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Innovative Medical Technology Overview | March 2024

# Artificial intelligence supported clinician review of chest x-rays from patients with suspected lung cancer

## Summary

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Artificial intelligence (AI) can be used to support clinicians with reviewing chest x-ray (CXR) images from patients with suspected lung cancer following referral from primary care. The intended use of AI in the clinical pathway is to read and flag higher risk CXR images so that clinicians can prioritise patients for urgent computerised tomography (CT).

The evidence for the use of AI supported clinical review of CXRs for patients with suspected lung cancer is emerging. No published evidence on the clinical effectiveness, cost-effectiveness, or safety of the AI use case was identified. No studies were identified that captured patient or staff views on the use of AI in this setting.

Interim analysis (n=41 reaching diagnosis stage, n=27 reaching treatment stage) from an ongoing service evaluation in NHS Grampian shows that use of AI alongside an adjusted clinical pathway shows promise in reducing time from CXR report to CT, reducing time to treatment, and increasing the identification of patients with treatable lung cancers.

## The technology and its use

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AI does not have a universally agreed definition.<sup>1</sup> A type of AI, known as machine learning, uses algorithms (that is, a sets of rules) to automatically learn from data, and find patterns or relationships within the data.<sup>2</sup> An advanced form of AI, often referred to as deep learning, is a sub-type of machine learning that attempts to simulate the neural structures of the human brain to learn from larger volumes of different types of information than in machine learning only.<sup>3</sup>

The use of AI to support clinical review of CXR in patients with suspected lung cancer is being explored in two NHSScotland health boards. The AI technologies being used are annalise.ai (Annalise AI, Sydney, Australia) and qXR (Qure.ai, Mumbai, India). Other AI tools with similar capabilities exist and fourteen similar technologies were reviewed in a recent health technology evaluation by the National Institute for Health and Care Excellence (NICE).<sup>4</sup>

NHS Grampian is using the Annalise Enterprise CXR AI module (annalise.ai) in a Scottish Government funded service evaluation in adults over 18 years old. The module was trained on more than 520,000 CXR studies, including over 820,000 individual deidentified CXR images. Using a machine learning model, annalise.ai scans for 124 potential issues in each CXR image, 34 of which are deemed priority findings.<sup>5, 6</sup> If the AI picks up any issues with a CXR image, it acts as an automated triage system and highlights that the patient should be urgently reviewed by a clinician.<sup>7</sup>

In NHS Greater Glasgow and Clyde (GGC), a pragmatic mixed-methods research study, funded by the manufacturer and Scottish Government, uses deep learning AI technology to highlight abnormalities on CXR images. The qXR (Qure.ai) module was trained on 4.4 million CXR images worldwide, validated on a set of more than 93,000 CXR images and has a processing time per CXR of under 20 seconds.<sup>8</sup> The qXR module analyses a CXR image and highlights whether the scan should be reviewed by a clinician.<sup>9</sup>

### What is innovative about the use of AI

The use of AI to support clinician review of CXRs is the first application of the technology in a clinical setting in Scotland. By assisting clinicians with prioritising referrals for urgent CT scans, the use of AI may speed up time to diagnosis and lead to earlier treatment and improved health outcomes for patients with suspected lung cancer.<sup>10, 11</sup>

### Regulatory information

- annalise.ai: Conformité Européene (CE) marked class IIb medical device.
- qXR (Qure.ai): CE marker class IIb medical device.

