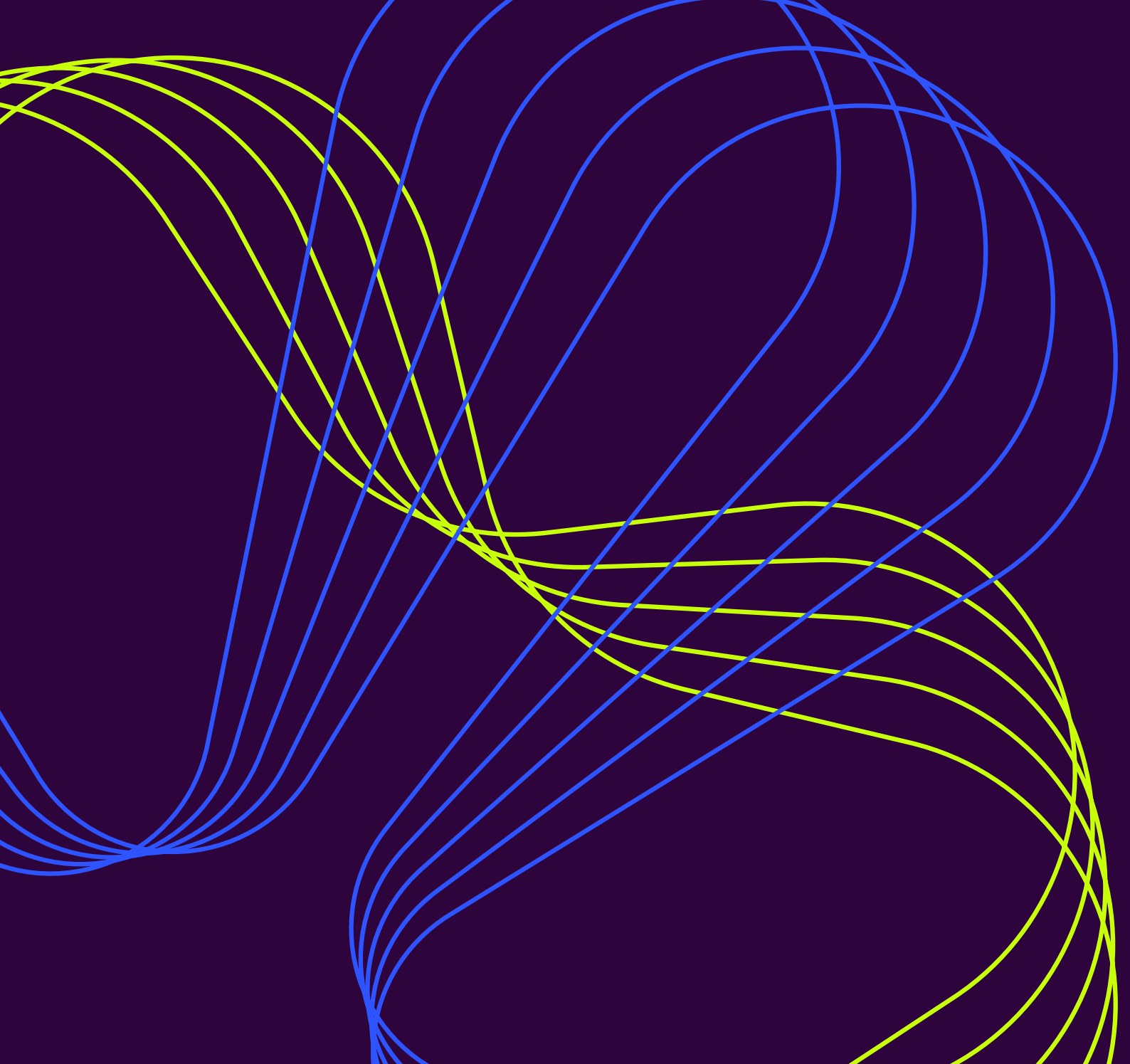




Integrating image analysis artificial intelligence with radiology reporting workflows (RIS and PACS), second edition

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Scoping statement

Artificial intelligence (AI) solutions in medical imaging are extensive and now exist to assist with most stages in the *Diagnostic radiology life cycle*.¹ This document focuses on the post-acquisition phase of the life cycle, where acquired images are analysed by AI algorithms in addition to and often before formal radiology reporting.

