The Royal College of Radiologists

The Royal College of Pathologists
Pathology: the science behind the cure

Embracing AI to support the NHS in delivering early diagnoses

Supplementary material to the report

Summary of the discussion

The following is a summary of the discussion that took place in 10 Downing Street on 30 November 2023. Rather than be presented in chronological order, the topics raised have been grouped by theme.

Challenges and opportunities

Those wishing to introduce an AI application into an NHS organisation currently face several challenges they must overcome. How significant each challenge is depends on the local context. Challenges identified in the discussion included:

Regulatory hurdles	
Challenge	• Existing information governance processes are cumbersome and vary significantly between organisations, which leads to lost time. The requirements to get the green light for a particular AI tool in one organisation will not be the same as the requirements needed in another organisation. E.g., there is no single Data Protection Impact Assessment (DPIA) form for each AI use-case; the same technology needs to undergo a different DPIA process in each organisation in which it is deployed. • Meeting participants reported that the implementation process for new healthcare technologies takes an average of 12–18 months, including the necessary information governance approval. This slows down the speed of implementation.
Solution	• Regulatory timelines need to be sped up and duplicative documentation processes removed.

IT infrastructure	
Challenge	• NHS IT infrastructure is disjointed and uneven. Most AI applications require modern IT systems to be successfully implemented. • Many organisations still use legacy systems and interoperability of different pieces of software is a challenge to clinicians' productivity.

	• Many pathology centres still rely on the physical transfer of glass slides between laboratories.
Solution	• There must be investment in organisations' IT infrastructure to enable different systems to interact smoothly. E.g. AI tools must be fully integrated with Picture Archiving and Communication Systems (PACS) to be useful to radiologists. • There needs to be full digitisation of pathology services in the UK as a prerequisite for AI to be used in assessing images from cancer biopsies. • Investment in digital pathology – The National Pathology Imaging Co-Operative, currently involving 40 of 105 NHS hospitals, has developed a digital pathology system for the NHS to digitally transfer images for analysis. This provides the opportunity for AI to be rolled out to all participating hospitals – but funding and support is needed to fully digitise pathology and facilitate AI-enabled pathology for the whole country.

Funding	
Challenge	• Investment is required for the adoption of AI at both the local and national levels. • NHS organisations' budgets are strained, meaning that often other financial considerations or projects are prioritised.
Solution	• Organisations will need additional financial support to implement AI. The AI Diagnostics Fund, the AI Deployment Platform, and the Health Technology Adoption and Acceleration Fund are positive steps towards reaching this goal. • Moreover, AI applications have the potential to be cost-neutral in the context of the whole clinical pathway. • An appropriate body must be responsible for assessing the costs and benefits of AI applications. The owner of this role needs to be clarified. NICE is best placed to carry out this work, because they already have processes in place to perform health economics evaluations of healthcare technologies.

Staff capacity	
Challenge	• Due to workforce shortfalls, staff lack the time required for service improvements, including the introduction of new technologies, because of clinical pressures in diagnosing or treating patients. • Workforce shortfalls among NHS IT staff present the same challenge. • Radiologists at the meeting spoke about the challenges they faced trying to introduce AI to their organisations, identifying the largest bottlenecks as staff capacity and IT infrastructure.
Solution	• Implementing the NHS Long-Term Workforce Plan recommendations for staff recruitment, and taking further action to improve staff retention in the immediate term. • Early involvement of both clinicians and IT staff in AI implementation.

Bringing the workforce along with the change

- Innovative technologies and ways of working must have patient safety at the core of their development. Clinicians emphasised the importance of ensuring they have time to safely introduce and use AI.
- Health Foundation surveys showed that confidence in AI among NHS staff and patients correlates with their familiarity with AI. Therefore, we must:
    - Involve clinicians from the beginning to implement AI. E.g., Brainomix's clinical decision support tool to aid radiologists diagnose and treat stroke patients was co-developed by clinicians from Oxford University.
    - Educate clinicians in the assessment and use of AI applications to enable rapid implementation and greater confidence. This will depend on the clinician's role and responsibilities and should be tailored as such. It is vital that clinicians know what form changes to their ways of working and clinical pathways will take.
- During the discussion, participants expressed the belief that clinicians add most value when interacting with patients or with their colleagues to make a diagnosis, plan a patient's care or deliver treatment.
- It was recognised, though, that not all NHS jobs will be equally affected by AI, with administrative roles perhaps more likely to be lost or scaled back when AI becomes prevalent.

