ Positive + True\ Negative + False\ Positive + False\ Negative}$$

Equation 17: Accuracy

3.3 Outcomes

In reviewing patient outcomes, the goal is to come to a conclusion about the injury the failure had upon the patient. There are three groups that were analyzed once the cardiac devices were identified, in the context of a positive (cardiac) and negative (non-cardiac group:

Extrusion

1. **Class One***: extrusion*
2. **Class Two***: non-extrusion*

Expulsion

1. **Class One***: expulsion*
2. **Class Two***: non-expulsion*

Migration

1. **Class One***: migration*
2. **Class Two***: non-migration*

There were 8,851 cardiac device records that belonged to the three failures of interest. The vast majority of the failures belonged to the migration group, with extrusion being second largest and expulsion being last. In order to determine the effect on the patient, a combination of statistical and manual analyses was performed to further understand outcomes. Frequency of event types were observed within each group: death, injury, malfunction and unknown/other. A chi-squared test was performed to compare the results of each device failure between cardiac and non-cardiac groups. The hypothesis is that there is a statistical difference between the cardiac and non-cardiac group in one or more failures. As mentioned in section 3.2.2.1 only REPORT_SOURCE_TYPE =M were considered when determining outcomes as per MAUDE documentation.

	Extrusion	Expulsion	Migration	Grand Total
Cardiac	1,721	79	7,051	**8,851**
Non-Cardiac	1,812	188	3,635	**5,635**
Total	**3,533**	**267**	**10,686**	**14,486**

Table 18: Number of Cardiac and Non-Cardiac Migrations, Extrusions and Expulsions Failures

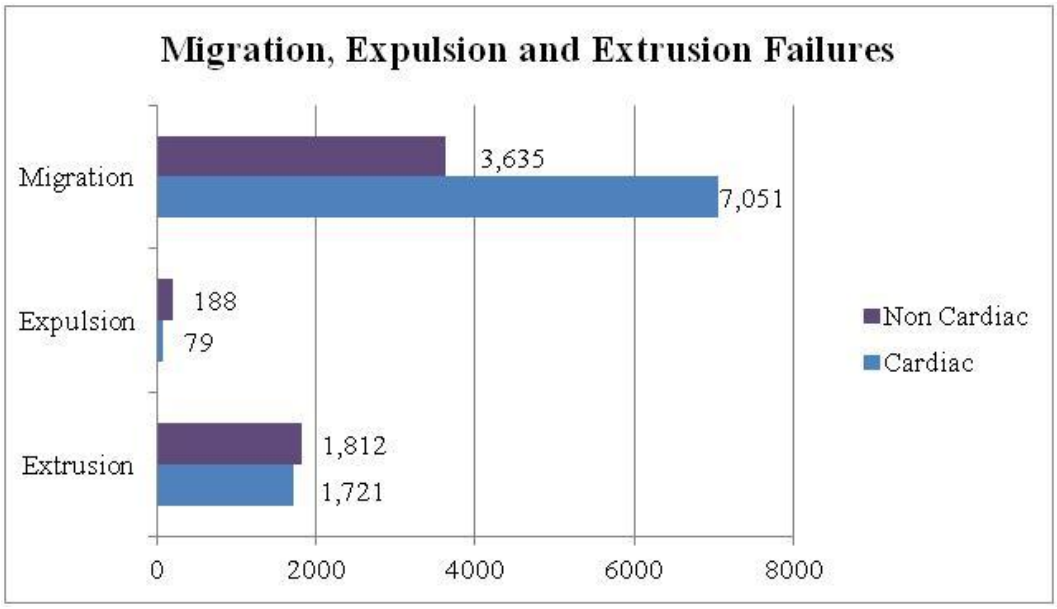

Figure 29: Number of Cardiac and Non-Cardiac Migrations, Extrusions and Expulsions Failures

Chapter IV

IV. RESULTS

4.1 Introduction

The machine learning text classification was performed and 21% of the testing set was identified as cardiac devices (349,776 records). These cardiac devices were then associated to narrative records to analyze failures of migration, expulsion and extrusion. There were more than 14,486 positive cases relating to these three failures, and within the realm of cardiac devices specifically, there were 8,851 identified records. The largest percentage of the cardiac device failures belong to migration, second to extrusion and lastly to expulsion. Unique cardiac device failures within the migration group belonged to certain devices, mostly pertaining to stents and leads.