01

Standards

- AI must be integrated in reporting (radiology information system [RIS] and picture archiving and communication system [PACS]) workflows seamlessly and in a way that does not add extra burden to radiologists or other reporting authors.
- AI algorithms must be deployed and used only for their intended use.
- The diagnostic accuracy of the AI algorithms must be clearly declared for the benefit of radiologists and others making decisions on patient management.
- AI findings must be communicated to the RIS via existing, widely used global technical standards (currently HL7 but future mechanisms based on FHIR [Fast Healthcare Interoperability Resources] can also be considered).
- AI findings must be communicated to the PACS using existing, widely used global technical standards (DICOM, Digital Imaging and Communications in Medicine).
- The workflow should be robust enough to ensure AI analysis is complete and available on PACS before a human reporter starts image interpretation.

02

Background and purpose

It is recognised that AI plays a significant and evolving role in medical imaging. Pre-analysis of images by AI solutions will help reporting authors to issue actionable reports.

Throughout this document, 'reporting author' is used to refer collectively to radiologists, reporting radiographers, sonographers and other appropriately trained healthcare professionals who undertake image reporting.

The purpose of this guidance is to help reporting authors integrate image analysis AI solutions into the reporting workflow without increased burden. Careful analysis of the reporting workflow and understanding of interoperability standards are essential. It is hoped that this guidance will support reporting authors and others who are involved in AI procurement in their departments.

This guidance is limited to the use of AI for image analysis.

This guidance does not:

- Advise reporting authors which AI algorithm solution they should buy or deploy
- Advise on the ethical issues around the use of AI
- Discuss AI solutions for radiology management efficiency.

03

AI-assisted image interpretation and report generation

Algorithmic analyses of radiology images for detection of specific conditions are emerging rapidly, for example in the detection of breast lesions, brain bleeds, stroke, fracture, aortic dissection and lung nodules. Human interpretation considers additional information such as a patient's signs and symptoms, previous images, blood tests and histopathology reports. Reporting authors should understand the limitations of algorithms, and may challenge interpretations made by AI after careful consideration. With that in mind, reporting authors should continue to issue the human-actionable report, personalised to the patient, even after the implementation of AI algorithms – retaining a human in- or on-the-loop during the formal issue of the report. Actionable reports provide a tentative diagnosis, potential differential diagnoses and advice on the next steps of management (often dictated by local circumstances and availability of services).²

The technology can enhance the reporting workflow for reporting authors in several ways.

- Medical image analysis can provide decision support algorithmic pre-analysis of radiology images to help detect and classify abnormalities.
- Medical image reports can be drafted by large language models (LLMs).
- Algorithm-assisted triage can help with prioritisation of reporting worklists when an abnormality is detected by AI.
- AI algorithms may be incorporated into a deferred reporting workflow.

LLM-generated reports require verification by reporting authors for accuracy and context.

If AI analysis and/or report generation takes place after the reporting author has made their report and there is a discrepancy, a radiologist should review the images and amend the report, if necessary, while remaining mindful of the potential for anchoring and automation bias, and ensuring unbiased reassessment of the findings. The process by which discrepancies are flagged should be determined locally and included in clinical protocols.

04

RIS workflows

Within radiology workflows, an LLM or other AI tools may interface with the RIS as a secure workflow-support layer, leveraging referral, scheduling, protocolling and reporting metadata to enhance efficiency and consistency. Use cases include requesting triage, protocol support, structured report generation, and facilitation of follow-up and communication tasks. LLM and other AI tool deployment should operate within defined governance frameworks, with role-based access, auditability and a clear separation between decision support and clinical responsibility, ensuring augmentation rather than replacement of radiologist-led care and safeguarding against inaccuracies including hallucinations.

05

Mitigating risks associated with AI adoption

A declaration must accompany all vendors' analytic documents, outlining the algorithm's limitations. The declaration should include the following.

- List of the abnormalities that were evaluated by the algorithm(s) in the platform and applied to the study (eg for computed tomography [CT] head this might be brain haemorrhage, skull fracture or brain infarct).
- Sensitivity and specificity (or true/false positives and true/false negatives) of the applied algorithms for each of the abnormalities evaluated.

Vendors must provide simple, readily accessible guidance on the sensitivity and specificity, with relevant clinical examples in the context of the specific pathology. It is vital that all doctors, including radiologists, are mindful of these limitations and do not assume that algorithm-generated reports are always 100% accurate. The focus is on the human interface of technology adoption and on mitigating risks to patients and is part of pre-deployment training.

AI algorithms must be deployed strictly within their approved and intended use. Uncontrolled expansion beyond validated or authorised use cases ('scope creep') risks performance degradation, inappropriate clinical application and potential patient harm.

