NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images.

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 23 March 2023

THEME: Recommendations for targeted screening

Comment number	Name and organisation	Section number	Comment	NICE response
1	UK National Screening Committee	1.2 and 1.3	Very helpful to see the recommendations about the need for data collection in targeted lung screening. The UK NSC is clear that this work needs to be done in a coordinated manner. Suggestions about how to firm up the NICE document are found in comments 3 and 4 below. It is not NICE' job to common or run research so we might call on NICE support to help drive that work.	Thank you for this comment which the committee considered.
2	NHS England Targeted Lung Health Checks Programme	1.1	Based on the results- this recommendation is inaccurate. Improved sensitivity and improved intra- and inter-reader agreement for measurement, as well as time-saving, was shown in a variety of studies, but your report rightly found heterogeneity of data quality. As your report acknowledges (in the Committee discussion), there has not been enough analysis of complementary review by clinicians alongside CAD and its impact on specificity. As such, I wonder if you would consider that the recommendation should actually be that "There is not enough high-quality evidence to recommend or refute the use of AI-derived computer-aided detection (CAD) software alongside clinician review of CT scan images to detect and measure lung	Thank you for this comment which the committee considered. Section 1 now includes separate subsections (1.1, 1.2 and 1.3) specific to each of the populations in the scope of this guidance. Recommendation 1.3 is specific to targeted lung cancer screening: 'For people having a chest CT scan as part of targeted lung cancer screening, AI-derived CAD software technologies have the potential to be cost-effective. But there is not enough evidence to determine which of them are the most clinically and cost effective. Centres using AI derived CAD software alongside clinician review as part of targeted lung cancer screening should generate further evidence. This is to make sure the potential benefits are realised in practice for people having screening and for clinicians using the

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Comment number	Name and organisation	Section number	Comment	NICE response
			nodules." You are unable to argue your statement either way- all you have found is uncertainty. I do not see why the specification on targeted lung cancer screening needs to be mentioned here, because the statement is not particular to the route of presentation.	software, and to allow comparisons between the different software.' The section 'why the committee made these recommendations' describes the evidence that was found in the different populations: 'When used in people having a CT scan because of suspected lung cancer or for reasons not related to lung cancer, using the software could lead to more people being identified with lung nodules that are not likely to be cancer. This could lead to people having CT surveillance they do not need, which may cause unnecessary anxiety. This is uncertain because there is not much evidence, so more research is needed. Although there is more evidence in targeted lung cancer screening, it is too limited to show which technologies are the most clinically and cost effective. But the model results suggest that using the software alongside clinician review has the potential to be cost effective. NICE considers also evidence that is lower in the hierarchy of evidence such as observational studies or real-world data.
3	NHS England Targeted Lung Health Checks Programme	1.2	Given the limitations I have pointed out in my comment on section 1.1, recommendation 1.2 should also be revised to "Centres already using AI-derived CAD software alongside clinician review as part of targeted lung cancer screening	Thank you for this comment which the committee considered. Recommendation 1.3 is now specific to targeted lung cancer screening and has been revised to read: 'For people having a

