General Information

Intended Use Statement:
Looking at the above, we see that the algorithm was trained on 56.5% male and 43.5% female patients only who spanned from ages 1 to 414. All patients were scanned for the chest X-ray and were labeled with 14 diseases and No finding.

From this information, the appropriate intended use statement would be:

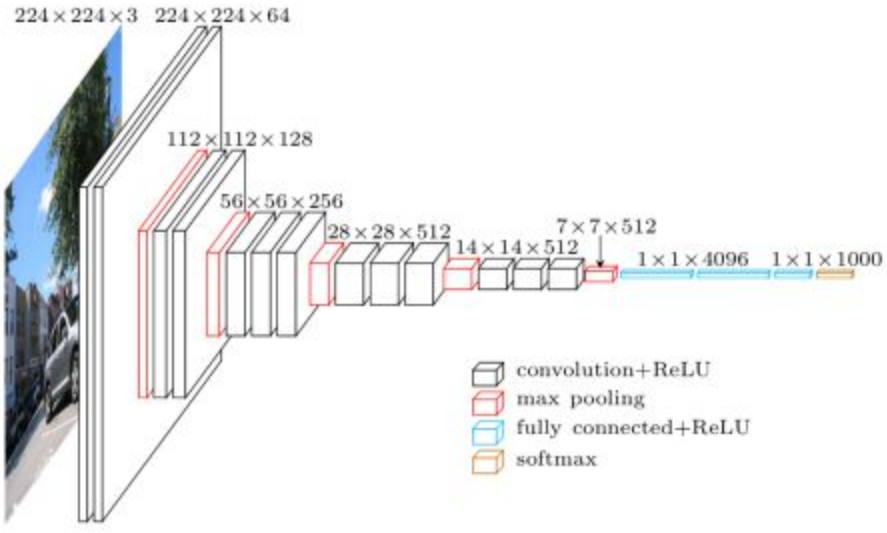
This algorithm is intended for use on Pneumonia patients from the ages of 1-100 who have been administered a screening chest X-ray and have never before demonstrated an abnormal Chest X-ray study.

Indication of Use:
The algorithm can be used for the screening of the chest X-ray which can be helpful in the early detection of Pneumonia.

Algorithmic limitations:

The results of the algorithm indicate that the presence of Atelectasis, Cardiomegaly, Consolidation, Edema, Effusion, Emphysema, Fibrosis, Hernia, Infiltration, Mass, Nodule, Pleural Thickening, or Pneumothorax in a chest x-ray is a limitation of this algorithm and that the algorithm performs very poorly on the accurate detection of pneumonia in the presence of above.

