Clinical Radiology
AI deployment fundamentals for medical imaging

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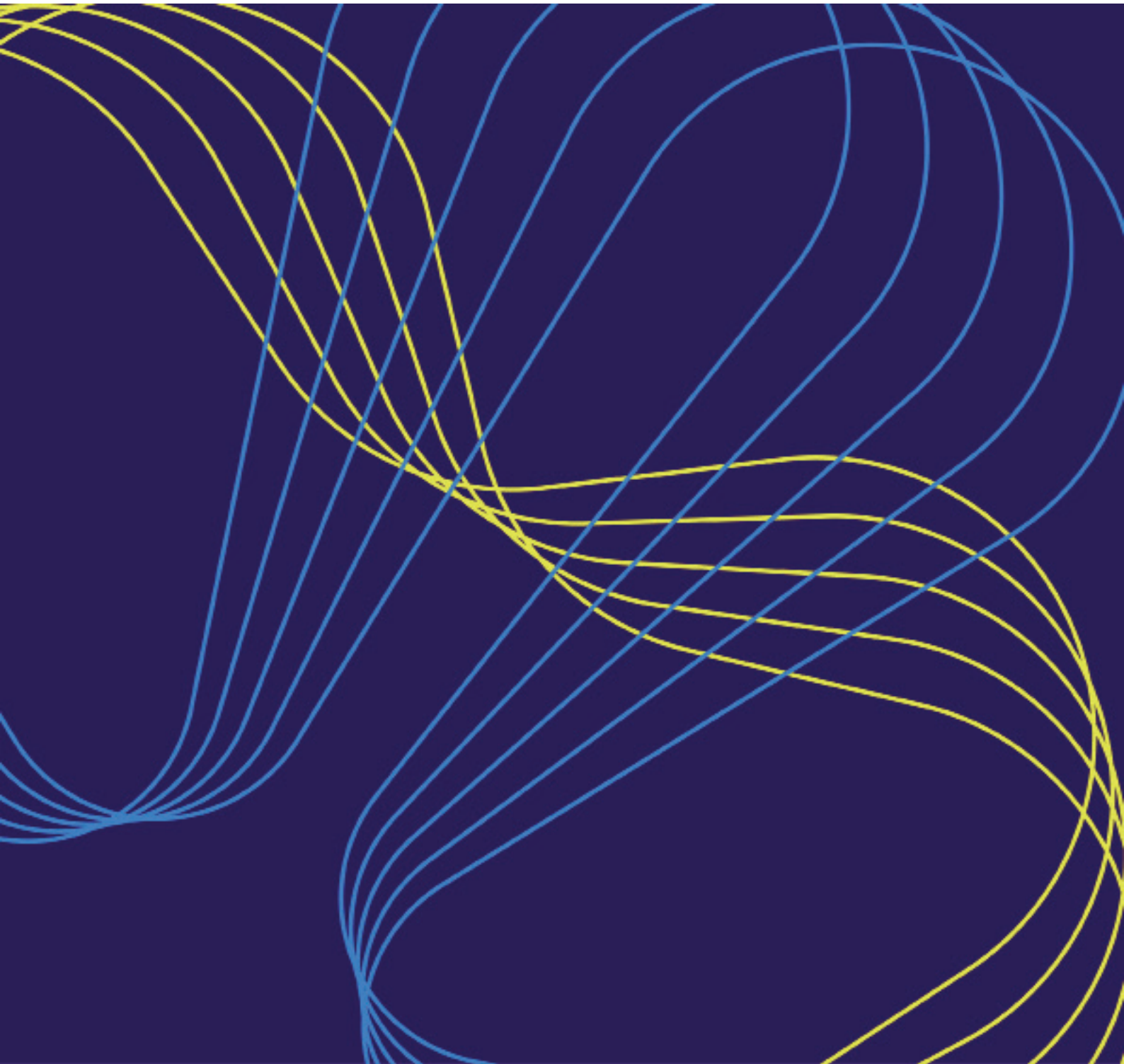
The Royal College of Radiologists



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Scope

This guidance aims to provide minimum standards for providers to deploy artificial intelligence (AI) solutions in radiology and focuses on the period between the algorithm achieving regulatory approval and its business-as-usual deployment. It is aimed at UK-wide AI adopters and provides a blueprint for teams to establish whether and how well an AI solution will perform for its intended purpose.

This guidance was developed by an expert panel and incorporates feedback from a global expert reference group. The expert panel acknowledge the AI field is constantly evolving. The content of this document details the minimum standards to deploy AI solutions in radiology at the time of publication, but the content will be reviewed regularly in light of any considerable changes to AI in the future.

The Royal College of Radiologists (RCR) recognises that appropriate infrastructure, expertise and funding are essential for formal evaluation and post-deployment monitoring within local institutions, imaging networks and health boards. This will depend on the resources available to individual institutions, imaging networks and health boards. Post-market surveillance is currently the responsibility of industry and is outside the scope of this guidance. This guidance acknowledges that providers will also need surveillance of AI tools within their local technology infrastructure and operational activity. The RCR will consider surveillance-related guidance in future.