Responsibility and liability

- There is currently a lack of clarity around this issue. A lack of prior case law means that there is no legal precedent for how responsibility should be apportioned between the clinician, the AI developer, and other parties in cases where there may have been malpractice involving the use of AI tools.
- Participants agreed that this matter will need to be clarified, and that this clarity will be vital for ensuring clinicians are able to use AI applications confidently.

Building the evidence base

- Further evidence is required to be able to say with confidence what effect AI tools are having on patient outcomes and clinicians' efficiency.
- E.g., In the lung cancer pathway, at least 20 AI tools are being used by radiologists to detect abnormal findings on chest X-rays.
- However, whilst NICE has provisionally approved these tools, it has withheld full approval, citing a lack of sufficient health economic evidence.
- The group agreed that a full evaluation is needed to confirm the accuracy of these and other AI tools currently in use.
- A comprehensive overview of what AI tools are currently being used across the NHS is also required. The RCR is developing an Artificial Intelligence Registry, with funding from the NHS AI Lab, which will be a comprehensive directory of all AI tools used in radiology in the NHS. This will aid further adoption by highlighting solutions already being used.

Ensuring AI works for patients

- The effectiveness of any AI application depends on the data with which it is trained.
- If an algorithm only sees chest X-rays from a narrow group of people, there is a risk it will under-perform when used in clinical practice scans of patients from other groups.
- Robust validation of AI applications is needed. To ensure they work for the UK's patient populations, AI algorithms must be trained on data reflective of those populations.

- This data should be held within Secure Data Environments (SDEs).
- Once introduced to clinical practice, AI applications' performance should be regularly assessed to ensure they continue to perform as they did in training.
- Patient impact studies should be conducted to gather real world data, tracking patients' outcomes over time. These would enable the assessment of the impacts of AI applications on those patients' health. There is some work to set this up already, though it is confined to specific sub-specialties, such as myeloma. Cancer Centre London are working with the UKHRA and have obtained ethical approval for a study of myeloma patients using generative AI and the Haematology Outcomes Network in Europe (HONEUR) data network. The need for urgency is due to the time taken for patient outcomes data to mature. Patients need to consent to a real-world data study at the outset of their treatment. Further studies of this kind would be of great value.

The AI Diagnostics Fund

- The participants agreed that the AI Diagnostics Fund presents an excellent opportunity to start some of this work. The Fund primarily involves deploying AI applications for chest X-ray across multiple organisations, alongside some chest computerised tomography (CT) applications.
- NICE have already specified what additional evidence they need to approve these tools.[3]
- The involvement of the National Institute for Health and Care Research (NIHR) and medical Royal Colleges has proved vital for shaping the Fund's activities and ensuring maximum benefit in terms of data and learning is gained. The NIHR will be conducting an evaluation programme, running until 2025, which will be essential if we are to assess how the algorithms affect clinical pathways.
- Further research will therefore be needed to evaluate the accuracy of the algorithms and what effect they have on patient outcomes.

Patient participation

- Members of the group were keen to ensure the discussion covered the impact of AI tools on patients and the importance to get patients on board with the change.
- The use of AI applications needs to be acceptable to patients. Patients may require interaction with human clinicians during their care to feel confident they are receiving the best possible treatment.
- They may also need to be confident that their care is being directed by human doctors, aided by but not determined solely by algorithms. This links to the complex issue of responsibility, raised previously (see above).
- Regardless, it was felt that clinicians' voices will be essential in determining whether and when patients feel comfortable with the widespread use of AI in their care.

