Introduction

The TB Detection Algorithm is a deep learning system that helps detect active pulmonary tuberculosis from Chest X-rays. Apollo Hospitals and Google Research have collaborated to build the base algorithm that can enhance diagnostic accuracy and expedite the diagnosis process by providing additional insights for radiologists. The algorithm has been trained using chest radiographs from 22,284 subjects and validated in a four-country test set of 1236 subjects. It has demonstrated an accuracy of over 88% and AUROC of 0.89 with superior sensitivity (88%) and Non-inferior specificity (79%) compared to radiologists.

Why is Chest X RAY TB Detection AI different?

1. A total of 1,65,754 images in 22,284 subjects (mean age, 45 years; 21% female) were used which were acquired between 1996 and 2020 from 10 countries for model development and testing.
2. In the four-country test set (1236 subjects, 17% with active TB), the receiver operating characteristic (ROC) curve of the DLS was higher than those for all nine India-based radiologists, with an area under the ROC curve of 0.89 (95% CI: 0.87, 0.91).
3. Compared with these radiologists, at the prespecified operating point, the DLS sensitivity was higher (88% vs 75%, P < .001) and specificity was non-inferior (79% vs 84%, P = .004). Trends were similar within other patient subgroups, in the South Africa data set, and across various TB-specific chest radiograph findings.
4. Feedback Loop from the prospective use in patients
5. Validated at different National and International Institutions
6. Integrated Clinical Decision Support Tool (What Next to do)
7. Decreases the workload of radiologists by increasing the speed of chest X-ray Anomaly detection significantly as it can analyse more images in less time.
8. Increases access in developing countries where there is a shortage of radiologists in remote locations.

Interpretation & Adoption Message

1. AI Algorithm + Clinicians – The Tb Chest X-ray model has been built as an adjunct tool for physicians to detect active Pulmonary Tuberculosis (TB).
2. Risk Identification and Prevention- This TB Chest X-ray Model helps in early and accurate detection of pulmonary TB but it is not to be used as the sole method for diagnosis of Tuberculosis.
3. Where to use - The TB chest X-ray model has been prepared for use in the Radiology Department specifically chest Radiographs to detect tuberculosis at Outpatient Clinics and Health Check Clinics

How to Use (For Clinicians Only) –

1. Provide Appropriate –
   a. Chest X Rays
   b. Obtain Patient Consent
2. Risk Factors Included –
   It is a computer vision model hence the digital images of chest radiographs are included as input.
3. Output
   a. Predicting the Image as Abnormal/Normal
   b. Abnormality of the X-Ray