Algorithm Design and Function

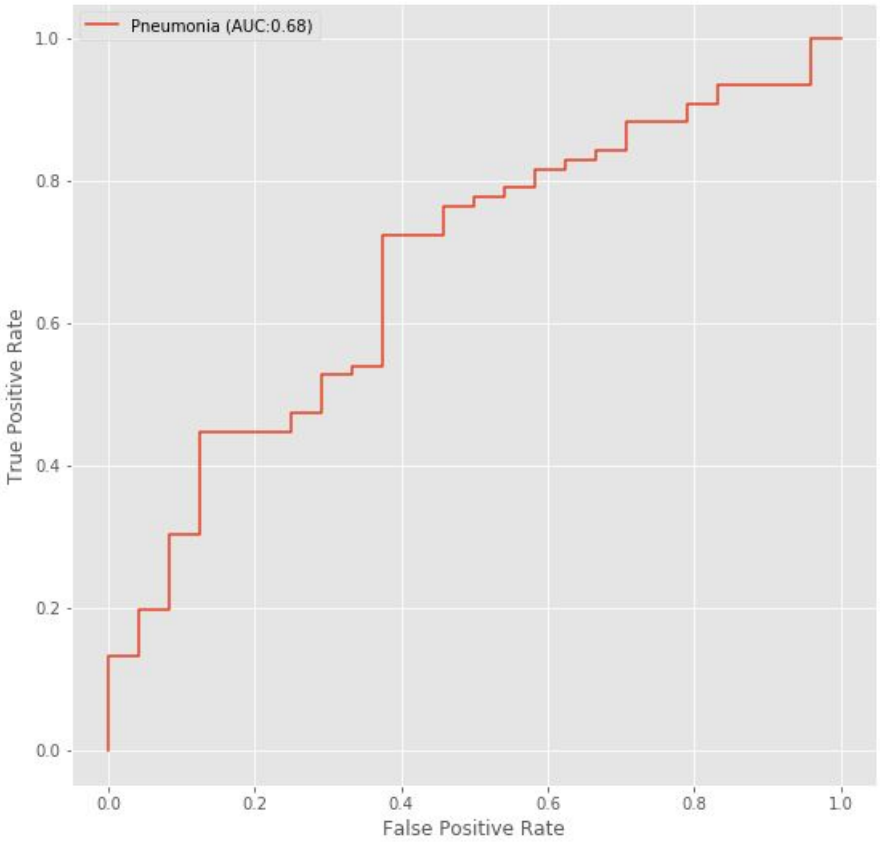


The algorithm is designed based on the pretrained vgg16 model. After the last convolution layer, one flattening layer then the dense layer was added. For training data augmentation, the image is

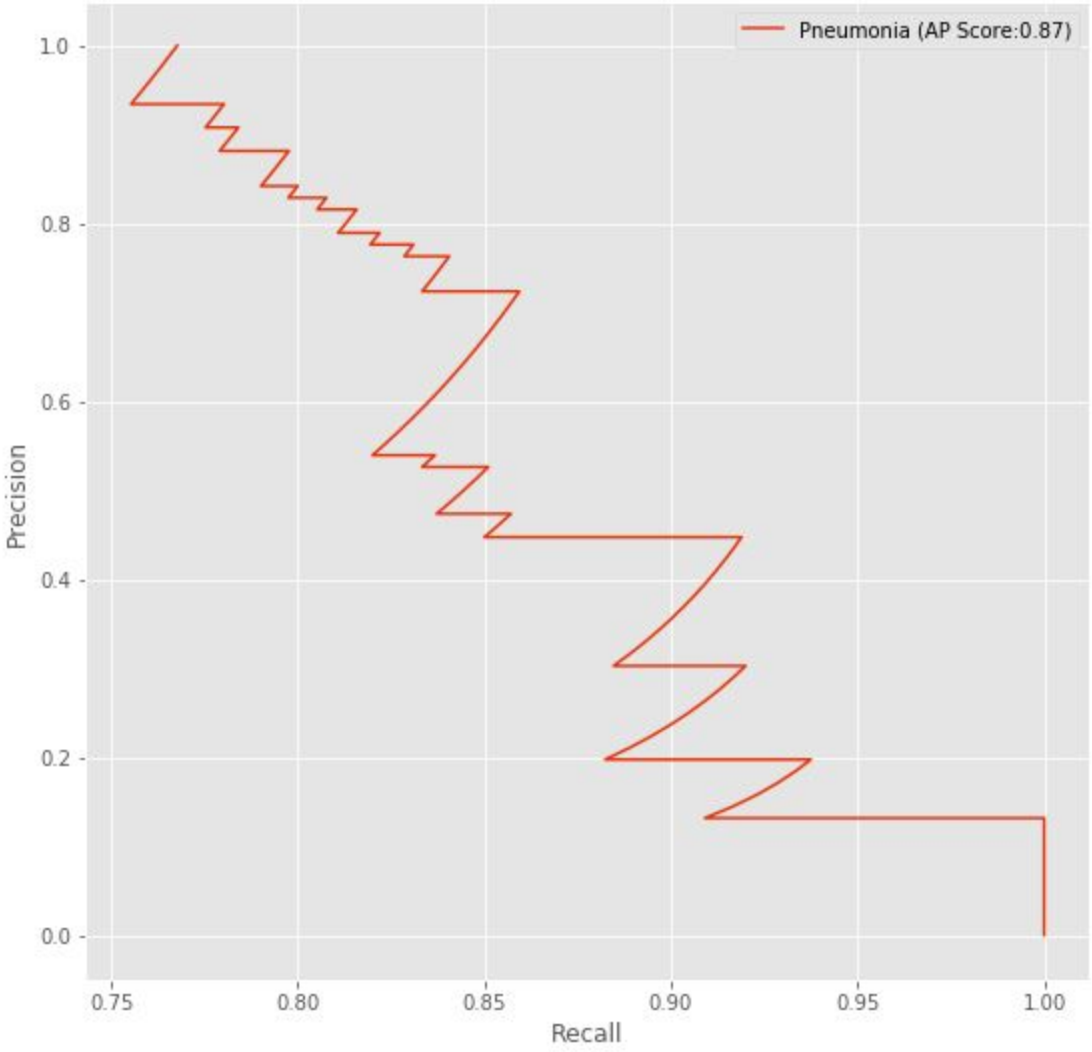
rescaled to 1/255, horizontal flip, height shift range of 0.1, width shift range of 0.1, rotation range of 20, shear range of 0.1, the zoom range of 0.1, so that model will consider those image as well which are slightly rotated or zoomed. For the training image generator, a batch size of 32 images is used.

