REFORM

Thinking on its own: AI in the NHS

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Kate Laycock

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Acknowledgements

Advisory board

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The arguments and any errors that remain are the authors' and the authors' alone.

Reform

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Foreword

One of the priorities of the Science and Technology Committee, which I have the privilege of chairing, is to ensure that society benefits from the immense opportunities presented by new technology. Scientific discovery and innovation offer hope of more effective public services, better quality of life, and high-value jobs, and nowhere are these benefits more evident than in the emerging revolution in Artificial Intelligence (AI).

The new *Industrial Strategy* sets out to put the UK at the forefront of innovation in AI, but to do this we must embrace the revolutionary potential of AI, algorithms and data in healthcare. We are on the brink of a major transformation in the way we diagnose, treat, and even prevent ill health. Whether it is wearable devices, AI surgical robots, or AI algorithms that can detect certain conditions with unprecedented speed and accuracy, these advances have the potential to propel the health and social care system into the 21st century – improving care both in the hospital and at home, and making much more efficient use of resources.

However, the Government has much to do to create the right conditions for AI to be fully harnessed in the NHS. The previous Committee's *Robotics and artificial intelligence* report highlighted the great potential of AI in healthcare, but also some of the challenges surrounding data and the key issue of consent.

More recently, the Committee has been examining the increased use of algorithms in decision-making, both in the public and business sphere. It launched an inquiry that aims to understand how they are created, the scope for unwanted bias and the impact they may have on individuals. There is still more to do for AI to win the hearts of all healthcare professionals, and these are just some of the issues that will occupy policymakers in the years ahead.

On that basis, I am delighted *Reform* has researched how AI could help the NHS deliver its service transformation plans, as well as the challenges that will need to be addressed to make this a reality. Infrastructure for collecting, sharing and accessing data need to be improved. Resolving the ethical questions surrounding AI in healthcare settings will be crucial, including setting the right regulatory framework.

I am pleased to see this report building on some of the recent policy developments around the life sciences and the industrial strategy, to provide some tangible solutions to these problems. The Science and Technology Committee recognises the important work of academics and think tanks to provide robust analysis, challenge government, and offer new and forward-thinking ideas. I hope that the insights and recommendations of this report will be of value to policymakers and to those tasked with driving innovation in technology and healthcare.

Norman Lamb MP, Chair, Science and Technology Committee

Executive summary

This report illustrates the areas where artificial intelligence (AI) could help the NHS become more efficient and deliver better outcomes for patients. It also highlights the main barriers to the implementation of this technology and suggests some potential solutions.

Early adopters

Despite the hype around AI in healthcare, examples of it being implemented and deployed in the NHS are sparse. Broadly speaking, it is incumbent on individual providers to introduce new technologies into the NHS. This has resulted in piecemeal applications and patchy realisation of benefits. With a different approach to technological adoption, however, which would gradually embed AI in service transformation plans, the future could look quite different.

Potential of AI in the NHS

AI could support the delivery of the NHS's Five Year Forward View, which aims to narrow three gaps in health provision. AI could help address the health and wellbeing gap by predicting which individuals or groups of individuals are at risk of illness and allow the NHS to target treatment more effectively towards them. The reduction of the care and quality gap could be supported by AI tools as they can give all health professionals and patients access to cutting edge diagnostics and treatment tailored to individual need. AI could help address the efficiency and funding gap by automating tasks, triaging patients to the most appropriate services and allowing them to self-care.

Improving buy-in

For AI to support a more efficient healthcare system that delivers better outcomes, it must overcome concerns of both the public and healthcare professionals. Public confidence and trust are vital for the successful development of AI. This also means increasing public confidence in the way data is shared both within the NHS and with external organisations.

Getting data right

The NHS will also need to get data right to truly harness the potential of AI in healthcare. This means collecting the right type of data in the right format, increasing its quality and securely granting access to it. The healthcare system is still heavily reliant on paper files and most of its IT systems are not based on open-standards. This limits the exchange of information across the health system. Increasing the quality of the data collected within the NHS is of crucial importance as the accuracy and fairness of AI algorithms are wholly dependent on the data they are being fed.

