Big Data Analytics for Ventilator Adverse Events in the MAUDE Database

Gehad Mohamed, Al Zahraa Mahmoud, and Shymaa Ali, Neveen Fathy

Abstract— the ongoing global pandemic of the coronavirus disease (COVID-19) was the reason of the rising need for ventilators. Ventilators help human patients with breathing when such a disease limits the lung capabilities. However, ventilators from different manufacturers can have different features and potential mechanical and electrical problems. In this project, we help healthcare managers and maintenance engineers in making informed purchase, maintenance, and replacement decisions for ventilators. In particular, we carried out a big data analysis for ventilator adverse events in the Manufacturer and User Facility Device Experience (MAUDE) database. [1] We made several illustrated comparisons between different types of ventilators, patient problems, and brands according to the device problems. We extracted files of adverse events of many types of ventilators from the MAUDE database. From these files, we extracted structured information on the Device Problems, Event Type, Patient Problem, Narrative, Event-Description, Brand Name, and Manufacturer. We analyzed this information to understand the variations and types of device problems. We also used manual analysis to understand the unstructured data of the Event Description and Narrative. More importantly, we created a 5000-sample dataset of adverse event reports, and hence trained machine learning classifiers for classifying such reports into 5 categories of device problems. Our results show that a linear SVM classifier achieves an accuracy of 86%.

I. Introduction

FDA MAUDE database contains information about issues with medical devices that are on the market in the United States. The MAUDE database contains adverse event reports that involve end user interactions with medical devices (also known as medical device reports). These adverse events describe suspected device-associated deaths, serious injuries, and malfunctions, with a wide range of causes (e.g., from manufacturing to usability issues), by MAUDE database analytics, it provides recommendations to manufacturers those who have low number of adverse events reports, it shows trends through current and last years, our project can be expanded for future work in more than one side, one of those is how to reduce the loss of information, which can be achieved by not ignoring the small details, as a result of that it will have reflection also on the automatic text analysis, it can be more precise and less confused, and getting more accuracy, another sider for future work is the trending through last years for unstructured data analysis, which can gain more experience on device problems and causes behind them.

In our study, we are going to

1_ Introduce number of adverse events reports of ventilators through last five years, number of reports in each device problem category, from that we managed to know the most frequent device problems occur, the trending of adverse events in increase or in decrease, and that by seeing the number of adverse events reports from 2016 to 2020, this work had been done through two weeks, the objective behind that is helping the manufacturers to improve their device technologies for longer use, and giving recommendations on which device to be bought based on having less number of malfunctions, this will help Egyptian Ministry of Health and hospitals in ventilator sell operation, and we could measure all this from 2016 to 2020 during two weeks.

2_ Analyze ICU ventilator adverse events reports in 2020 manually to create a Multiclass text classification [3] to predict the device problem category of the input report, we achieve an accuracy of 86% using linear kernel SVM model.

II. Materials and methods

MAUDE Database

Manufacturer and User Device Experience (MAUDE), is a (FDA) database that stores Medical Device Reports (MDRs) submitted to the FDA. Each report contains information such as Device name, Event type (malfunction, injury, death, other), Manufacture name such as Philips, Brand name, Device problem, Patient problem, Event Description and Manufacturer Narrative. We extracted the data related to the ventilator from MAUDE by developing web scraping tool that automatically retrieves all the reports related to two types of ventilators CBK and BTL ventilator over 5.5 million MAUDE records posted between January 2016 and December 2020 and get 60,000 records [1] [2].

B_ Manual Analysis

According to the extraction results of the device problems from the entire extracted adverse events, we got 745 different categories of device problems

1-we selected the first 200 categories of the highest frequencies, 2- we extracted the event description and narrative data of each device problem category, 3- after reading many reports we extracted key words and stop words of each category

C_ Document Similarity

We used adverse events reports with same device problem category to construct a corpus of documents. Suppose that we searched for “ventilators with power problem reports” and got back several event_ description_ narrative documents. We can then collect these documents and store them in a list. This will serve as our corpus. The process for calculating cosine similarity can be summarized as follows: [4]

1- Normalizing a corpus of text. [5] [6] 2- Vectorizing a corpus of text using TfidfVectorizer.3-Calculating the cosine similarity between documents/vectors.4- Plotting cosine similarity using a heatmap.