The algorithm is trained based on Adam optimizer and a learning rate of 10^-6 and also I have used the learning rate, reduce-factor of 0.3. For training the model first 17 layers of the model are frozen and remaining are fine-tuned for this case.

The current model has very high training loss, also the val_ loss and val_acc is constant for the 10 epochs.



The algorithm has an area under the curve for True positive rate and false positive rate of 0.68.



And the precision-recall curve has an AP score of 0.87.

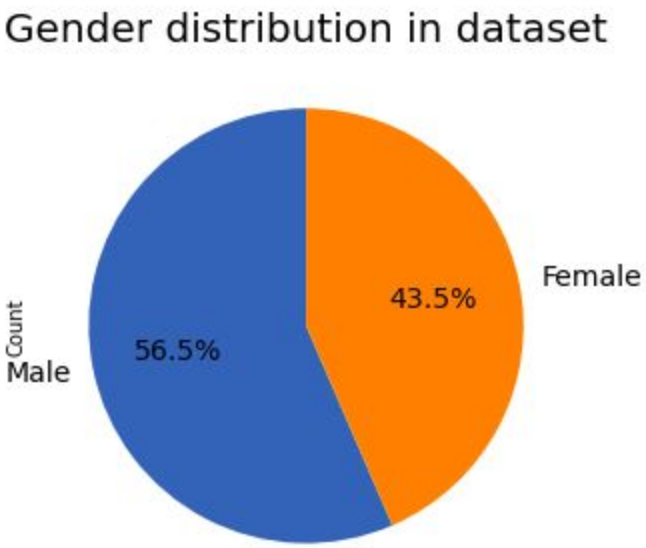
```
Precision is: 0.8
Recall is: 0.8421052631578947
Threshold is: 0.5386096
F1 Score is: 0.8205128205128205
```