In our initial findings in section 1.3, cardiac medical device failures accounted for a very small percent of the overall data, at just 5%, and the failures of interest accounted for .05%. Currently, within the machine learning test set combined with pattern string matching, cardiac device failures have consistently accounted for more than 20% of the

overall device data (15% increase). We have proven our initial hypothesis from section 1.4 to be correct as a larger percentage of cardiac devices were identified. This result more closely resembled cardiac device hospitalization discharge data from HCUP. Within HCUP data for select years, cardiac device discharges were no less than 80,000 per year on average. The specific failures interest, account for .69% of identified cardiac devices and .14% of overall devices. The low percentages of migration, expulsion and extrusion represent the rare nature of these occurrences or perhaps that these types of failures were likely not identified in a consistent manner within the textual notes explored.

4.2 Machine Learning Outcomes

4.2.1 Identification of Cardiac Devices

To identify cardiac medical devices, a Naive Bayes and Decision Tree model were used. Naive Bayes outperformed Decision Tree on nearly every measure. In evaluating the initial untuned results from each algorithm, Decision Tree performed especially poorly on the identification of actual cardiac devices within the testing set, which resulted in a 56.7% accuracy score. In stark contrast, Naive Bayes untuned model results performed exceptionally well, resulting in the trained model identifying the pattern, with a relatively low number of mistakes. The accuracy, recall and F1 scores were all in the high 90% range. When manually reviewing results from the scored test set, many of the devices were correctly labeled. Due to these results Naive Bayes was also used in order to identify the three cardiac device failures of interest.

Figure 30: Naive Bayes Model Output

Figure 31: Decision Tree Model Output

4.2.2 Identification of Cardiac Device Failures

Once the cardiac devices had been identified through an acceptable model, the task of identifying the failures of interest was performed. Naive Bayes performed well in the identification of cardiac device migration, but was unable to render similar results among expulsion and extrusion. The most likely reason for the poor results was there was not enough labeled data points within each failure category to train the model. Migration had the most examples within the dataset within a total of 10,686 of cardiac and non-cardiac records. Expulsion had the least with just 267 identified cardiac and non-cardiac records. The results are a direct reflection of the amount of data presented to the model.

True Positive	False Negative	Accuracy	Precision
3063	137	0.937	0.957
False Positive	True Negative	Recall	F1 Score
137	1009	0.957	0.957
Positive Label	Negative Label		
1	0		

Figure 32: Migration Device Failures

True Positive	False Negative	Accuracy	Precision
7	1064	0.727	0.055
False Positive	True Negative	Recall	F1 Score
121	3154	0.007	0.012
Positive Label	Negative Label		
1	0		

Figure 33: Extrusion Device Failures

True Positive	False Negative	Accuracy	Precision
0	75	0.980	0.000
False Positive	True Negative	Recall	F1 Score
14	4257	0.000	0.000
Positive Label	Negative Label		
1	0		

Figure 34: Expulsion Device Failures

4.3 Common Cardiac Devices

In observing the most frequently occurring cardiac devices, it was apparent that there were many identical devices and devices that served a similar purpose, but were identified as being unique due to variations in their labels. It is clear that the most common device among the three groups are coronary stents. The migration group also

contains devices related to spinal cord leads in error, due to the naming convention being similar to cardiac leads.