Post-deployment monitoring is essential for recognising when AI algorithms are performing in an unexpected manner. Software failure, operational drift or a change in algorithm version can all lead to a change in AI algorithm performance. The root cause of any decrease in AI algorithm performance needs to be addressed in an expedient manner to avoid putting patients at risk.

For additional guidance on AI deployment and post-deployment monitoring, see the RCR guidance *AI deployment fundamentals for medical imaging* and *Post-deployment monitoring and safety reporting of AI medical imaging devices in clinical practice*.^{3,4}

Post-deployment monitoring is essential for recognising when AI algorithms are performing in an unexpected manner. Software failure, operational drift or a change in algorithm version can all lead to a change in AI algorithm performance.

06

Training and AI workflows

The introduction of AI tools to reporting workflows has important implications for radiology training and must be managed carefully to preserve educational opportunities. AI outputs should be presented in a way that allows reporters to form an independent interpretation before being exposed to any AI analysis. From a technical and governance perspective, this strongly favours the use of toggleable, standards-based display mechanisms (such as DICOM presentation states or segmentation objects). This also includes controlling AI annotations as a reversible layer that can be switched off during the initial read and revealed later for learning and feedback. By contrast, AI analysis outputted as secondary capture images permanently embeds annotations onto the image, which cannot be unseen, creating a risk of anchoring bias and undermining perceptual learning for trainees.

Ideally, the AI workflow within RIS and PACS should be entirely configurable to allow AI tools to be disabled or hidden for users at first review, with subsequent controlled exposure that may be used as an educational adjunct, ensuring the development of independent diagnostic skills, confidence and professional accountability.

07

Technology components and interoperability requirements

The five main technologies that will be expected to work co-operatively for a radiology department are:

- Scanners and modalities
- RIS
- PACS
- AI platforms (containing one or more AI algorithm)
- AI orchestration tools.

They must support interoperability standards like DICOM and HL7 communications, as explained in Appendix 1.

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Guidance working group

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Appendix 1

AI platform

In line with the NHS digital first policy, AI platforms are seen as tools to support clinicians and improve efficiency.

AI platforms are separately hosted systems providing image analysis services using one or more hosted AI applications. Images are uplifted from a local PACS and analysed by the AI tool. The result is returned to the PACS with information embedded in the image as a secondary capture and to the RIS or other reporting IT system (eg NBSS, the national breast screening system used for reporting of screening mammograms). Platforms are required to be compliant with NHS security and data standards and operate within the NHS firewall. Platform companies can host many AI tools and be responsible for timely upgrades of tools and monitoring timely delivery of results, failure rates etc.

Outputs from AI platforms (into RIS and PACS)

Standard outputs from AI image analysis platforms must include the following.

- Graphical representation of the region of interest (of the detected abnormalities) or mark-ups/pointers should always be output using DICOM standards so that they can be viewed in the PACS viewers.

There are various options in DICOM for communicating graphical outputs.

- Secondary capture is currently used in practice although it is becoming increasingly difficult to justify in reporting workflows.
- DICOM structured report (SR) and DICOM segmentation (SEG) are preferred interoperability standards. SEG objects encode image-related regions of interest derived from image analysis, while SR objects encode findings (text, measurements and may reference images and segmentation objects). These standards are now being adopted by PACS and AI platform vendors and support interoperable, computable AI outputs and reduce dependency on proprietary integrations.
- DICOM presentation states are commonly used in clinical PACS. There is an on/off toggle option for graphics.
- DICOM overlay also has an on/off toggle option for graphics.
- AI abnormalities detected (or the text classification of abnormalities) will be output as text data (eg fracture, haemorrhage, consolidation, infarct, pleural effusion). This text data must be output in two formats:
 - DICOM SR – to communicate with PACS in DICOM format
 - OBX5 HL7 in the HL7 ORM message – to communicate with RIS.
- The 'Image analysis is complete' notification is essential for patient safety. This is an HL7 notification to RIS or PACS that image pre-analysis by the AI platform is complete. Such a notification allows the RIS to move the exam into the reporting worklist for the human reporter. Output from the AI platform should be 'ORC 5-A' as per HL7 Table 0038.⁵ 'A' stands for 'some but not all results available'. This also applies to similar notification systems. This is about the capability of the interfacing to support transmission of information (that AI additional information is available). It is not about the treatment of those notifications in the RIS or PACS.