Patients and data

- The discussion also touched on the use of patients' data in research to assess the efficacy of AI applications.
- The shift towards the use of AI at scale may require a new contract between patients and healthcare professionals, especially if patients' data is required to populate SDEs to train and re-assess AI applications.
- Suggestions included a patient opt-out regarding the use of their data in this way (as opposed to an opt-in), as well as the need to conduct a pilot study.
- It should be noted, though, that the NHS already uses patient data all the time, whether that be for teaching purposes or for audit.

- The Health Foundation's survey work suggests patients are amenable to the use of their data, though they do have concerns about their privacy that will need to be addressed.
- There is at least an argument to be made that the use of patient data to gather evidence on the efficacy of AI applications would constitute a public good, and so there would be an obligation on patients to allow this. This question needs further exploration.
- All participants agreed that the implementation of AI applications in diagnostics and healthcare more broadly can only be successful if patients are happy for those applications to be used.

Planning for the change

- Participants pointed out that it is not enough to simply purchase the technology in question; the technology's effect on clinicians' working lives and clinical pathways must also be forecast and assessed.
- It cannot be assumed that AI will automatically release time for clinicians. Nor is it safe to assume that this time would, if released, be used for direct clinical care or patient interaction.
- Indeed, without proper care, AI could *increase* demand on clinicians. If AI applications allow clinicians to see more pathologies, then it may be the case that the time taken to assess each patient's scan or test results would increase, rather than decrease.
- Or, if AI does free up extra time for a radiologist or pathologist, it is possible that they may use that extra time to review more scans or tests, rather than to spend time with patients or on other dedicated specialist activities.
- We do not here take a view on how freed up time ought to be used. However, if the NHS wants to introduce AI applications to enable healthcare professionals to spend more time directly caring for patients, then this needs to be planned for.
- A holistic view is needed. Members of the discussion agreed that AI is not a magic bullet and will need to be deployed alongside measures to address workforce shortfalls, poor IT infrastructure, equipment shortages and other barriers to high productivity.

Agenda

Agenda of the discussion held on 30 October 2023 at 10 Downing Street.

Programme	Speaker(s)
Opening remarks	Steve Barclay MP
Opening remarks	Dr Bernie Croal Dr Katharine Halliday
Digital Pathology and AI	Prof Darren Treanor
Potential of AI driven blood science algorithms	Dr Ellie Dow
The challenges of implementing AI tools in clinical radiology	Dr Qaiser Malik
The future of diagnostic technology	Dr Hugh Harvey
The practical application of AI in the cancer pathway	Professor David Baldwin
Can general AI and machine learning apps make physicians' lives better?	Dr Anne Kinderlerer

The impact of AI on the workforce	Dr Tim Horton
Discussion • Future pipeline of diagnostic AI/technology – what's coming when? • Barriers and enablers to make the most of this innovation • Implications for the future diagnostic workforce and how we can prepare now to maximize future impact	All to participate, led by Lord Ribeiro
Summary	Chaired by Dr Halliday and Dr Croal

Speaker biographies

Dr Katharine Halliday – President, Royal College of Radiologists

Dr Halliday, a Consultant Paediatric Radiologist, completed her radiology training in various locations before joining Nottingham University Hospital in 1998. She chaired the British Society of Paediatric Radiology from 2010 to 2016 and led the working group on updated guidance for imaging in cases of suspected child abuse. In September 2017, Dr Halliday assumed the role of National Clinical Lead for the Getting It Right First Time program, resulting in the publication of a GIRFT report for Radiology in July 2020. She became Clinical Director for Radiology at Nottingham University Hospitals in January 2021, and President of the Royal College of Radiologists in September 2022.

Dr Bernie Croal – President, Royal College of Pathologists

Dr Croal is President of The Royal College of Pathologists and past President of the Association for Clinical Biochemistry and Laboratory Medicine (ACB-UK) and is a Fellow of the Royal College of Physicians and Surgeons of Glasgow, as well as the Institute of Biomedical Science. He has also previously undertaken various roles within the Royal College of Pathologists, including Vice-President.

Professor Darren Treanor – Digital Pathology Lead, RCPath

Dr Darren Treanor is a Consultant Pathologist, honorary clinical Associate Professor at the University of Leeds and Guest Professor in Digital Pathology at Linköping University, Sweden. He runs the Leeds Virtual Pathology Project which has been carrying out digital pathology research and development since 2003. He leads the Royal College of Pathologists' group writing guidelines on digital pathology, using evidence gathered by the Leeds Digital Pathology research group, including the only systematic review of digital pathology in clinical diagnosis.