Our goal is to show how we can leverage NLP to semantically compare documents.

D_ Multi-Class Text Classification [3]

We seek to create a Multi-Class text classification system for the ICU ventilator adverse events reports in 2020

1- Problem Formulation:

The problem is supervised text classification problem, and our goal is to investigate which supervised machine learning methods are best suited to solve it. Given a new event_ description_ narrative comes in; we want to assign it to one of 5 device problem categories [Mechanical, Circuit failure, Calibration, Power and Software], the classifier makes the assumption that each new complaint is assigned to one and only one category. This is multi-class text classification problem

2- Data Exploration

We need only three columns: “Device_ problems”, event_ description and “Narrative” .We compined event_ description and “Narrative” together in one column

- Input: event_description_narrative
- Output: Device_ problems

We will remove missing values in “event_description_narrative” column, and add a column encoding the product as an integer because categorical variables are often better represented by integers than strings

3- Text Representation [7]

The classifiers and learning algorithms cannot directly process the text documents in their original form, as most of them expect numerical feature vectors with a fixed size rather than the raw text documents with variable length. Therefore, during The preprocessing step, the texts are converted to a more manageable representation.

One common approach for extracting features from text is to use the bag of words model: a model where for each document, an event_description_narrative in our case, the presence (and often the frequency) of words is taken into consideration, but the order in which they occur is ignored. Specifically, for each term in our dataset, we will calculate a measure called Term Frequency, Inverse Document Frequency, abbreviated to tf-idf. We will use sklearn feature_ extraction. TfidfVectorizer to calculate a tf-idf vector for each of event_description_narrative complaint narratives:

1- sublinear_df is set to True to use a logarithmic form for frequency, 2-min_df is the minimum numbers of documents a word must be present in to be kept, 3-norm is set to l2, to ensure all our feature vectors have a Euclidian norm of 1. 3-ngram_range is set to (1, 2) to indicate that we want to consider both unigrams and bigrams, 4-stop_words is set to "english" to remove all common pronouns ("a", "the", ...) to reduce the number of noisy features.

3- Multi-Class Classifier: Features and Design

To train supervised classifiers, we first transformed the “event_description_narrative” into a vector of numbers. We explored vector representations such as TF-IDF weighted vectors, after having this vector representations of the text we can train supervised classifiers to train unseen “event_description_narrative” and predict the “product” on which they fall, after all the above data transformation, now that we have all the features and labels, it is time to train the classifiers. There are a number of algorithms we can use for this type of problem

4- Model Selection

We experimented with different machine learning models, evaluate their accuracy and find the source of any potential issues. We will benchmark the following three models:

- Logistic Regression
- (Multinomial) Naive Bayes
- Linear Support Vector Machine

IV.RESULTS

Our results for:

1) Manual analysis:

We reduced the number of device problems categories into 5 main categories to help us in converting our problem into supervised problem and to check the similarity between documents of the same device problem category.

2) Document similarity using NLP [4]:

From Figure 2 we can see power problem reports cosine Similarity heatmap plot, where the most similar documents are document_13 and document_16. Whereas, the most dissimilar documents are the ones with similarity score of 0.0. One such example of documents that have no similarity is the pair document _7 and document _23. Shown below are the titles of these documents

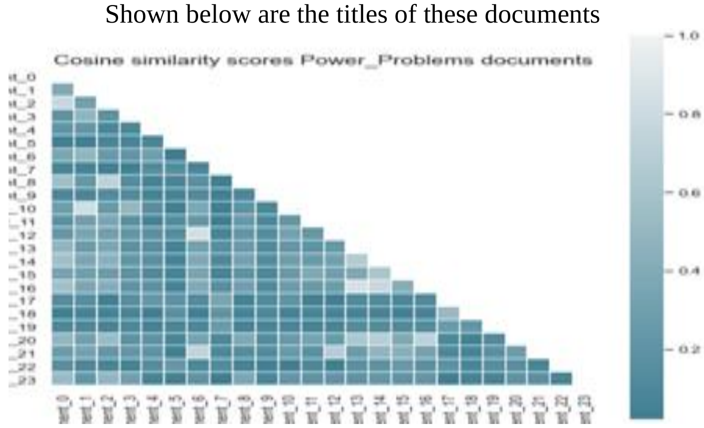

Figure 1 cosine similarity score power_ problem

The same is applied on the rest of 5 main categories reports to get the cosine similarity between documents which have the same device problem category.