## Population, setting and intended users

### Population

Lung cancer is one of the most common types of cancer in Scotland.<sup>12</sup> In 2021, 5,476 people (2,699 men and 2,777 women) were diagnosed with lung cancer, representing 15.5% of all cancer diagnoses in Scotland.<sup>12</sup> The rate of diagnosis for lung cancer is 100 people per 100,000.<sup>12</sup> Lung cancer is the leading cause of cancer related death in Scotland.<sup>12</sup> The biggest risk factor for developing lung cancer is smoking history. Other risk factors include occupational hazard exposure (for example, to asbestos), family history of lung cancer, and a higher level of socioeconomic deprivation.<sup>12</sup>

Most people who are diagnosed with lung cancer present late to clinical services. In 2022, 45% of people with lung cancer in Scotland were diagnosed when their cancer was late-stage (stage four).<sup>12</sup> A late-stage cancer diagnosis means that the cancer has spread to at least one other organ in the body and may no longer be treatable.<sup>13</sup>

By 2027, the percentage of people receiving a new diagnosis of lung cancer in Scotland is predicted to increase by 29% in women and by 12% in men<sup>14</sup>

### Setting and intended user

In NHS Grampian and NHS GGC, these AI tools are being used in secondary care to support clinical review of CXRs in patients with suspected lung cancer. Patients with suspected lung cancer have their scans reviewed by the AI technology. Patients do not interact with the AI technology directly as part of their experience on the care pathway. The AI tools flag CXR scans that are 'high-risk' for lung cancer and should be prioritised for review by a clinician. If the clinician agrees with the AI assessment of lung cancer risk, the patient will have an urgent CT scan.

## Current care pathway

When a person visits a General Practitioner with symptoms of lung cancer, they should be referred to secondary care for an urgent suspicion of cancer CXR.<sup>15</sup>

In line with waiting time targets published by Scottish Government, urgent referral to treatment should take place within 62 days following an urgent suspicion of cancer referral and time from decision to treatment should be within 31 days from diagnosis.<sup>16</sup> In 2022, shorter timescales for diagnosis and treatment were outlined to support better outcomes for people with lung cancer. Scotland's national optimal lung cancer diagnostic pathway encourages clinicians to aim for diagnosis by week three (day 21) from when patients with suspected lung cancer were first referred. Treatment for most people should start by week six (day 42) since patients with suspected lung cancer were first referred.<sup>17</sup>

For the use cases of AI in NHSScotland, AI supported clinical review is implemented at the early-stage of the clinical pathway, after CXR but before CT scan. Use of AI and pathway adjustments (additional staffing and CT lists) are intended to speed up time to treatment and identify those patients with more treatable cancers (primary outcome measures for NHS

Grampian). In NHS GGC, the primary outcome measure is time to decision to recommend a CT, or time to a decision not to undertake a CT based on the results of a CXR in cases of urgent suspicion of cancer. Both healthboards involved in the use cases of AI in NHSScotland aim for national target times for CXR (scan and report within 24 hours) and CT (scan and report within 72 hours), as outlined in Scotland’s national optimal lung cancer diagnostic pathway.<sup>17</sup>

## Costs

### AI technology cost

#### annalise.ai

The pricing structure for annalise.ai consists of a one-off implementation fee and an annual subscription fee.<sup>4</sup> The implementation fee covers installation, integration into the existing radiology information system, and staff training.<sup>4</sup> The annual subscription fee depends on the volume of CXRs analysed.<sup>4</sup> Ongoing subscription costs are renewable on an annual basis, with fees covering software licensing, annual maintenance, support services and updates.<sup>4</sup>

Excluding value added tax (VAT), the one-off implementation fee is £5,000–£25,000. The annual subscription fee is £51,250 based on tier pricing of up to 25,000 CXRs analysed per year.<sup>4</sup>

#### qXR

No information regarding the pricing structure or cost of qXR was available.