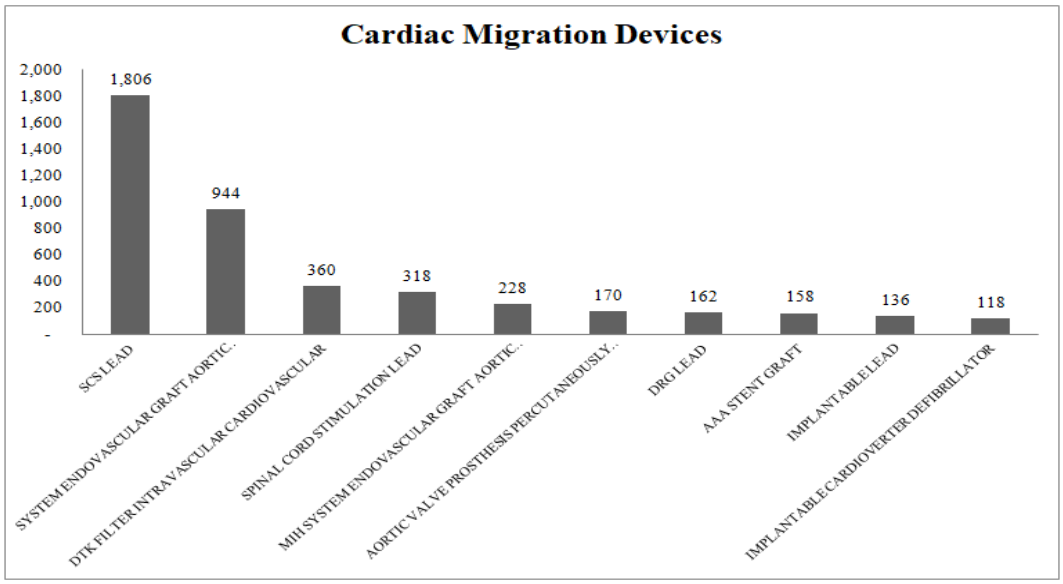

Figure 35: Migration Failures Common Devices

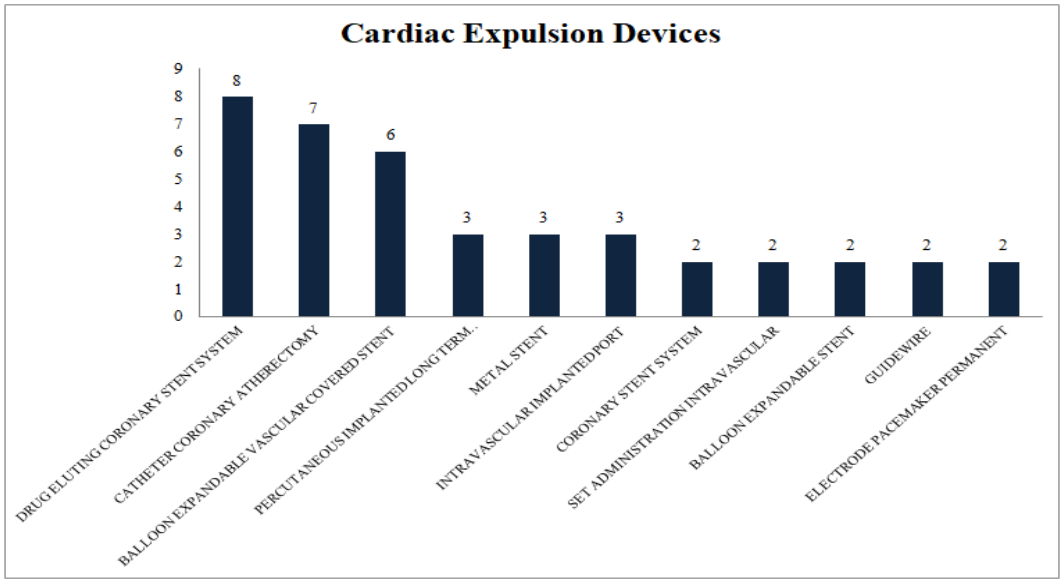

Figure 36: Expulsion Failures Common Devices

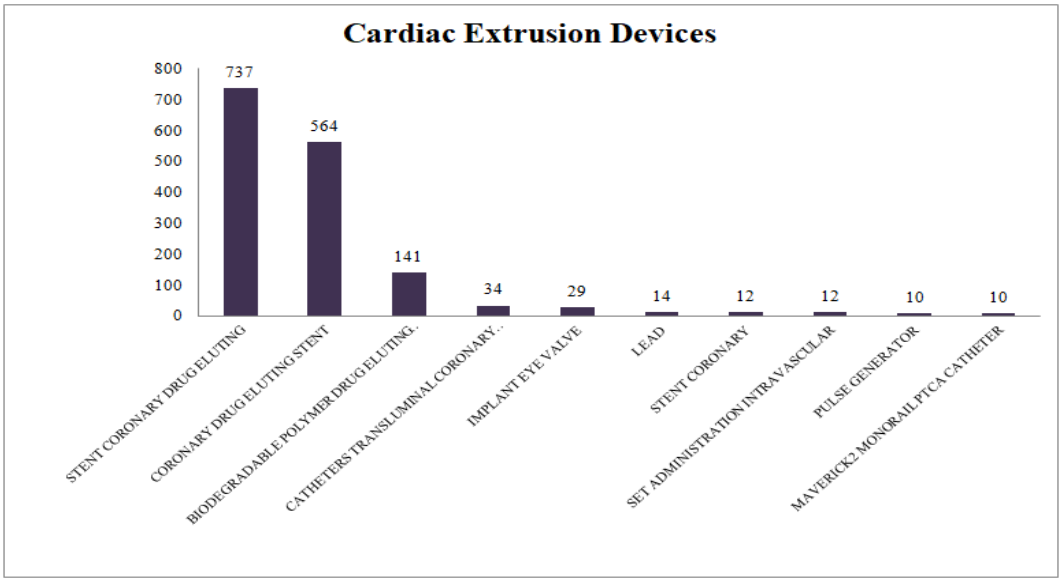

Figure 37: Extrusion Failures Common Devices

4.4 Patient Outcomes

Injury was the most common outcome within the three failure groups and between cardiac and non-cardiac. Expulsion has proven to be a rare failure overall, with a total of 267 total identified records. The percentages reflect the rare nature of this failure from our analysis. To revisit our hypotheses from section 1.4, it was theorized that device failures of this nature would be largely fatal; that has not been proven with our analyses. The results were analyzed within in each failure category rather than as a whole. In other words, 206 patients of the total 7,051 with a cardiac device migration died. This value was divided by the overall number of cardiac migrations, resulting in the percentage of 2.9%.

Death was an uncommon outcome within the data as a whole; cardiac device failures had the highest death percentage at 5% for expulsion and 2.9% for migrations, compared to non-cardiac migrations 1.3%, and 1.4% non-cardiac extrusions. Interesting to note,

injury is the most commonly identified failure, within all three groups; cardiac or non-cardiac. This outcome represents the highest impact to patients representing 79.3% of cardiac migrations, 76.8% of non-cardiac migrations and 85.8% of non-cardiac extrusions. It is clear within these three failures, that if and when they occur, the outcome of injury is the most likely risk to patients rather than death. Non-cardiac extrusion, the injury percentage was 85.8%, in contrast to cardiac extrusion at 11.6%, which may reveal that cardiac extrusion is somewhat of a rare failure while extrusion of another device is far higher. Results obtained from a chi-squared test that compared each failure by its cardiac and non-cardiac counterpart, tested the hypothesis whether there was a statistically significant result between the groups. Upon reviewing the P-value of each outcome group, the value exceeded 0.05 in all but injury. We reject the null hypothesis for injury; yet fail to reject the null hypothesis for death, malfunction, other and unknown.