Introduction

With the increasing number of commercial imaging AI solutions, national guidance is needed on how to deploy AI safely and effectively in and beyond the National Health Service (NHS) and how to gather the best evidence to support its use.

The RCR has been tasked with developing guidance, with representation from the Society of Radiographers, for independent benchmarking of AI algorithms following the Healthcare Services Safety Investigation Branch 2021 report *Missed detection of lung cancer on chest X-rays of patients being seen in primary care*.[1] In parallel, the National Institute for Health and Care Excellence (NICE) has conducted an early value assessment on chest X-ray AI software for suspected lung cancer in primary care.[2] Of note, NICE has highlighted the lack of supporting data and the need for more research. NICE recommends that current access to AI technology should be restricted to research or non-core NHS funding; centres already using AI should do so under an appropriate clinical evaluation framework.[3]

Following the launch of the NHS England AI Diagnostic Fund (AIDF), this RCR guidance targets imaging networks, health boards and NHS trusts looking to evaluate and deploy AI solutions in radiology that have been certified and registered with the UK Medicines and Healthcare Regulatory Authority (MHRA). The guidance uses chest X-ray AI as an example but is broadly applicable to other certified AI solutions.

This guidance emphasises clinical evidence generation and evaluation from the outset, given the need to ensure systems are safe and effective, from a risk–benefit and health economics perspective. The RCR recognises that appropriate infrastructure, expertise and funding are essential for formal evaluation and post-deployment monitoring within local institutions, imaging networks and health boards. This will depend on the resources available to individual institutions, imaging networks and health boards. While post-market surveillance falls outside the scope of this document, readers are encouraged to refer to the appropriate national or international recommendations for ensuring consistent monitoring and compliance.[4]

This guidance is part of a wider RCR initiative to provide education in AI, share expertise and experience of using AI in radiology and shape the future of AI in healthcare.

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01 Build a team to define the scope of the project

Selecting, deploying and evaluating AI solutions is a team effort, requiring input from and engagement by multiple stakeholders to ensure that the decisions made are clear and appropriate and have commitment from everyone involved. This section sets out the stakeholders who should be engaged, the initial steps that should be taken to define the specific problem the AI is intended to address and its location in the clinical pathway. Some of the following activities may evolve in parallel or a different order depending upon the use case but are presented serially here.

Engage stakeholders

1.1 Recruit a core working group of clinical pathway and imaging leads and technical experts. They should be familiar with current challenges in the pathway and service delivery and see the potential opportunity for AI to deliver service improvement and enhance patient outcomes.

1.2 Ensure the working group highlight any conflicts of interest they may have at the beginning and throughout the project for consideration.

1.3 Ensure indicative funding for evaluation, deployment and post deployment is available.

1.4 Engage in market research such as attending product demonstrations at regional and national events, observe and discuss the product(s) used at other sites if possible and arrange local demonstrations for the stakeholder group to consider the potential for conducting an AI evaluation project.

1.5 Engage with research and innovation leads to consider funding sources and opportunities to support AI projects, recognising that there may be insufficient evidence at first to commit core NHS funding through business cases. AI evaluation projects usually rely on industry, innovation or research funding applications.

1.6 Assemble a wider stakeholder group including clinicians, health professionals, clinical and operational managers and representatives from governance, patients, finance, IT and procurement to work up a project bid proposal, finance and implementation plan. Depending on the funding source this may include partnering with the supplier to submit a funding application, or it may require explaining the procurement approach. The stakeholder group should be clinically led and include radiology representatives.

1.7 Ensure the core working group and wider stakeholder group have adequate resources, protected time and funding available to deliver the AI solution.

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Build a team

Define the problem and pathway

1.8 Agree and clearly define the problem to be solved and its location in the pathway.
1.9 Agree the scope of the project and potential range of AI findings to be included, such as:
   a. Detection of normal versus abnormal
   b. Detection of diagnosis of cancer
   c. Multiple pathology detection.

1.10 Consider where in the pathway AI is to be implemented to address the problem (it may be at more than one site in the pathway). For example:
   a. Prioritisation of workflow and radiology reporting
   b. Clinical decision support including diagnosis (inside and outside of radiology).

1.11 Agree who will and who will not use the algorithm and consider the training needs for those professionals who will use the technology. Ensure that they have knowledge of known limitations, such as data trained on a limited population or demographic.
1.12 Establish that the intended purpose of the proposed algorithms is to address the identified problem within the pathway, and agree potential uses with those involved in the pathway.[5] Review of the current National Pathway Guidance or NICE guidance should be included.
1.13 Include all those involved in the specific pathway in discussions on algorithm use to consider the potential impact of the algorithm on the pathway and patient care.
1.14 Agree on any changes to the clinical pathway to be enabled through the use of the AI, including fast-track referrals such as straight-to-test computed tomography (CT) and notification, and agree on how the AI performance will be monitored. Consider the impact on other operational or clinical areas and ensure there is capacity for cross-sectional imaging in terms of staffing and time to scan.
1.15 Recognise that introducing AI can be a catalyst for wider pathway improvement and potential benefits, including report standardisation, coding, report templating and clinical communication. Consider the effect that introducing AI can have on staff roles and the implications of this.

