APOLO D SMARTCHECK AI RAPID SCREENING SYSTEM, EQUIPMENT FOR A QUICK IDENTIFICATION OF INDIVIDUALS WITH COVID-19

Based on available evidence up to 23 October 2020

INTRODUCTION

Since the availability of the genome of *severe acute respiratory syndrome coronavirus 2* (SARS-CoV-2), the gold standard of diagnosing Coronavirus Disease *2019* (COVID-19) is repeat reverse transcription polymerase chain reaction (rt-PCR) test.[1] However, issues such as supply of kits, sensitivity of rt-PCR test, laboratory turnaround time and laboratory error may pose a problem to rapid and accurate detection of COVID-19 for the control of disease spread and fast treatment.[2] Chest radiography (x-ray) and computer tomography (CT) has been used in triaging, diagnosis and prognostication of COVID-19, especially in resource constrained health care settings with low availability of rt-PCR tests.[3] The lung findings of COVID-19 have many similar manifestations with various types of pneumonia.[4] When there is severe shortage of radiologic expertise in these regions to allow for precise interpretation of such images, an artificial intelligence (AI) system may be a helpful adjunct to radiologists.[3] Artificial intelligence diagnosis algorithm specific to COVID-19 promises to have high efficiency, high repeatability and easy large-scale deployment.[2] A systematic literature review on the effectiveness of chest x-ray with artificial intelligence for diagnosis of COVID-19 was conducted.

Technology

Apolo D SmartCheck AI rapid screening system is developed in Brazil by VMI Securities to perform chest radiographs using a heat map to identify pneumonic changes and lesion extension (in percentage). The lung changes of COVID-19 pneumonia can be detected within 5-7 days of infection. It is a complete standalone medical x-ray scanner consisting of generator, tube, detector and artificial intelligence software (shown in Fig.1). With high-resolution digital detector, it can image capture within 5 seconds. After examination, special UV-C lamps in the equipment automatically disinfect the parts. The disinfection process takes 1 to 2 minutes. Results formulation is aided by the AI integration, where signs of affected lung infection extension is scored 0-100 in up to 20 seconds. The results will be immediately sent to the triage team which is connected remotely via local WiFi or Ethernet cable or/and mobile SIM card. The flowchart of the operation of Apolo D SmartCheck AI rapid screening system is illustrated in Fig. 2.

The Apolo D SmartCheck AI rapid screening system comes assembled in a cabin with easy installation public and private places, and can be made available to communities and places with infrastructure constraints using containers, or mobile units such as trucks, trailers and boats, as well temporary hospitals and prisons. It requires a 3 m x 3 m space and a single phase 110 V or 220 V, 50/60 Hz for operation. The Apolo D SmartCheck AI delivers 20 to 40 uSv/image captured, but has a radiation shield cabin to block the x-rays generated by the equipment. Therefore, it does

not need additional construction of radiation protection facilities such as x-ray shielding room. The cabin has a motorised door, controlled from the operator workstation, reducing risk of contamination. It can be used as a normal x-ray screening machine post pandemic.[5]