## Equality considerations

In the UK, a current or previous diagnosis of any cancer (including lung cancer) is considered a disability under the Equality Act 2010.<sup>13</sup>

AI bias may be introduced in the development and training of the tools, especially if the training set is not ethnically diverse and representative of local clinical populations.<sup>18, 19</sup> AI bias may risk delays to diagnosis (underdiagnosis) and treatment of people who need access to timely healthcare.<sup>18</sup>

## Summary of clinical evidence

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The focus of this IMTO is on studies relevant to the UK context that were published since the NICE<sup>4</sup> 2023 Early Value Assessment (EVA) on the use of AI to analyse CXRs for patients with suspected lung cancer in primary care. Beyond the NICE EVA (and associated follow-up review), only one additional observational study was identified.<sup>4,20,21</sup>

## Published evidence

### Maiter et al. (2023)<sup>20</sup>

#### Study size, design and location

A retrospective observational study of the cancerous lung nodule detection performance of Auto Lung Nodule Detection AI (Samsung Electronics, Suwon, South Korea) in 5,592 adults referred from primary care in the UK.

#### Interventions and comparator

AI review of CXR compared with radiologist reporting and diagnosis of cancer by a multiple disciplinary team (MDT).

#### Key outcomes

- AI compared with radiologist report for detecting suspicious lung nodules:
  - AI review of CXRs can detect a proportion of lung nodules that are also identified in radiologist reports (specificity=83.2%) and identify those that do not need review (negative predictive value (NPV)=99%)
  - some patients that had lung nodules identified in the radiologist report were missed by the AI (sensitivity=54.5%)
  - AI review of CXRs highlighted patients who did not need review (positive predictive value (PPV)=5.5%).
- AI compared with MDT confirmed cancer diagnosis:
  - AI review of CXRs can identify a proportion of lung nodules that are later diagnosed as cancerous (specificity=83.3%) and those that are not (NPV=99.2%)
  - some patients that had suspicious lung nodules that were diagnosed as cancerous at MDT were missed by the AI (sensitivity=60.9%)
  - AI review of CXRs highlighted patients who did not need review (PPV=5.6%).
- in 69.9% of 943 false positive cases (image flagged for abnormal anatomy, but the clinical report disagreed), normal anatomy was identified as an abnormality by the AI technology.

### NICE (2023)<sup>4</sup>

#### Study size, design and location

A NICE EVA (narrative data synthesis) provided an overview of the research on the use of AI supported clinical review of CXR scans for adults with suspected lung cancer. The adults included in the EVA were referred from primary care. Fourteen AI tools were looked at, including annalise.ai and qXR.

#### Interventions and comparator

AI supported clinical review of CXRs by a specialist, compared with clinical review only of CXRs.

## Key outcomes

- No studies met the inclusion criteria of the review.
- More research is required for technologies (including annalise.ai and qXR) designed to support clinical review of CXRs for suspected lung cancer in patients referred from primary care, including:
  - impact of AI on clinical decision making
  - costs and resource use of AI
  - impact of AI on review and reporting time (eg time to CT referral and diagnosis)
  - diagnostic accuracy of AI alongside clinical review
  - technical failure and rejection rates of AI
  - use of AI to detect lung abnormalities in different groups of people, such as in younger women who do not smoke
  - patient perceptions of the use of AI.

## Cedar Health Technology Research Centre (2023)<sup>21</sup> – follow-up to NICE (2023)<sup>4</sup>

### Study size, design and location

Follow-up review (narrative data synthesis), with a broader scope compared with the NICE EVA.<sup>4</sup> The review aimed to provide an overview of the research on the use of AI to interpret CXRs, compared with clinician review only. Fourteen AI technologies were reviewed by the NICE EVA, including annalise.ai and qXR.

### Interventions and comparator

AI interpretation of CXRs compared with radiologist specialist interpretation of CXRs.

### Key outcomes

- Nine studies were included in the review (one systematic review, five retrospective cohorts and three ongoing unpublished studies).
- High specificity and sensitivity for the AI technology in detecting lung abnormalities was reported, as well as a high rate of false positives.
- Limited research on the practical applications of AI technology exists.