Death Observed				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	206	8	4	218
Non-Cardiac	49	26	-	75
Grand Total	**255**	**34**	**4**	**293**
Death Expected				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	189.72696	25.29692833	2.976109215	**218**
Non-Cardiac	65.273038	8.703071672	1.023890785	**75**
Grand Total	**255**	**34**	**4**	**293**
p-value	3.05E-12			

Table 19: Outcome of Death for Migration, Expulsion and Extrusion Chi-Squared Test

Injured Observed				
	Migration	Extrusion	Expulsion	Total
Cardiac	5,592	200	25	5,817
Non-Cardiac	2,789	1,554	105	4,448
Grand Total	**8,381**	**1,754**	**130**	**10,265**
Injured Expected				
	Migration	Extrusion	Expulsion	Total
Cardiac	4749.3694	993.9618	73.6687774	**5817**
Non-Cardiac	3631.6306	760.0382	56.3312226	**4448**
Grand Total	**8,381**	**1,754**	**130**	**10,265**
p-value	0.00			

Table 20: Outcome of Injured for Migration, Expulsion and Extrusion Chi-Squared Test

Malfunction Observed				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	114	7	2	123
Non-Cardiac	141	6	6	153
Grand Total	**255**	**13**	**8**	**276**
Malfunction Expected				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	113.6413	5.793478261	3.565217391	**123**
Non-Cardiac	141.3587	7.206521739	4.434782609	**153**
Grand Total	**255**	**13**	**8**	**276**
p-value	0.429			

Table 21: Outcome of Malfunction for Migration, Expulsion and Extrusion Chi-Squared Test

Other Observed				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	14	-	1	15
Non-Cardiac	21	6	3	30
Grand Total	**35**	**6**	**4**	**45**
Other Expected				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	11.66666667	2	1.333333333	**15**
Non-Cardiac	23.33333333	4	2.666666667	**30**
Grand Total	**35**	**6**	**4**	**45**
p-value	0.148			

Table 22: Outcome of Other for Migration, Expulsion and Extrusion Chi-Squared Test

Unknown Observed				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	8	-	-	8
Non-Cardiac	5	4	1	10
Grand Total	**13**	**4**	**1**	**18**
Unknown Expected				
	Migration	Extrusion	Expulsion	Grand Total
Cardiac	5.777777778	1.777777778	0.444444444	**8**
Non-Cardiac	7.222222222	2.222222222	0.555555556	**10**
Grand Total	**13**	**4**	**1**	**18**
p-value	0.063			

