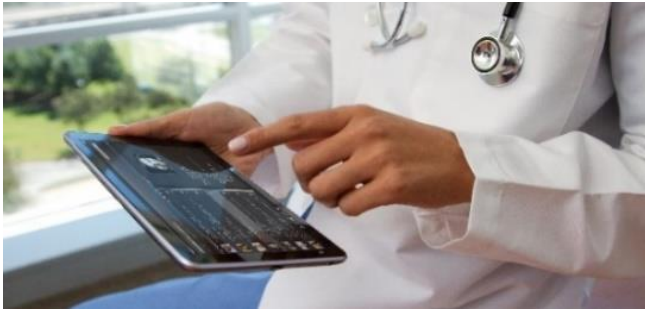


# AI and Healthcare



This POSTnote gives an overview of AI in the healthcare system and its potential impacts on the cost and quality of healthcare, and on the workforce. It summarises the challenges to wider adoption of AI in healthcare, including those relating to safety, privacy, data-sharing, trust, accountability and health inequalities. It also outlines some of the regulations relevant to AI and how these may change.

## Background

There is no universally agreed definition of AI, but it typically refers to systems that can perform tasks that usually require human intelligence.<sup>1</sup> AI systems are underpinned by algorithms; computerised instructions used to perform tasks (such as suggesting a certain diagnosis from a set of symptoms).<sup>2</sup> There are numerous applications of AI across healthcare, including improving diagnostics, monitoring patient health using apps and wearables, and automating administrative tasks.<sup>1-5</sup> Currently, AI is not used widely within the NHS, though some local trials are taking place. For example, the East Midlands Imaging Network and partners are testing AI tools to analyse mammograms for signs of breast cancer and manage screening resources.<sup>6-9</sup>

In the 2017 Industrial Strategy the UK Government stated its aim to use data and AI to “transform the prevention, early diagnosis and treatment of chronic diseases by 2030.”<sup>10,11</sup> In 2018, it invested £50m in five new centres of excellence for using AI to improve diagnostic imaging and pathology,<sup>12</sup> with a further £50m allocated as part of its long-term response to the COVID-19 pandemic.<sup>13</sup> In 2018, the Government published its code of conduct for data-driven health and care technology, aiming to promote best practice among those developing and using AI.<sup>14</sup> Improved use of AI and digital healthcare technologies is identified as a priority in the 2019 NHS Long Term Plan.<sup>15</sup> The 2019 Topol Review set out the new skills which would be required of the NHS workforce to implement these technologies successfully.<sup>16</sup>

## Overview

- Artificial Intelligence (AI) can be used for tasks such as helping clinicians make decisions and monitoring patient health.
- AI systems could lead to improved health outcomes, but few have been trialled and evaluated in real-world clinical settings.
- Automation may reduce the time spent by staff on routine work, though they may require new skills to use AI systems.
- There are some public concerns AI could dehumanise healthcare, though others argue staff time saved through automation could then be spent caring for patients.
- Patient data are often used to produce and test AI systems, raising issues around data quality, accessibility and patient privacy.

In 2019, the Government established NHSX, a new unit responsible for setting policy and best practice around the use of digital technologies in England.<sup>17</sup> This included the creation of an AI Lab with £250m of funding to support the development and deployment of AI technologies in the NHS and care system.<sup>18</sup> The NHS AI Lab’s activities include the AI in Health and Care Award, awarding £140m of funding to support the testing and evaluation of promising AI technologies.<sup>19,20</sup>

## Healthcare AI technology

Some clinical software has incorporated AI since the 1970s, but these systems typically use algorithms with a large set of pre-programmed rules.<sup>21</sup> Advances in AI have been made using machine learning (ML) algorithms (Box 1), which allow systems to learn from example data (known as ‘training data’).<sup>22</sup> ML capability has improved in recent years due to increasing computing power, greater availability of training data, and development of more sophisticated algorithms using techniques like deep learning (Box 1).<sup>22</sup> Healthcare AI systems are being developed in academia and industry, often in partnership with healthcare providers and professionals.

