**4.1. How can the qXR from qure.ai (/a CAD product that can be used for AI detection) be integrated into your clinical workflow (radiology practice)?**

*Consider integration with your information technology (IT) platform, check for compliance with ISO usability standards, and consider issues related to the practical management of the software.*

**Integration Steps**

A starting point is ensuring the Radiology practice checks for compliance with clinical guidelines and standards. This includes making sure that the software is updated with the latest evidence-based TB diagnosis and management guidelines. This is a medical device and has huge implications for patient diagnosis and treatment therefore it is important to ensure that it meets all the required standards. Some of these standards include ISO27001 usability standards.

Once the initial compliance checks are made, the medical imaging practise will then need to evaluate the several options to integrate qXR into their clinical workflow. qXR is designed to be used as an AI diagnostic tool to be used in conjunction with other tools for TB detection. It is important to consider how this will fit into current workflow and how it will be used by the Radiology practice’s clinicians.

Once the decision for the integration option has been decided we need to consider practical management of the software. This includes decisions on:

I. How to keep the software up to date if hosted locally

II. How to ensure that only authorized users have access to it, and

III. How to manage user permissions.

Once implemented, the radiology practice will need to train staff on how to use the qXR data to improve the efficiency and accuracy of their work. qXRs implementation and training is available from qure.AI.

**Integration Options**

qXR can be integrated into the clinical workflow of a radiology practice in the following ways:

- API based: Dicom images can be uploaded to the qXR REST APIs through a token-based authentication. Results can be downloaded using a separate API endpoint. While the API documents are simple and easy to use, we still recommend training to ensure successful implementation.

- PACS-based: Another option is to allow PACS integration based on DIMSE protocol to transfer raw scans and receive outputs. A gateway can be added as a Dicom node in the Radiology practice network which will receive images, anonymize them, upload them using the APIs, download results and send these results back to the PACS

The APIs provide a simple and intuitive method of accessing qXR and integrating the software into the existing radiology practice software workflow. However, finer-grained control exists when using the DIMSE protocol. This may be suited for a large radiology practise that has well-resourced in-house software engineering development capabilities. The advantage of having the raw scans means you can manipulate the images for example, using AI to upscale the size of the DICOM.

A simple alternative is provided by Integration via AI marketplace or distribution platform.

Companies such as Nuance, Incepto, Philips IntelliSpace, Sectra Amplifier Store, Blackford, GE Healthcare, Siemens provide direct integration using the existing workflow.

This is our recommendation as it encourages greater use through familiarity and minimal technical requirements on the part of the Radiology practice.

The use of an AI marketplace vendor removes this complexity as the integration is managed by the distributor. The Radiology practice benefits from a standard integration approach. A choice exists to use product manufacturer integrations such as Philips,Toshiba, Siemens Healthineers , GE healthcare or a vendor-neutral gateway such as Sectra or Blackford. The advantage of the latter is since they work with multiple vendors and do many integrations to connect multiple different algorithms they may work well in Radiology practices that have not adopted single vendor strategies.

**4.3. What are the requirements in terms of information technology (IT) infrastructure to implement the qXR from qure.ai (/a CAD product that can be used for AI detection)?**

*Consider on-premise vs. cloud solutions. Identify requirements in terms of hardware and network performance, consider network security issues*

**Common Integration Requirements:**

The API network requirements are: A high-speed internet connection A firewall to protect the network The API security requirements are: A SSL certificate to encrypt data in transit A password management system to protect sensitive data

**Common Hosting Requirements**

This can be deployed in both settings on-premise & Cloud. For cloud we do not require any additional hardware and existing systems can be used for installing our gateway, which anonymises the patient personal information before sending it to our cloud. For on-premise all data stays within your network.

**Cloud-Based**

Qure.ai maintains cloud hosting predominantly through AWS and Microsoft Azure. These are highly secure reputable cloud hosting options and do not require any specific requirements for the Radiology practice

**API Based-Private Cloud**

Maintaining a private cloud moves the security of the network and patches and upgrades into the responsibility of the Radiology practice. The advantage is that the data is under the control of the Radiology practice.

Private hosting of a cloud is a major undertaking for most Radiology firms.

**API Based-Local IT Infrastructure**

No specific requirements are listed on the Qure.ai website however common hardware requirements are High performance servers, AI enabled GPU’s and large storage systems with backup drives in case of failure.

With the advent of cloud-based hardware solutions such as virtual machines having a good broadband internet connection means that infrastructure can be scaled up as required.

Network security is maintained by ensuring data is encrypted and network access is limited to authorised and authenticated users.

