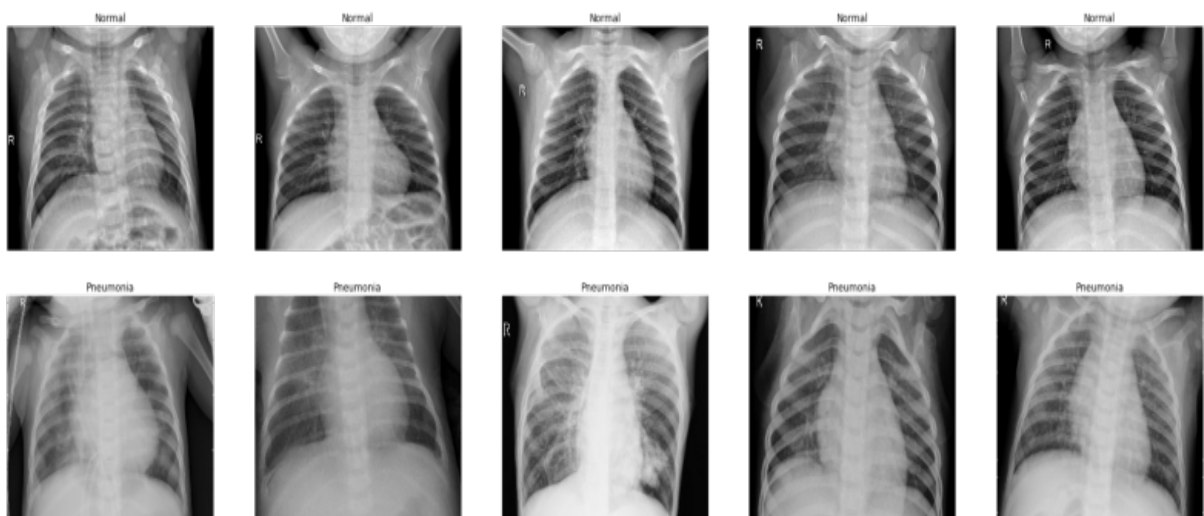


Pneumonia Detection from Chest X-Rays



AI for Healthcare Nanodegree Program

Project 1

FDA Submission

Your Name: Raghad Alharbi

Name of your Device: Deep Pneumo Detector

Algorithm Description

1. General Information

Intended Use Statement:

This algorithm is intended for use in assisting a radiologist with the detection of the presence of pneumonia in a chest X-rays screening.

Indications for Use:

This algorithm is indicated for use in screening chest X-Ray studies of pneumonia in men and women of ages 1-95 with posteroanterior (PA) or anteroposterior (AP) views. The algorithm should be integrated into the normal workflow of the diagnostic clinics. The X-Ray images should be available in DICOM format, respecting the HIPAA rules. The data is then sent through your algorithm and it first checks the conditions. If it satisfies the criteria, it makes the prediction. Once the prediction is complete, this data is sent to a radiologist, and then he/she will give the final decision based on his/her independent diagnosis as well as the data supplied by your algorithm.

Device Limitations:

This algorithm is not appropriate to be use in emergency sittings because of its performance based limitations. This algorithm needs a GPU to preforme well.

Clinical Impact of Performance:

The algorithm was designed to have higher F1 score and high recall which means there may be more false positive. This means it is more likely for the algorithm to classify a non-pneumonia x-ray image as having pneumonia. The algorithm can also produce false negative result where xray image with pneumonia may be classified as not having pneumonia, which is not an intended outcome, and can be a life threat if the predition was taken into consideration without any further assessment by a Radiologist.

2. Algorithm Design and Function

Algorithm Flowchart

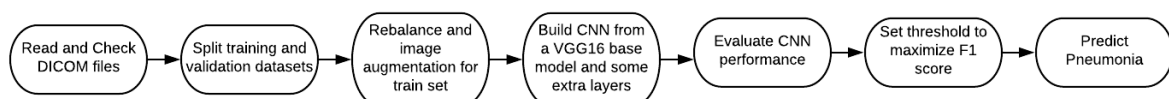


Diagram Steps:

- Read and Check DICOM files
- Split training and validation datasets
- Rebalance and image augmentation for train set
- Build CNN from a VGG16 base model and some extra layers
- Evaluate CNN performance
- Set threshold to maximize F1 score

- Predict Pneumonia

DICOM Checking Steps:

1. The Algorithm reads in DICOM File.
2. Extracts Patient and picture information.
3. Checks if Modality is 'DX'.
4. Checks if Patient Age is less than 100.
5. Checks if Body Part Examined is 'Chest'.
6. Checks if Patient Position is either 'PA' or 'AP'.

Preprocessing Steps:

1. Image is resized to 224 x 224 pixels.
2. Image intensity is normalized.

CNN Architecture:

- The base model is a [VGG16](#) model that was pre-trained on Imagenet data.
- Extra layers has been added to the top of the base model:
 - Flatten
 - Dropout with 30% probability
 - Dense, 1024 units with ReLU activation
 - Dropout Dropout with 30% probability
 - Dense, 512 units with ReLU activation
 - Dropout with 30% probability
 - Dense, 256 units with ReLU activation
 - Dropout with 30% probability
 - Dense, 1 unit with Sigmoid activation