Workflow for CXR TB App

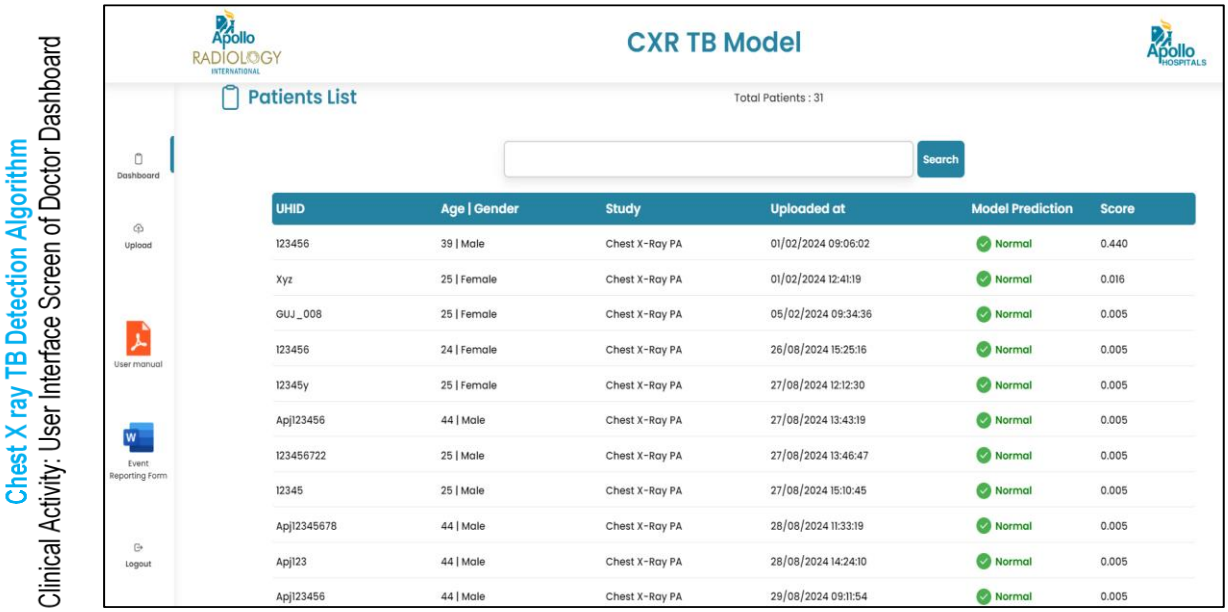

Figure 1. Doctor Dashboard

Doctor Dashboard: The first step to using the Chest X-Ray AI TB App is to log into the Doctor Dashboard using your unique credentials. Here, you will find an overview of your patient cases, both past and present. You can sort and filter cases by patient name, date, or anomaly detection status.

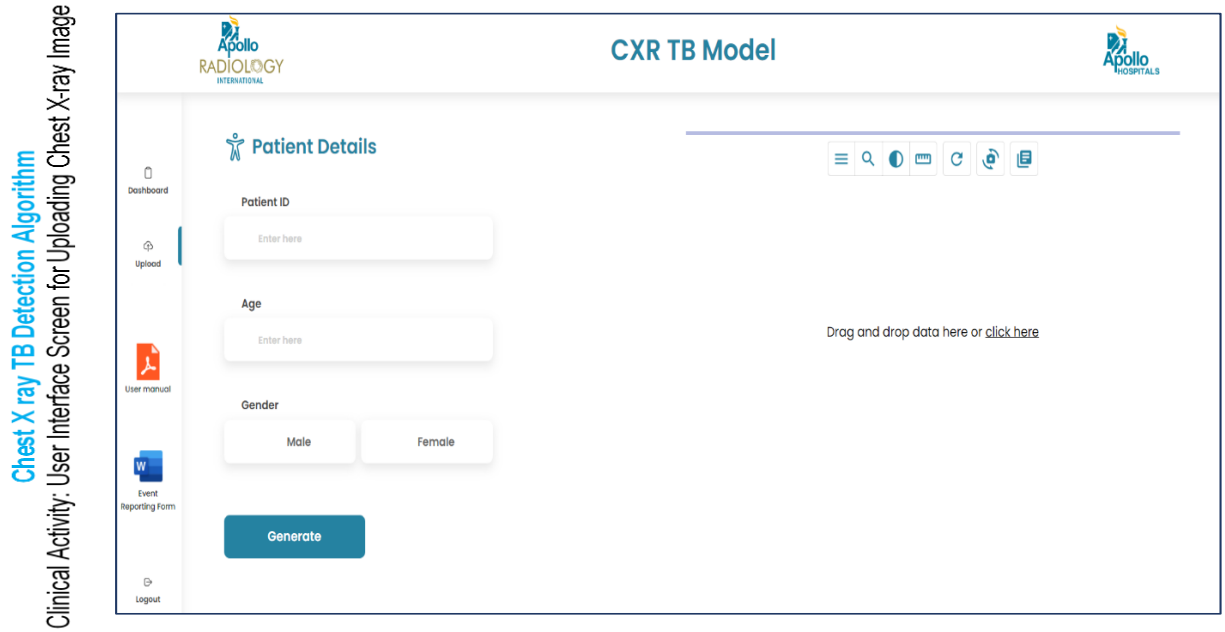

Figure 2. Uploading new CXR DICOM Image

Uploading New CXR DICOM: To upload a new Chest X-Ray (CXR) DICOM image, click on the "Upload" button, usually located at the top right corner of the dashboard. Browse through your computer's files and select the DICOM image you wish to upload. The file name should end with a .dcm extension. Once you've selected the image, click "Open" and the image will start uploading to the app. You should see a progress bar indicating the upload status. Once the upload is complete, the new case will appear in your dashboard.

