Research on the Correlation Between Receiving Pfizer-Biontech COVID-19 Vaccine and Getting Facial Paralysis

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Abstract: COVID-19 vaccines are widely administered to reduce the spread of COVID-19 and prevent serious illness and death after getting infected. Pfizer/BioNTech COVID-19 vaccines are administered the most within the United States, and facial paralysis is one of the adverse events found after receiving the vaccines. The primary aim of the paper is to develop a predictive model which uses the features of vaccine receivers to predict whether facial paralysis would emerge as an adverse effect. Four predictive modes trained by undersampled and oversampled data from the Vaccine Adverse Event Reporting System (VAERS) are developed using logistic regression and decision tree from the last quarter of 2021, and features are selected using chi-square statistics. The four performance metrics (accuracy, recall, precision, and F1 score) indicate the incapability of models in making decisions, which also implies the irrelevance of selected features. However, the associations between selected features and the high-level anxiety of the general public have in receiving vaccines under the pandemic are worth further research and physicians to study and explore for a more comprehensive understanding of the adverse events of COVID-19 vaccines, manufactured by Pfizer/BioNTech specifically. This paper finds that four performance metrics indicate these models are not capable of making sensitive predictions, which implies the irrelevance of the selected features and getting facial paralysis after receiving Pfizer/BioNTech COVID-19 vaccines. However, the connections between selected features and the huge amount of cases reported within a year reveal the high level of anxiety that the general public has in receiving vaccines under the pandemic.

1 INTRODUCTION

Since the December of 2019, the global pandemic caused by the SARS-CoV-2 virus has brought devastating impacts to the whole society and economy. According to the World Health Organization (WHO), as of 6 January 2022, the SARS-CoV-2 virus has infected 296,496,809 people worldwide and caused 5,462,631 deaths (Who coronavirus (COVID-19) dashboard, 2022). To protect the general public from getting COVID-19, to reduce the spread of COVID-19, and to decrease the severity of sickness after getting infected, CDC recommends people who are 5 years and older get vaccinated and remain up to date with their vaccines (Benefits of getting a COVID-19 vaccine, 2022). Further, a high level of protection against Multisystem inflammatory syndrome in persons aged 16-18 years after receiving 2 doses of COVID-19 vaccines, manufactured by Pfizer/BioNTech specifically (Li, 2020). As of 12 January 2022, there are 9 COVID-19 vaccines validated for use in Emergency Use Listing by WHO, including the Pfizer/BioNTech Comirnaty, the Moderna COVID-19 vaccine, Sinovac-CoronaVac, etc. (Coronavirus disease (covid-19): Vaccines, 2022).

Among the approved vaccines, approximately 284 million Pfizer/BioNTech are administered as of December 15, 2021, which is the most COVID-19 vaccine administered in the United States (Mikulic, 2021). CDC has suggested several possible side effects of getting the vaccine, including tiredness, headache, fever, etc. (Pfizer-biontech COVID-19 vaccine overview and Safety, 2022). Facial paralysis is one of the rare and serious adverse events found after getting vaccinated according to the Vaccine Adverse Event Reporting System (VAERS). Although a huge amount of self-reported adverse effects can be found in VARES, few predictive models are created to predict the relationship between specific features of the patients, such as the current

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medication and illness, and the adverse events that may take place.

In this paper, the relationship between specific features of the patient who got Pfizer/BioNTech vaccine and facial paralysis are studied by using the data from VARES during the last quarter of 2021, September 1st to December 10th specifically. To help determine the relationship, I first used a chi-squared test to select features and then applied logistic regression and decision tree to train the model separately, and finally check the accuracy, precision, recall rates, and F1 score of the model. The result can be used as a reference for people who intend to get Pfizer/BioNTech COVID-19 vaccines but are afraid of experiencing facial paralysis as a specific adverse event.

2 METHOD

2.1 Data Source

All of the data used in the paper are obtained from the Vaccine Adverse Event Reporting System (VAERS). VAERS was created by the U.S. Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), and CDC to receive reports about adverse events which might be associated with vaccines, among all age groups, after the administration of any licensed vaccine in the United States (Vaccine Adverse Event Reporting System, 2021).

2.2 Data Collection

Due to the large number of cases associated with Pfizer/BioNTech COVID-19 vaccines reported, nearly four hundred and fifty thousand until December 10th, 2021, and due to technological limitations and a lack of researchers, data from September 1st to December 10th are chosen for analysis.