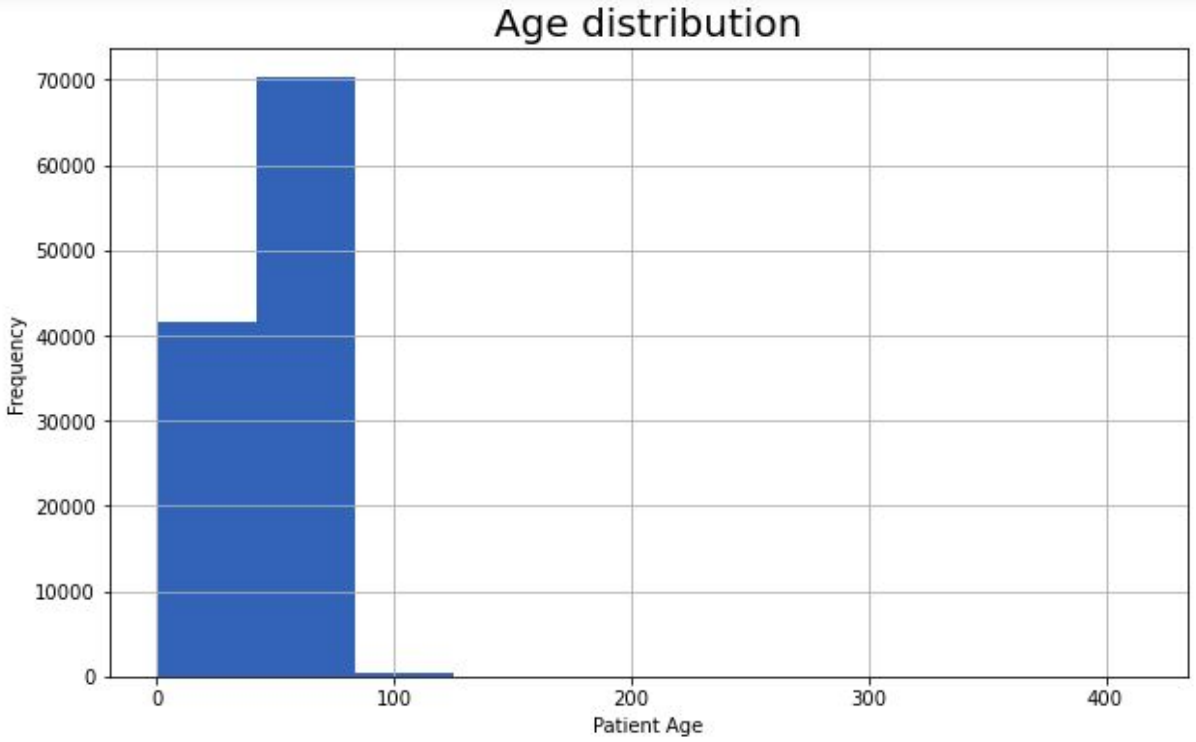
From the above, the calculated threshold is `0.5386096` for the precision of 0.8 and the F1 score of `0.8205128205128205`.