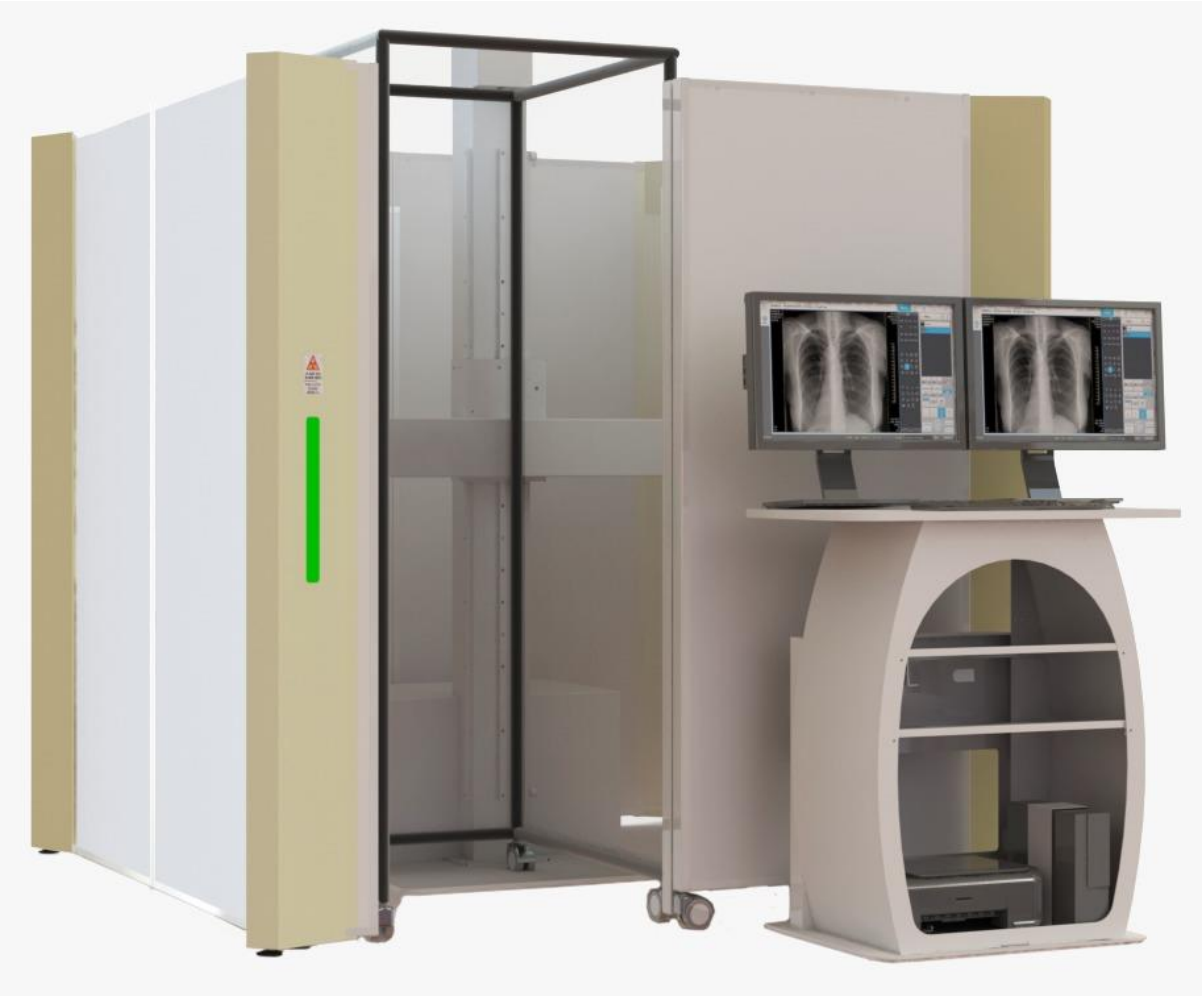

Fig. 1 The Apolo D SmartCheck AI with accessories

The Apolo D SmartCheck AI is designed for screening patients with symptoms and intended as an adjunct. The Apolo D SmartCheck AI rapid screening system is not a replacement of rt-PCR for diagnosis.[5]

EVIDENCE ON EFFECTIVENESS AND SAFETY

There was no article retrieved from the scientific databases such as Medline, EBM Reviews, PubMed and from the general search engines [Google Scholar and US Food and Drug Administration (USFDA)] on Apolo D SmartCheck AI rapid screening system.

Previously, there were two rapid review reports (April 2020) conducted by Health Technology Assessment Section (MaHTAS), Medical Development Division, Ministry of Health Malaysia which sought evidence on “Artificial Intelligence CT Scan for Covid-19 Detection and Monitoring”,[6] and

"Chest X-Ray with Artificial Intelligence for Diagnosis of Covid 19" systematically.[7] Both studies concluded the technologies were not adequately powered for diagnosis of COVID-19.