Document decisions

1.16 Document decisions made on the above points using an agreed template.
1.17 Record the current performance of the pathway prior to AI deployment, to enable comparison with post deployment, and record unintended consequences such as increased CT or magnetic resonance imaging (MRI) activity. Examples of what to include for chest X-rays, depending on the intended purpose of the AI and problem to be addressed, can be found in Appendix 1.

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02 Identify available AI tools

Before identifying possible AI tools, consider whether AI is the most appropriate approach and whether other solutions should also be considered. The RCR AI registry aims to support the identification of possible AI applications.

2.1 Review current sources of information about potential AI applications that are available, including:[3]
   a. NHS guidance on the adoption of digital technology[6]
   b. AI for radiology database[7]
   c. NICE early value assessment for the use of AI to identify lung cancer on chest radiographs.[2]

2.2 Consider whether the potential AI applications will meet the needs of the outlined problem. A key part of implementation is that the tool's regulated intended purpose aligns with the problem that has been identified.
2.3 Request documentation describing intended purpose, functionality, limitations and possible risks from the manufacturer, as required by regulations, and training data used for the model. A basic requirement for use in the NHS is a UK Conformity Assessed (UKCA) marking, which will have been provided through regulatory assessment by the MHRA. It is important to be aware that UKCA marking or regulatory approval does not necessarily equate to clinical effectiveness or cost-effectiveness in the proposed setting. A valid CE mark is equally acceptable until 30 June 2028. DCB0129 is a clinical safety standard that requires suppliers of digital health solutions to verify the safety of their products (NHS England only).

Understand the evidence

2.4 Assess and evaluate the evidence base behind the tool.
2.5 Review the NICE medical technology evaluation programme, NICE early value assessment for medtech or other relevant guidance documents such as those published by the UK National Screening Committee. This will outline the supporting evidence base, summarising the clinical effectiveness and cost-effectiveness for each technology.
2.6 Review published literature.[8] It is important that the tool is shown to be effective in the population that has been proposed for the clinical question or role. It is also important that the application and any data have been assessed in a local cohort of patients to ensure that any results are reproducible and valid.
2.7 Explore national evidence on the available AI tools and consider whether they are from comparable populations and IT infrastructure.

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Identify available AI tools

2.8 Evaluate levels of evidence underpinning each of the available applications. It is likely the levels of evidence will increase as more are tested and other trusted research environments are developed, along with other forms of research in clinical pathways into the effectiveness and downstream effects of AI algorithms.

2.9 Assess any data for diversity to minimise, as far as possible, unknown biases in the tested applications. Diversity may be considered in terms of reflection of local population demographics or be related to protected characteristics, hard-to-reach groups and health inequalities.

Assessment questions

2.10 Discuss what the acceptable threshold level of performance will be in the setting, pathway or environment that is being proposed by providing a set definition of the performance measurements in question, such as sensitivity, specificity and clinical utility. It is very likely that performance will differ between training or testing and real-life clinical settings.[9,10] Key questions to ask can be found in Appendix 2.

Develop an evidence-generation plan

2.11 Develop an initial local evidence-generation plan and study protocol to assess whether the AI will deliver the anticipated benefits, including the impact on radiology services, staff and patient outcomes.

2.12 Consider the data collection requirements, key clinical performance indicators and local capability and resources to undertake the evaluation, recognising some data will need to be collected at baseline before AI implementation and to support the bid proposal.

2.13 Ongoing post-implementation evaluation is essential and requires a robust plan prior to deployment. Assess the degree of automation of ongoing performance monitoring, data analytics and the provision of audit data by the AI tool and the AI vendor to minimise the personnel effort required for data collection and auditing at a later stage. There must also be a clear procedure for reporting unexpected errors to the vendor, with a named responsible person of contact.

2.14 Consider the process and frequency of product updates, staff retraining and any associated costs. Retesting and re-evaluation may be required as part of a product update, so resource requirements may need to be planned for as part of product updates.

2.15 Agree the procedures and process to follow in cases of immediate significant safety concerns. In this instance, product use should cease until remedial updates are available.

2.16 Consider the effect of false negatives and false positives on patients and the service prior to their occurrence. Have agreed mitigation plans in place for either occurrence, and record these in the local DCB0160.

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03 Generate evidence and evaluate the tool

This section outlines the key areas to be addressed in the evaluation of AI tools in the clinical pathway.

3.1 AI should only be implemented in the NHS if the claimed accuracy has been confirmed and there is a clinical impact that is significant enough to justify using the product.

3.2 Additionally, the impact of AI on the clinical pathway should be evaluated, including the impact on workflow, interaction with and acceptability for users, change of human decision-making and behaviour, what training and education is needed, monitoring of ongoing use, evaluation of updates, and acceptability for patients and the public.