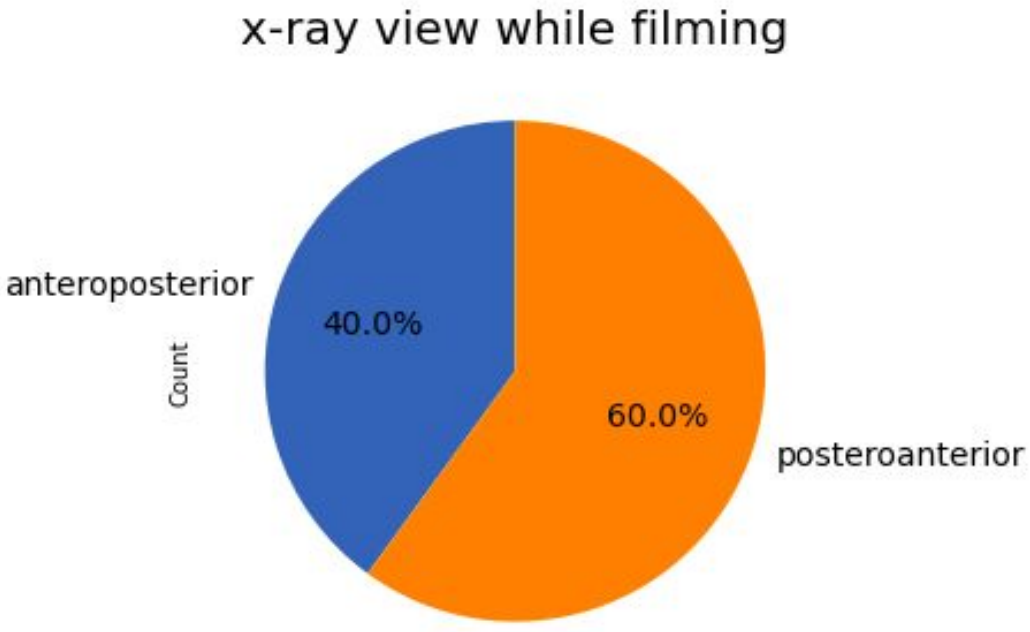
Databases

The dataset was curated by the NIH. There are 112,120 X-ray images with disease labels from 30,805 unique patients in this dataset. The disease labels were created using Natural Language Processing (NLP) to mine the associated radiological reports. The labels include 14 common thoracic pathologies:

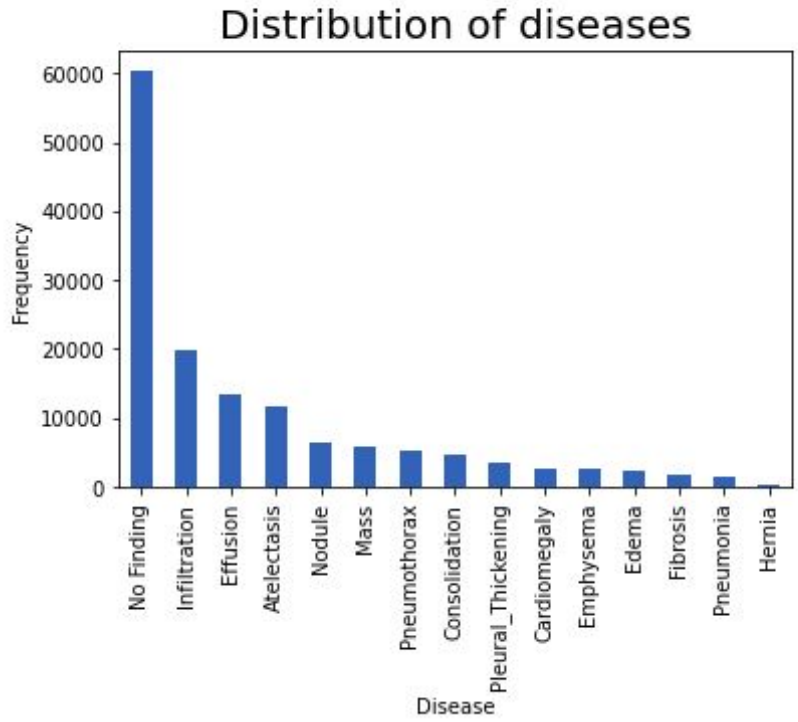
- Atelectasis
- Consolidation
- Infiltration
- Pneumothorax
- Edema
- Emphysema
- Fibrosis
- Effusion
- Pneumonia
- Pleural thickening
- Cardiomegaly
- Nodule
- Mass
- Hernia




Age distribution
70000
60000
50000
40000
30000
20000
10000
0
Frequency
0
100
200
300
400
Patient Age


x-ray view while filming
anteroposterior
40.0%
Count
60.0%
posteroanterior

Pneumonia case: 1431



Ground Truth

The biggest limitation of this dataset is that image labels were NLP-extracted so there could be some erroneous labels but the NLP labeling accuracy is estimated to be >90%.

FDA Validation Plan

For validation of the algorithm, the collected dataset made up of chest X-rays between the ages 1-100 for both male and female. However, it should be made sure that the validation set did not contain a patient with prior history of Pneumonia and other diseases like Atelectasis, Cardiomegaly, Consolidation, Edema, Effusion, Emphysema, Fibrosis, Hernia, Infiltration, Mass, Nodule, Pleural Thickening, or Pneumothorax. The silver standard approach of using several radiologists would be more optimal for the Algorithm.