The ethics of building AI

Public safety and ethical concerns relating to the usage of AI in the NHS should be a central matter of interest for healthcare regulators such as the National Institute for Health and Care Excellence, the Medicines and Healthcare Products Regulatory Agency and Government. If industry is to use NHS data to design AI, as it does now, the NHS should make sure that it can reap the benefits in the long term. In addition, healthcare is a high-risk area, where the impact of a mistake could have profound consequences on a person's life. AI systems are not infallible and are not devoid of biases. It is important for current regulations to be updated to make sure that the applications of AI in healthcare lead to a better and more efficient NHS, which reduces variations in the quality of care and healthcare outcomes.

Recommendations

Recommendation 1: NHS Digital and the 44 Sustainability and Transformation Partnerships should consider producing reviews outlining how AI could be appropriately and gradually integrated to deliver service transformation and better outcomes for patients at a local level. Caution should be taken when embedding AI within service transformation plans. It should not be regarded as tool that will decide what objectives or outcomes should be reached. AI is an enabler not the vision.

Recommendation 2: NHS England and the National Institute for Health and Care Excellence should set out a clear framework for the procurement of AI systems to ensure that complex to use and unintuitive products are not purchased as they could hamper service transformation and become burdensome of the healthcare professionals.

Recommendation 3: The NHS should pursue its efforts to fully digitise its data and ensure that moving forward all data is generated in machine-readable format.

Recommendation 4: NHS England and the National Institute for Health and Care Excellence should consider including the user-friendliness of IT systems in the procurement process of data collection systems and favour intelligent systems that flag-up errors in real-time.

Recommendation 5: NHS Digital should make submissions to the Data Quality Maturity Index mandatory, to have a better monitoring of data quality across the healthcare system.

Recommendation 6: In line with the recommendation of the Wachter review, all healthcare IT suppliers should be required to build interoperability of systems from the start allowing healthcare professionals to migrate data from one system to another. This would allow for compliance with the EU's General Data Protection Regulation principle of data portability.

Recommendation 7: NHS Digital should commission a review seeking to evaluate how data from technologies and devices outside of the health-and-care system, such as wearables and sensors, could be integrated and used within the NHS.

Recommendation 8: NHS Digital, the National Data Guardian and the Information Commissioner's Office, in partnership with industry, should work on developing a digital and interactive solution, such as a chatbot, to help stakeholders navigate the NHS's data flow and information governance framework.

Recommendation 9: NHS Digital should create a list of training datasets, such as clinical imaging datasets, which it should make more easily available to companies who want to train their AI algorithms to deliver better care and improved outcomes. It should also develop a specific framework specifying the conditions to securely access this data.

Recommendation 10: The Department of Health and the Centre for Data Ethics and Innovation should build a national framework of conditions upon which commercial value is to be generated from patient data in a way that is beneficial to the NHS. The Department of Health should then encourage NHS Digital to work with STPs and trusts to use this framework and ensure industry acts locally as a useful partner to the NHS.

Recommendation 11: The Medicine and Healthcare Products Regulatory Agency and NHS Digital should assemble a team dedicated to developing a framework for the ethical and safe applications of AI in the NHS. The framework should include what type of pre-release trials should be carried out and how the AI algorithms should be continuously monitored.

Recommendation 12: NHS Digital, the Medicines and Healthcare Products Regulatory Agency and the Caldicott Guardians should work together to create a framework of 'AI explainability'. This would require every organisation deploying an AI application within the NHS to explain clearly on their website the purpose of their AI application (including the health benefits compared to the current situation), what type of data is being used, how it is being used and how they are protecting anonymity.

Recommendation 13: The Medicine and Healthcare Products Regulatory Agency should require as part of its certification procedure access to: data pre-processing procedures and training data.