The three tables provided in VAERS are merged into one table by using the ID of each case. After filtering other vaccine names except for "COVID19 (COVID19 (PFIZER-BIONTECH))" and keeping the cases that have facial paralysis as one of the symptoms, four columns are kept for features selection, including "OTHER_MEDS," "CUR_ILL," "HISTORY," and "SEX."

"OTHER_MEDS" contains information about any prescription or non-prescription drugs the vaccine recipient was taking at the time of vaccination; "CUR_ILL" contains information about any current illnesses the vaccine recipient had at the time of vaccination; and "HISTORY" contains information about any pre-existing physician-diagnosed birth defects or medical condition that existed at the time of vaccination (Vaccine Adverse Event Reporting System, 2021).

The characteristics of patients are shown in table 1:

Table 1: Characteristics of Patients.

	Total (n = 113363)
Age (years), mean (SD)	48.8 (20.8)
Sex, n (%)	
Female	74638 (65.8)
Male	37889 (33.4)
Unknown	836 (0.7)
Facial Paralysis, n (%)	237 (0.2)

2.3 Data Pre-Processing

2.3.1 Data Variation

Because most of the cases are self-reported, a large number of variations in reporting the adverse events have appeared, including missing information, misunderstanding of requests, and different formats of writing. The first five rows of the four selected columns before feature extraction are presented in table 2:

Table 2: Selected Columns.

SEX	OTHER_MEDS	CUR_ILL	HISTORY
F	pre-natal vitamin, vitamine D supplément, Biotin, Vitamin C supplement.	none.	none.
F	Unknown	None listed	none listed
F	NaN	NaN	NaN
F	Vitamin D, C, and zinc	None	NaN
F	Multivitamin, cymbalta	None	Depression and anxiety

There are two ways in reporting adverse events: report online and through a PDF form, and the missing information may be due to the second method, as the PDF used by VAERS does not have the function of making people fill in essential blanks, such as age and gender. Misunderstanding of requests may because of the relatively complicated reporting system, which makes unwanted information filled in the form. For example, the type of tests done by the person, such as TB tests, are filled in blanks for the current illness. Different formats of writing generate the greatest barrier in pre-processing the data, as the long sentences provided by the vaccine recipients include different capitalizations between words, different punctuations or whitespaces in splitting the items listed, and different names of the same medicines or symptoms.

2.3.2 Features Selection

To select features from the four columns "OTHER_MEDS," "CUR_ILL," "HISTORY," and "SEX," I replaced all the punctuations with whitespaces and split the substrings by whitespaces. Then, the frequency of each substring is collected, and I picked 26 most frequent features from the four columns. For each feature selected, a chi-squared statistic is assigned. The chi-squared statistic is a commonly used method for feature selection, with the initial hypothesis H0, which assumes the features and the class label are unrelated. The greater the value of chi-squared statistic, the greater evidence against the hypothesis H0, which means the features and class label are more related (Chawla, 2002). The chi-squared formula is shown in equation 1:

$$\chi^2 = \Sigma_{i=1}^{k} \frac{(O_i - E_i)^2}{E_i} \quad (1)$$

In equation 1, k represents the number of features, represents the observed count for the group, and represents the expected count for the group.

The chi-squared statistics for the 26 features with respect to the target "Facial_Paralysis" is shown in table 3. Features with the ten highest chi-square statistics are selected for model training afterwards, including "Metformin," "Metoprolol," "Atherosclerosis," "Stroke," "Hypoglycemia," "Hypertension," "Diabetes," "Amlodipine," "Losartan," and "Gerd."

Table 3: Chi-Squared Statistics of Features.

Features	Score	Features	Score	Features	Score	Features	Score
Metformin	31.79	Amlodipine	13.80	Migraines	2.08	Sex	0.42
Metoprolol	30.34	Losartan	13.41	Atorvastatin	2.00	Levothyroxine	0.15
Atherosclerosis	29.98	Gerd	10.21	Osteoarthritis	1.22	Depression	0.01
Stroke	25.18	Apnea	9.61	Omeprazole	1.20	Asthma	0.01
Hypoglycemia	24.75	Lisinopril	8.07	Arthritis	1.05	Hypothyroidism	0.01
Hypertension	16.00	Aspirin	3.17	COVID	0.99		
Diabetes	15.83	Hyperlipidemia	2.30	Albuterol	0.60		

The ten features were further converted to numerical data by using one hot encoding, which is a process in converting categorical features into indicative variable for better model training.