3.3 During evaluation of the AI tool, further consider the effect of false negatives and false positives on patients and the service prior to their occurrence. Ensure practicable mitigation plans for either occurrence are recorded in the local DCB0160. Include error recognition and mitigation procedures in the training of staff using the AI algorithm.

Methods of evaluation

Methods used will depend on the focus of the evaluation of diagnostic accuracy and clinical impact. Two different approaches are recommended below.

Diagnostic accuracy study

3.4 A diagnostic accuracy study is performed on a cohort of patients with the condition (eg lung cancer) to determine the sensitivity of the test and a separate cohort of patients without the condition to determine the specificity of the test.

3.5 For clinical AI studies this should include the baseline accuracy of reporters without AI and the post-implementation accuracy of using AI in clinical practice. For AI decision support this is the accuracy of the reporters supported by the AI.

3.6 The RCR has produced an audit template with advice on how to identify a cohort of patients with lung cancer and determine the sensitivity of reporters with chest X-ray, with recommendations for reviewing the missed cases.[11] This can be adapted for other diseases and conditions.

3.7 When assessing patients without the condition to determine the specificity of the test, it is important that the sample is representative of the referral population as this will include other conditions that may mimic the disease. Such datasets need to be regularly updated to ensure they continue to reflect the population. A test with a low specificity will overcall the number of patients with the condition and may result in additional tests and a failure to meet cost-effectiveness thresholds.

3.8 The ability to run AI in 'shadow mode' enables the algorithm to be run over these cohorts retrospectively to determine the relative sensitivity and specificity. It is also possible to predict the effect of AI in clinical practice by reviewing the cases that are known to be missed by the reporters to assess the likely impact in clinical use.

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3.9 AI platforms using contemporary validated imaging data sets that have ground truth for the measured outcome can assist in performing diagnostic accuracy studies. These might be a large series of chest radiographs that each have some sort of robust confirmation of what they show, such as biopsy-proven cancer or long follow-up with no adverse consequences. Provided the images exactly reproduce what the AI will be applied to in the NHS and cover the diversity of patients and conditions, these data sets can be used to check accuracy of any AI algorithm and the updates very efficiently.

3.10 Once such data sets are developed and there are systems for them to be regularly updated, the risk of deploying a system that does not perform as claimed will be significantly reduced.

3.11 The data derived from this approach, when available, will provide information about likely impact on the clinical pathway, for example the effect on workflow of the number of false positives or areas where AI can potentially be autonomous, allowing for evidence-based consideration for regulatory changes and subsequently for the workforce to be deployed elsewhere according to service and patient need.

Longitudinal clinical impact study

3.12 Some elements of clinical impact may be modelled using diagnostic accuracy studies and platform-based evaluations, but for many clinical outcomes a longitudinal study is required to assess whether the addition of AI is better than the existing standard.

3.13 A longitudinal study is a research design that involves repeated observations of the same variables over periods of time. These can be based on real-world data (RWD) collected through routine clinical practice and can be supplemented by additional data captured as part of the study protocol.

3.14 A real-world historical control study is a type of longitudinal study where the baseline performance is assessed using a retrospective study, a change is implemented (eg AI is introduced into the pathway) and then the performance is reassessed after an appropriate interval. This is analogous to a clinical audit cycle. A repeat service evaluation is the same as a clinical audit except there is no predefined performance standard.

3.15 NICE has recommended the collection of data through real-world historical studies to generate evidence for AI-supported analysis of chest X-ray for suspected lung cancer in primary care referrals.[12] The NICE real-world evidence framework provides further guidance on the planning, conducting and reporting of RWD studies.[13]

3.16 A prospective cohort study is a type of longitudinal study that follows patients over time to see who develops the health outcome under consideration. This is typically set up as a clinical trial and involves following up patients who have the intervention (supported by AI) and those who do not and are managed by current best practice. A randomised control trial (RCT) is a prospective cohort study that randomises patients to help minimise the effect of co-variate factors that may influence the outcome.

3.17 Prospective cohort trials are time-consuming and expensive and run the risk of using AI that has been superseded by the time the study reports.

3.18 Ideally studies should be designed in such a way that the measured outcome is agnostic to the AI and depends only on the functionality of the product in influencing the outcome. For example, if immediate use of AI shows a marked reduction in time to diagnosis of cancer (an important clinical outcome) then any AI produced that has confirmed accuracy at least as good as the product tested in the trial could be deployed.

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Evaluation priorities

3.19 Many other elements of evaluation of AI exist (see Table 1) and they are all important, but the imperative now is to at least confirm the two principal elements: assessing diagnostic accuracy and measuring clinical impact.

3.20 NHS trusts should assess their internal capabilities before seeking external procurement. Increasingly, trusts have in-house teams with the skills needed to develop and maintain diagnostic tools. Reaching out to these teams early on can help determine whether an in-house solution would be more sensible and cost-effective. When available, in-house expertise may offer potential advantages in terms of customisation and immediate availability of expertise.