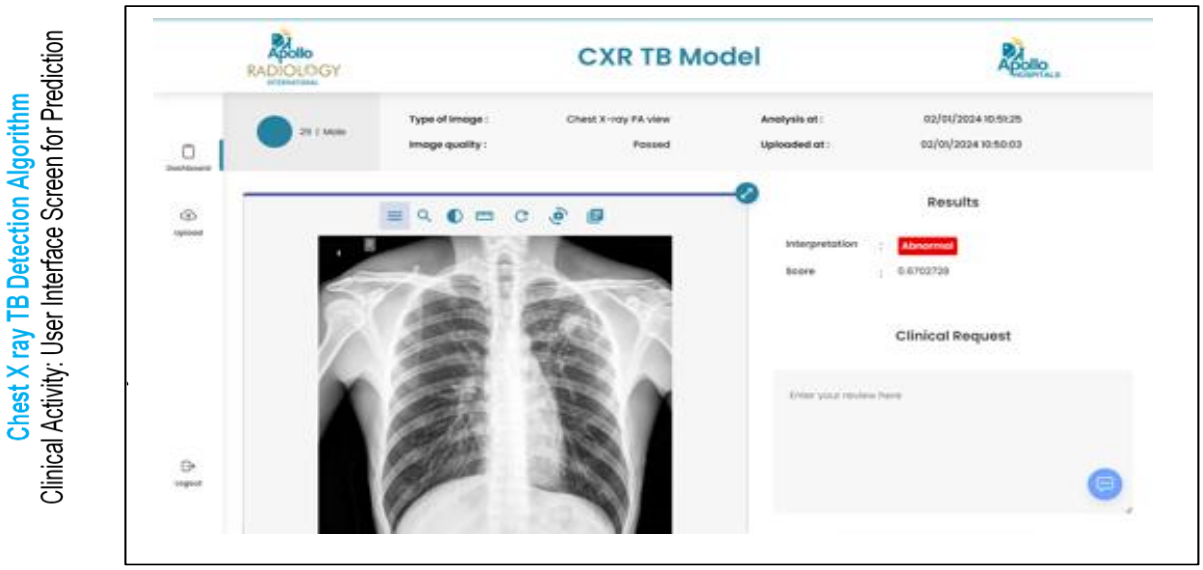

Figure 3. Model Predicting the Image as Abnormal

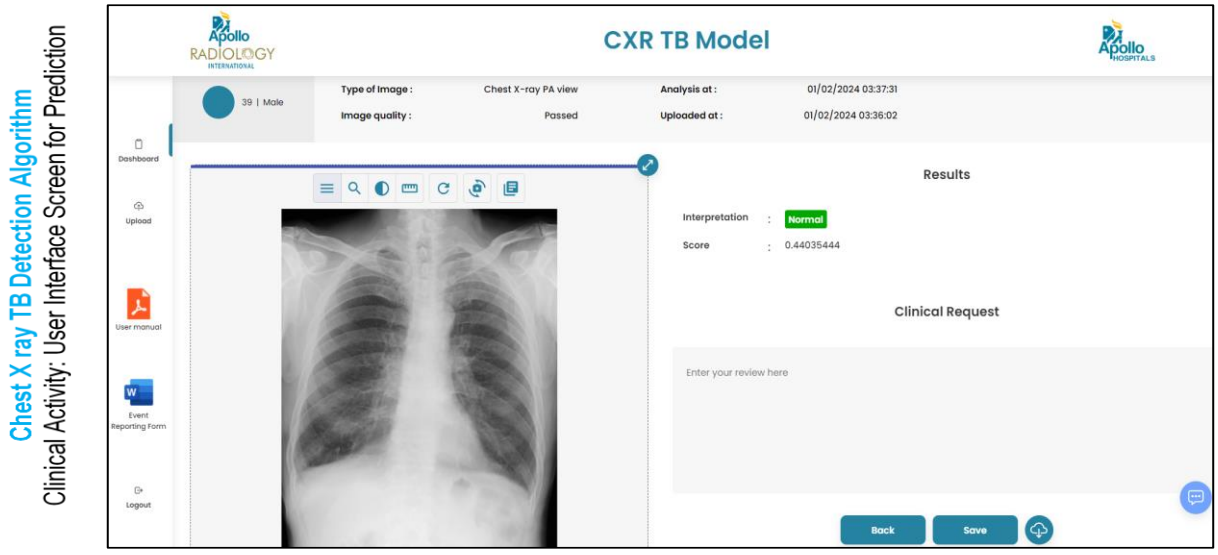

Figure 4. Model Predicting the Image as Normal

AI Model Predicting the Image as Abnormal/Normal and Doctor reviewing it: Upon successful upload, the AI model will automatically analyze the DICOM image. Once the analysis is complete, the AI will categorize the image as either Normal or Abnormal, based on the TB detection. This result will be shown in the dashboard next to the respective DICOM image. To review the AI's analysis, click on the