**Analysis of the MAUDE Database for Medical Device Absorbable Suture Complaint Trends**

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**Abstract**

Absorbable suture’s are considered a medical device by the Food and Drug Administration in which complaint data is mandated to be reported and collected in the Manufacturer and User Facility Device Experience (MAUDE) database. Complaint data relating to manufacture’s defects is collected in field titled “Device Problems” where reporters submit events related to issues experienced with the medical device. The data is passively collected and unstructured during collection. One complaint can have one or more events associated with it when entered into the MAUDE database. The MAUDE database also has a data limitation of 500 rows of data per export. Several data clean up exercises were implemented to make the data useful for analysis. Python was used to combine all the data extracts into one data table. Then the data was portioned so that each event reported was represented as one complaint count which consisted of splitting the complaints that had multiple events reported. Each event was analyzed for statistical increases over time by comparing the number of events received in one year compared to the number of events in previous years. Complaint trends were observed visually with Tableau program. Events with 10 or more complaints reported were trended by year to observe any variations in complaint frequency. The r program was utilized to conduct the statistical test. The majority of events showed no statistical increase in volume except for the event Component Misassembled. This particular event showed a statistical increase when comparing the number of events in the current year when compared to the past seven years. Datamining and analyzing the complaint data that is entered into the MAUDE data base can give organizations insights into their perspective products performance. Trending data and identifying increases in complaint events can assist decision makers in actions that may need to be taken to direct future directives. Once the data housed in the MAUDE database is cleaned and organized, it can be used in analytical applications to understand complaint data related to absorbable sutures or other medical devices complaints that are collected in the MAUDE Database.

**Introduction**

Medical devices have gained popularity and enhance peoples lives by improving their health and well being. Some medical devices are categorized by the type of assistance they offer the patient and the risk they involve. In general medical devices that are lower risk for a patient are class 1 type of devices. These type of devices are non electric wheelchairs, bandages, etc. On the other end of the spectrum are class 3 devices. These type of devices are more intrusive for a patient and are more risk involved. Class II devices have a moderate to high risk of patient safety and require special controls to for use. An examples of a type II device is absorbable sutures. The regulatory requirement to market absorbable sutures to patients differs between different health authorities. One of the biggest markets in the world for these type of medical devices is the American market, in which the U.S. Food and Drug Administration (FDA) sets requirements for licensing and distribution. The FDA helps with customer assurance that once a medical device is marketed it is safe for and effective for the intended use (Norman 2016). Once approval and licensing is obtained by manufactures to distribute absorbable sutures the FDA requires that the products are monitored post market. To accomplish this some organizations create departments to monitor the medical devices through departments such as a medical device post market surveillance(MDPMS) departments. The MDPMS department would have several responsibilities including obtaining post market data and then analyzing the data. Data coming into the MDPMS team would be known as complaint data. When users of the medical device experience an issue with the product they can call the organization to log their complaints on the product. Another avenue that the MDPMS can collect complaint data is through FDA itself. FDA collects complaint data on various medical devices and also mandates that organizations report complaint data to the health authority.

In the United States of America medical device manufacturers are required to report adverse events to the Food and Drug Administration (FDA) to comply with governmental regulations that allow the manufacture to distribute their product. After data collection the FDA redacts any company trade secrets and Patient Identifiable Information (PII) from the submitted information and houses the data in the Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE data base was established in 1991 to monitor medical device malfunctions and patient related adverse events (Sawaya, 2021). Once the data is entered into the MAUDE database it is made available to the public for use and analysis. Making the data available is great for transparency and offers a lot of potential for data analysis and product understanding. The manufacture of interest for this research project is the Ethilon manufacturer. Ethilon markets a product known as Vicryl which is a absorbable suture material. Vicryl sutures are made from a synthetic compound designed to dissolve in the body after several weeks of implantation. The data that the FDA collects on Vicyrl is rich with possibilities and offers a lot of possibility for manufactures and users of the suture to understand the product performance post market.