## Data and development

Large, good-quality datasets are needed to train and test AI systems, and may be taken from various sources depending on the intended use. Some systems, such as those used for treatment recommendation and drug discovery, use chemical databases or public clinical literature.<sup>23,24</sup> In other cases,

developers use data from individuals. They may use data from healthcare providers, such as Electronic Health Records (EHRs) ([POSTnote 519](#)) or medical images.<sup>1,5</sup> In some cases, they may collect data directly using apps or wearable sensors.<sup>25–27</sup>

Developers obtain patient data through data sharing agreements. These may be made with NHS trusts, other healthcare providers, or holders of regional or national datasets.<sup>28</sup> Such datasets include data volunteered by patients to studies like the UK Biobank,<sup>29–32</sup> and data gathered from healthcare providers by NHS Digital (which provides data and IT services for health and care organisations in England).<sup>33–35</sup>

## Applications of AI

Commercial AI systems are already used in some NHS settings.<sup>36</sup> However, most AI products for healthcare are still at the research or development stage,<sup>37</sup> with a few at various stages of trial and evaluation in NHS settings.<sup>38–40</sup> This section outlines some of the applications of AI in healthcare settings. It does not cover the use of AI in medical research.

### Medical imaging

There is a large amount of development activity in medical imaging, due to widespread use of standard image formats that provide suitable datasets to train AI systems on and recent improvements to image recognition from deep learning (DL, [Box 1](#)).<sup>37,41</sup> DL has the potential to offer faster and more accurate interpretation of medical images.<sup>42–46</sup> Research has shown DL can be used across various specialties, including:

- **Radiology.** AI systems can be used to detect bone fractures and tumours in X-ray images.<sup>8,47–50</sup> Head CT scans can be analysed to detect and characterise strokes,<sup>51–53</sup> traumatic brain injuries and dementia.<sup>54,55</sup>
- **Pathology and endoscopy.** Benign and malignant tumours can be distinguished by analysing microscopic images of tissue samples.<sup>56,57</sup> Cancerous and pre-cancerous polyps can be highlighted in real-time colonoscopy videos.<sup>58,59</sup>
- **Ophthalmology.** Diseases such as glaucoma, diabetic retinopathy and age-related macular degeneration can be diagnosed and monitored using retinal photographs.<sup>60–62</sup>

### Logistics and administration

Administrative and clinical staff spend a significant amount of time on operational tasks, with surveys indicating some staff believe this detracts from clinical work.<sup>63–65</sup> AI has the potential to automate some of these tasks. For example, speech processing techniques can be used to transcribe patient notes.<sup>66,67</sup> Patients who are likely to miss appointments can be automatically predicted and sent reminder messages.<sup>68,69</sup> AI can also be applied to complex logistical problems, such as managing resources and schedules.<sup>70–77</sup>

### Treatment planning and patient monitoring

Decision support systems are software-based AI tools that can support clinicians with tasks, including prescribing drugs,<sup>78</sup> diagnosing conditions,<sup>79,80</sup> and identifying patients at risk of adverse events.<sup>81,82</sup> Systems using pre-programmed rules based on clinical knowledge or guidelines originated in the 1970s,<sup>21,83</sup> and are widely used.<sup>83</sup> Current research on ML-based systems aims to improve performance by learning rules from patient data or clinical literature.<sup>24,84–88</sup> AI systems can also directly

monitor patient health. In hospital, systems using cameras and wearable sensors to provide early warnings of adverse events; such as pressure ulcers,<sup>89</sup> delirium,<sup>90</sup> or circulatory failure;<sup>91</sup> have been researched. High-risk patients outside hospitals can be remotely monitored for deterioration, to avoid unnecessary hospital admissions.<sup>92</sup>

#### Box 1: Machine Learning

A machine learning (ML) algorithm learns to perform a task by coming up with a set of rules to describe patterns in training data.<sup>93</sup> It then applies the rules it has learnt to unfamiliar data. Generally, the more data used to train a ML system, the more accurately it can match true patterns in the data it is applied to.<sup>94</sup> There are two main types of ML algorithm used in healthcare:<sup>93,95</sup> Supervised algorithms learn pre-existing categories in data (such as learning from labelled X-ray images, then detecting tumours in new images).<sup>47–49</sup> Unsupervised algorithms identify categories in data by themselves (for example, finding groups of patients with similar symptoms to help identify common causes).<sup>96</sup>

#### Deep Learning

Many recent advances in ML can be attributed to deep learning (DL), which is a type of ML design inspired by the way neurons transmit information in the brain.<sup>41,93</sup> Deep learning methods have driven improvements in areas such as image and speech recognition ([POSTnote 633](#)).<sup>22,41</sup>