Table 1. AI evaluation in the clinical pathway

Topic category	Brief description	Time of evaluation	Method of evaluation
Accuracy (and safety)	External evaluation of the accuracy of the product	Before deployment and at regular intervals	Validated external test data sets
Clinical outcome	A change to an important clinical outcome	Before deployment but time-consuming	Randomised trial or cohort study or similar
Bias	AI can be associated with a variety of biases, some based on non-representative data and others on human behaviour	Before and during deployment	External validation using large data sets with sufficient technical and demographic heterogeneity to be able to detect differential Multi-reader, multi-case studies can be used to evaluate the impact of AI on human decision-making
Workflow	AI can impact positively and negatively	Before and during deployment, with ongoing evaluation	Some information from platforms, in-service evaluations and modification to practice
Human–AI interaction	Humans are influenced by AI and it is important to maximise the benefits and avoid harms	During deployment with ongoing monitoring	Nested psychological experiments, educational intervention testing, testing of accuracy, ethnography
Education and training	Use of AI will evolve and clinicians need to stay up to date	Before and during deployment	Education sessions, surveys of use, audits and qualitative document review, including training plans and training records
Patient and public acceptance	Patients and the public have a right to know how their data are used	Before and during deployment	Surveys and information provision based on concerns of focus groups
Cost-effectiveness	AI should be cost-effective in the NHS	Before and during deployment	Health economics evaluation* at baseline followed by in-service evaluation

* The method of evaluation should include a comprehensive cost analysis, accounting for the resources required to conduct the evaluation itself. This includes personnel, equipment, data collection and analysis costs, which should be weighed against the expected benefits of the AI implementation. The overall cost-effectiveness of the AI solution should be assessed in light of both the direct and indirect costs of the evaluation process

04 Acquisition and deployment

Once AI solutions that have the potential to solve the specific problem have been identified, the next steps are to agree how a preferred AI tool will be acquired and to articulate the requirements of both the tool and the vendor in greater detail.

Acquisition

4.1 Identify the means of acquisition of the AI tool(s), such as tender, national procurement framework, trial, national award process. An example is the NHS England procurement framework strategy recommendations.[14]

4.2 Consider the potential benefits and drawbacks of available funding routes. For example, the ability to enable collective and collaborative procurement (eg across imaging networks or health boards) may deliver value and unlock potential savings, but it may necessitate the involvement of more decision-makers.

4.3 Be clear on who needs to recommend or take decisions once options that meet initial stakeholder requirements have been considered.

Comprehensive requirements planning

4.4 **Stakeholder fundamentals:** Finalise requirements of all stakeholders and use these to create AI tool and supplier assessment criteria. Two fundamental considerations are:

a. Ensure that the supplier's statement of intended purpose aligns with the clinical problem to be solved that the stakeholder group has agreed.
b. Include evidence of independent validation of the efficacy of the AI tool as part of the bid (see below for further detail). Example AI tool supplier assessment criteria are available in the NHS AI buyer's guide.[15]

4.5 **Organisational requirements:** Define and document what stakeholders need from the organisation to deliver the project successfully. For example:

a. Trusts must ensure adequate clinical, technical and project support resources with time allocated to staff leading the acquisition and requirements planning stage.
b. The project team must design the planning stage to enable tool acquisition that is deliverable (to time targets), affordable, aligned to the original scope or enables achievement of outcomes, and achieves sufficient clinical evidence and technical reassurance.

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c. Set clear intended shadow mode (see 'Shadow mode' below) and go-live deployment dates, with realistic project timelines and targets agreed with all stakeholders at the planning stage.
d. Conduct periodic evaluations to assess the impact on clinical workflows, patient outcomes and system performance. Post-implementation evaluation is a crucial aspect of monitoring and ensuring AI tool effectiveness.
e. Clearly define within the vendor agreements the frequency of updates and the processes for evaluating the impact of these updates on tool performance and patient outcomes. This ensures continued compliance with safety and efficacy standards.
f. Keep records of equipment and software version numbers that provide information to the AI tool, such as imaging acquisition units. Changes in the IT infrastructure can influence the performance of some AI tools.[16]
g. Ensure the expected duties and responsibilities of the trust and the vendor are clearly described so that resources can be scheduled accordingly.

4.6 **Technical requirements:** Ensure assessment criteria for the tool and the supplier incorporate the following technical requirements as a minimum:

- Pillar 3 – Software/SaaS/Apps – Clinical.[12]
- The AI tool uses the NHS number as patient identifier or digital imaging and communications in medicine (DICOM) field.
- The AI tool must be MHRA compliant as it is a medical device.
- The AI tool deploys a web-based or mobile application user interface if appropriate.
- The supplier's handling of data is GDPR compliant – see 'Data protection impact assessment' section.
- The supplier is Cyber Essentials certified or ISO 27001 certified.
- The supplier and tool comply with relevant NHS policies (see Appendix 3).

4.7 **Integration requirements:** Identify how the tool needs to integrate with existing local systems such as IT networks and firewalls and existing security, picture archiving and communication system (PACS) and radiology information systems (RIS). Specify any limitations of the current IT infrastructure and potential requirements for additional resource.