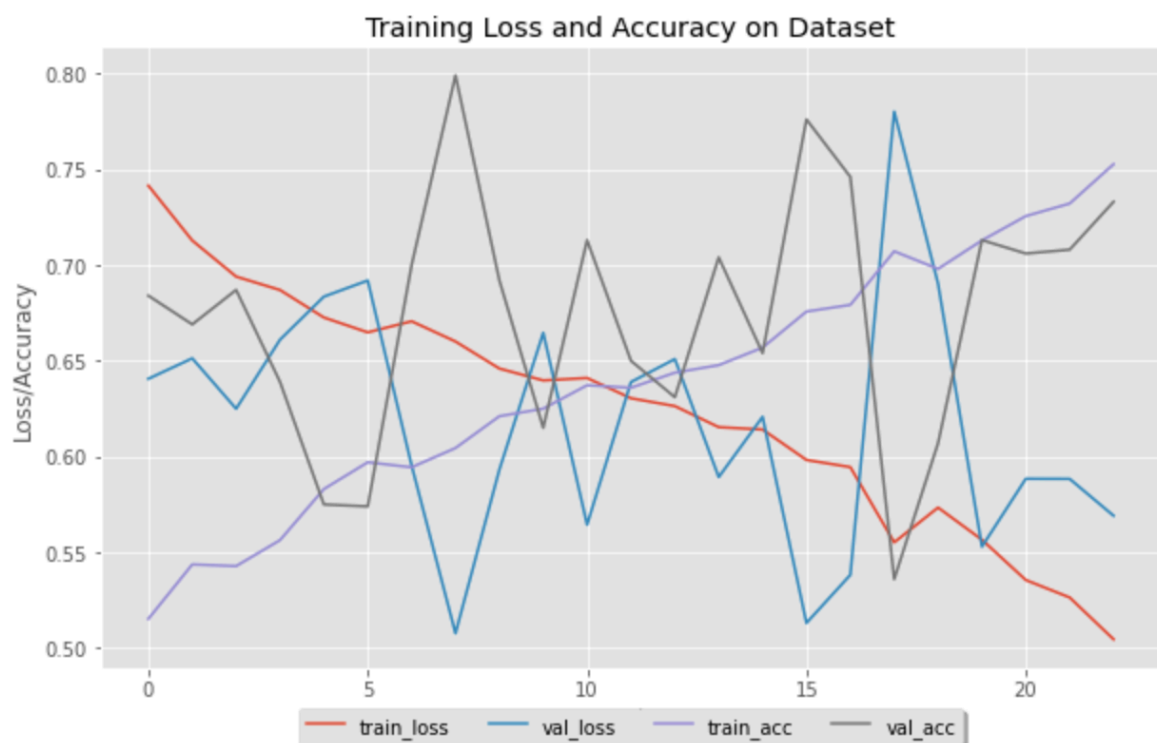
3. Algorithm Training

Parameters:

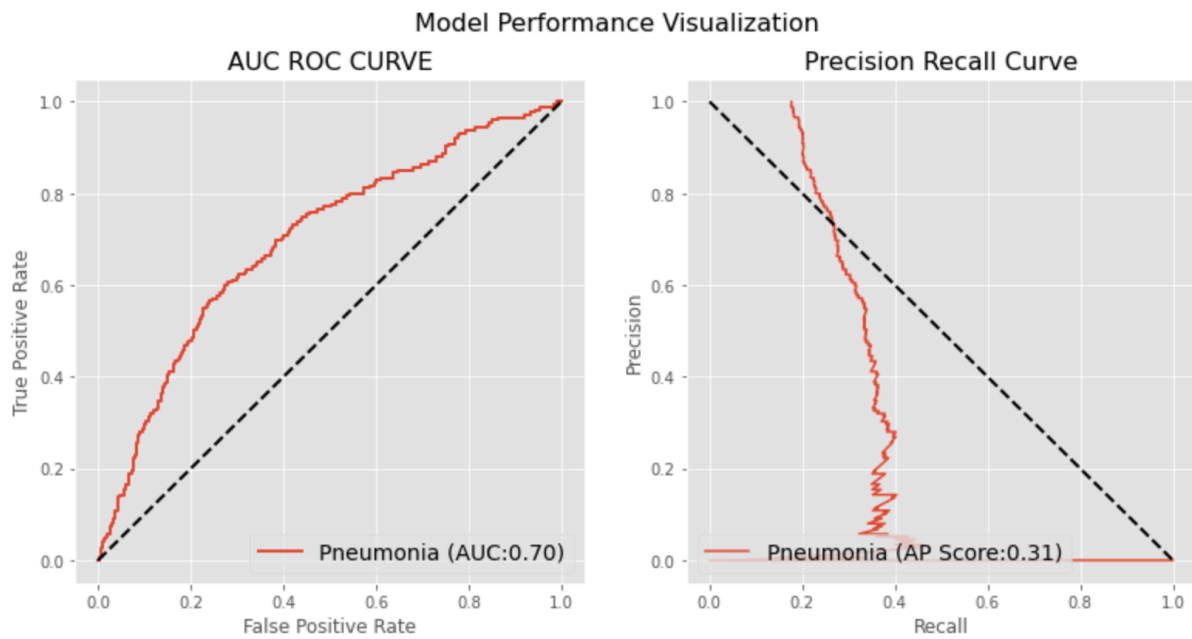
- Types of augmentation used during training:
 - rescale=1. / 255.0
 - horizontal_flip = True
 - vertical_flip = False
 - heightshift_range = 0.1
 - widthshift_range = 0.1
 - rotation_range = 10
 - shear_range = 0.1
 - zoom_range=0.1

- Types of augmentation used during validation:
 - rescale=1. / 255.0
- Batch size:
 - Training set batch size = 128 images
 - Validation set batch size = 1000 Images
- Optimizer learning rate: 1e-4
- Layers of pre-existing architecture that were frozen:
 - The first 17 layers of the VGG16 base model
- Layers of pre-existing architecture that were fine-tuned:
 - All layers other than the first 17 layers
- Layers added to pre-existing architecture:
 - Flatten
 - Dropout with 30% probability
 - Dense, 1024 units with ReLU activation
 - Dropout with 30% probability
 - Dense, 512 units with ReLU activation
 - Dropout with 30% probability
 - Dense, 256 units with ReLU activation
 - Dropout with 30% probability
 - Dense, 1 unit with Sigmoid activation