Recommendation 14: The Medicine and Healthcare Products Regulatory Agency Review in partnership with NHS Digital should design a framework for testing for biases in AI systems. It should apply this framework to testing for biases in training data.

Recommendation 15: Tech companies operating AI algorithms in the NHS should be held accountable for system failures in the same way that other medical device or drug companies are held accountable under the Medicine and Healthcare Products Regulatory Agency framework.

Recommendation 16: The Department of Health in conjunction with the Care Quality Commission and the Medicine and Healthcare Products Regulatory Agency should develop clear guidelines as to how medical staff is to interact with AI as decision-support tools.

Introduction

Healthcare in the UK needs reform if it is to remain a high-quality national health service free at the point of care.[1] Funding growth has declined and is unlikely to meet increasing demand,[2] driven by an ageing population with multiple and chronic health conditions.[3] Bridging this gap between supply and demand will require more than "simply throwing more resources at healthcare"[4] as highlighted by Alan Milburn. The NHS recognises this and highlights the role of technology and the better use of data to deliver high-quality care and better outcomes while responding to its budgetary challenge.[5]

Recently, attention has turned to the use of artificial intelligence (AI) in healthcare to help deliver an NHS fit for the future.[6] AI promises to boost productivity[7] and lead to "major economic and social benefits."[8] Both the *Life Sciences Industrial Strategy* and the Government's review, *Growing the Artificial Intelligence Industry in the UK*, highlight the great potential of AI in healthcare, which can be used to "improve outcomes in the NHS and, ultimately, to reduce cost."[9] It is a rich and diverse field with many domains of application. These range from decision-support tools that help clinicians make more informed diagnostic decisions, to intelligent virtual assistants that can help with more efficient scheduling.[10]

The NHS has, however, had a history of difficulties in realising the benefits of technology as it has often "simply been layered on top of existing structures".[11] Given the hype around AI,[12] there would be a danger of replicating those past mistakes, when a different approach to technological adoption is required.[13] Technology should be embedded within service transformation plans and not be an afterthought. For this reason, it is crucial to understand what AI can do to help reform the NHS and the challenges that will have to be tackled to fully reap the benefits of this technology.

This report seeks to do just that.[14] It will highlight the areas where AI can make the NHS more efficient[15] and deliver better outcomes through better prediction,[16] detection[17] and management of health conditions. These applications potentially hold the key to reducing demand on the system, improving the quality of care and patient outcomes, whilst reducing cost. It will also highlight the main barriers to the implementation of this technology such as issues with accessing data, data quality and the certification of these AI algorithms. Finally, it will suggest potential solutions to overcome these challenges.

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1 NHS England, *Five Year Forward View*, 2014, 2.

2 NHS England, *Five Year Forward View*; National Information Board, *Personalised Health and Care 2020: Using Data and Technology to Transform Outcomes for Patients and Citizens* (NHS, 2014); Ruth Robertson et al., *Understanding NHS Financial Pressures* (The King's Fund, 2017); Alan Milburn, 'Technology and Innovation Are Key to Saving the NHS', *The Guardian*, 21 October 2017.

3 The King's Fund, 'Demography: Future Trends', Webpage, 2017; Department of Health, '2010 to 2015 Government Policy: Long Term Health Conditions', Webpage, 8 May 2015.

4 Milburn, 'Technology and Innovation Are Key to Saving the NHS'.

5 NHS England, *Five Year Forward View*; National Information Board, *Personalised Health and Care 2020: Using Data and Technology to Transform Outcomes for Patients and Citizens*.

6 Professor Sir John Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector* (HM Government, 2017); Professor Dame Wendy Hall and Jérôme Pesenti, *Growing the Artificial Intelligence Industry in the UK* (Department for Digital, Culture, Media & Sport and Department for Business, Energy & Industrial Strategy, 2017); HM Government, *Industrial Strategy: Building a Britain Fit for the Future*, 2017.

7 Benjamin L. W. Sobel, *Artificial Intelligence's Fair Use Crisis* (Rochester, NY: Social Science Research Network, 2017), 3; Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 9.