Table 23: Outcome of Unknown for Migration, Expulsion and Extrusion Chi-Squared Test

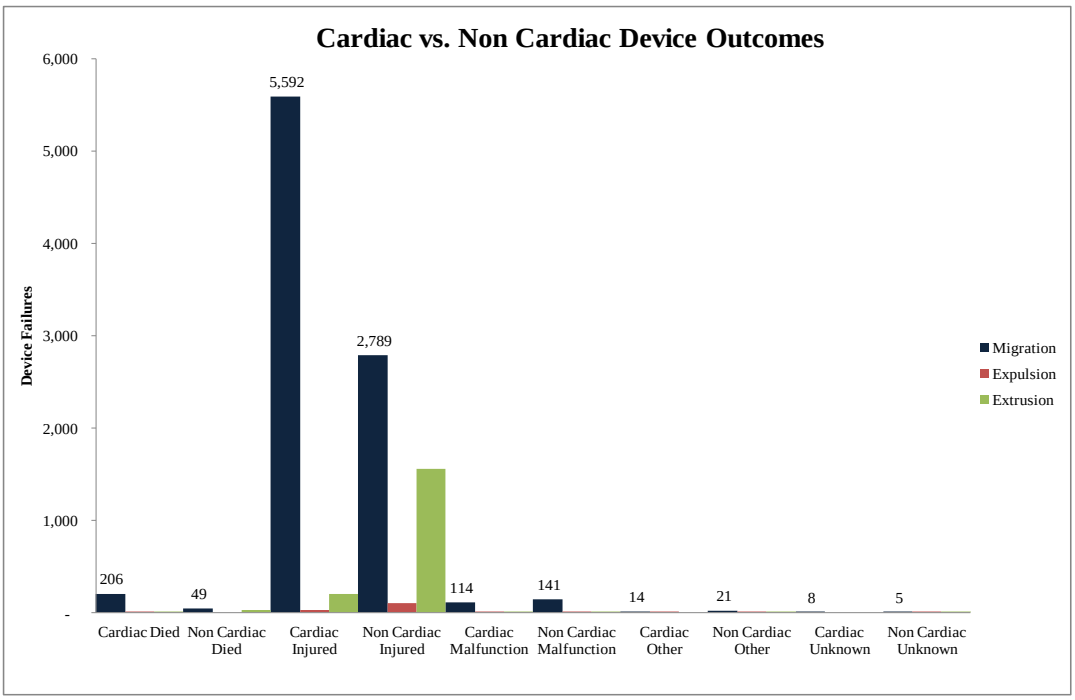

Figure 38: Cardiac vs. Non-Cardiac Device Outcomes

Cardiac						
	Cohort	Died	Injured	Malfunction	Other	Unknown
Migration	7,051	206	5,592	114	14	8
Expulsion	79	4	25	2	1	-
Extrusion	1,721	8	200	7	-	-

Non-Cardiac						
	Cohort	Died	Injured	Malfunction	Other	Unknown
Migration	3,632	49	2,789	141	21	5
Expulsion	188	-	105	6	3	1
Extrusion	1,811	26	1,554	6	6	4

Table 24: Cardiac vs. Non-Cardiac Device Outcomes Within Failure Group

Cardiac Cohort	Died	Injured	Malfunction	Other	Unknown
Migration	2.9%	79.3%	1.6%	0.2%	0.1%
Expulsion	5.1%	31.6%	2.5%	1.3%	0.0%
Extrusion	0.5%	11.6%	0.4%	0.0%	0.0%

Non Cardiac Cohort	Died	Injured	Malfunction	Other	Unknown
Non Cardiac Migration	1.3%	76.8%	3.9%	0.6%	0.1%
Non Cardiac Expulsion	0.0%	55.9%	3.2%	1.6%	0.5%
Non Cardiac Extrusion	1.4%	85.8%	0.3%	0.3%	0.2%

Table 25: Cardiac vs. Non-Cardiac Device Outcome Percentages Within Failure Group

Chapter V

V. DISCUSSION

5.1 Research

In this research, we have determined that a large percentage of overall medical device failures reported in the MAUDE database are cardiac in nature. This research was iterative and sought objective answers within the data. A combination of data analysis, predictive analysis, and statistical analysis was employed to evaluate results. An iterative approach was beneficial in order to adjust approach when it was clear that the prior approach was inappropriate. During this research, we have observed the obvious implication of device failures and how injury can be likely, but obtaining the data and performing analysis is time consuming for the average person. Upon searching The FDA's website, there is not a user-friendly option to view the data for insights for consumers to understand the implications of device failures and making informed decisions before treatment.