4.8 **Training requirements:** Identify how the vendor will support training of all staff who have access to the AI findings, and explore with AI and PACS vendors how access to the AI findings might be limited to trained users only. This may not be possible, so consider awareness and education among your entire PACS user base about the potential applications and limitations of AI findings available in PACS. Plan for anticipated retraining where AI tools are updated and new functionality is incorporated, and agree the frequency and means for this training with the vendor as part of the procurement terms. The product will have a lifetime of use but will at some point be decommissioned. Agree at procurement the terms for cost and timescale expectations and limits for the conversion of dependent data for the end of contract period.

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Data protection impact assessment

A data protection impact assessment (DPIA) will need to be completed as a standard part of project documentation and will require approval through the organisation's governance channels. The DPIA is helpful both for those procuring an AI solution and for vendors, and completing it helps clarify data flow requirements.

4.9 Map out the data flow and planned integrations at the acquisition and requirements planning stage, and feed this into the DPIA. Knowing which population you will use the tool for and where data will flow internally (eg remapping DICOM headers) and capturing this in a detailed data map is essential if the DPIA is to be approved.

4.10 Share your detailed data map with potential vendors. Integration of AI tools with the same PACS and RIS providers is challenging due to variations in local implementation and configuration. Making a detailed data map available at this stage will enable vendors to indicate whether they have managed similar implementations in the past and demonstrate specifically how they will achieve the requirements for any procurement process.

4.11 Obtain a data processing agreement with the AI vendor if any personal data is transferred outside your organisation, or the vendor needs to remotely access the solution to troubleshoot and view data. This may be a separate contract (some trusts use their own) or may be contained within the contract you have with the vendor, often as a schedule or appendix.

4.12 Ask if your supplier will need access to any personal data in the solution to support you and the application (whether pseudonymised or not) from outside the UK or European Economic Area. If the answer is yes, you will need an International Data Transfer Agreement (IDTA) in addition to the DPIA and data processing agreement

Independent validation

4.13 Identify whether independent validation will be required as part of the bid. Currently there is little independent evaluation of AI performance in chest X-rays within a UK population. Options would likely include a combination of real-world performance monitoring (as outlined in Section 3) from other sites, or evaluating tools against benchmark data sets, such as the use of the Personal Performance in Mammographic Screening (PERFORMS) database to benchmark AI in breast radiology.[17]

a. When considering benchmarking, it is important to consider whether the AI tools have been benchmarked against a data set that reflects the real-world population, or an enriched data set that may more reliably identify limitations but may overstate algorithm performance.
b. This may be limited by a current lack of availability of benchmarking data sets.
c. When referring to published benchmarks, the methodology and results should be checked to ensure they are relevant for the local intended purpose.

4.14 Identify whether suppliers will be willing to make data available for independent validation by trusts prior to a decision to deploy.

4.15 Develop a post-market surveillance plan as part of this stage.

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Potential hazard and safety implications

4.16 Review the Health and Social Care Act 2012, Section 250, which sets out the statutory obligations to complete risk assessments for digital solutions deployed in the NHS in England and relevant legislation in the devolved nations.[18]

4.17 It is mandatory to consider the potential hazards and safety implications of using AI in clinical practice prior to deploying an AI solution.

4.18 Review the DCB0129 manufacturer and DCB0160 deployment organisation information standards, including the requirements to produce a clinical safety report and hazard log in England, and relevant legislation in the devolved nations. DCB0129 forms part of the Digital Technical Assessment Criteria (DTAC) for deploying AI and is commonly included within the contractual requirements with the AI supplier.[19]

4.19 Ensure the clinical hazard log is tailored to the intended purpose of AI and consider the possibility of the AI inadvertently causing patient harm. This includes the likelihood and potential adverse consequences from AI 'overcalling' abnormalities (false positives) and AI missing significant abnormalities (false negatives). Overcalling findings can potentially lead to unnecessary further investigations and interventions, and missing abnormalities may delay the patient's diagnosis. The hazard log should record any mitigations to reduce the risk, including any preclinical shadow mode assessments and staff training required prior to deployment.

4.20 Assess patient safety requirements in the clinical safety case and determine whether Care Quality Commission (CQC) registration of the AI supplier should be sought before deployment.

Shadow mode

4.21 Evaluate AI in shadow mode as a standard deployment model for AI. This is where AI is enabled to run in the background on real patient data but the findings are not made available to be used in clinical practice. Enabling shadow mode provides data on how AI will perform in real-world conditions and enables comparison of the AI model with the current operational performance and clinical outcomes. This also serves as a baseline and a test of how data and outcomes are recorded, which may lead to recommendations for the subsequent clinical evaluation protocol, including what metrics to record and code to support the analysis.

4.22 Test an enriched data set of positive and negative cases from the local institution to supplement shadow mode evaluation. The idea is not to redefine the performance metrics of the software, as this should have already been made clear by the manufacturer, but rather to ensure that the AI software is functioning as intended in the context of the local population, staff, scanners, protocols and systems. For example, AI can be run in shadow mode on a retrospective sample of chest X-rays of patients with lung cancer, identified through performing the RCR audit of cancers at baseline.[8] This enables you to determine if AI can pick up any cases that were missed by the reporters, and conversely whether AI may miss any cancers that were detected by the reporters (false negative rate).