specific case. You will be taken to a detailed view of the image. This AI model serves as a tool to assist doctors and does not replace a professional diagnosis.

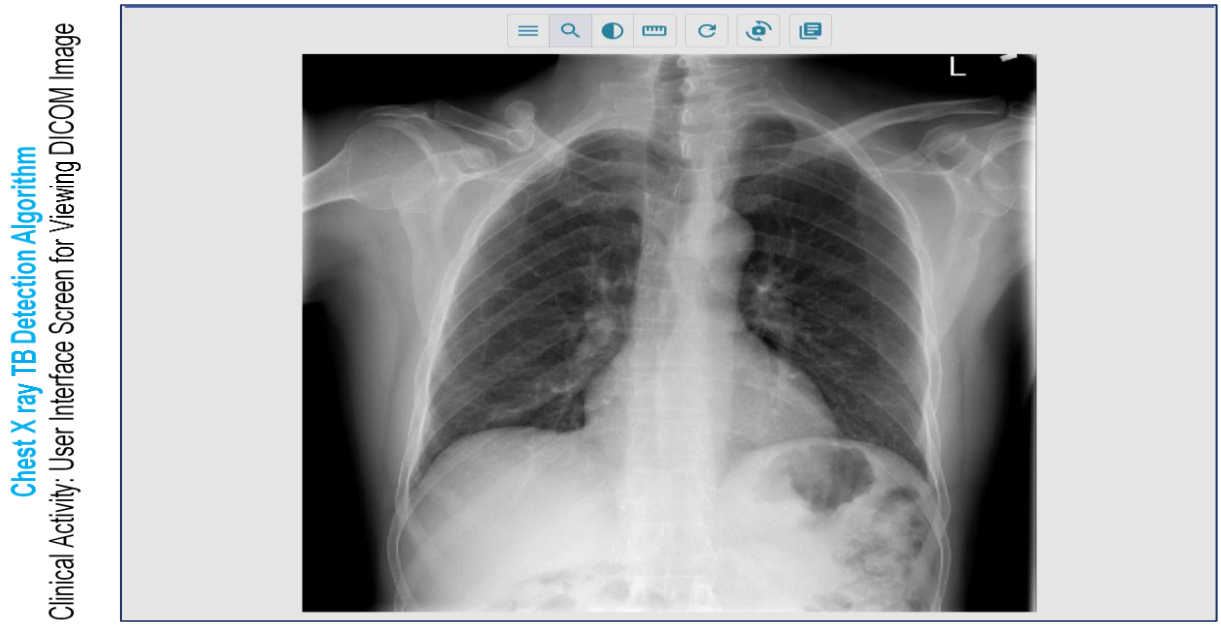

Figure 5. Doctor Reviewing the DICOM Image in a Web Browser with Relevant Tool

Doctor Reviewing the DICOM Image in a Web Browser with Relevant Tools: To review the DICOM image in detail, use the built-in viewing tools provided by the app. You can zoom in and out, adjust brightness and contrast, and move the image around for a better view of certain areas. You can also manually