### Patient-facing applications

Some voice assistants and text-based chatbots can be used directly by patients to check symptoms or access treatment.<sup>97–102</sup> Smartphone apps, sometimes with wearable sensors and other devices, can help patients to self-manage conditions like respiratory illnesses,<sup>103–106</sup> diabetes,<sup>107,108</sup> or epilepsy.<sup>109</sup> AI can be embedded in these systems to help to track a patient's condition and offer tailored guidance. Similar systems can be used by patients to self-administer electrocardiography (ECGs)<sup>38,110,111</sup> and urine tests.<sup>112</sup>

### Impact on healthcare

#### Cost of healthcare

Automation of administrative and clinical tasks with AI could cut costs and increase productivity.<sup>113,114</sup> Estimated cost savings vary, but a 2018 report by the Institute for Public Policy Research estimated that AI and automation could save the NHS £12.5 billion per year by freeing up staff time.<sup>115</sup> Some studies have reported AI systems that can equal or outperform clinicians at certain diagnostic tasks, for example in the diagnosis of skin cancer and diabetic retinopathy.<sup>45,46</sup> This could mean diseases are diagnosed earlier or more accurately, reducing future treatment costs.<sup>5,11</sup> However, some researchers have raised concerns around studies of AI performance, noting that few compare performance in real-world clinical settings.<sup>116–119</sup> New reporting standards for evaluation studies have been developed to address this issue.<sup>120–125</sup>

#### Patients

Earlier or more accurate diagnosis of an illness could allow patients to access treatment before complications develop, improving health outcomes.<sup>5,11</sup> There is also evidence of some home monitoring apps enabling patients to engage more with their treatment plans, improving self-management of long-term conditions.<sup>126,127</sup> Some stakeholders have raised concerns that

the use of AI risks dehumanising the healthcare system.<sup>128</sup> Studies of public opinion have suggested people believe human empathy is an important part of healthcare, and that it is important AI systems do not erode the patient-doctor relationship. Some feel that doctors are able to make more holistic judgements about diagnoses or treatments than AI systems.<sup>129–131</sup> Other stakeholders have suggested automation of routine work would allow staff to spend more time with patients, and AI could enable more personalised care.<sup>3,16,132</sup>

### Healthcare workforce

Healthcare staff may require new skills and training. For example, they will need the technical knowledge to operate and understand the limitations of AI systems.<sup>16,133</sup> Improved skills in data collection and curation would assist in the development and evaluation of AI systems.<sup>16</sup> New technology-focused roles may be created, such as roles focused on data engineering or governance.<sup>134</sup> PwC predicts a 22% increase in UK healthcare jobs in the period 2018–2028, as the use of AI increases.<sup>135</sup> Health Education England (HEE), which coordinates the training of healthcare workers in England, has established programmes to educate healthcare leaders and clinicians on digital technologies. These include the NHS Digital Academy,<sup>136,137</sup> and the Topol Programme for Digital Fellowships.<sup>138</sup> Some bodies are aiming to professionalise the workforce that develop and use IT and data-driven technologies.<sup>139–141</sup> The Faculty of Clinical Informatics and Federation for Informatics Professionals are working to do this in the healthcare sector.

### Ethical, social and legal challenges

In 2020, consultancy company Oxford Insights ranked the UK's overall readiness for AI as second best in the world, behind the US.<sup>142</sup> However, some stakeholders have highlighted long-standing difficulties scaling up innovations in the NHS, citing problems such as a lack of dedicated funds and fragmented organisation of services.<sup>143–146</sup> A number of technical and ethical issues are also associated with AI implementation.

### Safety and efficacy

While AI systems have the potential to improve patient outcomes,<sup>147</sup> they may also present significant safety risks if they are poorly designed or do not work as intended.<sup>4,148,149</sup> An AI system may give dangerous recommendations in situations that its programming does not expect, or which were not included in its training data.<sup>150</sup> For example, there have been reports of some chatbot apps missing simulated signs of heart attacks and child sexual abuse during testing.<sup>151,152</sup> If a system is programmed to be overly sensitive, it may over-diagnose patients, leading to unnecessary and risky clinical interventions and increased healthcare costs.<sup>153,154</sup>

Even if an AI system is shown to perform well during development, there may be challenges to its implementation that reduce its effectiveness.<sup>133</sup> For example, a Google retinal disease detection system was found to behave poorly when deployed in several hospitals in Thailand, despite performing as accurately as a human specialist during development.<sup>46,155–157</sup> This was because retinal scans taken in practice were of worse quality than those on which it had been trained. There are also issues around human interaction with AI systems. Health

professionals' cognitive biases can cause them to place undue trust or distrust in an automated decision.<sup>150,158</sup>

NHSX and the National Institute for Health and Care Excellence (NICE), in collaboration with other stakeholders, have each published assessment criteria for digital health technologies.<sup>159–162</sup> These set out the evidence of safety, clinical efficacy, usability and cost-effectiveness that healthcare providers should seek from a developer before purchasing an AI system.