2.3.3 Oversampling and Undersampling

The total number of cases in the quarter data is 113,363, but only 237 of the cases have facial paralysis, which makes the data in cohort imbalanced. Classifiers that are trained on extremely imbalanced data would be biased towards the majority class, which is not having facial paralysis in this case. In the experimenting process, the Logistic Regression model trained with original data, which was split into 67% training set and 33% testing set, had achieved nearly 100% accuracy, but the problem was that the predictive model tried to predict everyone in the testing set without facial paralysis. For better model training, both oversampling and undersampling methods are used separately for training models.

For oversampling, the synthetic minority oversampling technique (SMOTE) is used. The basic idea of SMOTE is oversampling the minority class by

taking every minority class sample and applying synthetic examples along the line segments that join any or all of the k minority class nearest neighbors (Bidgoli, 2012). The optimal SMOTE ratios for different models are found through hyperparameter tuning, using an Exhaustive Grid Search from Scikit learn with a three-fold cross validation and F1 score as the scoring method.

For undersampling, random undersampling is used. The basic idea of random sampling is randomly deleting examples in the majority class. I randomly deleted the majority class till the imbalanced cohort has 50:50 class ratio, because when random undersampling the negative class to half of the ratio, similarities can be found in the average performance when comparing to the model using the entire big dataset (Hasanin, 2018).

2.4 Model Training

The datasets after oversampling and undersampling are split into 67% training set and 33% testing set. Two machine learning algorithms are selected to train the predictive model, including logistic regression (Hosmer, 2013) and decision tree classifier (Song, 2015), using the features with 10 highest chi-squared statistics as independent variables and facial paralysis as the dependent target. Therefore, there are four models in total to predict whether the patient with given features will have facial paralysis after getting Pfizer/BioNTech COVID-19 vaccine, including logistic regression classifier with undersampled data, logistic regression classifier with oversampled data, decision tree classifier with undersampled data, and decision tree classifier with oversampled data.

The criterion for choosing the optimum split in the decision tree classifier is entropy. Entropy is the measure of the disorder level of the features selected with the target, and in this case, entropy is the disorder level of the ten features with facial paralysis. The higher the entropy of features, the higher level of disorder, which makes the optimum split chosen by the least entropy. The entropy formula is shown in equation 2:

$$S = -\Sigma_c p_c \log_2 p_c \quad (2)$$

In equation 2, is the proportion of data points in a node with label C.

Pipelines are created for models with the oversampling method in the training process. All the pipelines include oversampling approach, SMOTE, with sampling strategy obtained by hyperparameter tuning and the machine learning algorithms used.

2.5 Model Evaluation

The performances of the four predictive models are evaluated based on the four scores obtained from 10-fold cross validation, including accuracy, recall, precision, and F1 score. All four scores are calculated by using True Positive (TP), True Negative (TN), False Positive (FP), and False Negative (FN). Equations of the four metrics are shown:

$$accuracy = \frac{TP+TN}{TP+TN+FP+FN} \quad (3)$$

Equation 3 shows the formula of accuracy, which represents the proportion of correctly predicted observations in total observations, which is important when the dataset has a nearly equal number of False Positives and False Negatives.

$$recall = \frac{TP}{TP+FN} \quad (4)$$

Equation 4 shows the formula of recall, which represents the proportion of correctly predicted positive observations in total actual positive observations, which is important when the cost of False Negatives is high.

$$precision = \frac{TP}{TP+FP} \quad (5)$$

Equation 5 shows the formula of precision, which represents the proportion of correctly predicted positive observations in total predicted positive observations, which is important when the cost of False Positives is high.

$$F1\ score = \frac{2TP}{2TP+FP+FN} \quad (6)$$

Equation 6 shows the formula of F1 score, which represents the harmonic mean of precision and recall, which is important when a balance in precision and recall is needed and the dataset is imbalanced.