5.2 Limitations

5.2.1 Data Integrity

This research had several limitations that affected overall results. Although the dataset from MAUDE was expansive, data integrity was less than ideal. This is partially due to a variety of sources have submitted reports to the FDA, without any clear consistency in how this is done. The problem codes being unreliable made the identification of a variety of other failures more difficult, since there was not a structured method to obtain this information. Device names were used to identify cardiac devices and narrative text was used to identify the failures of interest.

There were nearly 350,000 records that did not have a device name associated with the record, which made determining the nature of the device challenging, so they were omitted for purposes of this research. Within the remaining device names, there were some devices that were included that were not actually cardiac related-yet had similar names to other cardiac devices. Upon evaluating the most commonly occurring device names, many were similar where it is likely that the devices are identical in their treatment, with variations in their names. In using narrative text, in order to initially identify the failures of interest for machine learning, too few fit pattern string matching that pertained to migration, extrusion and expulsion. It may be likely that more records that pertain to these failures exist within the MAUDE, but are referred to differently than what was used in this research. This is also where having reliable problem codes would be useful.

5.2.2 Machine Learning

The performance of each machine learning algorithm depended heavily upon the volume and quality of data. Naive Bayes in the identification of cardiac devices performed well, due to labeling 1 million records, while Naive Bayes for the 2 of the 3 device failures performed very poorly. This was a direct result of simply not offering the algorithm enough data to train well. Being able to provide more labeled data points to the algorithm can be beneficial in building solutions that are meaningful.

5.2.3 Patient Outcomes

Due to the obvious data integrity issues, and problematic results in training machine learning algorithms on too few records, this affects the results for patient outcomes. We have attempted to provide good faith effort in providing an objective analysis of patient outcomes, this should be viewed as a semblance of what is occurring rather than of absolute accuracy. The Healthcare Cost and Utilization Project (HCUP) database was used as a comparison of patient outcomes in assessing injury. Device migration injury was the most prevalent outcome within MAUDE data between both cardiac and non-cardiac groups. Within HCUP, we selected specific ICD-10 codes (T82), to capture cardiac device migration or displacement. The total number of discharges for year 2016 was 3,675. This value supports our findings within MAUDE that migration injury is a prevalent failure type.

Chapter VI

VI. SUMMARY AND CONCULSIONS

6.1 Summary

Cardiovascular disease is prevalent throughout society, being the leading cause of death of adults worldwide. One of the many ways to address disease that affect the cardiovascular system is through medical devices. We referred to these medical devices as cardiac. We sought to explore what portion of medical device failures were meant to treat this particular disease and what impact did their failures have upon patient safety. We choose three failures in this research: migration, extrusion and expulsion. We performed a literature review on the topic of cardiac medical devices as well as cardiac medical device migration, extrusion and expulsion. The body of research available is limited at this time, and was scarce regarding the three failures of interest.

The FDA collects data regarding medical device failures, and the data is available to the public through a database known as Manufacturer and User Facility Device

Experience (MAUDE). This database contains records since the early 90's, and each record contains information about the event, pertinent patient information, and narrative text. Within the research conducted, we focused on years events reported between 1997 and 2017, in order to have a large enough dataset to perform advanced analysis. The data was downloaded from the MAUDE website in the form of textual files. To identify cardiac medical devices, we used pattern string matching within certain fields. The initial results in pattern string matching returned an unusually small number of devices, at just 5% of total device failures from the time period of interest. The result did not align with our assumptions that cardiac medical devices will be a large portion of our dataset considering cardiovascular disease is a worldwide health issue. We used a generic name field associated with each record that once mapped with a list of cardiac terms proven a reliable means of basic identification.

To identify failures of interest, we began to use the problem code information provided with the events. The problem codes were a map of problems that were used to classify and describe failures. Upon reviewing problem codes, it was clear that using these as a means to identify failures would not be acceptable as this only rendered 3,064 (.05% of initial identified cardiac devices). When researching the phenomena in more detail, it was clear that problem codes were not a reliable means of understanding failures, due to the very low values, that were inconsistent with the number of events. Based on our observations, we needed to pursue alternative means to classifying cardiac devices and subsequently identifying failures in an iterative step-process. Upon review of the narrative textual files associated with each event, we have found that this information

to be more reliable and consistent than problem codes, and may be useful in the identification of failures.