Dr Ellie Dow – Consultant in Biochemical Medicine, NHS Tayside

Dr Ellie Dow, a leading consultant in biochemical medicine, jointly created, with Professor John Dillon at the University of Dundee and NHS Tayside, the intelligent liver function tests (iLFTs) at Ninewells Hospital. Dr Dow leads on the laboratory aspect of this work. These tests use advanced laboratory technology to automatically assess blood samples when liver disorders are suspected, resulting in a remarkable 44% increase in liver disease diagnoses. iLFTs have already benefited over 25,000 patients in NHS Tayside, with 30% receiving early treatment. Dr Dow's and Dr Dillon's pioneering work is transforming liver disease diagnosis and patient care.

Dr Qaiser Malik – Medical Director for Membership and Business, RCR

Dr Qaiser Malik, a consultant radiologist, Clinical Director of Radiology at Mid and South Essex NHS Trust, and lead medical appraiser for Basildon and Thurrock University Hospital, graduated from Imperial College School of Medicine. He is an Honorary Senior Lecturer at UCL Medical School, serves as Clinical Lead for the East 2 Imaging Network, and has an extensive background in musculoskeletal MRI and ultrasound. Dr Malik is deputy chief medical officer at behold.ai, which provides instant triage by identifying abnormalities across modalities within seconds. He is Medical Director for Membership and Business at the Royal College of Radiologists.

Dr Hugh Harvey – Managing Director, Hardian Health and member of RCR Informatics Committee

Dr Hugh Harvey is an accomplished radiologist and academic. He was awarded an MD from the Institute of Cancer Research, where he specialised in improving functional imaging for prostate cancer to help doctors to target radiotherapy more precisely. Since then, he has held senior roles at two flagship UK startups, leading both to successfully gain world-first regulatory approvals for medical software based on artificial intelligence (AI). He co-chaired the Topol Health Technology Review and is now involved in the Royal College of Radiologists' Informatics Committee and AI Policy Reference Group. Dr Harvey is currently the Managing Director of Hardian Health, advising digital health startups on routes to market. He also maintains an academic role on the editorial board of *Nature: Digital Medicine*.

Professor David Baldwin – Lead Clinician for lung cancer, NHSE and Adviser to the UK National Screening Committee

Professor David Baldwin is a consultant respiratory physician with a focus on lung cancer and mesothelioma. He's also an Honorary Professor at the University of Nottingham. Dr Baldwin’s research primarily centres on CT screening and lung cancer epidemiology, where he leads recruitment for the 4-in-the-Lung-Run project and played a significant role in the UK CT lung cancer screening trial. Across his career, he has served in various roles including Lead Clinician for Lung Cancer with NHSE, Chair of the Quality Standards Group on Lung Cancer, Chair of the Screening Prevention and Early Diagnosis Group for the National Cancer Research Institute, Clinical Lead on the NICE Lung Cancer Guideline Development Group, and advises the UK National Screening Committee at DHSC. As an accomplished author, he has published 240 papers, including influential guidelines.

Dr Anne Kinderlerer – Digital Health Clinical Lead, Royal College of Physicians

Dr Anne Kinderlerer is a consultant rheumatologist, Associate Medical Director for Patient Safety, and Clinical Director for Discharge and Integrated Care at Imperial College Healthcare NHS Trust. She leads on the Royal College of Physician’s digital health strategy, which guides and supports members and Fellows to grasp the opportunities presented by digital health to improve patient care. In her clinical leadership roles, Dr Kinderlerer’s focus over much of the past decade has been on how to improve systems and processes so that they work for patients.

Dr Tim Horton – Assistant Director, The Health Foundation

Dr Tim Horton has been an Associate Director at the Health Foundation since 2015, focusing on promoting innovation and improvement in healthcare. Prior to his current role, he served as health policy adviser to the Leader of the Opposition from 2011 to 2015 and was Head of Public Services at the Labour Party. His extensive experience includes positions such as Research Director at the Fabian Society, Special adviser at the Department of Trade & Industry in 2005, and policy adviser on science and innovation at HM Treasury.