Adverse events are reported in the MAUDE database and categorized by three genres of events. The first categorization is by the “Event Type.” Event Type categorizes complaints as Malfunction, Injury or Death. The next category is labled as “Device Problem.” Device problem captures events that are related the medical device. These type of events can be thought of as technical events and are directly related to the product. Some examples of device problems are breakage, material slippage, fraying, material separation. The third category is Patient Problem, which captures medical adverse events experienced by a user of the product. Some examples of patient problems that can be reported are infections, wound dehiscence, hernia, seroma, etc. There is no set standardization for device problems or patient problems that are reported because different events and side effects are unique to each patient and product. A systematic approach to understanding and categorizing the data that is reported to the FDA can help highlight potential issues of the medical devices (Reed, 2010). Data cleaning and analysis can be advantageous in drawing useful information out of the MAUDE database.

**OBJECTIVES**

The capability to classify the various adverse events that get reported in the complaint data for analysis will be beneficial in understanding the product performance post market. Because the range of adverse events can be great, one of the goals would be to find a method to categorize the adverse events so that they can be trended on similar characteristics rather than the specific event that is reported. The quantity of adverse events reported against a medical device can indicate where attention should be guided for development and improvement of the product (Beydon, 2010). Some adverse events may occur more quickly then other adverse events. A person experiencing a allergic reaction to the device may experience the adverse event more early after use than someone who develops a carcinogenic reaction to the device. Not only does the variation between adverse events need to be known but the variation between patients themselves. Some patients may develop the same adverse event much later or earlier then other patients. Improving the accuracy of adverse event reported will thus improve patient safety (Lalani 2021).

**OVERVIEW OF STUDY**

The data that is extracted out of the MAUDE data base will be used to develop an understand of the events that are reported. Data will have to be extracted in multiple exports do to the data limitation that the FDA sets for use of its system. There are nine filter criteria that can be used to extract the data. The only two filter criteria that were used were Brand Name and Date Report Received. Brand Name will be set to to Vicyl. Data was extracted in annual exports by selecting an annual date range in the Date Report Received filter criteria for the past five years. The data was exported in five comma separated value files, each representing one year of data based on the Date Report Received filter. Leveraging the schema of each of the files the tables were stacked in Python. The combined file that was created in Python will then be synthesized to align events that share similar characteristics with each other. Improving the accuracy of adverse event reported will thus improve patient safety (Lalani, 2021). The combined file will then be utilized in the r program. A students t-test statistical analysis will be performed in r to measure events from the current year against the same events from the previous years. If any statistical difference are found that would indicate a change in reporting. Trend charts were developed in Tableau program for visual analysis of the data using control chart methodology.

**RESEARCH QUESTIONS AND HYPOTHESES**

Research Question

Are there any significant increases of reported events against the medical device Vicryl?

Null Hypothesis

There are no significant increases in reported events against the Vicryl absorbable suture.

Alternate Hypothesis

There is a significant increase in reported events with the absorbable suture.

**LITERATURE REVIEW**

The article titled *FDA Adverse Event Problem Codes: Standardizing the Classification of Device and Patient Problems Associated with Medical Device Use* (Reed, 2010) provides good support as to the data misclassifications that occurs in the FDA MAUDE database. The paper highlights recommendations to handle erroneous data and classify data more appropriately for analysis. Grouping adverse events and problem codes that are similar in characteristics can illustrate meaning and conduct statistical analysis on the data. Part of the grouping of the data is harmonization of the data and developing appropriate hierarchy for the data. The direction to classify data from the MAUDE data base for processing helps illustrate the analysis.

This research focuses on the adverse events reported to the FDA for sutures by the medical manufacturer Ethicon. Ethicon make a absorbable suture under the product brand of Vicryl. In order to classify and organize the adverse events into suitable hierarchy for analysis an understanding of adverse events for absorbable sutures was required is provided by the article *Adverse events of sutures: Possible interactions of biomaterials* (Holzheimer, 2005). The paper summarizes the material that the sutures are made from and the associated events that can occur and provides insight in adverse event analysis.