8 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 10.

9 Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector*, 10.

10 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 11.

11 Candace Imison et al., *Delivering the Benefits of Digital Health Care* (Nuffield Trust, 2016), 14–20.

12 British Journal of Healthcare Computing, 'Is an AI-Driven Health System a "Realistic" Vision?', 13 October 2017.

13 NHS England, *Five Year Forward View*.

14 This report is based on a thorough literature review and 35 semi-structured interviews.

15 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 11.

16 Ibid.

17 Dean Arnold and Tim Wilson, *What Doctor? Why AI and Robotics Will Define New Health* (PwC, 2017); Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 11.

1
What is artificial intelligence?

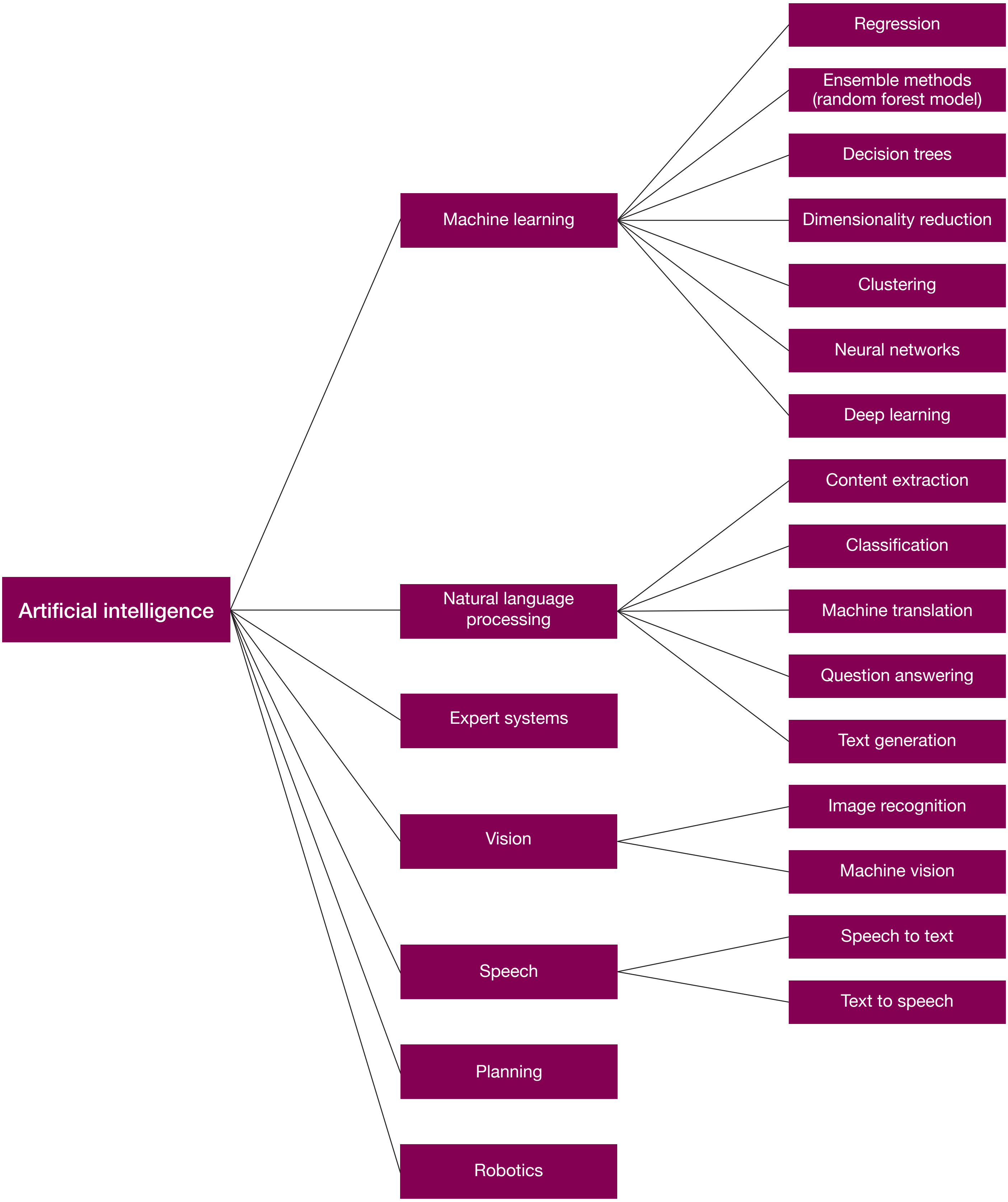
AI describes a set of advanced technologies that enable machines to do highly complex tasks effectively – which would require intelligence if a person were to perform them.[18] There is, however, "no standard definition of intelligence"[19] and no single agreed definition of AI. [20] In addition, the line between AI and other techniques, such as big data analytics, can be blurred.[21]