DIAGNOSTICS ASSESSMENT PROGRAMME

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			should continue to adhere to its use in line with the Standard Protocol developed for that programme, and collect further data to make sure the benefits for people attending screening and clinicians using the software are realised in practice."	chest CT scan as part of targeted lung cancer screening, AI-derived CAD software technologies have the potential to be cost-effective. But there is not enough evidence to determine which of them are the most clinically and cost effective. Centres using AI derived CAD software alongside clinician review as part of targeted lung cancer screening should generate further evidence. This is to make sure the potential benefits are realised in practice for people having screening and for clinicians using the software, and to allow comparisons between the different software.'
4	NHS England Targeted Lung Health Checks Programme	1.2	This needs to be re-phrased. The NHSE TLHC protocol will continue to mandate CAD and will also grow to include new sites/centres as part of the same programme/protocol. I would suggest that this is reworded to allow for further sites but within the same NHSE TLHC protocol. -Perhaps something like Existing and new centres that are part of the NHSE and/or evolving NSC TLHC Programme can continue to do so...	Thank you for this comment which the committee considered. Recommendation 1.3 is now specific to targeted lung cancer screening and has been revised to read: 'For people having a chest CT scan as part of targeted lung cancer screening, AI-derived CAD software technologies have the potential to be cost-effective. But there is not enough evidence to determine which of them are the most clinically and cost effective. Centres using AI derived CAD software alongside clinician review as part of targeted lung cancer screening should generate further evidence. This is to make sure the potential benefits are realised in practice for people having screening and for clinicians using the software, and to allow comparisons between the different software.'

DIAGNOSTICS ASSESSMENT PROGRAMME

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THEME: Research recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
5	UK National Screening Committee	1.3	Prevalence of nodules – do you mean how this is influenced by the CAD?	Thank you for this comment which the committee considered. The committee noted that more data on the prevalence of nodules in this (symptomatic) population need to be collected before the influence of AI-derived CAD can be estimated in the health economic modelling. The order of the research recommendations in section 1.4 and 4 has been changed to make it clearer that research on assessing the prevalence of nodules in people who have a chest CT scan because of signs or symptoms that suggest lung cancer does not need to involve CAD software.
6	UK National Screening Committee	1.3	Do you need to divide detection and measurement into two topics – this is because they may have different implications for outcomes.	Thank you for this comment which the committee considered. The committee noted that the accuracy of detection and measurement may have different implications for outcomes, but the two aspects of test performance are not completely separate. The committee decided to keep detecting and measuring in the same recommendation. Growth of the nodules was added to the features to investigate because this is used to aid decisions in surveillance that may follow detection of a nodule.
7	UK National Screening Committee	1 and 2.4	Should you also include research on decision making?	Thank you for this comment which the committee considered.

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AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images.

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Diagnostics Advisory Committee date: 23 March 2023

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				The committee recalled that the external assessment group found very little research evaluating whether AI-derived CAD had different impact on clinicians with different levels of experience, seniority or specialisation. It decided to add how using the software alongside clinician interpretation affects clinical decision making to its research recommendations in section 1.4 and 4.
8	UK National Screening Committee	1 and 2.4	Should you recommend comparisons between AI?	Thank you for this comment which the committee considered. Section 3.15 of the guidance document describes what researchers should consider and suggests that ideally, studies should compare more than 1 software. To further highlight the need for these comparisons, research recommendations in section 4.2 now also mention that studies should ideally compare more than 1 software. The recommendation 1.3 now includes that further evidence generation in targeted screening should also aim to enable comparisons between the different software.
9	NHS England Targeted Lung Health Checks Programme	4.1	There should be some mention of a focus of research on "real world reporting paradigms" because, as currently written, the reader would think there is no research on these reading paradigms in any form- which is inaccurate, since there are already multiple studies.	Thank you for this comment which the committee considered. Section 3.15 of the guidance document describes what researchers should consider and makes reference to real-world evidence generation to help compare different strategies for targeted screening: ‘Studies should include groups of people similar to those seen in the NHS. Ideally, studies

DIAGNOSTICS ASSESSMENT PROGRAMME

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Diagnostics Consultation Document – Comments

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				should compare more than 1 software. The committee noted that the DART project, an ongoing research project that collects data from NHS England's Targeted Lung Health Checks programme, may be a helpful data source for comparing different technologies for targeted screening.' A further real-world evidence generation consideration has been added to this section: 'Auditing before and after introducing the software into a new centre, or a cluster randomised controlled trial, could help generate further evidence on the potential benefits of the software.'