Algorithm training performance visualization:

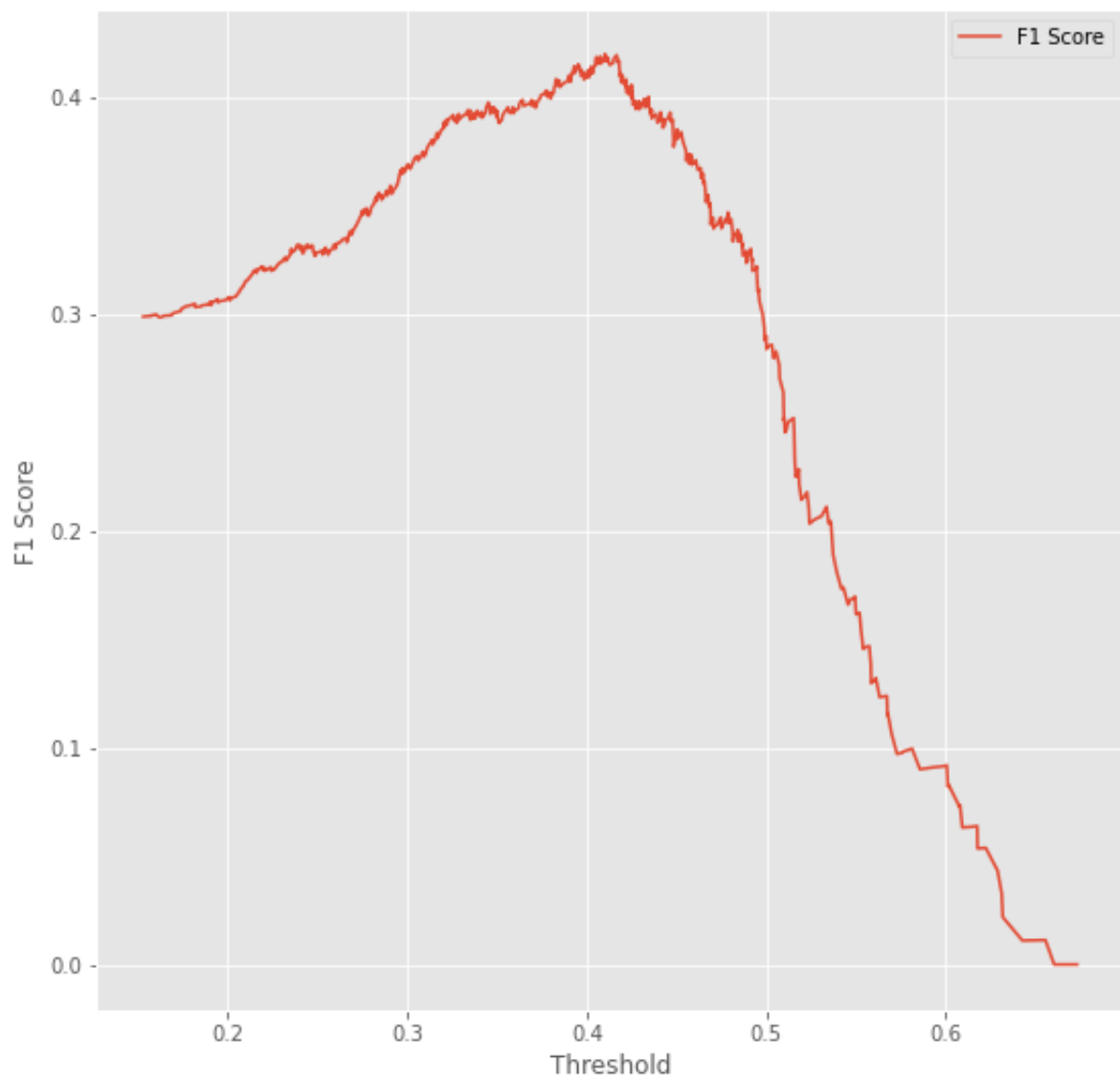


AUC and P-R Curve:



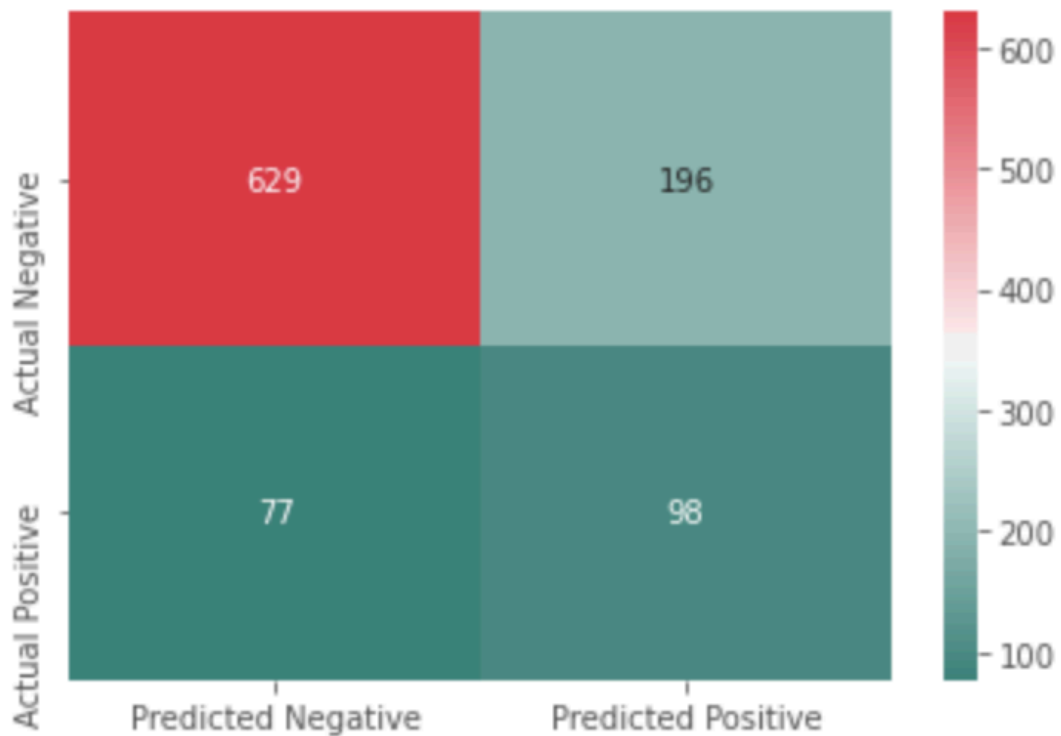
Final Threshold and Explanation:

Threshold of 0.41005385 was chosen based on the best F1 score, which was 0.417910



- Accuracy = 0.727
- Precision = 0.3333333333333333
- Recall = 0.56
- F1 Score = 0.41791044776119407
- Sensitivity = 0.56
- Specificity = 0.7624242424242424

Confusion Matrix:



4. Databases

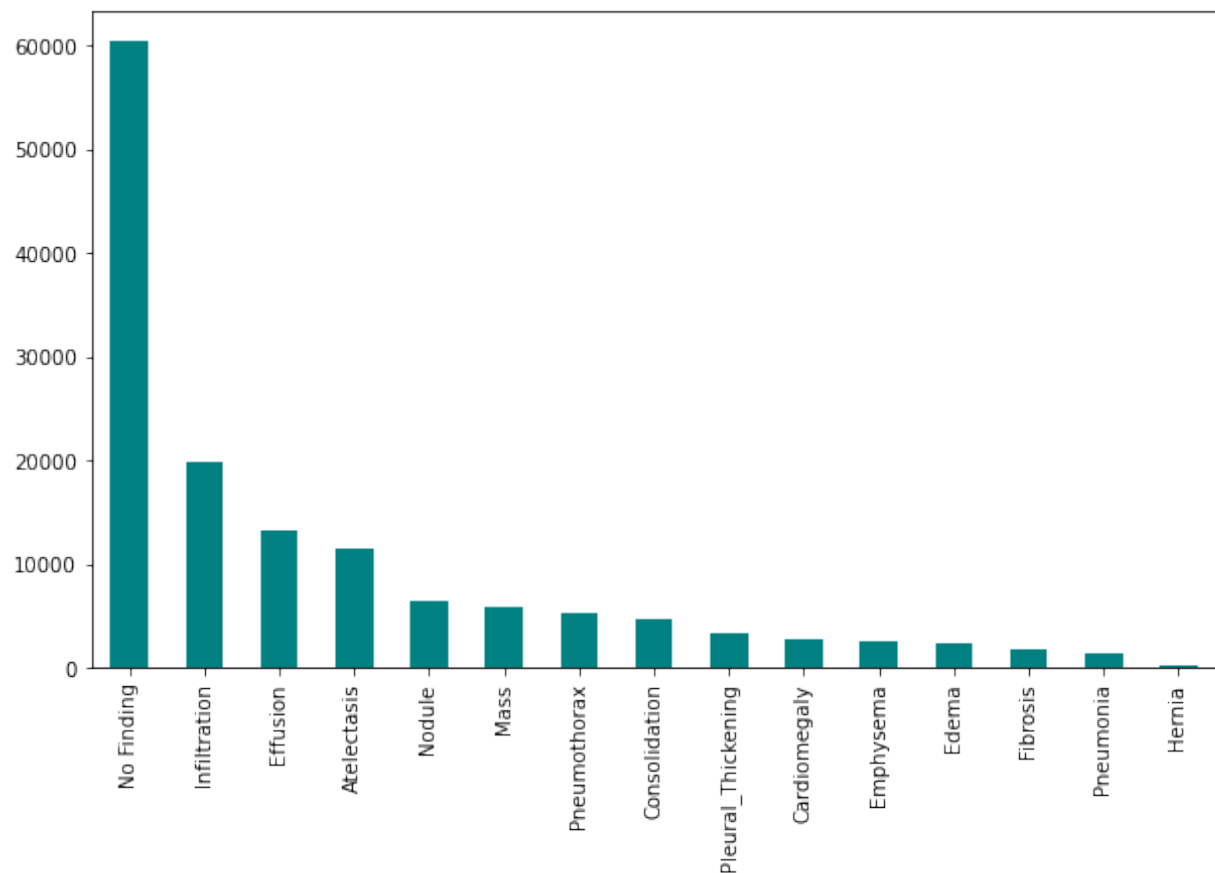
This NIH Chest X-ray Dataset contains 112,120 X-ray images with disease labels from 30,805 unique patients. The disease labels were created using Natural Language Processing (NLP) to mine the associated radiological reports. The labels include 14 common thoracic pathologies:

- Atelectasis
- Consolidation
- Infiltration
- Pneumothorax
- Edema
- Emphysema
- Fibrosis
- Effusion
- Pneumonia
- Pleural thickening
- Cardiomegaly
- Nodule
- Mass
- Hernia