The methodologies that are encountered when attempting to analyze the passively collected data in the MAUDE database from product surveillance departments entered by different organizations are reviewed in the article *Reporting of Death in US Food and Drug Administration Medical Device Adverse Event Reports in Categories Other Than Death* (Lalani, 2021). It mentions that some data can be misclassified and that data cleaning techniques need to be implemented in order to increase the accurately of the data analysis. The paper uses techniques such as implementing a natural language processing algorithm to classify the data. The type of analysis methods employed by these researchers was useful in analysis of the MAUDE data of absorbable sutures.

Useful analysis for large data sets through machine learning via text mining algorithms is explored for data submitted to the FDA in the paper *Development of an automated assessment tool for MedWatch reports in the FDA adverse event reporting system* (Han, 2017). A random forest model was used to help provide an understanding of the data. A similar approach was used to interpret the MAUDE database for absorbable sutures adverse events that are collected in the database.

The journal article *An analysis of FDA adverse event reporting data for trends in medical device use error* (Knisely*, 2020)* enforces the idea that the data that is available from the MAUDE data base needs to be organized before any analysis can be performed. The method that would be relevant is performing multiple data extracts from the MAUDE data base, since there is a data limitation on exports, and then organizing the data into one data set with Python. It also mentioned that because of the complexities of how the data is entered, classifying the data is necessary to group adverse events with similar characteristics before performing data analysis.

The MAUDE data base consist of 9 search fields and 11 columns of data available for extract. The article *Using the FDA MAUDE and Medical Device Recall Databases to Design Better Devices* (Liebel, 2020) provides recommendations as to how analyzing the MAUDE data can be useful for medical device organization to learn from data that is available. It mentions that categorizing the adverse events to separate out those that are considered human error may be ideal for medical device organizations. It also provides insight as to how to utilize the search criteria to extract the data out of MAUDE for analysis.

**RESEARCH DESIGN**

Methodology

Thw data was cleaned and categorized in Python, the next step would be to perform statistical analysis. The r program was useful in developing the data models and performing statistical analysis on the reported patient problems and device problems. The r program would be used to build a data model that compares the most resent reported events with events reported historically. The last two years of reported events can be used to build a baseline that would be compared to events reported in the latest year. Once the baseline is determined upper and lower control limits can be set to determine if events reported in the current year have been exceeded above a threshold or not. Several of the Nelson control chart rules can be utilized to monitor the trend analysis. If events are discovered to be increasing the students t-test can be applied to determine if the difference is significant or not, which would either support or reject the null hypothesis.

To visualize the data the software program Tableau would be employed. The data graphs in Tableau would help articulate the outcome of the data and make it easy to understand (Sadiku, 2016).

Limitations

Having complaint data from the organization is useful data because it allows the capability to monitor the product for health, safety and improvement to the product if possible. Because thousands of products are sold every year there are thousands of complaints received every year as well. Having all the complaint data available for analysis can prove to be really useful for the health authority, organization and the patients. One of the hurtles that medical device complaint data will have are the type of complaints that are reported. Complaints can have a large range of severities, categories and characteristics. Because complaints can be very different from one another can make the ability to analyze them difficult. For example some complaints can be targeted against the device itself and have no patient involvement. Maybe there was a batch of implants where the implant packaging was damaged. Because the packaging was damaged it can logically be assumed that the product may have also been damaged so customers will call in to report a damaged packaging complaint and ask for a new device to be sent out. Alternatively, the device can have already been implanted where the patient may now experience an adverse event such as pain or discomfort. The patient may go back to their surgeons office who can possibly remedy the adverse event through treatment and will report the adverse events that the patient experienced as complaints. However not all adverse events are the same, and some may be more serious then others. A patient who experiences pain would have a different severity than a patient who experiences a more critical health event such as lymphoma or capsular contracture. The treatment for a more critical adverse event may be more involved then the treatment for a health event that has less severity.