DIAGNOSTICS ASSESSMENT PROGRAMME

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THEME: Feasibility of collecting data for targeted screening

Comment number	Name and organisation	Section number	Comment	NICE response
10	UK National Screening Committee	1.2	It needs to be acknowledged that CAD for nodules is mostly standard practice as so the recommendations in 1.3 may be very difficult.	Thank you for this comment which the committee considered. The section 3.3 of the guidance document now specifies that the use of CAD software is included in protocol for NHS England's Targeted Lung Health Check programme. Section 3.15 of the guidance document describes what researchers should consider and mentions the DART project, an ongoing research project that collects data from NHS England's Targeted Lung Health Checks programme, may be a helpful data source for comparing different technologies for targeted screening. This section now also suggests that auditing before and after introducing the software into a new centre, or a cluster randomised controlled trial, could help generate further evidence on the potential benefits of the software.
11	UK National Screening Committee	1.3	The link to further data collection here is not clear – how are these research questions going to be answered just by collected data from and already implemented and used CAD?	Thank you for this comment which the committee considered. Section 3.15 of the guidance document describes what researchers should consider and mentions the DART project, an ongoing research project that collects data from NHS England's Targeted Lung Health Checks programme may be a helpful data source for comparing different technologies for targeted screening. This section now also suggests that auditing before and after introducing the software into a new centre, or a cluster randomised controlled trial, could help generate further evidence on the potential benefits of the software.

DIAGNOSTICS ASSESSMENT PROGRAMME

AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images.

Diagnostics Consultation Document – Comments

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THEME: Feasibility of collecting data for targeted screening

Comment number	Name and organisation	Section number	Comment	NICE response
12	UK National Screening Committee	1.3	Would it not be better to recommend a test platform for the use of CAD where real cases are used with and without CAD. It is not quite the same as in the real-world but probably a better measure of all of the questions set out in 1.3.	Thank you for this comment which the committee considered. Section 1.4 recommends further evidence generation and researchers can consider the best study designs to generate this data. This could also be through a study as suggested by the stakeholder in this comment.
13	NHS England Targeted Lung Health Checks Programme	3.8	I submit that the committee should also concede that it will be impossible to perform a real-time pragmatic comparison of reading a CT scan with and without CAD, without at least one of those readings being done in "laboratory conditions". If a CT scan is read without CAD in a prospective clinical practice setting, and a study result/report issued, the reading subsequently performed with CAD will be under experimental conditions. The same will be true if the reading paradigm was reversed. As such, it should be acknowledged that recommending a head-to-head comparison of reading paradigms in a real-world setting on the same patients is impractical.	Thank you for this comment which the committee considered. Section 3.15 of the guidance document that describes what researchers should consider now also suggests that auditing before and after introducing the software into a new centre, or a cluster randomised controlled trial, could help generate further evidence on the potential benefits of the software.

DIAGNOSTICS ASSESSMENT PROGRAMME

AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images.

Diagnostics Consultation Document – Comments

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THEME: Equality

Comment number	Name and organisation	Section number	Comment	NICE response
14	Royal College of Radiologists	Intro	On any equality issues: There are no equality issues for the recommendations.	Thank you for this comment which the committee considered. Section 3.7 of the guidance document describes the committee's considerations of the groups of people that could particularly benefit from the AI-derived CAD software being used. The research recommendations in section 1.4 and 4.2 of the guidance document now also specify that research on how using CAD software alongside clinician review of CT scan images affects the accuracy of detecting, measuring and assessing the growth of lung nodules, should consider groups of people with underlying lung conditions, and people whose family background means they are more likely to have subsolid nodules.