## Unpublished evidence

### Scottish Health Technologies Group (SHTG) analysis of NHS Grampian service evaluation data

#### Study size, design and location

The NHS Grampian service evaluation is a cohort study with retrospective and prospective phases. Seven months of interim data (n=41 patients reaching diagnosis stage, n=27 patients reaching treatment stage) on the implementation of AI supported clinical review (annalise.ai) of CXRs in patients with suspected lung cancer were collected in NHS Grampian in 2023.

Annalise.ai implementation data were compared with 12 months of data from retrospective clinician review only (n=110) from NHS Grampian in 2019 (chosen as a pre-COVID-19 pandemic baseline). Patients with suspected lung cancer were referred from primary care.

### **Interventions and comparator**

AI supported clinical review of CXRs in patients with suspected lung cancer and clinical pathway adjustment (additional staffing and CT lists) compared with clinician review of CXRs only.

### **Key outcomes**

Following introduction of annalise.ai and the pathway adjustment:

- patients in NHS Grampian receive a CT scan seven days more quickly following a CXR report (statistically significant)
- there is a 9-day reduction in average time to treatment from pre-pandemic baseline (57 days) to post-implementation (48 days), but this was statistically non-significant
- there was an 11% increase in the number of patients diagnosed with treatable cancers from a pre-pandemic baseline of 41% to 52% post-implementation, but this was statistically non-significant
- AI supported clinical review can successfully prioritise patients for urgent CT referral who have a high-risk flag(s) for lung cancer from those who do not:
  - performance of annalise.ai compared with clinician review: AI supported clinical review in NHS Grampian can identify patients who have a high-risk flag or flags for lung cancer from those who do not (specificity=91%, NPV=99.89%). Twenty-two percent of patients who should have been flagged for review were missed by annalise.ai (sensitivity=78%).
  - performance of annalise.ai compared with clinician-confirmed diagnosis: use of annalise.ai can successfully identify patients who do not have lung cancer (specificity=90%, NPV=100%). Fifteen percent of patients who did have lung cancer were missed by annalise.ai (sensitivity = 85%).
- Following adjustments to the pathway, fifty-six percent of patients received their CT scan more than three days after referral. Twenty-four percent received their CT scan within the same day as referral.

A full report on the results of the interim analysis by SHTG is available on request.

## Clinical trials

We identified four ongoing clinical trials in the UK (*Table 1*).

*Table 1: UK based ongoing clinical trials on the use of AI supported clinical review of CXRs from patients with suspected lung cancer*

Trial ID	UK country	Study title and description	AI tool	Estimated completion date
<a href="#">NCT05489471</a>	England	<p>A study to assess the impact of an AI system on CXR reporting.</p> <p>A prospective study aiming to assess the impact of AI on assessing abnormalities on CXR, sensitivity for detection of lesions and impact on reported confidence. The study will also explore the impact of AI on turnaround times and patient pathway from CXR to CT.</p>	Lunit INSIGHT CXR	July 2023 <sup>a</sup>
<a href="#">NCT06075836</a>	England	<p>AI assisted detection of CXR.</p> <p>A retrospective validation study aiming to assess the use of AI for diagnostic accuracy, speed and confidence of healthcare professionals in inpatient and emergency departments.</p>	Lunit INSIGHT CXR	December 2023 <sup>b</sup>
<a href="#">ISRCTN78987039</a>	England	<p>Impact of immediate AI enabled patient triage to chest CT on the lung cancer pathway.</p> <p>A multi-centre prospective randomised controlled trial aiming to assess clinical effectiveness of AI for reading and worklist prioritisation on time to diagnosis of lung cancer and time to CT from CXR.</p>	qXR (Qure.ai)	October 2024
<a href="#">NCT06044454</a>	Scotland	Radiograph accelerated detection and identification of cancer in the lung (RADICAL).	qXR (Qure.ai)	February 2025

Trial ID	UK country	Study title and description	AI tool	Estimated completion date
		A prospective clinical effectiveness study across three sites in NHS GGC. The primary aim of the study is to assess the clinical effectiveness of qXR to prioritise patients with suspected lung cancer for follow-up CT.		