This report will define intelligence as an "agent's ability to achieve goals in a wide range of environments"[22] and AI as any manmade agent (i.e. software or robot) which exhibits intelligence. In this report, AI will therefore be used in its broadest sense to describe the set of methods illustrated in Figure 1.

In the public discourse, AI is often characterised as sentient machines having human-like capabilities,[23] whilst, the state-of-the-art is somewhat off this vision. Current AI is 'narrow', with systems learning to carry out only specific functions, without the ability to apply their intelligence more generally.[24] For example, an AI algorithm trained to recognise whether or not a scan shows a cancerous tumour only knows how to do that specific task.

18 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*.
19 Shane Legg and Marcus Hutter, 'A Collection of Definitions of Intelligence', *Frontiers in Artificial Intelligence and Applications* 157 (June 2007): 1.
20 House of Commons Science and Technology Committee, *Robotics and Artificial Intelligence, Fifth Report of Session 2016–17*, HC 145 (London: The Stationary Office, 2016), 5.
21 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 24.
22 Legg and Hutter, 'A Collection of Definitions of Intelligence', 8.
23 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*, 2017.
24 Ibid., 24.

Figure 1: AI methods



Source: *Reform* interviews and research – NB: The third column of nodes does not provide an exhaustive list of all methods.

2
The current picture

2.1 Early adopters 14

This past year has seen the profile of AI and robotics rise across government. The *Digital Strategy* showed enthusiasm for these technologies. In it, the Government awarded £17.3 million in Engineering and Physical Sciences Research Council grants to support the development of AI and robotics in UK universities.[25]

The *Life Sciences Industrial Strategy* called for a new regulatory framework to be established to "capture…the value in algorithms generated using NHS data."[26] It recommended improved commercial access agreements and a clear national strategy for data and interoperability standards across the NHS, academia, charities and industry. Furthermore, it suggested a new regulatory framework for algorithms generated using NHS data to evaluate their safety and efficiency.[27] Dame Wendy Hall and Jérôme Pesenti recently carried out an independent review, *Growing the artificial intelligence industry in the UK*, as part of the *Industrial Strategy*.[28] It prioritised health as an area for research investment and identified a lack of trust in the use of sensitive data[29] and a complex and expensive system of data access as barriers to developing algorithms.[30] It proposed Data Trusts – proven and trusted frameworks and agreements – as a potential solution.[31]

The *Industrial Strategy* committed to put the UK "at the forefront of the artificial intelligence and data revolution."[32] The new Industrial Strategy Challenge Fund identified AI and robotics as priority areas for research that will receive £93 million of the £1 billion available in the first wave of investment.[33] However, this funding will focus on the use of systems that can be deployed in extreme environments and not healthcare.[34] In the second wave of investment, £210 million of the further £725 million will be allocated to a 'data to early diagnostics and precision medicine' programme.[35] It will focus on using data for the early diagnosis of life-changing diseases and for the development of "precision treatments to cure them."[36] However, no explicit emphasis has been placed on the use of AI in this programme.