DIAGNOSTICS ASSESSMENT PROGRAMME

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Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 23 March 2023

THEME: Measuring test accuracy

Comment number	Name and organisation	Section number	Comment	NICE response
15	Royal College of Radiologists	3.12	Our experts question whether the software-assisted readings were done pre or post human reading as this may have influenced outputs. This may need to be included in future research, particularly in relation to observer experience.	Thank you for this comment which the committee considered. The external assessment group explained that in their review, the studies where software-assisted readings and unaided readings were done by the same human readers, software-assisted readings tended to be done after unaided reading after varied wash-out periods. Further details are provided below. **Hsu 2021:** In second-read CAD mode, readers read the CT images without CAD first and then combined the displays of the CAD results to make the final decision. After an 8-week interval, CAD results were simultaneously displayed to readers during the reading. **Zhang 2021:** Human read without CAD first (clinical practice). Reading with concurrent AI as part of a reader study. **Kozuka 2020:** First without CAD and then with CAD (at least 14-day interval). **Hall 2022:** Expert radiologists without AI in clinical practice first. Radiographers with concurrent AI use as part of a reader study.

DIAGNOSTICS ASSESSMENT PROGRAMME

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Diagnostics Consultation Document – Comments

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				Lo 2018: Part 1 involved unaided reading at baseline, and part 2 involved concurrent reading aided by CAD with a minimum interval of 37 days (mean, 57 days). **Park 2022**: Readers first read the images without CAD, then with CAD, with a 6-week interval.

DIAGNOSTICS ASSESSMENT PROGRAMME

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Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 23 March 2023

THEME: qCT-Lung

Comment number	Name and organisation	Section number	Comment	NICE response
16	Qure.ai	2.5	qCT-Lung is registered under EU-MDR as class IIB medical device. MHRA registration certificate can be provided if required.	Thank you for this comment which the committee considered. NICE also acknowledges the receipt of the class 2b medical device CE certificate for qCT-Lung. Text describing qCT-Lung's CE mark class in section 2.5 has been amended to reflect this.
17	Qure.ai	3.4	qCT-Lung has peer reviewed published evidence which is publicly available. The two published evidence along with their DOI is given below: 1. Challa, Vikash, Vanapalli Prakash, Saigopal Sathyamurthy, Arunkumar Govindarajan, E. Dwivedi, Souvik Mandal, Ankit Modi, Preetham Putha, Sai NAREN V S, Arpit Kothari, Bhargava MR REDDY and Prashant Warier. "NEEDLE IN A HAYSTACK: OPPORTUNISTIC SCREENING OF LUNG NODULES AMIDST COVID-19 USING DEEP LEARNING." Chest 162 (2022): A1646 - A1647. DOI: https://doi.org/10.1016/j.chest.2022.08.1377 2.Ebrahimian, Shadi, Anjaneya SINGH KATHAIT, Subba Rao Digumarthy, Vanapalli Prakash, Vikash Challa, Preetham Putha, Ankit Modi, Bernardo C. BIZZO, Keith J DREYER and Mannudeep K. KALRA. "CORRELATING MALIGNANCY RISK FROM AN ARTIFICIAL INTELLIGENCE (AI) ALGORITHM AND LUNG-RADS-BASED CLASSIFICATION FROM	Thank you for this comment which the committee considered. The external assessment group explained that the cited publications are conference abstracts published after the search date (January 2022) and deadline for accepting submission of new evidence (31 August 2022). Upon examination neither would have been eligible for the assessment report: 1. This was a conference abstract presented on 19 October 2022. The study was conducted in India during the peak of its second COVID-19 wave and therefore was unlikely to be generalisable to UK settings. Data available in the abstract would not allow test accuracy to be calculated. 2. This was a conference abstract presented on 19 October 2022. This study focused on malignancy risk score generated by the AI-derived CAD, which is outside the scope of this assessment/appraisal.