<sup>a</sup> the trial is registered as 'not yet recruiting'. No further update on progress in the registry as of March 2024.

<sup>b</sup> the trial is registered as 'active, not recruiting'. No further update on progress in the registry as of March 2024.

### Pilot studies

We identified two pilot studies in the UK that do not appear to be registered clinical trials (Table 2).

*Table 2: UK based ongoing pilot studies on the use of AI supported clinical review of CXRs from patients with suspected lung cancer*

UK country	NHS trust	Study description	Pilot study website	AI tool
England	Somerset NHS Foundation Trust	Use AI to support reduction in time to lung cancer diagnosis	<a href="https://www.digitalhealth.net/2022/08/ai-algorithm-somerset-lung-cancer/">https://www.digitalhealth.net/2022/08/ai-algorithm-somerset-lung-cancer/</a>	Behold.AI red dot
England	Frimley Health NHS Foundation Trust	Use AI to support the efficient triaging and prioritisation of patients with lung cancer	<a href="https://htn.co.uk/2023/09/01/ai-trial-at-frimley-health-nft-aims-to-support-prioritisation-of-lung-cancer-triage-and-diagnosis/">https://htn.co.uk/2023/09/01/ai-trial-at-frimley-health-nft-aims-to-support-prioritisation-of-lung-cancer-triage-and-diagnosis/</a>	qXR Qure.ai

### Unpublished rapid review

We identified one unpublished rapid review.<sup>22</sup>

**Wale et al (2023)<sup>22</sup>**

#### Study size, design and location

Unpublished rapid review of 28 studies (lung cancer studies n=7) assessing the effectiveness of AI in cancer diagnosis (any imaging modality) in children and adults referred for suspected cancer.

#### Interventions and comparator

Use of AI compared with usual care without AI.

## Reported key outcomes

- Use of AI may improve diagnostic accuracy of lung nodule detection or be as accurate as experienced clinicians, but the level of certainty is unclear.
- Use of AI may be a supportive tool for inexperienced clinicians, but the level of uncertainty is unclear.
- Results may be dependent on the type of AI model being used.

## Summary of safety evidence

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### Published evidence

We did not identify any published research describing the impact of AI supported clinical review of CXRs for patients with suspected lung cancer on patient safety.

Evidence from NICE and Cedar did not find any research that discussed technical failures or adverse events.<sup>4, 21</sup>

### Unpublished evidence

In their rapid review, Wale et al (2023) highlight that further research is needed to see what the impact of AI is on patient safety.<sup>22</sup>

## Patient/user experience

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We did not identify any published research describing the patient or clinician perspective on the use of AI supported clinical review of CXRs for patients with suspected lung cancer.

The NICE and Cedar reports recommended more research is developed in this area and that the patient and clinician perspective is sought.<sup>4, 21</sup>

## Summary of economic evidence

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### Published evidence

We did not identify any published research describing the cost-effectiveness of AI supported clinical review of CXRs compared with clinical only review of CXR scans for patients with suspected lung cancer.

The NICE EVA included a basic budget impact analysis, at NHS Trust level, of adopting annalise.ai for all patients referred by a GP for a CXR.<sup>4</sup> The results of the budget impact analysis are provided in *Table 3*.

Using the mid-point implementation fee (£15,000), the total cost of adopting annalise.ai during year one per NHS Trust for all patients referred by a GP for a CXR, excluding VAT, was estimated to be £66,250.

The cumulative costs over the first 5 years (non-discounted), excluding VAT, were estimated to be £271,250. Based on the assumption of 25,000 images analysed per year, the indicative cost per image analysed was £2.71. The results do not include an estimate of the staff costs associating with using annalise.ai.