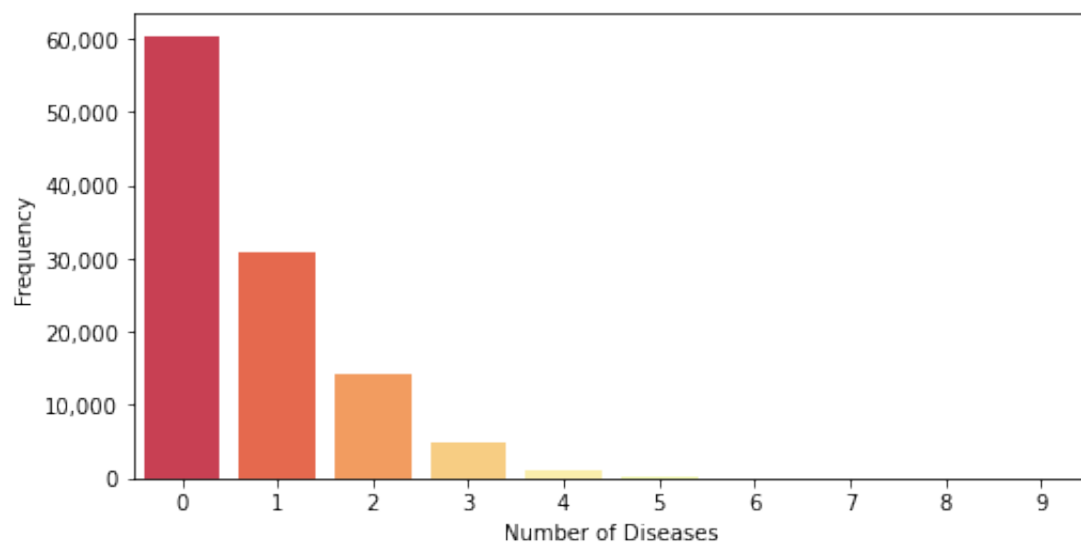
Some statistics about all patients in the dataset:

All patients in the dataset:

Distribution of Diseases in the Dataset

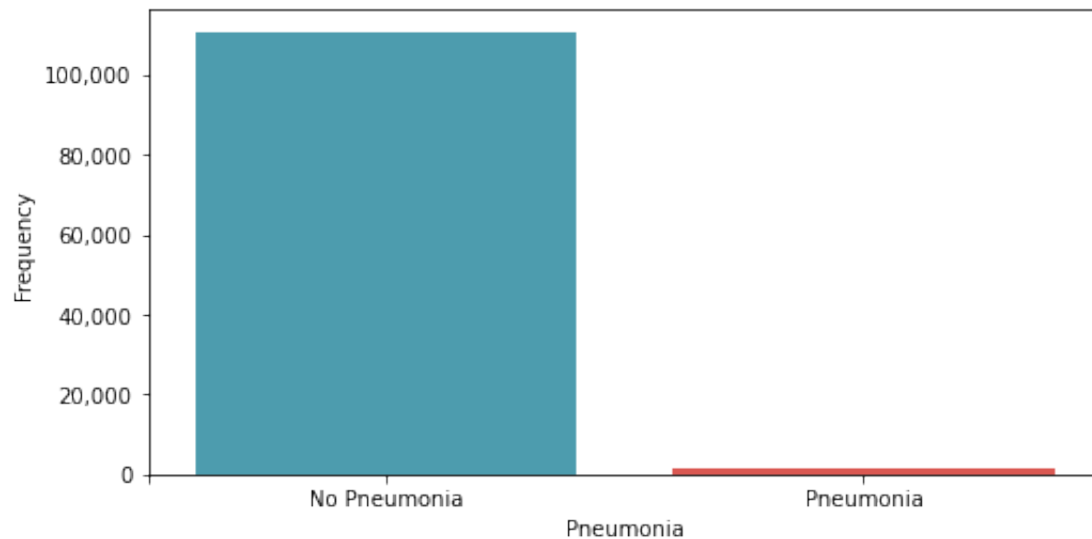


The Distribution of Number of Diseases in all Patients



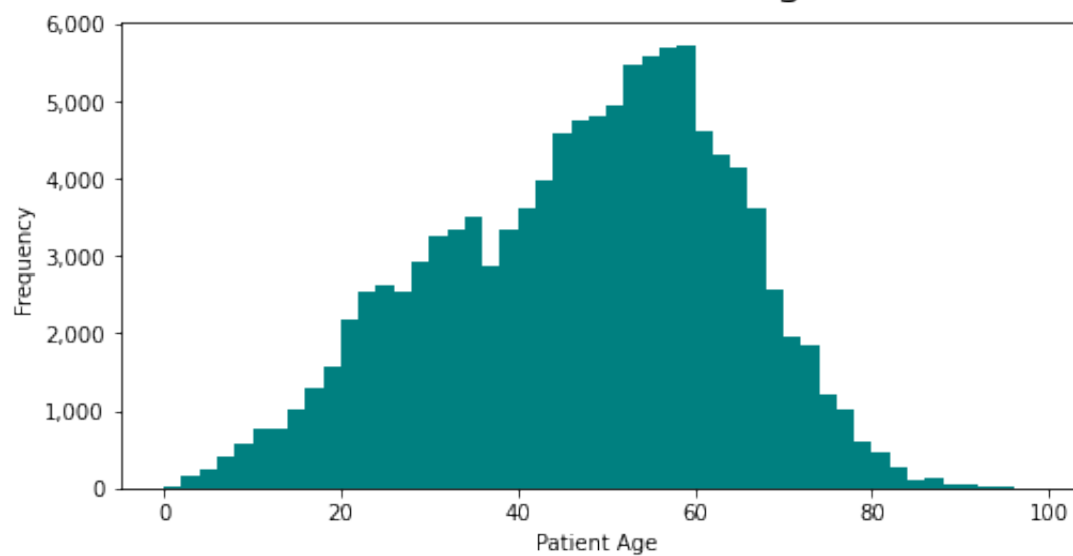
The population is highly imbalanced between pneumonia and non-pneumonia cases. There are total of 110689 samples with no pneumonia, and 1431 samples with pneumonia in the dataset.