DIAGNOSTICS ASSESSMENT PROGRAMME

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THEME: qCT-Lung

Comment number	Name and organisation	Section number	Comment	NICE response
			SCREENING LOW-DOSE CT IMAGING." Chest (2022): DOI: https://doi.org/10.1016/j.chest.2022.08.1341	The committee concluded that no changes to the guidance were needed.
18	Qure.ai	4.1	As mentioned earlier, further research has been done using qCT-Lung. A retrospective trial was conducted on 210 adult patients who underwent clinically indicated low-dose chest CT for lung cancer screening. The study concluded that AI-estimated malignancy risk scores have high sensitivity and moderate specificity for predicting nodule malignancy from low-dose CT for lung cancer screening". The published evidence along with their DOI is given below: Ebrahimian, Shadi, Anjaneya SINGH KATHAIT, Subba Rao Digumarthy, Vanapalli Prakash, Vikash Challa, Preetham Putha, Ankit Modi, Bernardo C. BIZZO, Keith J DREYER and Mannudeep K. KALRA. "CORRELATING MALIGNANCY RISK FROM AN ARTIFICIAL INTELLIGENCE (AI) ALGORITHM AND LUNG-RADS-BASED CLASSIFICATION FROM SCREENING LOW-DOSE CT IMAGING." Chest (2022): DOI: https://doi.org/10.1016/j.chest.2022.08.1341	Thank you for this comment which the committee considered. The external assessment group explained that the cited publication is a conference abstract presented on 19 October 2022 and so published after the external assessment group's search date (January 2022) and deadline for accepting submission of new evidence (31 August 2022). Upon examination this abstract would not have been eligible for the assessment report because the study focused on malignancy risk score generated by the AI-derived CAD, which is outside the scope of this assessment/appraisal. The committee concluded that no changes to the guidance were needed.

DIAGNOSTICS ASSESSMENT PROGRAMME

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Diagnostics Advisory Committee date: 23 March 2023

THEME: Terminology and clarity of wording

Comment number	Name and organisation	Section number	Comment	NICE response
19	UK National Screening Committee	1.1	Does not appear to be a recommendation but rather a statement, suggest rewording into a recommendation or include as a statement.	Thank you for this comment which the committee considered. Section 1 now includes separate subsections (1.1, 1.2 and 1.3) specific to each of the populations in the scope of this guidance and each has been amended. The recommendation 1.3 that is specific to targeted lung cancer screening now reads: 'For people having a chest CT scan as part of targeted lung cancer screening, AI-derived CAD software technologies have the potential to be cost-effective. But there is not enough evidence to determine which of them are the most clinically and cost effective. Centres using AI derived CAD software alongside clinician review as part of targeted lung cancer screening should generate further evidence. This is to make sure the potential benefits are realised in practice for people having screening and for clinicians using the software, and to allow comparisons between the different software.'
20	Royal College of Radiologists	3.5	Our experts suggest the including more explanation regarding the importance of differentiating per person rather than per nodule results. An example may be useful to include as the concept may be confusing for a lay reader.	Thank you for this comment which the committee considered. The section 3.5 now further explains why the committee considered that reporting accuracy results per person instead of per nodule was important: 'This is because many people have more than 1 lung nodule identified in their CT scan images. When there are multiple nodules, clinical decisions are made at a person-level based on the largest nodule. Per-nodule results would only tell whether nodules were missed or

DIAGNOSTICS ASSESSMENT PROGRAMME

AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images.