The MDPMS department would have the task of collecting all the complaint data and analyzing the data but because the data can be widely distributed in terms of adverse event severity the ability to draw meaningful conclusions from the data can be difficult. Another difficulty that the data may encounter is that the adverse events that occur in a patient may not all occur at the same time nor will they all occur immediately after implantation. The broad spectrum of adverse events that are reported present a serious challenge for health organizations in quantifying and understanding the data (Reed 2010). Some adverse events may take years to develop before an issue is recognized and reported. Not only do some adverse events take years to develop, every patients body can react differently to the breast implant. Some patients may develop capsular contracture in one year where as others it may take several years to develop. Understanding the variability between patients occurrence for the same adverse event as well as the variability between the adverse events them selves can help an organization understand their product more intimately and offer more information to customers and patients.

Ethical Considerations

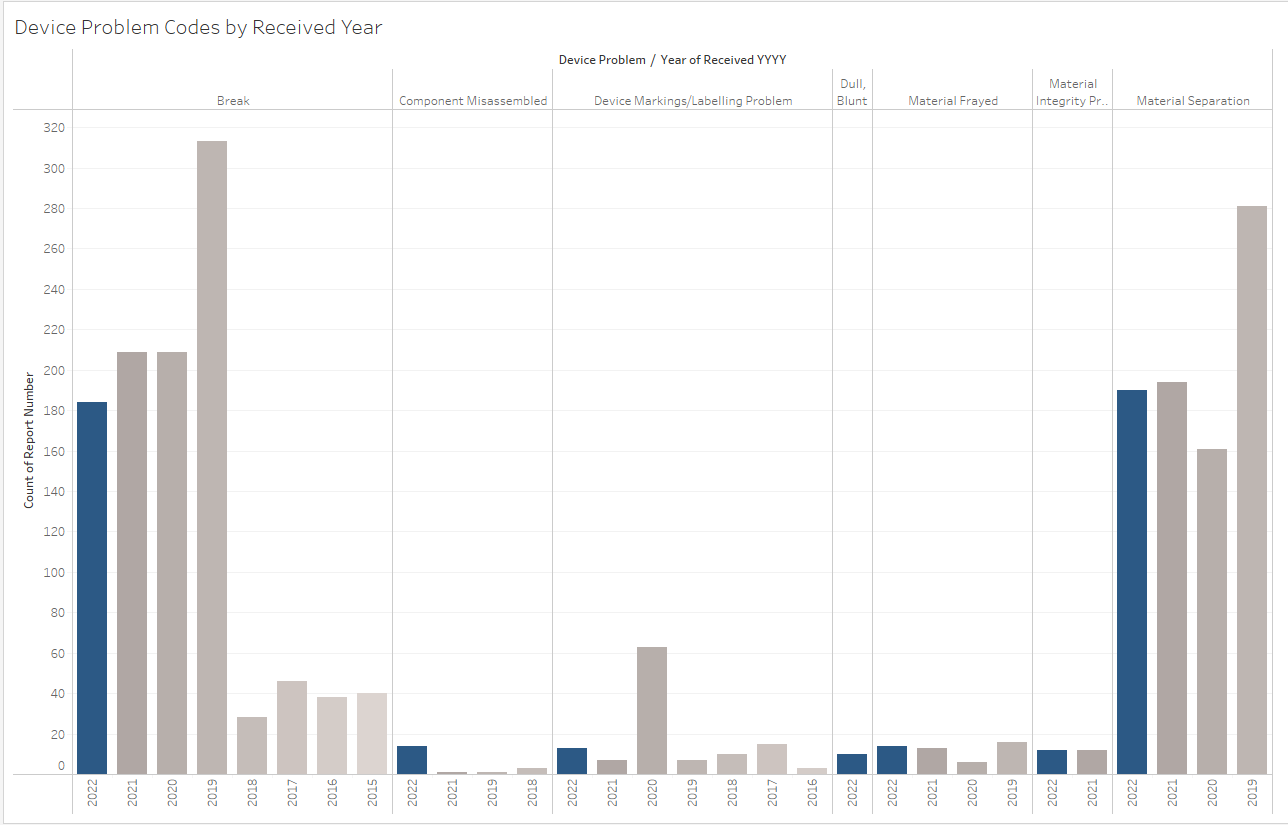
A professional medical practitioner may or may not agree with the classification of events that have been reported. For example, patient complaints of nodule, granuloma and seroma may be interpreted as having similar characteristics in order to classify as one group, however a trained medical practitioner may have a strong and good reason as to why they should not be classified in the same group.