The Distribution of Pneumonia in all Patients

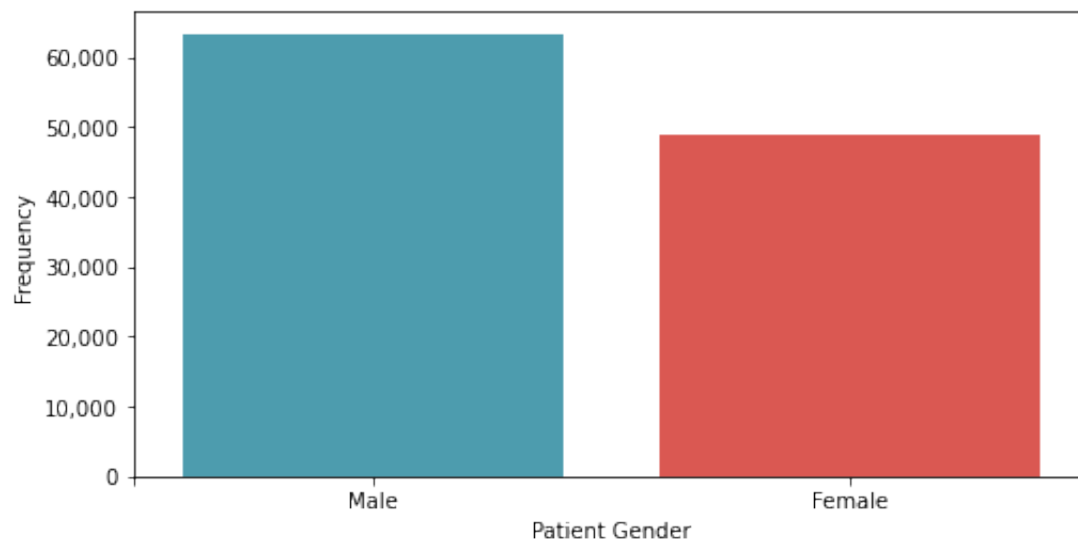


The patient population for these images were 1-95 year olds and 56.5% male and 43.5% female.

The Distribution of Age



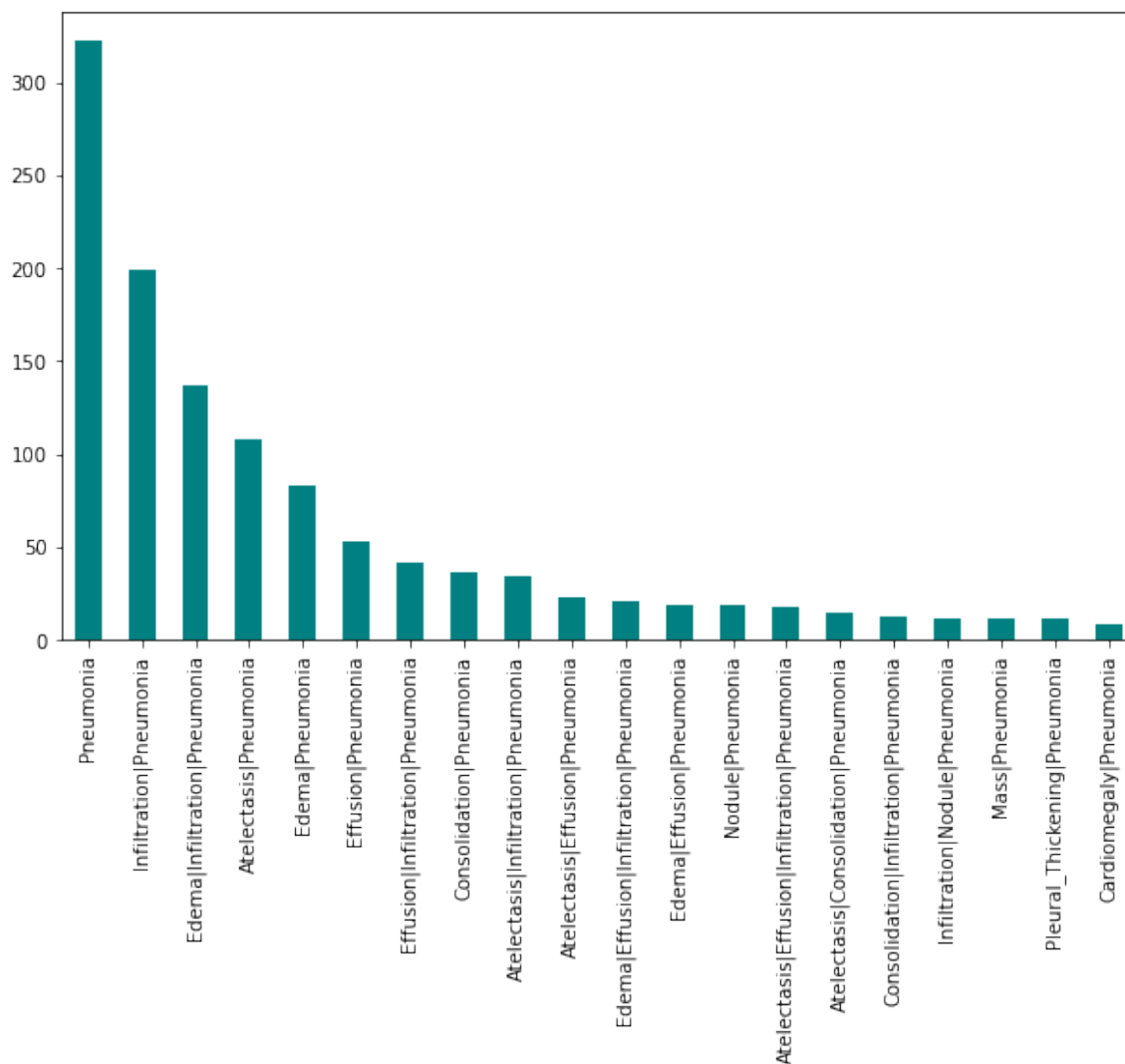
The Distribution of Gender in all Patients