mark areas of interest. Once you've finished reviewing and annotating the image, you can save it and move on to the next case.

4. Disclaimer
    a. This tool is designed to assist in anomaly detection and should not be solely relied upon for making a diagnosis. This is not a diagnostic tool and it does not guarantee the accuracy of the result and cannot be independently acted upon.
    b. This Prediction score and Clinical Algorithm is a general guideline for Physicians. Any additional laboratory investigations, Diagnostic Imaging, Treatment, or Patient Education related to lifestyle management is under the Physician's discretion.
    c. To ensure the information in the report is up to date, accurate, and correct, the Doctor shall be consulted for interpretation of the report.
    d. Apollo Hospitals and its Staff do not offer any assurance on the information made available or be liable for any loss or damage as the said report is based on the Chest X-ray anomaly Detection Algorithm without any intervention from their side.
    e. By usage of the Chest X-Ray Anomaly Detection Algorithm, it is deemed that the beneficiary of this service has agreed to get the same done at his own risk and further agrees with this disclaimer without any limitation or any clauses or sub-clauses

Research

Tuberculosis (TB) is a highly infectious disease that poses a significant global health challenge. Early and accurate detection of TB is crucial for effective treatment and containment of the disease. Traditional diagnostic methods, such as microscopy and culture, may be time-consuming and less sensitive. In a healthcare setting with a high prevalence of TB, medical professionals face the challenge of timely and accurate diagnosis.

The purpose of Deep Learning Detection of Active Pulmonary Tuberculosis for analyzing chest Radiograph images may help increase diagnostic accuracy and reduce time to diagnosis by providing additional information for radiologists. The technology automatically reads medical images and identifies abnormalities.

Apollo Hospitals and Google Research have collaborated to build the base algorithm using data from nine countries and tested the Deep learning system (DLS) on data from five countries, together covering multiple countries with a high TB burden and a wide range of races and ethnicities as well as clinical settings which detect active pulmonary Tuberculosis with an accuracy of over 88%.

Ethics Perspectives

Title	Deep Learning Detection of Active pulmonary Tuberculosis at chest Radiography	Centers	India(Apollo hospitals), South Africa, China (Shenzhen), United States (Montgomery, MD), Zambia (Lusaka),Europe (Azerbaijan, Belarus, Georgia, Moldova, Romania)
Principal Investigators	Dr Raju Kalidindi (Apollo), Rory Pilgrim (Google)	Institutional Ethics Committee Approval	April 2023
Data	Retrospective chest radiographs from 10 countries 1996 to 2020	Safety	Model distinguishes Normal & Abnormal Chest Radiograph for Tuberculosis that are interpreted by clinicians through safe Machine (API) – Human (Clinician) Interaction
Sample Size + Missing Data	22,284 subjects, 165,754 Images , (mean age, 45 years; 21% female) were used for model development and testing. In the four-country test set (1236 subjects, 17% with active TB) |No imputations	Inclusiveness & Fairness	Model Tested & Trained using 10 country data set. At admission data Chest Radiographs| No socioeconomic discrimination
Personal Health information	De-identified all PHI during analysis, model building, API hosting and Prospective Use	Privacy & Confidentiality	Data secured at Apollo Azure Tenant with all relevant compliance + conforming to laws
Addressing Bias (Geographical / Ethnic / Temporal / Gender etc.)	Multiethnic – All Adult Population Group – Male to Female – 79 :21 – Time Period –1996-2020 ,10-country dataset, tested in diverse regions, Automation Bias addressed at API Clinical Use	Accuracy + Efficacy	Classification Metrics -DLS sensitivity 88%, specificity 79%; Noninferior to radiologists at prespecified operating point, AUROC - 0.89 in the four-country test set
Risk Groups	Chest radiographs: Normal - Abnormal for active pulmonary tuberculosis	Informed Consent	Yes – Template & Protocol (Prototype Attached)
Model Specification	Deep learning method + Attention Pooling + semi supervised learning ("noisy-student")	API – Ease of Use + Interpretation	Flows to Clinical Algorithm Standard User Manual
Clinical Algorithm Update (Version)	Version 1 - December 2023	Validation + Peer Review	Radiology; Scientific Reports
Certifications	ISO 13485:2016 Certification | MD 763515	Regulatory Compliance	CDSCO Application No| Apollo-Hyder-TE/M/MD/007509