#### Box 2: Governance of patient data

Research use of patient data is subject to several laws and codes of practice. Under the EU General Data Protection Regulation (GDPR)<sup>163</sup> and the Data Protection Act 2018,<sup>164</sup> there must be a lawful basis for use of personal data, such as a patient giving their explicit consent, or more usually provisions for research, medical or public health purposes.<sup>163</sup> Under Common Law, patients must consent to any use of confidential patient data.<sup>165</sup> Researchers can apply to the Health Research Authority to set this condition aside in England and Wales, with other arrangements in Scotland and Northern Ireland.<sup>166–168</sup> There are legal exemptions available for use of such data in public health emergencies.<sup>169</sup> Patients in England can prevent such data being used for purposes outside their individual care, under a national opt-out mechanism.<sup>170</sup>

#### Anonymisation

Under the GDPR and guidance such as the Caldicott Principles, researchers are expected to mitigate risks to privacy by using the minimum confidential personal data necessary to accomplish a given task.<sup>163,171</sup> They may do this by removing certain identifying information.<sup>172,173</sup> Data that have had such information removed may still be classed as personal data under GDPR. Fully anonymising data so that it is not in scope of data protection law may make it less useful for research.<sup>172</sup>

#### Security measures for patient data

All organisations using patient data are expected to have robust security systems and procedures in place.<sup>163,174</sup> Such measures may include encryption,<sup>175</sup> use of synthetic datasets,<sup>176</sup> or only allowing access to data at secure cloud computing facilities (POSTnote 629)<sup>177</sup>

### Privacy and data sharing

While use of patient data is governed by various rules and principles (Box 2), the use of large amounts of data to develop AI systems raises questions over privacy. For example, in 2017, the Information Commissioner's Office (ICO) found that the Royal Free Hospital had failed to comply with data protection law after sharing identifiable patient data with DeepMind for development of a diagnostic system for kidney injury.<sup>178,179</sup> Some evidence suggests a lack of awareness among the public of how patient data are shared,<sup>180</sup> and public scepticism towards sharing it, particularly with industry. In a 2018 survey of 2080 UK adults, 50.3% were willing to share anonymised data with research institutions, while 12.2% were willing to share it with industry for healthcare improvement purposes.<sup>181</sup>

There is wide variation in the terms of existing data sharing agreements between the NHS and industry.<sup>28</sup> Some stakeholders have raised concerns that NHS leaders lack the expertise to negotiate data sharing agreements that reflect the value of the patient data held by the NHS.<sup>182</sup> In 2020, the UK Government established the NHSX Centre for Improving Data

Collaboration.<sup>183</sup> It aims to ensure data sharing partnerships are made for the benefit of the whole NHS.<sup>184</sup>

### Data quality

Large, high-quality training datasets are needed for AI systems to produce accurate outputs.<sup>93–95</sup> Inaccurate or incomplete data can lead to poor performance.<sup>1</sup> Data must also usually be in a structured digital format, which can easily be processed by an ML algorithm.<sup>22</sup> However, the quality and organisation of data varies widely between different NHS services, depending on the degree to which data are being recorded in electronic format.<sup>28</sup> For example, paper records are still common in secondary care.<sup>185</sup> In 2017, 54% of NHS trusts reported staff could rely on digital records for all the information they needed.<sup>186</sup> In addition, many IT systems used in the NHS are unable to communicate with other systems, making it difficult to connect them with AI software and to gather data in a consistent way.<sup>28</sup> The NHS Long Term Plan (and other frameworks)<sup>14,160,187</sup> prioritise the use of interoperability and data collection standards to tackle this issue. Under the plan, all NHS providers are expected to reach a 'core level of digitisation' by 2024.<sup>15</sup>

### Security

Commentators have raised concerns that widespread use of AI and other technologies in healthcare increases the potential for cyber-attacks on such systems ([POSTnote 554](#)).<sup>188</sup> The need to share large datasets with external developers during AI development may increase the risks of a data breach.<sup>189</sup> In addition, hackers or other bad actors may seek to manipulate an AI system's outputs to disrupt or defraud the healthcare system,<sup>190–192</sup> or to extract patient data used in training.<sup>189,193</sup>