- The use of AI tools may lead to the detection of diagnoses requiring a critical alert before the study has been formally interpreted and reported by a reporting author (eg intracranial haemorrhage). The preferred method of handling this situation is to escalate and notify reporting priority on the radiology worklist to indicate the need for expedited urgent reading and reporting. At the discretion of the radiologist this may include the use of a critical alert code in accordance with the Academy of Medical Royal Colleges' recommendations on alerts and notification of imaging reports⁶.

As the direction of travel of all radiology data is to be encapsulated in open and structured formats, suppliers and implementers are encouraged to provide key elements (eg algorithm identity, intended use sensitivity/specificity) as structured coded DICOM SR content within the study. As a short-term interim solution, it is possible to put the key AI element information into a DICOM-wrapped PDF (encapsulated PDF storage) that is included as part of the study, but this unstructured data capture is not encouraged.

PACS supporting AI workflow

When implementing an AI platform, reporting authors must ensure that their PACS is capable of:

- Displaying DICOM SEG (segmented region of interest areas and text overlay) and DICOM SR from AI – which can be toggled on and off by the PACS viewer. This requires support of DICOM SR display, DICOM presentation state standards and so on (as described previously).
- Displaying the declaration information from the AI platform about the algorithms applied to the study. This should include the sensitivity and specificity for each of the abnormality detected.

PACS and RIS administrators should receive formal training to ensure a clear understanding of PACS integration with AI platforms – whether embedded or standalone – and to enable effective troubleshooting of technical, interoperability and workflow-related issues.

For additional information, see the *IHE Radiology Technical Framework Supplement – AI Results (AIR)* profile and related DICOM extensions defined by DICOM Working Group 23, which describe interoperable patterns for the exchange and display of AI-generated imaging results.^{7,8}

RIS supporting AI workflow

When implementing an AI platform, reporting authors must ensure that their RIS and/or PACS can receive an additional HL7 ORM message from the AI platform and has additional data fields to parse the data sent by the AI platform.

1. Trigger for human reporting

Commonly, human reporting is triggered when the reporting author makes a status change to 'exam completed' on the RIS. With AI image pre-analysis implementation, status completion (CM) should trigger the AI platform image analysis.

Once image pre-analysis is complete, the reporting system(s) (RIS and/or PACS, depending on the reporting model) must be notified using standard messaging. In an HL7-based workflow, this may be achieved via an outbound ORM message with ORC-5 set to 'A' (AI assessment completed), triggering progression of the study onto the reporting worklist.

Alternatively, the availability of AI results may be communicated through DICOM mechanisms, such as the publication of a DICOM SR associated with the study, or through appropriate DICOM object update/notification workflows.

2. Additional data fields in RIS (or other reporting system) for reporting worklist prioritisation

Many RIS data items are sorted and filtered to consider account prioritisation or individual reporters' tasks. These include referral location type (eg emergency department, inpatient, outpatient or general practitioner), modality type (eg CT, MRI, DR), specialty of the referrer (eg ear, nose and throat, paediatrics, gastroenterology), referrer's urgency (eg urgent or routine), intended reporter (work allocation by operators) and date and time of exam completion. Radiologists prioritise their work based on the session being covered. For example, during an emergency duty or on-call period, the radiologist will filter out all the CT and MRI (magnetic resonance imaging) for emergency department and inpatient referrals.

The additional data fields required in RIS reporting worklists with AI implementation are:

- AI abnormalities – this list will be populated by data items such as fracture, lung nodule or haemorrhage, sent in the OBX5 field of the HL7 ORM message from the AI platform. This information should be stored in the RIS database and used by reporting authors for filtering and sorting of reporting worklists.
- AI alerts – the platform should also send AI alerts in OBX 8 when alertable abnormalities are detected, such as brain haemorrhage.

3. FHIR-based communication of AI information

HL7 v2 messaging is currently the predominant mechanism for RIS integration in many current deployments, but the longer-term direction of healthcare interoperability is towards HL7 FHIR-based APIs and resource (information) exchange.

Future RIS architectures should follow NHS guidance and support FHIR resources such as diagnostic report and observation as transport mechanisms for AI-derived findings and workflow signals. Radiology departments and suppliers should be aware of this trajectory and design AI integrations in a manner that does not preclude future FHIR-based interoperability.

DICOM remains the authoritative domain for image data, segmentation objects (SEG) and structured imaging results (SR). FHIR-based mechanisms will provide a more transportable representation of selected AI outputs for enterprise-wide clinical, governance and analytics use.

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