*Table 3: Anticipated budget impact of AI software at NHS Trust level (England) for all patients referred by a GP for a CXR<sup>4</sup>*

Company name (Technology name)	Implementation fee	Annual subscription	Total first year cost (VAT applied at 20%)	Cost over first 5 years, non-discounted (VAT applied at 20%)	Indicative cost per image over 5 years, non-discounted
annalise.ai (Annalise Enterprise CXR)	£5,000-£25,000	£51,250 <sup>a</sup>	£66,250 assuming mid-point of implementation fee (£79,500])	£271,250 <sup>b</sup> (£325,500)	£2.71

<sup>a</sup> based on tier pricing for annual subscription of 'up to' 25,000 images per year.

<sup>b</sup> based on a volume of 16,945 images per year.

VAT = value added tax.

### Unpublished evidence

Information from NHS Grampian regarding the cost of adopting annalise.ai is reported in *Table 4*.

Costs provided by NHS Grampian include an estimate of the staff costs associated with using annalise.ai, as well as acquiring the technology. The total cost per year is estimated at £278,634.

Table 4: Annalise.ai costing information from NHS Grampian (November 2022)

Resource	Description	Cost per year
Lung pathway co-ordinator	Mid-point for staff costs and required information technology equipment <sup>a</sup>	£35,000
Radiologist (CXR out-of-hours reporting)	85 hours per month at a cost per hour of £111.72. Figures assume use of current trained staff.	£113,954
Additional CT lists	Figure accounts for radiographers, administration, and reporting. Estimated 1,040 patients at a cost at £67 per patient.	£69,680
Annalise CXR	Software acquisition.	£60,000
<b>Total</b>		<b>£278,634</b>

<sup>a</sup> Figures do not account for pay awards to NHSScotland staff from 2022 onwards.

CT = computerised tomography; CXR = chest x-ray.

## Conclusions

The use of AI in healthcare is an emerging technology. Evidence on the use of AI supported clinical review of CXRs for patients with suspected lung cancer is promising but, particularly in relation to clinical effectiveness, remains limited in quantity and quality.

As part of their EVA, NICE advise that AI could still be used to support review of CXRs in adults with suspected lung cancer referred from primary care but ‘only under an appropriate evaluation framework and only alongside clinician review.’<sup>4</sup>

There are ongoing studies, based in the UK, which will contribute to the research base in the next year or two. The ongoing service evaluation in NHS Grampian and the multi-site prospective clinical study in NHS GGC will help to address gaps identified in the research base.

## What is an IMTO?

An IMTO provides a high-level summary of health and care innovations. IMTOs include a description of the technology and its potential use in Scotland, and an overview of the evidence to help gauge the potential impact of the technology on people and health and care services.

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## Appendix 1: Abbreviations

<b>AI</b>	artificial intelligence
<b>CE</b>	Conformité Européene
<b>CfSD</b>	Centre for Sustainable Delivery
<b>CT</b>	computerised tomography
<b>CXR</b>	chest x-ray
<b>EVA</b>	Early Value Assessment
<b>IMTO</b>	Innovative Medical Technology Overview
<b>MDT</b>	multi-disciplinary team
<b>NHS</b>	National Health Service
<b>NICE</b>	National Institute for Health and Care Excellence
<b>NPV</b>	negative predictive value
<b>PPV</b>	positive predictive value
<b>SHTG</b>	Scottish Health Technologies Group
<b>UK</b>	United Kingdom
<b>VAT</b>	value added tax

## Appendix 2: Definitions of diagnostic accuracy terms

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<b>Term</b>	<b>Description</b>
<b>NPV</b>	The probability that, given a negative test result, the person does not have the disease. <sup>23</sup>
<b>PPV</b>	The probability, given a positive test result, the person does have the disease. <sup>23</sup>
<b>Sensitivity</b>	The probability that a person having a disease will be correctly identified by a clinical test. <sup>24</sup>
<b>Specificity</b>	The probability that a person not having a disease will be correctly identified by a clinical test. <sup>24</sup>