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4.23 Review performance metrics, which may vary according to the use case, local service context and care or treatment pathway. For example, the incidence of true positive cases of a disease from low-risk primary care referrals will be different to that in a screening population. Various influencing factors should be discussed with stakeholders (including manufacturers and vendors) and consensus reached for initial data collection. Review of performance metrics should include the data collected and the performance of the metrics in providing an adequate evidence base and reassurance.

4.24 Use shadow mode prior to deployment to estimate the incidence of AI findings in the referral population. Review a sample of cases for each abnormality to predict how often AI may overcall abnormalities (false positive rate) to help set expectations in user training. Manufacturers do not normally provide these figures for deployment as the rates depend on the prevalence of the findings in the referral population. Agree a method to record and share findings with stakeholders, including vendors.

Staff training

Staff will need to be sufficiently trained in issues specific to AI in healthcare as part of the acquisition and requirements planning stage. This includes understanding AI capabilities and an awareness of algorithm bias and human–AI interactions, clinical integration across the pathway and how the tool may have downstream effects. There should be a local procedure in place to develop a training plan and keep training records for staff. Detail should include who has responsibility for maintenance of the records and frequency of any updates and ongoing training. The provision for newly employed staff members and agency workers should be considered.

4.25 Train staff to ensure they have general AI knowledge, including knowledge of commonly used terminology, generic and specific risks, performance of the chosen AI algorithm and domain AI expertise (such as thoracic imaging). Training should underpin staff confidence and their ability to manage basic AI questions. This should allow them to fulfil duties with respect to informed consent, supporting patients and multiprofessional colleagues with queries.

4.26 Training should include the specifics of at what points in the pathway the AI will be used, by which staff and how. This will help ensure weaknesses in human and AI decision-making are minimised and the AI complements existing human expertise.

4.27 Consider how the introduction of AI will impact the training of implicated staff (radiologists, and diagnostic radiographers and medical physicists).

4.28 Identify appropriate training in how to interpret the findings where AI is to be used as clinical decision support. Radiologists and clinicians are used to assimilating evidence to help them come to a clinical diagnosis, some of which may be conflicting. The potential risk with AI is that if users are unaware of how AI works and its strengths and weaknesses, they may be unduly influenced by the technology, a phenomenon known as 'automation bias'. One purpose of AI training is to maximise the benefits of the AI while minimising the risk of automation bias.

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4.29 Collate sample cases while in shadow mode to use for training, including 'wow' cases where AI can identify hard-to-spot abnormalities and make a difference to patient care. Balance these with examples where AI may overcall or miss findings. Educate users on the anticipated false positive and false negative rates of AI to set appropriate expectations. Staff who have appropriate situational awareness of AI are potentially more likely to use it appropriately.

4.30 Train users to make their own interpretation first and then to review the AI findings. This can be supported by the technology through use of display protocols and requiring an extra step to click to view the AI. Some AI providers can also display a level of confidence in the AI findings, based on pre-market studies and the performance in shadow mode. However, the vendor should be consulted to make clear what these confidence levels are actually referring to because there can be different interpretations between vendors.

4.31 Train all staff who have access to the AI findings, and consider whether it is necessary to limit access to the AI findings to trained members of staff.

4.32 Inform staff that if the AI findings are accessible on the system, it must be clear that the interpreted findings are provisional and require validation by trained reporters, as appropriate to the terms of the AI product regulatory licence.

Peri-deployment

4.33 Identify whether the AI performs as expected and the mitigations are effective during peri-deployment activities, including shadow mode.

4.34 Gather, analyse and act upon user feedback, which will provide valuable insights into user experiences, potential issues and areas for improvement.

4.35 Collate lessons learned for early live clinical evaluation, which can help inform other projects and should be shared with the supplier as part of the post-market surveillance activities.

Deployment

4.36 Continuous monitoring of ethical considerations such as bias and fairness is vital. Addressing any ethical concerns that arise during actual usage helps maintain trust in the AI system.

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Abbreviations

AI	artificial intelligence
AIDF	AI Diagnostic Fund
CQC	Care Quality Commission
CT	computed tomography
DICOM	digital imaging and communications in medicine
DPIA	data protection impact assessment
DTAC	Digital Technical Assessment Criteria
FHIR	Fast Healthcare Interoperability Resources
ICD	International Classification of Diseases
IDTA	International Data Transfer Agreement
NICE	National Institute for Health and Care Excellence
MHRA	Medicines and Healthcare Regulatory Authority
MRI	magnetic resonance imaging
PACS	picture archiving and communication system
RCT	randomised control trial
RIS	radiology information systems
RWD	real-world data
UKCA	UK Conformity Assessed