Frequently Asked Questions

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Where can the physicians use the Chest X RAY TB Detection AI tool?

The TB chest X-ray model has been prepared for use in the Radiology Department specifically chest Radiographs to detect tuberculosis at Outpatient Clinics and Health Check Clinics.

What are the Risk Factors Included?

It is a computer vision model hence the digital images of chest radiographs in the PA (Posterior Anterior) view are included as input.

What is the Output and Follow-Up for the Model?

The tool produces a probability indicating the likelihood of pulmonary tuberculosis or its absence.

Is this a diagnostic tool?

This is not a diagnostic tool, it does not guarantee the accuracy of the result and cannot be independently acted upon.

Does this contradict the Physician's view?
This TB chest X-ray model is an adjunct model to help Physicians detect active pulmonary Tuberculosis. Any additional laboratory investigations, Diagnostic Imaging, Treatment, or Patient Education related to lifestyle management is at the Physician's or Pulmonologist's discretion.

How does one ensure the accuracy of the Chest X-ray TB Detection AI tool?
To ensure the information in the report is up to date, accurate, and correct, the Doctor shall be consulted for interpretation of the report.

Is this a substitute for any diagnostic test or clinician's advice?
Absolutely No. This is an adjunct tool developed with Digital Images of chest Radiographs in PA view. It doesn't substitute for any tests or advice. It complements and supports the diagnostic process by providing another perspective on the chest X-ray images if the chest X-ray has any TB findings.

What are the disclaimers for the use of this tool?

a. Apollo Hospitals and its Staff do not offer any assurance on the information made available or be liable for any loss or damage as the said report is based on the Chest X-ray TB Detection AI tool without any intervention from their side.
b. By usage of the Chest X-ray TB Detection AI Model, it is deemed that the beneficiary of this service has agreed to get the same done at his own risk and further agrees with this disclaimer without any limitation or any clauses or sub-clauses.

Can the report be shared with other clinicians?
Yes, each patient shall get a printed report or PDF copy which can be kept by the patient to maintain privacy and confidentiality.

Is this tool validated for research ethics committees?
Yes. Institutional Ethics Committee Approval for All Centre's and annually followed. Further, the study adhered to the tenets of the Declaration of Helsinki.

How is Safety addressed?
The model advocates risk scores clinicians interpret through a safe machine (API) – human (clinician) interaction. Informed consent from each individual is obtained before detection of active pulmonary Tuberculosis using the chest x-ray TB Detection Tool.

What is the specific focus of the chest X-ray TB detection tool, and which forms of tuberculosis does it not currently address in its scope?
The chest X-ray TB detection tool specifically identifies active pulmonary TB infections and does not extend its scope to detect other forms of TB, such as multi-drug-resistant TB, mono-drug-resistant TB, or extra-pulmonary TB.

Definition

Tuberculosis
Tuberculosis (TB) is an infectious disease that most often affects the lungs and is caused by a type of bacteria.
Source: World Health Organization