Once the alternative methods were applied for both identification and for failure analysis, there were more than 13 million textual records to accompany the nearly 6 million initially identified cardiac records. Given the vast amount of records, machine learning was a practical means of analyzing the records for further insights. In order to generate a training set for the model, we needed to label a subset of the data as both a positive class (cardiac) and a negative class (non-cardiac), we wanted to ensure the algorithm also identifies a similar number of cardiac devices. We used a random seed and labeled an equal number of records (1 million, 500,000 each class), that we used to train the machine learning classifiers. We employed two supervised learning approaches for classification: Naive Bayes as the base algorithm, and Decision Tree for a validation model.

The results from Naïve Bayes was consistent with our initial estimation that roughly 20% of the overall medical devices were cardiac in nature based upon results from the testing output. The Naïve Bayes model identified 21% of the data as cardiac devices. However, results from the Decision Tree model were less than ideal in which the model was unable to generalize well, likely due to a poor choice in classifier. A similar approach was used to identify the three failures of interest, using narrative text. An initial dataset was identified, and a labeled set was provided to a Naïve Bayes classifier. Migration accounted for the largest portion of the three failures, while expulsion and extrusion suffered from few records identified. Due to this, the model that was trained

with migration failures performed well, while the other two failures were not able to generalize and produce an acceptable output.

In measuring patient outcomes, the groups were analyzed in the context of a positive and negative group (cardiac vs. non-cardiac) and a chi-squared test was performed to determine statistical significance. There was no statistical significance found within the categories of: death, malfunction, other or unknown. However, within the category of injury there was a statistically significant result, with the p-value being less than 0.05. Migration injury was the most frequent outcome of the cardiac group at 79.3%, with expulsion following at 31.6%, and lastly extrusion at 11.6%.

The non-cardiac cohort outcome of injury was more than 50% for each failure, with extrusion accounting for 85.8% of patients with a non-cardiac extrusion failure. Our initial assumption was a failure of migration, expulsion or extrusion would be largely fatal, however, our findings were unable to support that assumption. We have concluded that the risk of serious injury is high when a patient experiences a medical device migration, expulsion or extrusion. Although death is a relatively uncommon outcome, it accounted for nearly 3% of cardiac migrations, and 5% of cardiac expulsions. These outcomes should be made clear to any patient that is considering receiving a device to treat a condition; injury is likely if the device has one of these specific failures.

6.2 Conclusions

Between 1997 and 2017, we have found a total of approximately 20% to 21% of all medical device failures reported to the FDA to be cardiac in nature. This confirms our original hypothesis that a large portion of medical device failure would consist of cardiac

devices. We discovered through our research that certain device failures have a high risk of injury to the patient, and it seems that injury can include a number of outcomes that fall outside of death. While death was uncommon, it occurred nearly 3% within the cardiac migration group, 5% within the cardiac expulsion group, and far less with non-cardiac extrusion and expulsion. Our original hypothesis was that cardiac migrations, expulsion and extrusions to be largely fatal was not proven, however, cardiac and non-cardiac migrations, extrusions and expulsions possess a high likelihood of injury to the patient.

6.3 Recommendations

The original purpose of this research was to contribute to the greater scientific and research community by generating new insights regarding the safety of cardiac medical devices, and to help create a standard for medical device data collection and oversight. The goal of this research is also to advocate for data transparency and information sharing for the research community and medical device patients. In favor of this goal, we offer recommendations for further research and to the FDA.

6.3.1 FDA

The FDA having these files available for research is a useful endeavor in evaluating the safety of medical devices, but due to obvious limitations it is questionable as to whether this goal is being satisfied. In order to perform analysis, a series of textual files need to be downloaded into a database and then associated to one another. We recommend this process to be simplified and provided in a user-friendly data portal where data can be downloaded that accompanies data visualization such as a dashboard,

that produces clear, understandable output. A data portal that is intuitive, that anyone, of relatively any background can use with ease. In reviewing the current data portal, it does not give a hierarchy of device type, and one must search through the Product Classes in order to get a basic understanding of what condition the device was used to treat. The output of results is less than ideal.