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Glossary

automation bias	Occurs when users are unaware of how AI works and its strengths and weaknesses and they may be unduly influenced by the technology.
clinical and operational managers	Refers to (but not limited to) clinical safety officers, chief clinical information officer, chief nursing officers, chief nursing information officers, chief information officer and/or chief allied health professions information officer.
co-variate	Any variable used during analysis that is not part of the main experimental manipulation but is considered to have a statistical relationship with the dependent variable.
diagnostic accuracy study	Measures the reliability of diagnostic tests outside of the highly controlled research environment.
health professionals	Refers to (but not limited to) medical physicists (who may have experience with data flow requirements), clinical scientists, radiographers and scientific computing teams.
intended purpose	Regulated software, including AI algorithms, which are considered medical devices, must adhere to the UK Medical Device Regulations. The statement of the intended purpose of the software is a component within the regulations and should provide clarity on the context in which the software may be used. The intended purpose statement has four key elements: structure and function of the device, intended population, intended user and intended use environment. The intended purpose of the product and supporting details should be supplied by the manufacturer of the medical device as part of the information it provides to potential customers.
longitudinal clinical impact study	A research design that involves repeated observations of the same variables over periods of time.
market research	Assessing the market to gather information about available products, suppliers, evidence and quality standards. This helps to make informed decisions about the product requirements and deployment objectives.
nested psychological experiments	Controlled studies embedded within the broader AI deployment project, designed to evaluate how healthcare professionals interact with AI systems. These studies help identify user behaviour, decision-making changes and potential biases influenced by AI outputs.
peri-deployment	Around the time of deployment: the period before (including shadow mode), during and following (including early live clinical use) deployment.
post-deployment monitoring	Periodic evaluation of device performance and clinical impact by institutions.
post-market surveillance	Regulatory required monitoring of device safety and performance by industry.
shadow mode	Allows AI to be run in the background on live clinical data without displaying the results or changing diagnostic processes. It provides indicative data on how AI will perform in real-world conditions and enables comparison of the AI model with the current operational performance and clinical outcomes.

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A1 Document decisions: potential things to include

Potential inclusions when recording the current performance of the pathway prior to AI deployment, to enable comparison with post deployment and record unintended consequences such as increased CT or MRI activity.

- Number of chest X-ray examinations performed on the specific pathway annually. This should be categorised by referral source (eg general practitioner, emergency department) and into presentation and follow-up if possible.
- Number of those with prior chest X-rays – if this is difficult to determine then use a sample three-month period to estimate the annual number.
- The time from chest X-ray referral (if not walk-in) to chest X-ray performed and reported.
- Number already referred via the faster cancer diagnosis pathway.
- Number of referrals onward for CT or clinic appointments and time from chest X-ray report to scan or appointment.
- Number and proportion of normal and abnormal chest X-rays in the given pathway.
- Number and proportion of cancers originally detected or missed on chest X-ray.

A2 Identification of available AI tools: key questions to ask

a. Has the AI tool in question already been deployed in the same way with comparable healthcare organisations? A consultation with other trusts already using the tool could be considered.
b. Have you considered the recommendations made by the manufacturer?
c. What is the status of integration with the PACS and RIS?
d. How was the algorithm trained – has it been trained on representative patients and pathologies?
e. Is the performance acceptable – does it do the required task well?
f. Under what circumstances should the AI tool not be applied and what are its limitations?
g. Are the results generalisable – are the same results likely in your proposed population as those that have been tested?
h. How will you avoid AI outputs adding bias to the clinical decision-making process when comparing AI to current diagnostic tools?
i. What pre-deployment testing is likely to be required?
j. What are the likely downstream effects of implementation? Consider the expected changes in existing pathways or services, whether services will be able to cope with those changes and the impact this may have on implementation.

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A3 Possible technical requirements for the tool and the supplier to include

NHS policy or requirement	Purpose or expectation
Public cloud first	Digital services should move to the public cloud unless there is a clear reason not to do so.
Internet first	All new health and social care digital services should be internet facing.
HL7 FHIR conformant supporting FHIR UK Core	UK Core is an implementation guide that provides a four-nation approach to Fast Healthcare Interoperability Resources (FHIR), which applies across jurisdictions and care settings.
HL7 FHIR Code System, Value Set and Concept Map, including all operations	Adherence to HL7 FHIR requirements supports integration with other digital products in use within the service or network.
DCB0129 conformant	DCB0129 is a clinical safety standard that requires suppliers of digital health solutions to verify the safety of their products (NHS England only).
SNOMED CT conformant	SNOMED CT is a structured clinical vocabulary for use in an electronic health record.
ICD10 conformant	The World Health Organization (WHO) International Classification of Diseases (ICD) is the global standard that categorises and reports diseases in order to compile health information related to deaths, illness or injury.
ODS conformant	The Organisation Data Service (ODS) issues and manages unique identification codes (ODS codes) and accompanying reference data for organisations that interact with any area of the NHS.
WCAG 2.1 at AA level for any web-based or mobile user interfaces	Web Content Accessibility Guidelines (WCAG) 2.1 defines how to make web content more accessible to people with disabilities.
Aligns to National Cyber Security Centre cloud security principles	Application of the cloud security principles assists in choosing a cloud provider that meets minimum cybersecurity needs.

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