Although these four metrics are useful in evaluating the performance of a model, they focus on different perspectives as mentioned above. In our case where the dataset is highly imbalanced, with only 0.2% positive cases, precision, recall, and F1 score are more preferred than accuracy. Despite False Positives and False Negatives are both undesirable outcomes, the consequence brought by False Negatives in medical prediction is worse because patients would get the incorrect prediction and be exposed to the risk in getting facial paralysis after receiving Pfizer/BioNTech COVID-19 vaccine. Therefore, the importance rank of the four metrics would be recall, precision, F1 score, and accuracy.

Further, to avoid an optimistic estimate of the model performance, the 10-fold cross validation is

performed on the original training and testing sets (before SMOTE and random undersampling) with the model trained on resampled data (after SMOTE and random undersampling). Table (4) provides a summary of the performance of the four models:

Table 4: Model Performance.

	Logistic Regression		Decision Tree	
	SMOTE	Random Undersampling	SMOTE	Random Undersampling
Recall	1.84%	28.00%	3.09%	20.00%
Precision	1.30%	0.44%	2.16%	0.50%
F1 Score	1.36%	0.87%	2.73%	0.98%
Accuracy	99.63%	87.24%	99.46%	91.90%

Comparing between the metrics of the four models, the Logistic Regression model with data after undersampling is the best-performing model, with 28.00% for recall, 0.44% for precision, 0.87% for F1 score, and 87.24% for accuracy. However, the Logistic Regression model trained with data after oversampling using SMOTE has the worst model performance, with 1.84% for recall, 1.30% for precision, 1.36% for F1 score, and 99.63% for accuracy.

Although the Logistic Regression model trained with data after random undersampling has the best performance among the four models, it is still incapable for predicting whether the person who received Pfizer/BioNTech COVID-19 vaccines with given features would get facial paralysis. Apply the metrics in the best-performing model in context, among those patients who had facial paralysis, only 28% of them are successfully predicted, and among those who are predicted to have facial paralysis, only 0.44% of them really suffer from it. Therefore, all of the four models that are trained by using the ten highest chi-squared statistics features are incapable in making predictions, which further reveals the fact that the features selected are relatively irrelevant to the target class facial paralysis under the condition of receiving Pfizer/BioNTech COVID-19 vaccines.

3 DISCUSSION

Given the broadly administration of COVID-19 vaccines to combat with the global pandemic COVID-19, a notable number of adverse events has emerged. Facial paralysis is one of the adverse events occurred after receiving Pfizer/BioNTech COVID-19 vaccines according to the Vaccine Adverse Event Reporting System (VAERS). Using Logistic Regression and Decision Tree Classifier, I developed four models to predict whether the person might get facial paralysis after receiving Pfizer/BioNTech COVID-19 vaccines given the ten features, including “Metformin,” “Metoprolol,” “Atherosclerosis,” “Stroke,” “Hypoglycemia,” “Hypertension,” “Diabetes,” “Amlodipine,” “Losartan,” and “Gerd.” The 26 features are selected based on the appearing frequencies in the dataset among four columns (“OTHER_MEDS,” “CUR_ILL,” “HISTORY,” and “SEX”) in the merging dataset tables at first. Further, a chi-squared statistic is assigned to each feature, and the ten features with the highest chi-square statistics are kept for final model training. Due to the imbalance proportion of positive and negative cases in the original dataset, random undersampling and synthetic minority oversampling technique are applied to the dataset in order to train the model unbiasedly and improve the overall performance. The performance of models is evaluated through a 10-fold cross validation on four metrics, including recall, precision, F1 score, and accuracy.

The Logistic Regression model trained with random undersampling data has the best performance among the four models built, according to the performance metrics. Recall is the most determining performance metric as the cost of False Positive is high in medical cases, whereas the best model only achieves 28% for recall, which indicates all the models are not sensitive enough do the prediction. This also implies the features selected are not relevant enough to getting facial paralysis as the result of receiving Pfizer/BioNTech COVID-19 vaccines.

Although the 10 features are not predictive or causal to facial paralysis as one of the adverse events after receiving Pfizer/BioNTech COVID-19 vaccines, the relations between features might worth to be researched by further studies or considered by physicians. Within the ten features, 6 of them are illnesses and the rest 4 are medications, where strong relationships could be found.