3) **Model selection for our Multiclass text classification**

model_name	accuracy
LinearSVC	0.866992
LogisticRegression	0.850457
MultinomialNB	0.736394

Figure 2 Models accuracy

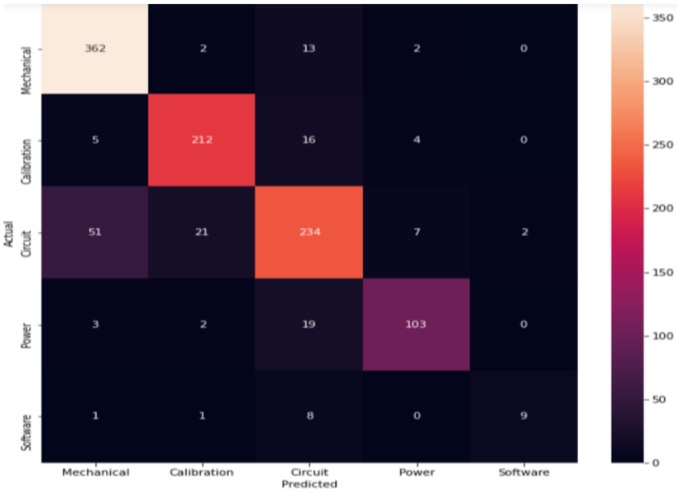

Figure 3 Confusion Matrix using SVC model

The linear kernel SVM achieves the best performance with accuracy around 86% in our supervised problem for classifying the event description and narrative into which device problem class.

4) Our results from structured data analysis:

A- Firstly for ICU Ventilator (CBK)