**4.5. Will the data from the qXR from qure.ai be accessible to non-radiologists (referring physicians, patients)?**

*Check whether the form of the output is suitable for communication with patients/referring physicians* For cloud based & on-premise (intranet) deployments all images can be made available to all physicians with their logins. These can be shared with external physicians as well with just a web-link as well. An original image is also given to remove any biases for the readers.

The raw data from the X-Ray and qXR’s output is not sent to anyone other than the reporting radiologists.

A report generated from the qXR software will be sent to the practitioner who requested the patient’s scan. This report will state Yes or No to the thirty abnormalities/diagnoses that are tested. Once the report is received, the doctor will discuss these results with the patient. This standardised protocol is due to compliance procedures. The practitioner is the one who is responsible for the patient's care. The practitioner will use the information in the report to make decisions about the patient's treatment.

*Inset data compliance*

**4.6. Are the qXR from qure.ai AI model’s results interpretable?**

*Check whether and which interpretability tools (i.e. visualization) are used*

Secondary capture has AI annotations on top of the original image. A DICOM viewer also comes along with it with tools such as measurements, levels, zoom etc.

The generated report is easily interpretable for all medical healthcare professionals, clearly stating if there is or is not a detection of a certain abnormality. This simple reporting structure decreases the time for a practitioner to interpret the results, hence improving efficiency in the workplace.

The structured report involves:

- Probability score as well as dichotomous output indicating whether each abnormality is present or absent

- Probability score for TB as well as dichotomous output indicating whether TB is likely present or likely absent

- A box indicating the location of the abnormalities

- Abnormalities detected by the product for which a separate abnormality score is given include: abnormal, TB, opacities (atelectasis, cavities, calcification, consolidation, fibrosis, nodules, reticulonodular pattern), emphysema/hyperinflation, pleural effusion, blunted costophrenic angle, pneumothorax, cardiomegaly, tracheal shift, degenerative spine changes, scoliosis, hilar prominence, rib fractures, COVID-19, pneumoperitoneum, mediastinal widening, elevated hemidiaphragm, abnormal diaphragm shape, lines and tubes (4 types) and lung nodule malignancy risk for nodules

<https://www.ai4hlth.org/product-profiles/Qure.ai>

**6.3 How is the maintenance of the qXR from qure.ai ensured?**

We have a dedicated team which provides support for all our clients in running the services. There is no AMC for cloud deployments.

The service team from qure.ai constantly monitors the performance of the qXR to ensure that it is running smoothly and efficiently. In case of any issues, the team is always available to provide support and assistance.

*Insert the importance of maintance*

**6.4 How will potential malfunctions or erroneous results from qXR from qure.ai be handled?**

In cases AI might miss some obvious findings, it can be reported to our team from the feedback section in the application or writing to support email ID.

The process for identifying erroneous results from qXR scans may vary depending on the particular implementation. However, some possible methods for identifying such errors could include comparing the results of multiple qXR scans of the same patient (to look for discrepancies), reviewing the images generated by the qXR scan for signs of artifacts or other abnormalities, or consulting with a radiologist or other expert to interpret the scan results.

If a potential malfunction is detected from qXR, the system will automatically generate a notification to the user. The qure.ai team will investigate and determine the root cause. If the root cause is a software issue, a fix will be deployed. Once the issue is identified the qure.Ai engineers patch the issue and write a regression test to make sure the issue is resolved. If the root cause is a hardware issue, the hardware will be replaced.

Malfunctions from qXR will be detected by the qure.ai team through a variety of means, including but not limited to:

-Reviewing error logs

-Monitoring user feedback

-Testing the qXR system regularly

Malfunctions will be fixed by the qure.ai team through a variety of means, including but not limited to:

-Patching the qXR system

-Updating the qXR system

-Contacting the hardware manufacturing team

There are a few potential consequences of malfunctions from qXR qure.ai. They include:

There are a few potential consequences of erroneous results:

1) Inaccurate results – If the qXR qure.ai malfunctions, it could provide inaccurate results. This could lead to patients not getting the proper treatment or diagnosis.

a. False positives – Another potential consequence of a qXR qure.ai malfunction is false positives. This could lead to patients being unnecessarily sent for expensive and invasive molecular testing for conditions they do not have.

b. False negatives – Another potential consequence of a qXR qure.ai malfunction is false negatives. This could lead to patients not getting the treatment or diagnosis they need.

2) Delayed results – Another potential consequence of a qXR qure.ai malfunction is delayed results. This could cause a delay in treatment or diagnosis, which could be detrimental to the patient.