

#DHSS23

Deep dive: safely deploying Al in the NHS

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27-28 July

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Director AI, Imaging & Deployment NHS Transformation Directorate

Deploying AI technologies at scale

- 1. Targeted and evidence-based intervention to accelerate the deployment of the most promising AI technologies using a risk-based approach: We will improve outcomes for clinicians and patients by facilitating wider deployment of safe, effective and ethical AI, enabling faster diagnosis, more effective triage, and better treatment for patients.
- 2. Support and increase strategic Al alignment: We will ensure that health and care requirements are well coordinated and understood by wider cross-government Al partners and stakeholders, in order to strengthen domestic and international strategic partnerships to deliver on wider economic ambitions to grow the UK's standing in Al.
- 3. Generate necessary evidence and develop clear and robust pathways as well as practices to help remove barriers to adoption: We will deliver AI Lab investments in flight and ensure they are sufficiently resourced to enable evidence generation and benefits realisation by the end of AI Lab life cycle.

Current Regulations for AI

- We look to avoid AI 'exceptionalism,' AI should be treated like other software unless there is a very good reason
- For example, AI as a Medical Device (AIaMD) is a subset of Software as a Medical Device (SaMD)
- There are no specific legislations governing the use of AI in the UK. Instead, **AI's use is** regulated by an assortment of more general legislation, such as the UK Medical Device Regulations 2002 or the Data Protection Act 2018, covering certain uses of AI.
- The key regulators are very engaged in AI regulation, and we work closely with them. In particular, **NICE, MHRA, CQC and HRA**.
- For example, MHRA announced plans for an extensive 'Change Programme' to drive regulatory changes to ensure medical devices are appropriately evidenced, as well as address wider issues of transparency of AI, and adaptivity.

Wider AI Regulation

- On 29 March 2023, DSIT published a White Paper entitled "A pro-innovation approach to AI regulation". The White Paper does not commit to adopting new legislation to regulate AI. Instead, the UK would require existing regulators to take responsibility for the establishment, promotion, and oversight of responsible AI in their respective sectors.
- The White Paper does **put forward suggestions for centralised functions** including a cross sector regulatory sandbox and horizon scanning.
- We are in close contact with DSIT on how the White Paper can **add value to the current** regulatory work in health and care.

Past projects

Project Name	Description	Lead	Status
Streamlining Data Driven Research (SDDR)	To make it easier for researchers and developers of data driven technologies to identify what research consent processes they need to engage with and accelerate the end-to-end application process	HRA	Completed
Evidence Standards Framework	Provide refreshed evidence requirements to ensure commissioning decisions for the sourcing of AI technologies are robust and based on suitable evidence	NICE	Completed
Yellow Card	To enable the MHRA's Yellow Card System to better identify patterns and trends in reporting incidents to better inform safety regulations	MHRA	Completed
Synthetic Data	To develop and demonstrate the efficacy of artificial datasets as a tool which can support the training and validation of medically focused algorithmic technologies	MHRA	Completed

Current Projects

Project Name	Description	Lead	Status
AI and Digital Regulations Service	A cross-regulatory advisory service supporting developers and adopters of AI and digital technologies. The service provides guidance across the regulatory, evaluation and data governance pathways. This will bring benefits to the entire health and social care landscape through safer and more effective use of technology.	NICE	Launched in June
Liability and accountability	NHS AI Lab commissioned NHS Resolution to write a report that sets out the current liability position for use of AI in clinical settings. The clinical settings include AI as the first reader, AI to triage patients, AI discounting diseases, and AI diagnosis and misdiagnosis.	NHS Resolution	Ongoing
Legal Framework	NHS AI Lab commissioned DHSC Legal to write a note that sets out the current legislation which may impact the use of AI in clinical settings. The report will cover the legislative landscape on the use of AI in clinical settings in England.	DHSC	Ongoing

AI and Digital Regulations Service

- It is a **multi-agency collaboration** between **four organisations** involved in regulating and evaluating health and social care technologies and ensuring they deliver value for money
- The online service maps out the **regulatory and health technology assessment pathway for AI and digital technologies**. Service users from the Beta have described the format as 'friendly' and 'easy-to-use'. This helps developers and adopters understand and navigate the pathway more effectively. The service provides **guidance on each stage of the pathway**. All content is continually refreshed, keeping it up-to-date and aligned with new developments.
- The site also provides access to existing support services where users can receive more bespoke advice. This includes transactional services, such as NICE Scientific Advice, and free services, such as the NHS Innovation Service.

A cross-regulatory perspective

The breadth of on AI & digital tech in health and care necessitates a cross- regulatory approach

	Product regulation (or inputs)	Data and Research Governance	Service provision regulation	Professionals regulation	Clinical & cost effectiveness
partners	Medicines & Healthcare products Regulatory Agency	Health Research Authority	Care Quality Commission		NICE
Wider partners	Approved bodies NHS Digital Clinical Safety Team Standards bodies Al auditors	ICO National Data Guardian	NHS Resolution *NHSE&I policy teams + spec comm	General Medical Council Health Education England Nursing & Midwifery Council Royal Colleges	UK National Screening Committees (NHSE)
Human rights law	^Equalities Commission ^		luman Rights Commissi	on	
Public recourse	^Healthwatc	:h	^Parliamentarians	; MPs, local and select o	committees
Good practice / researchers / policy-setters	*Turing Institute */ Ir	Ada Lovelace *Centre Institute Ethics & Innovat	for Data *Office for Al ion	*Academia *Reg Cou	gulatory Horizons ncil

[^]Other legal / statutory instrument ^{*}Thought-leadership

AI Diagnostic Fund

The NHS AI Lab and the NHSE Digital Diagnostics Capability (DDC) Programme will launch a **£21 million ring-fenced fund** for NHS trusts to procure AI diagnostic imaging technologies and begin deployment ahead of Winter 2023

Chest X-Ray

The most common type of diagnostic scan, with over 600,000 scans completed each month in England, and are a key step in the identification of lung cancer.