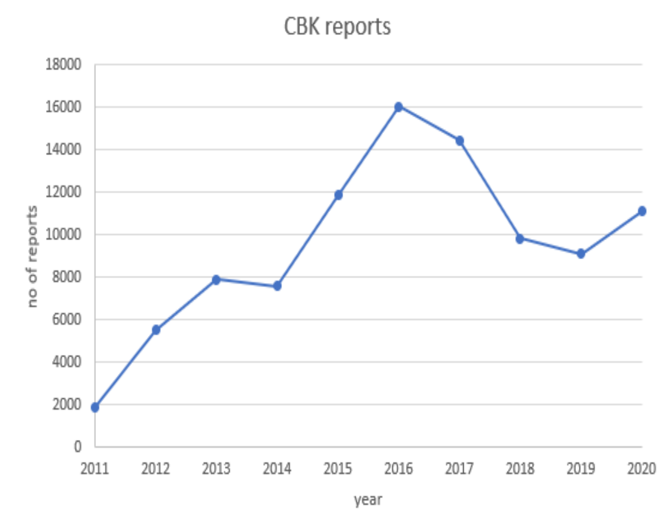

Figure 4 CBK reports last ten years

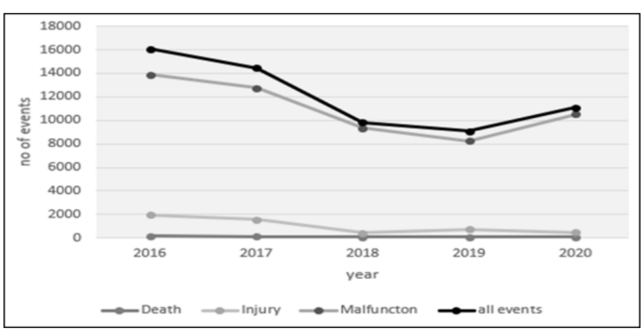

Figure 5 Adverse Event Type through last 5 years

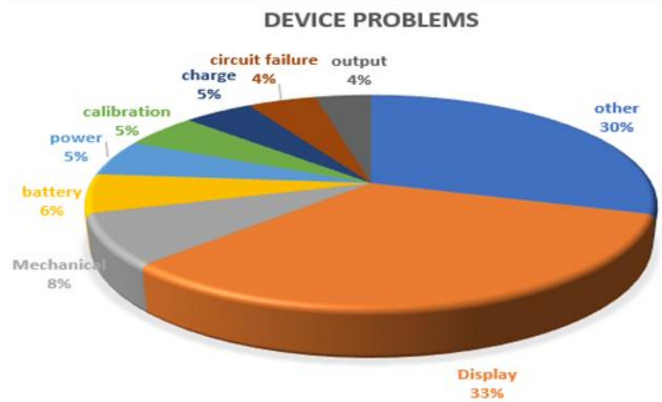

Figure 6 Device problems Categories for ICU ventialtor

Then the relation between device problems and manufacturer

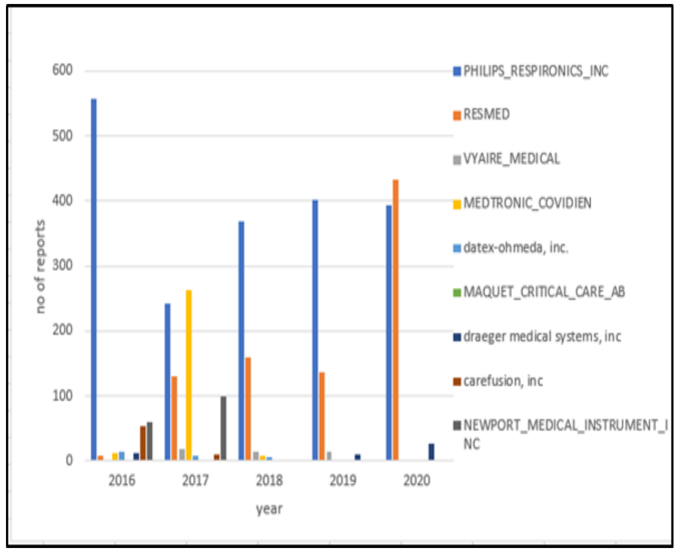

Figure 7 Manufacturer and Battery problem reports

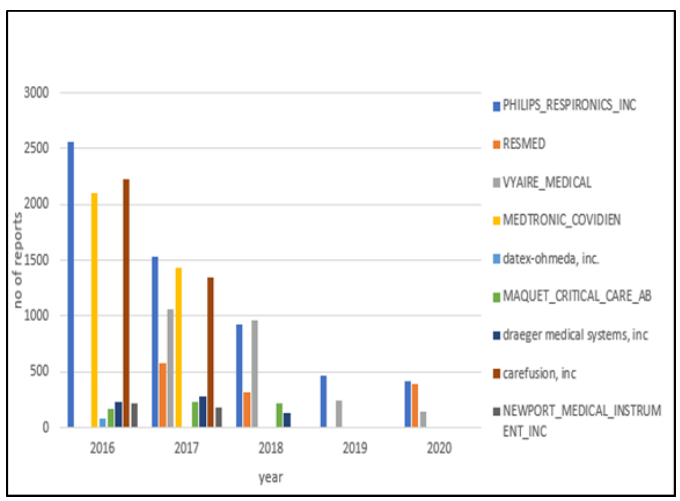

Figure 8 Manufacturers and display problem reports

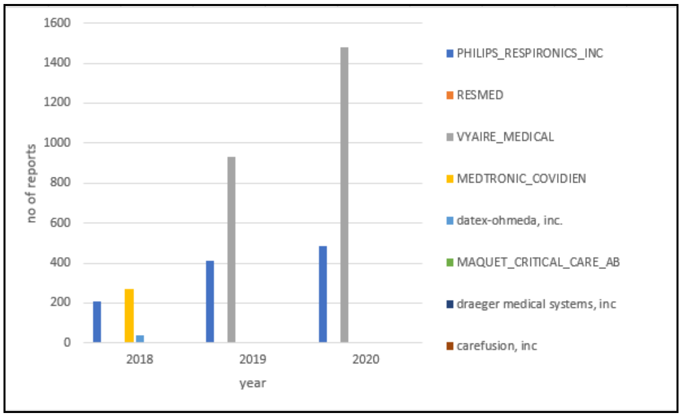

Figure 9 Manufacturers and Mechanical problem

- Most manufacture with mechanical device problem reports was VYAIRE_MEDICAL through last 2 years

All previous results were related to data analytics on ICU Ventilator (CBK) adverse events reports from MAUDE database.