Abstracts

The following are abstracts of the presentations delivered by the seven speakers at the outset of the discussion.

Digital Pathology and AI

Professor Darren Treanor

Histopathologists are the doctors who diagnose cancer using microscopes to examine biopsies. Artificial intelligence shows great promise in this area; it could improve the speed and accuracy of diagnosis with automated image analysis. The Royal College of Pathologists supports AI to improve diagnosis, and pathologists should lead this important work.

Digitisation is a necessary first step before AI can be applied to cancer images. However the level of digitisation in pathology is far behind radiology, relying on physically transferring glass slides and paper forms between labs.

A recent initiative – the National Pathology Imaging Co-operative (npic.ac.uk) has developed a unique national digital pathology system for the NHS which will accelerate the development and safe adoption of AI in digital pathology. With professional leadership and the right infrastructure there is the potential for the NHS to be a leader in the safe deployment of AI for cancer diagnosis in pathology.

The Potential of AI-driven blood sciences algorithms

Dr Ellie Dow

Blood Sciences departments annually perform some 1.5 billion tests, yet serious liver disease is complex and challenging to diagnose in primary care. Intelligent liver function testing (iLFT) uses algorithmic processes within blood sciences systems to enable the correct testing of patients with potential liver disease right from the start, and advises primary care on the correct actions for the results.

The right patients are identified for specialist assessment, speeding up referral, diagnosis and management. This improves the outcome for patients and increases efficiency across health and social care sectors. Major investment is required for IT infrastructure, staff and testing for better IT and AI systems within blood sciences. There is a need to interrogate this large volume of data more efficiently, as current systems lack interoperability and machine learning. Investment could be cost neutral. For liver disease, the current five-year spend is estimated to be £17billion for alcohol related disease alone.

The challenges of implementing AI tools in clinical radiology

Dr Qaiser Malik

The implementation of AI in the real world is faced with a number of challenges. There are lots of different systems and processes that need to be overcome, and these can vary across different organisations. However, there are a number of use case examples that can be learnt from.

At Mid and South Essex NHS Trust, we deployed Brainomix as a solution for stroke diagnosis and management. There were various information governance processes that needed to be completed and this varied across the trust. This meant that there was an inordinate amount of delay in getting the solution in place. There is also a lot of disconnect between the various stakeholders. For example, the stroke physicians, who were very keen to have this solution in place, had not communicated adequately with the radiology department and vice versa.

This is something that we need to be aware of when deploying solutions that have impact on various clinical pathways and clinicians. A good example of this is the chest x-ray and the CT chest solutions

that are being touted for early lung cancer diagnosis. These will have a direct impact on the respiratory physicians and the Lung MDT pathway. All of the stakeholders need to be involved in the decision-making process.

There is an IT and infrastructure bottleneck when it comes to deploying new systems within the NHS and also the various third-party vendors and projects can sometimes get held up in a queue waiting to be deployed, despite there being a clinical decision and appropriate funding allocated.

Another key obstacle is appropriate training of staff to be able to use and interpret the AI output. This must not be underestimated, as clinicians who do not understand the technology will either not trust it or not use it. This is true of any new tech adoption and must be appropriately resourced and delivered.

There are also regulatory concerns to deployment of new technology. For example, there is need to confirm the sensitivity and specificity of the system that is being touted. This needs to be independently verified to ensure both clinical and patient confidence. Another important part of the process is to ensure patient involvement. This is something that could be done on a regional or national level to ensure that patients are aware of the system being used to deliver their healthcare and where the governance responsibilities lie.

The future of diagnostic technology

Dr Hugh Harvey

AI progress in radiology has yielded single-use case products, such as pneumonia detection on chest X-rays, which are now regulatory approved but require human oversight and consistent monitoring. Future AI generations, like generative AI for generating text summaries from images, remain in the research stage, awaiting regulatory approval with concerns about accuracy and reproducibility.