- There are a range of products in these categories that have received MHRA authorisation and are already beginning to be used for direct patient care in England.
- The benefits would depend on the tools deployed.
 E.g. Red Dot by Behold can reduce the time taken reduced the time from Chest X-Ray to CT scan from 7 days to 2.8 days for suspected lung cancer.
- Initial analysis indicates that a £21m fund could support between 40-50 trusts to deploy an AI product on a 2-year contract.

NHS AI Deployment Platform Pilot

Our vision is to make **diagnostics more efficient and scalable** by giving NHS organisations access to an **'AI Model Store'** to choose approved AI medical imaging technologies from a range of vendors.

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Al in Clinical Practice

Greater Manchester PACS Integrated AI Chest X-Ray Pilot













Proportion and number of cases of stage IV cancer by tumour type, England 2018



Number of cases of Stage IV cancer per year



Lung Cancer GIRFT Programme National Specialty Report

by Dr Paul Beckett, Dr Sarah Doffman and Dr Elizabeth Toy GRT Cleical Leads for Larg Cancer

Victoria Anderson and Monica Hugh Sentiality Maning Leads for Lang Cancer April 2022



GRET is part of an aligned set of programmer within NHS England and NHS to proveneed

Missed detection of lung cancer on chest X-rays of patients being seen in primary care

Independent report by the Healthcare Safety Investigation Branch NI-000836

October 2021

Safety recommendation R/2021/154:

HSIB recommends that NHSX, in collaboration with relevant stakeholders such as The Royal College of Radiologists and The Society and College of Radiographers, develops guidance to support independent benchmarking and validation of artificial intelligence algorithms for the identification of lung diseases such as cancer.

Greater Manchester CXR AI Evaluation

- A. Use AI findings to **model** optimum use of AI
 - Prospective 250,000 adult CXR
 - Retrospective CXR in 3000 patient diagnosed with lung cancer
- B. Present AI findings in PACS as clinical decision support
 - Does AI reduce missed lung cancer diagnosis?
 - Does AI decision support speed up reporting?
- C. Use AI findings to prioritise patients on PACS worklists
 - Can we use AI to reduce the time to report CXR in patients with lung cancer?

A. Use AI findings to model optimum use of AI

1. Turn on 'Shadow Mode'

Sectra Amplifier Marketplace

Easily add artificial intelligence to your clinical workflows

Imaging AI marketplace for easier, faster, and more secure application deployment

A. Use AI findings to model optimum use of AI

1. Turn on 'Shadow Mode'

Qure.ai Unreported Worklist 76 patients, 76 examinations				^
10 Priority 1	18 Priority 2 4	9 Priority 3 and 4 0 Qure.ai processing 0 Qure.ai not processed		
Status	Priority (qXR - Q	List of findings (qXR - Qure ai)	P Name ↑2	
Com	Priority 1	Reticulonodular Pattern, Nodule, Lung Nodule Malignancy, Fibrosis, Opacity, Atelect	Pseudonymised	
Com	Priority 4		Pseudonymised	
Com	Priority 4		Pseudonymised	
Com	Priority 3	Blunted Costophrenic Angle, Abnormal, Fibrosis	Pseudonymised	
Com	Priority 2	Opacity, Abnormal, Fibrosis	Pseudonymised	
Com	Priority 1	Nodule, Opacity, Abnormal	Pseudonymised	

Integrating artificial intelligence with the radiology reporting workflows (RIS and PACS)



The Royal College of Radiologists

1. Artificial intelligence must be integrated in reporting workflows seamlessly and in a way that does not add extra burden to radiologists.

B. Present AI findings in PACS as clinical decision support



B. Present Al findings in PACS as clinical decision support



Please note this is NOT the formal Radiology Report. This is an Artificial Intelligence (AI) report that is only intended to support radiologist/radiographer reporting as part of an evaluation project. The formal radiology report remains the key outcome to guide clinical management.

qXR Interpretation

Abro ma	
Lungs	
Opacity	YES
Consolidation	NO
Fibrosis	NO
Nodule	YES
Malignancy Risk	LOW
Emphysema	NO
Cavity	NO
Pleura	
Blunted Costophrenic Angle	NO
Pleural Effusion	NO
Pneumothorax	NO
Mediastinum	
Tracheal Shift	NO
Hilar Prominence	NO
Mediastinal Widening	NO
Heart	
Cardiomegaly	NO
Diaphragm	
Pneumoperitoneum	NO
Bones	
Rib Fracture	NO

qure.ai



C. Use AI findings to prioritise patients on PACS worklists

GP CXR Referrals

Prioritising 31% CXR by AI will include 87% of cancers

Exam to Report days – GP CXR



Potential Saving: 6114 days (6.4 days per CXR)

A&E CXR Referrals

Prioritising 52% CXR by AI will include 88% of cancers

Exam to Report days - A&E CXR





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Overcoming Barriers to Al Implementation in Imaging Outcome of an RCR Expert Stakeholder Day

- Develop a single, national information governance set of policies, or policies framework.
- Convene regional/national expert teams to help deploy AI in trusts.
- Focus on a network-level approach to facilitate the rollout of AI.
- Make revenue funding for AI available to each region, for which trusts or local systems (such as imaging networks) can bid.
- A greater emphasis on providing guidance and education to support Al deployment.
- Gather more evidence on patient outcomes and the health economic impact of AI deployment.
- Speed up a cloud-first national strategy.



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