NHS leaders have supported the expansion of AI in healthcare with Simon Stevens, NHS Chief Executive, declaring that "NHS England is to invest more in AI over the next 12 months and will roll out new regional patient data schemes."[37] He highlighted pathology and imaging as priority investment areas following previous proposals from the National Information Board (NIB) to use AI for self-care and better triage systems in general practice and emergency care.[38]

2.1 Early adopters

The Government would like to "make the UK a world-leader in healthcare innovation" to ensure that people throughout the country have access to world-class care.[39] Despite these intentions, George Freeman MP has highlighted that "there is a gap between our ability to innovate within the UK and turn these innovations into health benefits for the population".[40] The NHS recognises the value of the use of AI but is lacking clarity about both the strategic direction to take and where to start. There has been a wave, however, of early adopters which has resulted in piecemeal applications with patchy realisation of benefits.

25 Department for Digital, Culture, Media & Sport, *UK Digital Strategy 2017*, 2017.
26 Bell, Life Sciences Industrial Strategy – *A Report to the Government from the Life Sciences Sector.*
27 Ibid.
28 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*.
29 See glossary.
30 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*.
31 Ibid.
32 HM Government, *Industrial Strategy: Building a Britain Fit for the Future*, 10.
33 Public Technology, 'Robotics and AI Get £93m in Industrial Strategy Challenge Fund', Webpage, 24 April 2017.
34 Environments such as nuclear and space.
35 HM Government, *Industrial Strategy: Building a Britain Fit for the Future*, 77.
36 Ibid., 38.
37 Ben Heather, 'NHS England Will Invest in Artificial Intelligence, Says Stevens', *Health Service Journal*, 12 September 2017.
38 Ibid.; National Information Board, *Annual Report* (Department of Health, 2016).
39 Department of Health, 'Getting Patients Quicker Access to Innovative Healthcare', Press Release, 24 October 2016.
40 George Freeman, 'Challenging the NHS to Innovate', Speech, Department of Health, 3 September 2015.

Currently, examples of AI in the NHS are sparse. Broadly speaking, it is incumbent on individual providers rather than national bodies to adopt new technologies into the NHS. Nuance Communications issued a Freedom of Information request to 45 Trusts asking about their use of AI, 30 responded. Of these, 43 per cent were investing in what they considered to be AI.[41] The Trusts had chosen virtual assistants, speech recognition technology and chatbots to ease the pressure on healthcare workers. Trusts and industry have been supported by interventions from central organisations including:

> The NHS Innovation Accelerator which aims to accelerate use of high-impact innovations for patient benefit and to enable the change necessary within the NHS for proven innovations to be adopted faster and more systematically.[42] The accelerator has supported some organisations that also use AI, including HealthUnlocked, now the third largest health website in the UK. Working with the South Devon and Torbay Clinical Commissioning Group (CCG), their AI recommendation engine provides personalised self-care advice and a gateway to information and support available. It is designed to engage individuals with their health and improve outcomes.[43] AliveCor, also part of the accelerator, has been approved by the National Institute for Health and Care Excellence (NICE). It is a mobile heart monitor that uses AI to detect, monitor and manage atrial fibrillation, an irregular heart rhythm responsible for a third of strokes.[44]

> The Accelerated Access Pathway which was designed following the 2015 Accelerated Access Review to "allow products with a transformative designation to meet regulatory requirements, agree commercial arrangements, receive revenue and achieve market access as quickly as possible."[45]

> Fifteen Academic Health Science Networks (AHSNs) were established in 2013 by NHS England as an incubator to foster innovation at pace and scale.[46] They connect the NHS, academics, social care organisations, public-health professionals and industry to accelerate the adoption of innovation and promote economic growth whilst driving improvements in the quality and efficiency of care.[47] Bering Limited created an AI platform meant to help CCGs "identify complex patients, prioritise comorbidity profiles, and plan future care." [48] The platform also aims to predict the impact of an intervention. Bering has been working with Somerset CCG to roll-out this model.

