



## **Position statement from the Royal College of Pathologists (RCPATH) on Digital Pathology and Artificial Intelligence (AI)**

**February 2023**

There is an increasing body of research and development in AI in pathology as well as interest from pathologists in using AI tools, which could assist pathologists in diagnosis. The purpose of this document is to outline the College's approach to artificial intelligence (AI) in cellular pathology and to set out the case for further work in this area.

The scope of this document is limited to the use of artificial intelligence in cellular pathology.

### **Key messages:**

- Digital pathology and artificial intelligence (AI) are technologies which have the potential to transform the way pathologists work. The College supports the use of these technologies to improve healthcare.
- The use of AI in healthcare must be clinically led.
- AI will not replace the need for pathologists to be involved in diagnosis. They will still be needed to interpret and analyse information to produce an overall pathological assessment. However, AI does have the potential to free up time for pathologists, improve laboratory workflow or enhance the accuracy or consistency of diagnosis.
- For the NHS to start benefitting from AI there needs to be a significant investment in digital pathology and AI in the NHS – only a handful of UK trusts are using digital pathology currently – as well as an investment in training pathologists to understand and use AI.

### **College view of artificial intelligence**

#### **General**

1. The College supports the use of digital pathology and AI to improve patient care. AI is a very powerful technology with the potential to improve pathology diagnosis and / or provide novel prognostic or predictive information.
2. AI is applicable across different pathology specialties but will have very different types of application in blood sciences, microbiology and cellular pathology. The scope of this document is its use in cellular pathology.
3. Pathologists should be involved in the development of AI and take a leading role in its evaluation and deployment.

#### **Applications of AI**

4. Image analysis and artificial intelligence are already extensively employed in pathology research, for example to quantify tissue characteristics in disease and quantify tissue biomarkers.

5. AI has the potential to introduce efficiencies into pathology services by freeing highly trained pathologists from more routine and repetitive work – for example by searching lymph nodes for cancer (a task which takes human pathologists a lot of time and effort), performing simple quantitative tasks, or by automatically ordering additional tests on patient samples prior to review by a pathologist, saving time.
6. AI could also improve accuracy or consistency in pathology diagnosis.
7. AI could also have a role in improving training and education in pathology.

**Best practice for use of AI in clinical practice / Maintaining quality with AI / High quality use of AI**

8. As well as being the main end users of many pathology AI systems, pathologists need to have a central role in the development, testing and ongoing evaluation of AI.
9. AI is medical device software for which developers must obtain regulatory approval before clinical use (e.g., CE marking or UKCA marking). The development and deployment of AI in pathology has to be a part of a wider collaboration between pathologists, computer scientists, regulatory bodies and industry.
10. Successful use of AI in the short term may involve a pathologist as a “human in the loop” to interpret and combine the outputs of an AI tool to get the right diagnosis.
11. To maintain high standards of diagnostic accuracy, pathologists should ensure that AI has been robustly evaluated before deployment, and adequately monitored during clinical use, including the use of post-deployment monitoring and quality assurance. Guidance on Development, deployment, and monitoring of data-driven technologies is also available from the Health Research Agency <sup>i</sup>
12. The integration of extra data and information into a comprehensive diagnostic report requires a human expert. AI could be an additional source of diagnostic information for the pathologist to integrate into the overall diagnostic picture.

**Gaps and additional work**

13. For the successful use of AI in the NHS, there is a need for significant investment both in the underlying digital pathology technology to create digital images (i.e., scanners, image management systems and storage) as well as the deployment and support of the AI tools themselves.
14. The pathology workforce needs to be an educated competent user of digital technologies, including AI, so should be equipped with the ability to evaluate and use AI safely. This includes an understanding of AI so that pathologists can use their expertise and judgement to decide how to incorporate AI tools into their diagnostic process.
15. AI is still a very novel and relatively unproven technology in healthcare. Additional work and research is needed in several areas including:
  - Establishing the best ways to evaluate AI tools, including comparing the performance of AI tools which perform the same clinical task
  - Develop safe ways to deploy and manage AI in clinical practice

- Develop common standards to ensure interoperability and portability
  - Develop ongoing quality control of AI in clinical practice
16. Work by the Academy of Medical Sciences <sup>ii</sup> suggests that patients strongly support the use of AI in healthcare provided it improves quality and frees up time for doctors to spend with patients. However, there is also mixed public understanding and literacy regarding AI, as well as ongoing debates around AI ethics and safety, both of which could impact patient and public support in the future. <sup>iii iv v</sup> There is a need, therefore, for more engagement with patients about the potential use of AI in their healthcare in order to maintain broad public support.
17. The use of AI in clinical work may raise ethical challenges for pathology around patient privacy, autonomy, health equity and trust. These applied ethical questions speak to broad societal values and addressing them will therefore require ongoing multistakeholder dialogue across the medical sciences, computer science, the social sciences, public policy, and patient and public involvement.
18. New standards for AI and other digital health technologies are emerging and should be reviewed and adhered to in the development, evaluation and deployment of these tools. The National Institute for Health and Care Excellence (NICE) Evidence Standards Framework (ESF) which has recently been updated to include artificial intelligence technologies. <sup>vi</sup> A series of AI-specific reporting guidelines are emerging for reporting of a range of AI research studies. <sup>vii,viii,ix,x,xi,xii</sup>

#### **The College will:**

1. Engage with government and funders to support funding for digital pathology infrastructure and artificial intelligence deployment and evaluation
2. Work with regulators, other bodies (NHSD, ISO) and industry to ensure AI is robust and safe for clinical use
3. Support the development of relevant education and training activities in AI for pathologists
4. Support engagement with the public and patients about the use of AI in pathology, including increasing transparency about the use of AI
5. Promote and where appropriate help to develop standards and interoperability to ensure the successful use of AI
6. Develop more detailed guidelines to assist pathologists in evaluation and deployment of AI, including quality assurance and audit requirements

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