Additionally, the theoretical concept of multimodal AI, combining electronic health record data with image data, poses significant challenges related to data infrastructure and compatibility. Key challenges in the field include duplicative documentation processes, with NHS mandates overlapping with regulatory requirements. Regulatory timelines are slow, with lengthy waitlists for audits of new tech, and a solution involves increasing capacity within regulatory bodies. Data access and quality problems arise due to data silos and incompatibility, suggesting the need for data format standards and federated data platforms.

Furthermore, the issue of liability for AI errors in medicine is uncharted territory, necessitating the creation of clear guidance and legal frameworks. Expertise from the Royal Colleges is essential to aligning stakeholders and ensuring safe and effective deployment of novel AI technologies.

The practical application of AI in the cancer pathway

Professor David Baldwin

For AI to have a substantial impact on healthcare it needs to address a common challenge and be capable of achieving important improvements. Cancer is a major healthcare challenge, and more people lose their lives from lung cancer than other common cancers, more in fact than for breast and bowel combined. Early diagnosis and faster diagnosis have both been scientifically proven to have a substantial benefit. Last year, screening for lung cancer was recommended by the UK National Screening Committee, and funding announced for England in June 2023. For faster diagnosis we have a national accelerated diagnostic and treatment clinical pathway (the National Optimal Lung Cancer Pathway or “NOLCP”).

The NOLCP often begins with the chest X-ray, the most common image used in the NHS with more than 10 million tests each year, and 2 million directly requested by GPs in England in 2022. A number (over 20) of AI solutions are available, and some deployed, to detect and classify abnormal

findings. However, recently NICE did not find any evidence strong enough to support their introduction. Research and evaluation are needed to confirm the clinical impact, both positive and negative, and how this very promising area can be used to maximise benefit to our patients by reducing the time to diagnosis. One such study is underway and was highlighted by NICE as a potential source of evidence.

The screening programme relies on CT scans, again one of the most commonly used images and key to diagnosing lung cancer early. AI is currently in routine use in the screening programme and in some NHS organisations to detect and measure the size of “pulmonary nodules”. (These are a bit like skin moles – mostly harmless but sometimes early cancer.) Detection is thought to be reliable, and this will be monitored in the screening programme, but measuring the size is less well evaluated. Evaluation platforms that can be used for both initial and ongoing testing are needed. More advanced AI can determine which of the nodules are cancer and hence provide an opportunity for earlier treatment (or reassurance that there is no cancer). One of these diagnostic systems is being evaluated in a real-world research setting.

AI is making a difference now and has huge potential to transform early diagnosis and hence clinical outcomes of lung cancer and other cancers. There is an urgent need for proper evaluation to confirm the accuracy of AI, the clinical impact, and the way in which healthcare professionals interact with AI to achieve the best outcomes.

Can general AI and machine learning apps make physicians’ lives better?

Dr Anne Kinderlerer

The real usefulness depends on building learning health systems that are able to turn routine health data into knowledge. AI is one of the tools that allow us to do this, and then to feed that data back into clinical systems to improve care predictive tools for flow. For example, predicting when patients will be medically optimised, and surfacing that prediction to teams to reduce unnecessary time in hospital. Predictive tools for deterioration are topical at the moment. For instance, can we predict sepsis better and therefore prevent deterioration? AI could also be used to prioritise cases and in the creation of triage systems in outpatient clinics. We may also be able to use open AI systems to rewrite clinical information in more patient friendly ways.

AI and the evolution of the NHS workforce: some strategic considerations

Dr Tim Horton

The evolution of healthcare roles and professions in response to technology should not be a passive process, but one that is actively planned for and shaped – not only by policymakers and system leaders, but by staff themselves and their representative bodies.

The Health Foundation’s experience of supporting innovation highlights some key strategic considerations for successfully embedding AI in healthcare, particularly with regards to radiology and pathology. These considerations include the need for staff and patient engagement in change, the need to understand the requirements of successful implementation, and the need to plan for how time ‘released’ by technology can subsequently be used. Policy implications include greater implementation support, agile education and training strategies, and more opportunities for NHS staff to signal the technologies they need.