The better-known partnerships have been between trusts and global leaders in AI. Specifically, Moorfields Eye Hospital is working with Google DeepMind using an algorithm to identify disease on imaging of the back of the eye.[49] Babylon has partnered with North Central London CCG to trial an instant triage system to replace 111.[50] IBM Watson has partnered with Harrow Council using the Watson Care Manager system to enable individuals and caregivers to select the most appropriate provider to deliver services.[51] It has also collaborated with Alder Hey Children's Hospital to develop a chatbot that allows children to ask Watson questions about hospital admission.[52]

41 Nuance Communications, 'New Data Reveals Nearly Half of NHS Trusts Are Investing in AI for Patient Services', Press Release, 2 February 2017; Nuance Communications, 'Nearly Half of NHS Trusts Are Investing in AI for Patient Services', Webpage, 2 February 2017.
42 NHS England, *Innovation into Action*, 2015, 26.
43 NHS Innovation Accelerator, 'Two NIA Companies Recognised as UK's Fastest Growing Technology Companies in Deloitte Technology Fast 50', Webpage, 22 November 2016, 50; NHS Innovation Accelerator, 'South Devon and Torbay CCG to Adopt New Digital Tool Launched by NIA Company', Webpage, 13 September 2016.
44 NHS England, 'NHS Chief Launches New Fast Track Funding so NHS Patients Get Treatment Innovations Faster', Webpage, 17 June 2017.
45 Sir Hugh Taylor and Sir John Bell, *Accelerated Access Review: Final Report* (Wellcome Trust, 2016).
46 Academic Health Science Networks, 'About Academic Health Science Networks', Webpage, AHSN Network, 2017.
47 Ibid.
48 NHS England, 'Spreading Innovation, Generating Economic Growth', Webpage, 2017.
49 DeepMind, 'DeepMind Health and Research Collaborations', Webpage, 2017.
50 Paul Bate, 'Bringing the Digital Revolution to Healthcare', Reformer Blog, 6 February 2017; Ben Heather, 'Babylon Health to Power NHS 111 with "AI Triage" Bot', Webpage, Digitalhealth, 5 January 2017.
51 Harrow Council, 'IBM and Harrow Council to Bring Watson Care Manager to Individuals in the UK', Webpage, 9 September 2016.
52 IBM, 'IBM Cognitive Stories – Alder Hey with Watson', Webpage, 23 March 2017.

Despite central government's enthusiasm for AI, current applications within the NHS are piecemeal. The following Chapter will highlight how the NHS could use AI to deliver its service transformation plans.

3
Potential of artificial intelligence in the NHS

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Demand for healthcare has changed significantly since the NHS was formed.[53] People are living longer and chronic diseases now account for 70 per cent of health and social care spending.[54] Moreover, healthcare professionals face a huge knowledge challenge as the pace and complexity of medical knowledge now "exceeds the capacity of the human mind."[55] With funding pressures increasing, the NHS needs reform if it is to continue delivering good quality care. AI could be an enabler of these reforms.[56]

The *Five Year Forward View* has provided a vision for service transformation.[57] It aims to narrow three gaps in health provision: the *health and wellbeing gap,* the *care and quality gap,* and the *efficiency and funding gap*.[58] Reducing these three gaps would imply a refocus on the triple aims of healthcare: improving the patient experience of care, improving the health of the population and reducing the cost per person.[59] This Chapter will provide examples[60] of how AI could help deliver the *Five Year Forward View* and narrow these gaps.[61]

3.1 The health and wellbeing gap

The *health and wellbeing gap* focuses on prevention to improve healthy life expectancy.[62] AI could predict individuals or groups of individuals at risk of illness and allow the NHS to target treatment more effectively towards them.