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 23 March 2023

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				wrongly detected, but not if people were wrongly identified as having nodules or if those with nodules were missed.'
21	Royal College of Radiologists	3.13	Our experts suggest using clearer terminology for 'human' reading versus 'software-assisted' reading throughout.	Thank you for this comment which the committee considered. For consistency and clarity, the guidance document now refers to 'using CAD software alongside clinician review of CT scan images' for software-assisted reading and to 'clinician review alone' for 'human' reading.
22	NHS England Targeted Lung Health Checks Programme	2.3	The use of the terms "AI-derived CAD" and "Computer-aided detection (CAD) software with artificial intelligence (AI)-derived algorithms" is misleading in this report. In section 1.4 of the Assessment report, I note that the definition used is intended to be broad and encompasses "machines that perform tasks normally performed by human intelligence, especially when the machines learn from data how to do those tasks" as per the National AI strategy. However, the wider perception and understanding of the term "AI" is that it refers to newer technologies where some element of machine learning has been utilised to develop algorithms, not the multiple number of CAD systems that hitherto did not utilise such methods, many of which have been analysed in this report. The use of the phrase "...with artificial intelligence (AI)-derived algorithms" in section 2.3 here serves to highlight the potential confusion, as the more established technologies have not been derived from "AI".	Thank you for this comment which the committee considered. The external assessment group only included studies evaluating technologies listed in the NICE final scope that have incorporated some element of machine learning or artificial neural network in the development of their algorithms. Consequently, the technologies for which evidence was summarised in the DAR and considered by the committee are suitably described as 'AI-derived' by the committee in the guidance document. Use of the term 'computer-aided detection (CAD)' without referring to AI would potentially cover many older technologies not involving machine learning or artificial neural network. Evidence related to those older CAD systems was neither included in the DAR nor considered by the committee. Section 2.4 of the guidance document further explains what is meant by AI-derived: 'All software technologies in clinical

DIAGNOSTICS ASSESSMENT PROGRAMME

AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images.

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 23 March 2023

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			As such, I wonder why the committee felt the need to include the term "AI-derived" at all, since what this assessment is really focussing on is "Computer-aided detection"- which is already a very expansive term, and much less misleading.	settings use fixed algorithms. They cannot adapt in real time using data from the clinical practice setting in which they are used. In the NHS, AI-based technologies are only used alongside healthcare professionals, not as standalone interventions. The healthcare professional who reviews the CT scan using the software makes the final reporting decision.'

DIAGNOSTICS ASSESSMENT PROGRAMME

AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images.

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 23 March 2023

THEME: General

Comment number	Name and organisation	Section number	Comment	NICE response
23	UK National Screening Committee	3.3	The committee surely understood that the technology is in use in lung cancer screening?	Thank you for this comment which the committee considered. The section 3.3 of the guidance document now specifies that the use of CAD software is included in protocol for NHS England's Targeted Lung Health Check programme.
24	UK National Screening Committee	3.4	Should there be a change to the regulations as these techs have no evidence?	Thank you for this comment which the committee considered. The external assessment group did not find relevant published evidence in their searches or receive relevant unpublished evidence from the companies for the technologies listed in section 3.4 of the guidance document. Further evidence on these technologies may have been submitted to relevant regulatory authorities. Medical device regulations are outside of NICE's remit. At the time of writing, JLD-01K and Lung Nodule AI were not available in the UK and so the section 1 of the guidance document does not include recommendations for these 2 technologies.
25	Royal College of Radiologists	Intro	NICE: Has all of the relevant evidence been taken into account? Yes - all the relevant evidence has been considered.	Thank you for this comment which the committee considered.
26	Royal College of Radiologists	Intro	NICE: Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	Thank you for this comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

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Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 23 March 2023

THEME: General

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			The summaries regarding clinical and cost effectiveness are reasonable interpretation of that evidence, but have been largely based on modelling due to a lack of published literature.	
27	Royal College of Radiologists	Intro	NICE: Are the recommendations sound, and a suitable basis for guidance to the NHS? The recommendations are currently sound for guidance in the NHS but may subsequently change as the software continues to develop with inputting of more data and more research as recommended.	Thank you for this comment which the committee considered.
28	Association of Respiratory Nurse Specialists	1	On behalf of the Association of Respiratory Nurse Specialists. We agree with the findings that 1. There is not enough evidence to recommend AI-derived computer aided detection (CAD) software alongside clinician review of CT scans to detect and measure lung nodules in or outside of targeted lung screening. 2. Centres already using Ai may continue with the proviso that data is collected to acknowledge benefits (or not) 3. Further data is needed as well as research to make a more through and complete decision on Ai.	Thank you for this comment which the committee considered.