B- Secondly for Ventilators in emergency with product code (BTL)

We found 8 cases of deaths and five of them their manufacturer was smith medical group, 60 cases injury and 54 cases of them their manufacture was smith medical group.

We found over 1,174 records that 26% of device problems was break problem, 25% was alarm problems, 16% was pressure problems, and 7% was volume problems (Volume Accuracy, Tidal Volume Fluctuations) and 26% other problems.

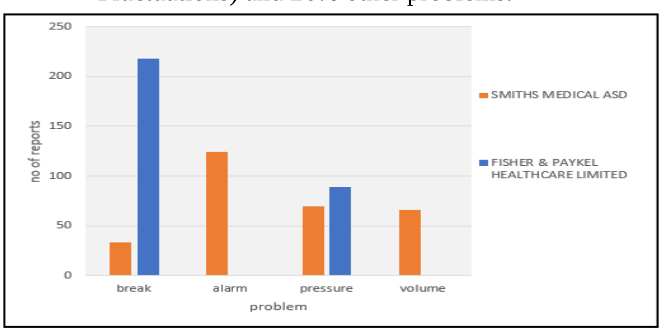

Figure 10 BTL Manufacturers and device problems

III. Discussion

This discussion on the results from structured data analysis we found that, there are three main event types of mechanical ventilators: injury, death and malfunction. We analyzed the existence of each adverse event in 2016, 2017, 2018, 2019 and 2020.The main global manufacturers of ventilators and their products are:

- ResMed (AstralTM100, AstralTM150)
- Philips Healthcare (Trilogy100, Trilogy200)
- Vyaire Medical (Fabian™ HFO BELLAVISTA™ 1000 VENTILATOR)
- Medtronic (Puritan Bennett™ 980 Ventilator)
- Draeger (Evita® V800)
- Fisher&Paykel Healthcare (F&P 850)

For CBK ventilators. In 2016 the highest adverse event was the malfunction, but the lowest was the injury. Passing through the period of study until 2020, malfunction and injury came down clearly.

After analyzing the device problems, the battery problems, mechanical problems, and display problems were the most frequented between the manufacturers.

We compared the manufacturers in the last five years depending on the main device problems. The highest manufacturer in causing battery problems was Philips but the lowest was Draeger. For mechanical problems, the highest was Vyaire Medical, but the lowest was Philips. For display problems, the highest was Philips, but the lowest was Draeger. So we don't recommend Philips ventilators.

About BTL ventilators, the main manufacturer was Fisher&Paykel Healthcare and Smith Medical Group. We found 8 cases of deaths and five of them caused by Smith Medical Group, 60 cases injury and 54 cases of them were Caused by Smith Medical Group too

IV. Conclusion

We introduced FDA MAUDE database which contains information about issues with medical devices that are on the market in the United States, we introduced how to extract this data, we analyzed its structured data and we got lot of plots

This indicates to which manufacturers have specific device problem categoty than others, we analyzed its unstructured data manually to make data transformation, and this transformation helped us to apply nlp technique for check the similarity between document with same class, this transformation which was based on manual technique helped us for applying multiclass text classification to predict for unseen reports to be classified with its device problem category, we end up with model which gives us accuracy with 86%, this model was linear kernel support vector machine, and for future work we'll need to reduce the loss of data during manual analysis for data transformation to get more precized results, also for future work we can work on the unstructured data analysis for more than one year and that is for gaining more experience.

V. References

[1] MAUDE Adverse Event Report: VYAIRE MEDICAL VELA VENTILATOR VENTILATOR, CONTINUOUS, FACILITY USE (fda.gov)

[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[3]https://analyticsindiamag.com/multi-class-text-classification-in-pytorch-using-torchtext/

[4].https://searchenterpriseai.techtarget.com/definition/natural-language-processing-NLP

[5] https://www.nltk.org/_modules/nltk/tokenize/regexp.html

[6]https://www.analyticsvidhya.com/blog/2021/06/text-preprocessing-in-nlp-with-python-codes

[7]https://www.analyticsvidhya.com/blog/2020/02/quick-introduction-bag-of-words-bow-tf-idf/