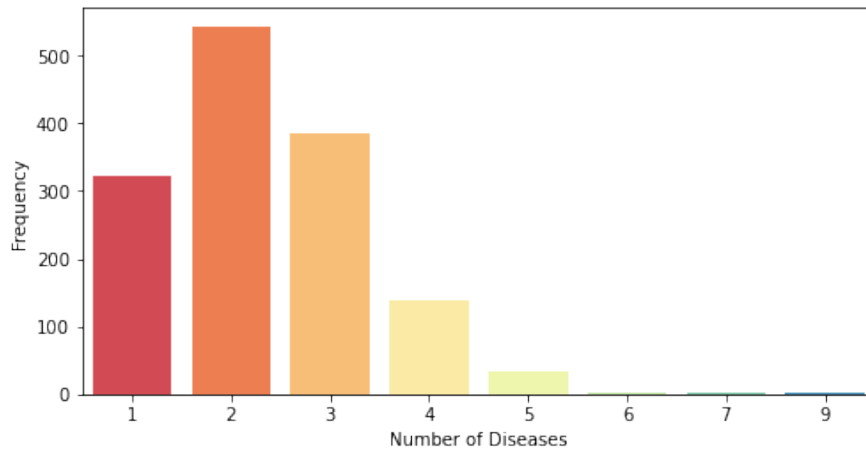
Some statistics about Pneumonia patients in the dataset:

Pneumonia patients in the dataset:

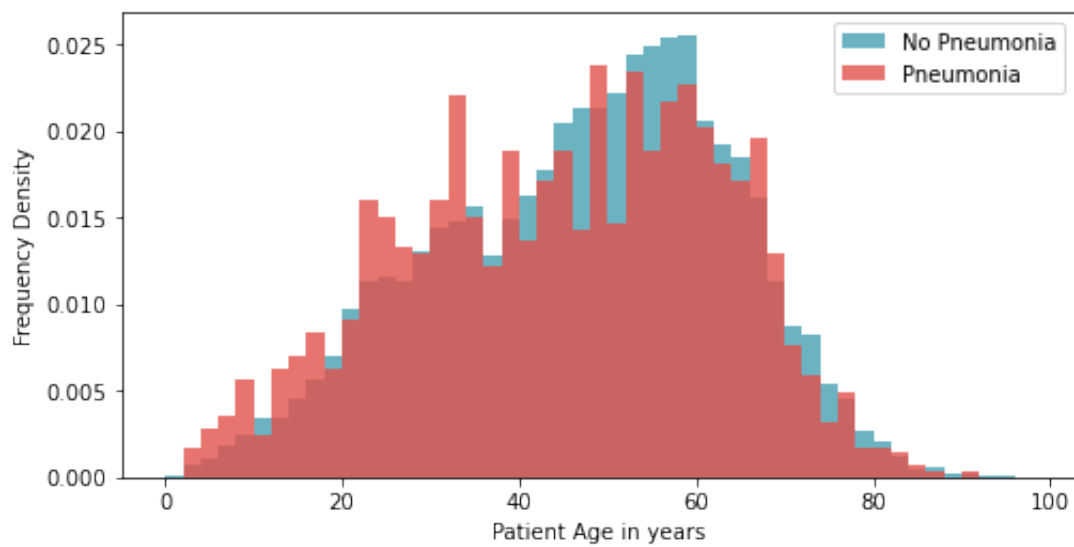
Distribution of Diseases in Pneumonia Patients in the Dataset



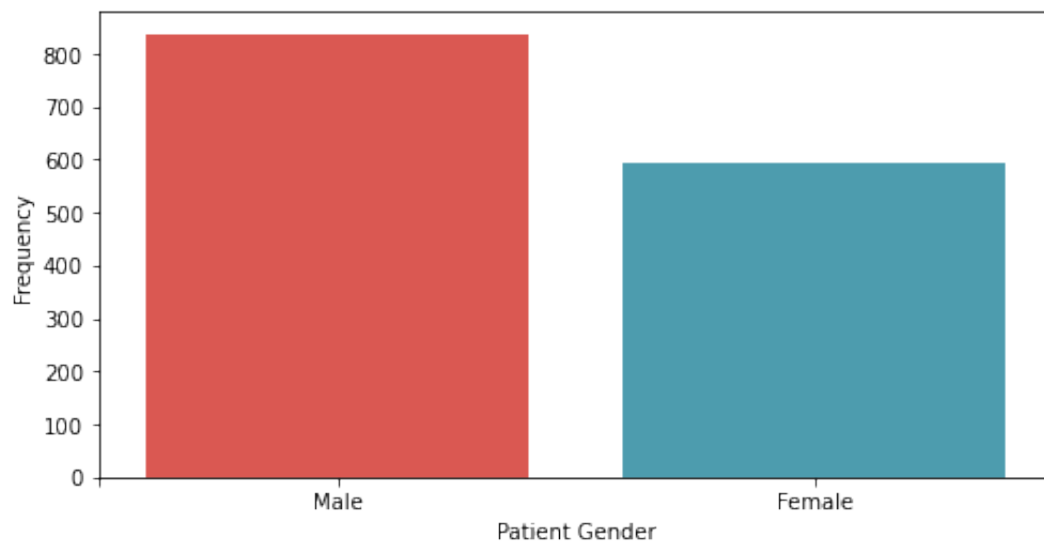
The Distribution of Number of Diseases in Patients with Pneumonia