The second ethical consideration I should give is a disclaimer about the data. The data in the MAUDE data base has two inherent issues. One is that even though manufacturers are mandated to report events, the health care professionals and patients are voluntary reporters which can lead to inconsistent data collection. The second inherent issue is that there is no distribution data provided with the data. The distribution data would help in normalizing the complaint rates, however distribution data is considered proprietary business information and is not released.

**FINDINGS**

The device problem codes for Vicryl were analyzed for any trending patters and statistical differences that may exist in the data. The focus is to determine if there are any increases in the number of events that are reported in the MAUDE data base. The number of events for each of the device problem codes was aggregated by year. A unique report number is allocated each time a complaint is logged in the MAUDE data base. Each complaint may have one or more devices problem codes associated with it and are concatenated into one data field in the database. To obtain an accurate number of events per product code each of the events were separated into their own data field to facilitate the analysis. Figure one below visualizes the data counts. Any problem codes with less than 10 counts received in 2022 were excluded from the analysis because the goal is to determine if complaints are significantly increasing.

**Figure 1 Problem Code Events by Received Year**



Eight years of data was extracted to perform the analysis, with the oldest seven years of data forming the baseline for comparison to the most current year, which for this data set is 2022. Based on visual analysis of Figure we, it can easily be recognized that most problem codes are being reported fairly similar to past years with the exception of the problem code “Component Misassembled.

A one sample t-test was performed on the problem code Component Misassembled to test the hypothesis and determine if there was a significant difference between the current year of reporting and past years of reporting. An alpha level of 0.025 was chosen on a one-tail t-test to determine significance. The degrees of freedom was n = 6, with a sample mean of 0.7 and standard deviation of 1.1. A t score of 2.447 or greater was required to achieve a 95% confidence level that a significant difference existed. The data was uploaded into the r program and calculated using the counts of component misassemble received in 2022 as the test period. The result was a t value of 31.6 which indicates that the number of complaints received in 2022 is significantly different then the number of complaints received in the past seven years.

**CONCLUSION**

The number of complaints received for Component Misassembled has dramatically increased with a statistical difference between complaint counts received in the most recent year of 2022 versus complaints received in the past seven years. Based on the statistical results of the data for Component Misassembled complaints the null hypothesis is rejected and the alternative hypothesis is accepted. The remaining problem codes reported in 2022 did not show a statistical difference or increase in volume when compared to previous years, therefore the null hypothesis is accepted for all other reported problem codes. Problem codes with less than 10 events reported in a year were excluded because the volatility of low counts can occur without having a meaningful impact on the Vicryl suture medical device.

**RECOMMENDATIONS**

Analysis of the data demonstrated that the majority of the problem codes reported are reasonability trending similarly to past reporting with the exception of one problem code Component Misassembled. The number of reported events for Component Misassembled has a statistical increase when compared to the number of events reported in past years. This data indicates that there could be an issue at the manufacturing or distribution centers and should be investigated and formerly documented. Discovering an issue early for an organization can help avoid product recalls and keep customer confidence high as well as financial incentives for keep a high quality product on market. Beyond statistically testing the data, practical limits and risk limits should be employed that would trigger an investigation when the threshold is reached. For example the number of Breaks and Material Separations reported in 2022 is consistent with what has been reported in past years but makes up 82 percent of the events reported.

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