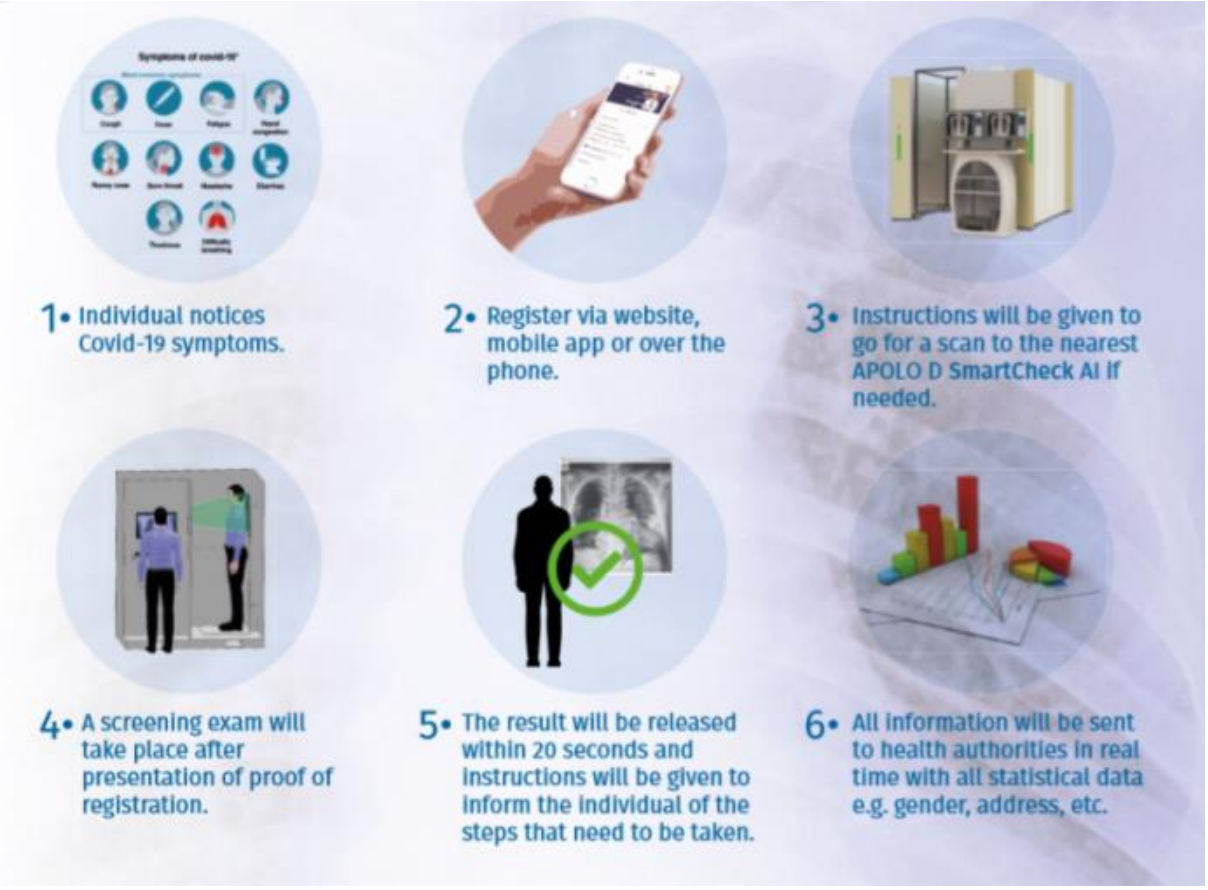

Fig. 2 Flowchart of Apolo D SmartCheck AI rapid screening system

Chest x-ray (CXR) is considered not to be sensitive for detection of early stage of the disease.[8] However in a study in Italy, which retrospectively analysed 240 rt-PCR positive cases, CXR showed abnormalities (bilateral peripheral reticular alteration, and ground glass opacities later) in 75% of the rt-PCR confirmed cases. This confirm that CXR can be an imaging technique in diagnosing COVID pneumonia.[9]

However the decision to use CXR as part of triage screening process is based on individual countries, and have been used in low resource countries with limited access to rt-PCR tests.[10] In the Malaysian context, a multicenter cohort study of 316 SARS-CoV-2 positive patients showed only 34.5% (109/316, $p<0.001$) had an abnormal baseline chest radiograph. Therefore it shows that the sensitivity of chest radiograph in our population is low.[11]

GE Healthcare's collection of AI algorithms to detect suspected pneumothorax, Critical Care Suite, developed by University of California San Francisco (UCSF) that can be embedded directly on mobile x-ray solutions, received FDA approval on September 12. [12]

RADLogics received FDA 510(k) clearance for AI-Powered CXR pneumothorax application which uses the deep learning model on September 23. This is available on Nuance cloud hosting platform. The array of AI-Powered solutions for CT and x-ray are designed to improve efficiency and reduce burnout for radiologists that are under greater pressure than ever before.[13]

The Apolo D Smartcheck AI rapid screening system is both ANVISA (Brazil's FDA equivalent) and CE certified.[5] However no evidence of validation of the AI system was retrieved.

No reference price of the Apolo D SmartCheck AI rapid screening system was retrievable.

CONCLUSION

There was no evidence retrieved from the scientific databases on the effectiveness, safety and cost-effectiveness of Apolo D SmartCheck AI rapid screening system for quick identification of individuals with COVID-19. Further study to ascertain its effectiveness is suggested to support its use.

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Disclaimer: This rapid assessment was prepared to provide urgent evidence-based input during COVID-19 pandemic. The report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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