The Distribution of Age



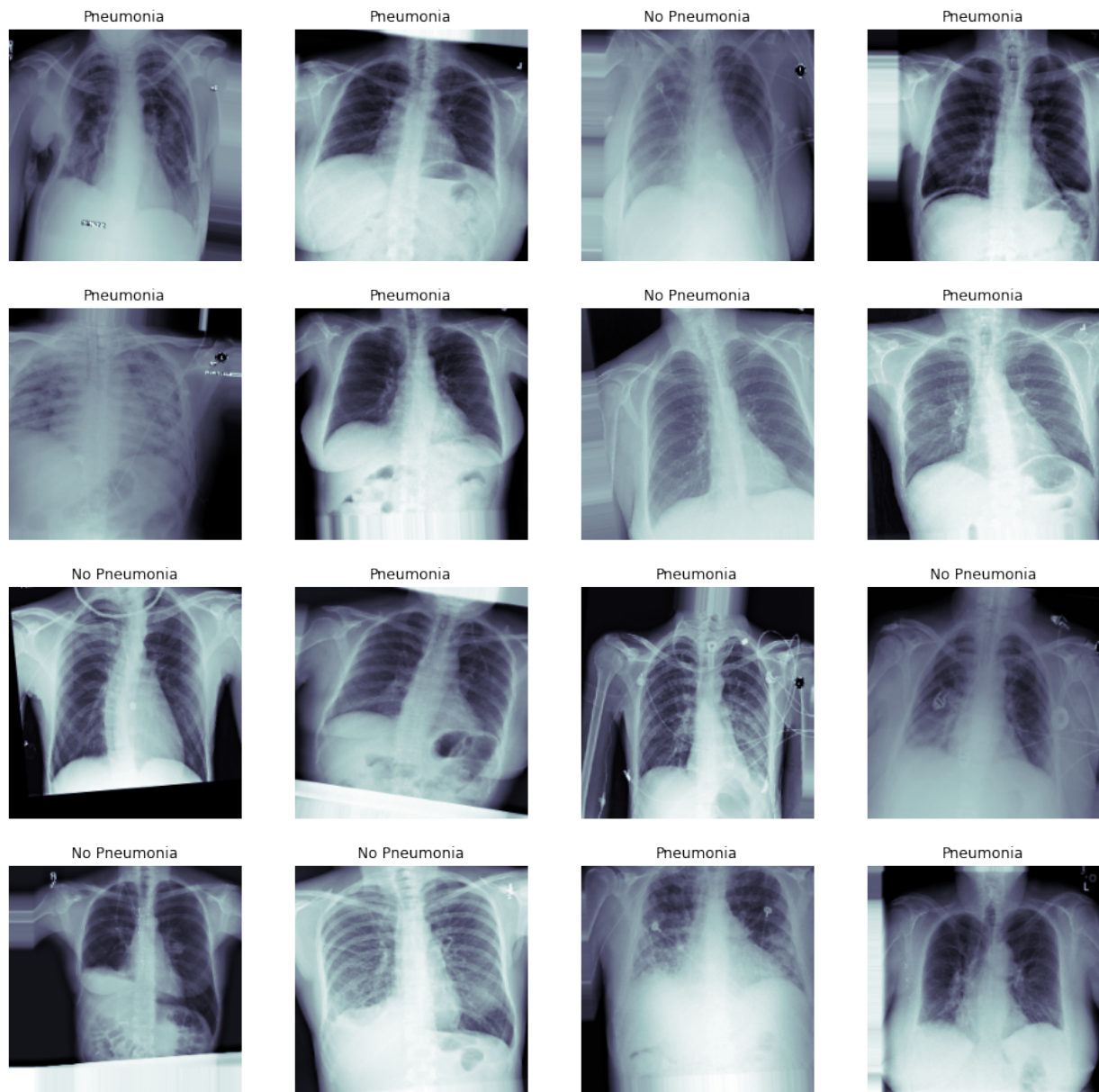
The Distribution of Gender in Patients with Pneumonia



Description of Training Dataset:

80% of the full dataset was selected to be in the training dataset. There are 2288 images in the train dataset after balancing the two classes. Prevalence of Pneumonia is 0.5. Number of pneumonia cases in the train data is 1144. Number of non-pneumonia cases in the train data is 1144.

Example of the images in the train dataset after augmentation and their labels:



Description of Validation Dataset:

20% of the full dataset was selected to be in the validation dataset. There are 1716 images in the valid dataset. Prevalence of Pneumonia is 0.166. Number of pneumonia cases in the valid data is 286. Number of non-pneumonia cases in the valid data is 1430.

5. Ground Truth

To create these labels, the authors used Natural Language Processing to text-mine disease

classifications from the associated radiological reports. The labels are expected to be >90% accurate and suitable for weakly-supervised learning. The original radiology reports are not publicly available but you can find more details on the labeling process in this Open Access paper: "ChestX-ray8: Hospital-scale Chest X-ray Database and Benchmarks on Weakly-Supervised Classification and Localization of Common Thorax Diseases." ([Wang et al.](#))

6. FDA Validation Plan

Patient Population Description for FDA Validation Dataset:

The sample population of the FDA validation dataset should digital X-ray images from the chest area that are taken from men and women distributed between the age of 1 and 100 with with posteroanterior (PA) or anteroposterior (AP) views.

Ground Truth Acquisition Methodology:

As a silver standard for validating X-ray images, we need at least 3 independent practicing radiologists to create the labels. The final diagnosis is then determined by a voting system across all of the radiologists' labels for each image. The silver standard method is described in the "[CheXNet: Radiologist-Level Pneumonia Detection on Chest X-Rays with Deep Learning](#)" paper.

Algorithm Performance Standard:

Similar to the CheXNet study, We calculate the algorithm's F1 score and F1 Scores of the silver standard method produced by the voting of three radiologists' diagnosis. Then, both are compared to determine the performance of the algorithm compared to the radiologists.