### Accountability and legal liability

Surveys have reported various levels of public awareness and trust of AI and automated decision-making in healthcare and other areas,<sup>129,194–199</sup> with some concerned that AI could lead to unclear or reduced responsibility for decisions.<sup>194,195</sup> In a 2016 survey of 12,003 adults across 12 countries by PwC, 39% of UK respondents said they would be willing to engage with an AI system to get a diagnosis or treatment/health advice and 50% said they would not be willing to do so.<sup>199</sup> Currently, most AI systems provide recommendations to clinicians, who balance these against their own knowledge and experience. A series of Academy of Medical Sciences workshops with 53 patients and members of the public, recommended that AI should support, rather than overrule, decision-making by clinicians.<sup>130</sup>

From a legal perspective, if a recommendation from an AI system led to a patient being harmed by a clinician, the clinician, developer and healthcare provider could face criminal charges or civil claims. The clinician could also face professional disciplinary proceedings.<sup>200–207</sup> There is a lack of precedent for how these cases would be resolved, and no professional regulators have introduced guidelines for AI use. Professional bodies, including the Academy of Medical Royal Colleges, have noted concerns about the uncertainty around accountability and liability.<sup>2,208</sup> These issues are further complicated by the use of 'black box' systems,<sup>209</sup> whose complexity makes it difficult to fully understand how a decision has been reached ([POSTnote 633](#)).<sup>210,211</sup> Some stakeholders have argued that new legal mechanisms may be required for AI in the future.<sup>212–214</sup>

### Health inequalities

Depending on how they are developed and used, AI systems have the potential to reduce or increase health inequalities. For example, AI systems could reduce variations in care by providing more consistent recommendations of treatments and diagnoses, based on up-to-date medical advice.<sup>133,215,216</sup> However, there is a risk of AI systems exhibiting 'algorithmic bias', providing recommendations that discriminate against certain demographic groups ([POSTnote 633](#) Box 2).<sup>217–220</sup> This can arise from decisions made during development of an AI system, or use of training data that under-represent a certain group or reproduce historic biases. For example, one commonly used skin cancer research database mainly contains fair-skinned patient images. Some experts have suggested that ML systems trained using these images may have difficulty diagnosing cancers in patients with darker skin types.<sup>221,222</sup> Data protection law requires users of personal data to mitigate risks of discrimination.<sup>189</sup> The Equality Act 2010 prohibits decisions that discriminate on the basis of certain characteristics.<sup>223,224</sup>

### Regulatory issues

AI systems that have a direct medical purpose will qualify as medical devices, *in vitro* diagnostic devices, or active implantable devices.<sup>225–227</sup> In the UK, these are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).<sup>206</sup> EU device regulations that existed prior to the end of the Brexit transition period remain in place as 'retained EU law' under the European Union (Withdrawal) Act 2018.<sup>228,229</sup> The Government has published guidance on the requirements for placing medical devices on the market in Great Britain from January 2021.<sup>229</sup> Requirements differ in Northern Ireland. Future UK regulations will be developed under provision of the [Medicines and Medical Devices Bill 2019-21](#). The Government has indicated new regulations will aim to increase safety and be more responsive to new technologies, including AI.<sup>229,230</sup>

The use of personal data in AI systems is governed by the ICO.<sup>231</sup> There are extra safety standards for software used in the NHS.<sup>232,233</sup> Development of AI systems within the NHS is classed as medical research, and usually requires approval from the Health Research Authority.<sup>234</sup> The Care Quality Commission has stated that suppliers of any future AI systems that make diagnoses or treat patients without human intervention would need to be registered.<sup>235</sup> With many bodies involved, some stakeholders view existing regulatory processes as difficult to navigate and a barrier to innovation.<sup>236,237</sup> The NHS AI Lab is funding projects to streamline regulatory processes,<sup>20</sup> including the creation of a multi-agency advice service, which will provide a single point-of-contact for AI developers seeking guidance.<sup>238</sup>

Some ML systems present challenges under existing regulation; they continue to learn and optimise as they are given new input data.<sup>22</sup> There are questions around how such systems could be monitored to ensure they remain safe and effective.<sup>239</sup> The US Food and Drug Administration has proposed regulations that would allow developers to pre-specify a safe process for future changes to AI systems.<sup>240</sup> The British Standards Institution is working with a US partner to consider how international standards for medical devices could be changed to meet the challenges posed by AI.<sup>241,242</sup>

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