We recommend the FDA ensures the quality of the data in submissions and provides structured fields whenever possible. This may include streamlining the process for submitters to submit data to the FDA, in again, a more user-friendly-manner such as a web-based portal. A method for streamlining this process would include a combination of dictation to text, having a facility code/physician code that auto fills when the submitter signs into the portal, and barcode tracking when a new device is received by the facility by physician. This method would also include a dictation to text method for capturing the device failure and narrative summarizing the event that would associate a problem code with the report, so the submitter would not need to search for the code themselves. This method should be completely paperless, and requiring only a few minutes per report. This type of solution would ease the need to spend hours typing and collating information, which can be difficult for health professionals that are busy and/or cannot easily locate the information. The quality of the data deeply affects the quality of resulting analyses. If starting with poor data, this will unfortunately result in poor insights. This includes requiring certain fields contain information and not have the option to leave them blank. Our solution for auto filling that information that cannot be left blank will be a sound method to address this. We have noticed in our analysis that there were many fields that

were left empty, greatly limiting the effectiveness of certain fields. The fields that were affected by lacking or missing information that greatly affected our research:

-*Problem Codes*

-*Generic Device Name*

-*Facility*

-*Location*

We have found a significant number of records did not contain problem codes at all, as well as generic device names. Due to this, we were unable to use problem codes as a reliable method of classifying failure types. Due to a lack of generic device names, we were unable to use those records and as a result, they were excluded. Allowing for a streamlined manner for data to be submitted, as well as requiring certain fields containing information will likely result in higher data volume and quality. Without information about the facility as well as location of the event negatively impacted the ability to perform geographic and cluster analyses. This information would be particularly useful for patients to identify problematic facilities and to perhaps seek care elsewhere.

We recommend that devices be listed under a device type based upon where in the body they are meant to treat in a user-friendly manner, such as a data visualization as mentioned above. In this visualization or filter a user can select the part of body where the device will be implanted. In our case, we were interested in cardiovascular devices. From there, a user can then select the problem codes of interest and a time period. At that

point, output that contains count by year will be produced, and an option to download the dataset will be visible to the user.

We *highly* recommend the FDA being more transparent about the data they receive and provide through the same data visualization portal as recommended above, a user-friendly web report that updates quarterly on the state of medical devices. The general public is largely unaware regarding the safety and efficacy of medical devices, which is harmful. Many patients only are aware of medical device issues once they have negatively affected large groups of people and/or after a class action lawsuit. Allowing a more informed patient population will be crucial for them to understand potential risks and common issues with medical devices so they are able to take precautions, or perhaps make other decisions. But, patients cannot do this, unless they are aware of this information to begin with. patient health should be prioritized over monetary gain. In conclusion, we recommend the FDA address these key issues:

-Provide a streamlined web portal for data download. Allow for data download in various file formats.

-Provide a dashboard where interested parties can explore medical device failure trends that include patient outcomes, by time period, facility, geographic location, problem codes, device type/generic device name and implantation site (part of body).

-Streamline the submission process by providing a web portal that auto fills information such as the name of physician, facility, and the devices that were received by the facility/physician. Using a dictation to text solution, the submitter can briefly summarize

the event/issues with the device, and from there, they keywords and context can be captured that will associate the report with a problem code(s).

-More transparency in the information that is received by the FDA, by making good faith effort in education g the general public of medical device risks and potential outcomes by use of available data and information as mentioned above.

6.3.2 Further Research

This research provided some semblance into the state of cardiac medical device related to very specific failures. There are numerous opportunities for further research on this topic, or related topics.

Machine learning for the classification of medical devices has shown promise to analyze large datasets. Further research could extend to include a wider variety of medical devices, or the full spectrum of devices. Further classification of devices would be able to address medical device safety as a whole. Targeted research from this point can include patient demographics, barriers to access of care, and geographic analysis such as where in the country are certain types of devices failures occurring. There may be clusters of device failures indicating an issue with the manufacturing of a device or an issue with a particular medical facility. As far as patient demographics, such as age or race, there are many sources that support research proving marginalized groups are unable to receive medical care or the same level of medical care as other groups.

There is a great opportunity to transform MAUDE data into a user-friendly, visual format to increase consumer engagement and interest in this information. There are many examples of organizations that have disseminated information in a usable manner, such

as the CDC. The MAUDE database, while containing valuable information, is difficult to navigate, and the way to understand insights from it requires downloading multiple textual files and analyzing them. This is not something a potential patient will do to understand risks of certain medical devices. A user friendly-dashboard(s) will engage more, inform more, and offer a transparent alternative to what is currently available.

Finally, there is an opportunity for the combination of MAUDE with other health surveillance programs. At the time we are conducting this research, the COVID-19 pandemic has affected the lives of millions of people worldwide. As this novel virus continues to claim the lives of many, it would be useful to know if/how medical devices affect patient outcomes. We are finding that open collaboration of health programs is essential in being able to provide better care that can save lives.

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