Feature "Stroke" could cause oro-facial impairment directly, which can be described as facial paralysis (Schimmel, 2017). Further, features "Diabetes" and "Hypertension" are the two main systemic comorbidities associated with Bell's Palsy, another form of facial paralysis, and hypertension is also a major modifiable contributor to stroke (Mancini, 2019; Buonacera, 2019). Feature "Atherosclerosis" has an ischemic stroke as one of its major clinical manifestations (Herrington, 2016). Feature "Hypoglycemia" is one of the essential issues for diabetic patients, and repeated hypoglycemia could rise the risk of cardiovascular diseases (Tourkmani, 2018).

From the medication features' perspectives, feature "Metformin" is widely used to treat type 2 diabetes at early stages (Lv, 2020). Features "Metoprolol," "Amlodipine," and "Losartan" are used to reduce morality in patients with hypertension and coronary heart diseases, which might further reduce the risk of hypertensive stroke (Kwon, 2013; Pareek, 2010).

The relations between the ten selected features are presented graphically in Figure 1:

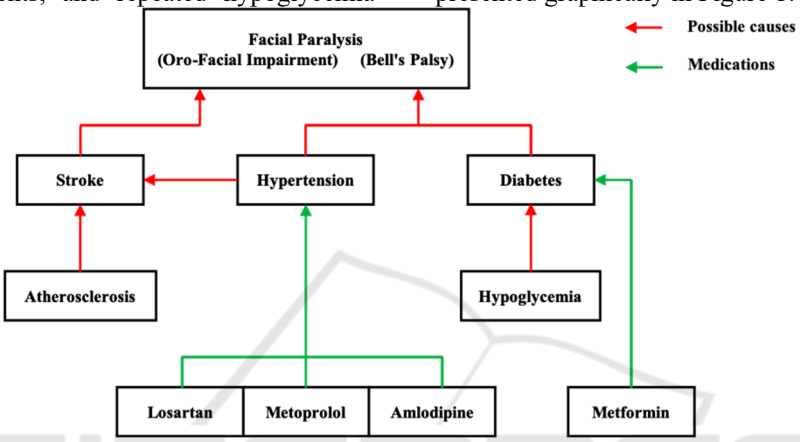

Figure 1: Relations of Features.

Therefore, the weak-performing models and the direct relations between selected features and facial paralysis indicate this specific adverse event reported in VAERS might because of the pre-existing conditions and current medications intake of patients but not because of receiving Pfizer/BioNTech COVID-19 vaccines. However, further studies with sufficient time and funds are needed to utilize the whole dataset in order to reach a more comprehensive conclusion.

Furthermore, nearly 450 thousand adverse events associated with Pfizer/BioNTech COVID-19 vaccines were reported within a year, beginning December 15th, 2020, and ending December 10th, 2021. Such a huge amount of reported cases for a single brand of vaccine in a relatively short period of time could imply the anxiety of people after receiving vaccines during a pandemic. It is worth noting that there is a bidirectional temporal association between facial paralysis and anxiety (Tseng, 2017). Therefore, the prevalent anxiety could be another risk factor for the facial paralysis cases, and further studies need to explore the correlation between anxiety and facial paralysis under the condition of receiving Pfizer/BioNTech COVID-19 vaccines.

4 CONCLUSION

The primary goal of this study is to develop a model to predict whether the Pfizer/BioNTech COVID-19 vaccines receiver would get facial paralysis as an adverse event based on the data from VAERS. The self-report system of VAERS where everyone is able to submit an adverse event case makes the data incomprehensive and easily biased, and the feature extraction process during data analysis might miss information by breaking the completeness of sentences. Another major limitation is the partial data involved, as only the last quarter of the records are used due to huge amount of data involved and limited research resources. Further explorations of the association between facial paralysis and receiving Pfizer/BioNTech COVID-19 vaccines with more comprehensive data and more cost-sensitive models are expected. Although four predictive models are developed using features with the highest chi-squared statistics, four performance metrics indicate these models are not capable in making sensitive predictions, which implies the irrelevance of the selected features and getting facial paralysis after

receiving Pfizer/BioNTech COVID-19 vaccines. However, the connections between selected features and the huge amount of cases reported within a year reveal the high level of anxiety that general public has in receiving vaccines under the pandemic. Further studies are needed to investigate the association between anxiety and other diseases before and after receiving COVID-19 vaccines. Because getting vaccinated could reduce the spread of COVID-19 and prevent serious illness and death after getting infected (Stay up to date with your vaccines, 2022), the general public should be positive towards COVID-19 vaccines and be confident in the fight against COVID-19.

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