3.1.1 Health promotion

The health service should aspire to keep patients well in the community wherever possible.[63] Wearables can monitor information related to health and wellbeing, such as the number of steps taken or vital signs such as the heart rate. AI can interpret this information to give people greater access to knowledge about their physical condition.[64] One in seven UK adults own wearable fitness trackers, reflecting the UK's appetite for wellbeing.[65] The data collected on such devices could be used by AI to keep people well and change behaviour. For example, the app Noom uses AI to analyse a person's exercise and food logs and suggests personalised diet and fitness plans.[66] Industry research of 35,921 users found 77.9 per cent reported weight loss over two years, 25 per cent lost more than 10 per cent of their body weight and nearly 80 per cent said they kept the weight off for more than nine months.[67]

53 NHS England, *Five Year Forward View*, 2.
54 Department of Health, '2010 to 2015 Government Policy: Long Term Health Conditions'.
55 Ziad Obermeyer and Thomas H. Lee, 'Lost in Thought — The Limits of the Human Mind and the Future of Medicine', *New England Journal of Medicine 377*, no. 13 (September 2017): 1209–11.
56 The Academy of Medical Sciences, *Response the House of Commons Science and Technology Committee Inquiry into Algorithms in Decision-Making* (House of Commons Science and Technology Committee, 2017); Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector*; Owen A. Johnson, 'AI Can Excel at Medical Diagnosis, but the Harder Task Is to Win Hearts and Minds First', *The Conversation*, 12 August 2016; Steven E. Dilsizian and Eliot L. Siegel, 'Artificial Intelligence in Medicine and Cardiac Imaging: Harnessing Big Data and Advanced Computing to Provide Personalized Medical Diagnosis and Treatment', *Current Cardiology Reports* 16, no. 1 (January 2014); The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*.
57 NHS England, *Five Year Forward View*.
58 Ibid.
59 Kathleen Merkley, Michael Barton, and Tracy Vayo, 'Improving Healthcare Outcomes: Keep the Triple Aim in Mind', Webpage, Health Catalyst, 28 January 2016; Donald M. Berwick, Thomas W. Nolan, and John Whittington, 'The Triple Aim: Care, Health, and Cost', *Health Affairs* 27, no. 3 (2008).
60 The examples selected by the authors are not meant to provide an exhaustive list of the applications of AI in healthcare. However, the authors have tried to illustrate as best as possible the large breadth of applications.
61 NHS England, *Five Year Forward View*.
62 Ibid.
63 Ibid.
64 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*.
65 Joel Snape, 'Three Million Fitness Bands Were Sold in Britain Last Year, so Why Aren't We Getting Any Fitter?', *The Telegraph*, 26 January 2016.
66 Michael Grothaus, 'Popular Data-Driven Weight Loss App Mixes AI And A Human Touch To Boost Success', Webpage, Fast Company, 3 January 2017.
67 Ibid.

3.1.2 Prevention

AI could enable clinicians to identify those individuals with health conditions who are more likely to develop certain complications. The School of Computer Science and the Health Informatics Centre at the University of Manchester have used health data to cluster individuals into groups of people with similar characteristics.[68] The team are finding "clusters of patients and new patterns of comorbidity that would not be recognised in any one centre or by one clinician."[69] The Manchester team have plotted patients with diabetes, cardiovascular and respiratory disease together and are in the process of generating hypotheses that, had a this approach not been taken, may never have been formed.[70] The clusters could be highly significant as new correlations are found in the data that could be used to deliver preventative interventions and more precise medicine, including the use of novel diagnostic and treatment options.

3.2 The care and quality gap

The reduction of the *care and quality gap* seeks to standardise high-quality care.[71] AI can give all health professionals and patients access to cutting edge diagnostics and treatment tailored to individual need.[72] AI algorithms with superior diagnostic accuracy to clinicians could reduce variation in quality of decision making whilst offering personalised care universally.[73]

3.2.1 Augmenting cognitive capacities

The pace of medical research and the vast accumulation of data means that clinicians cannot keep fully up to date. Each year, 2.5 million scientific articles are published in English-language journals.[74] AI can be deployed in healthcare to help clinicians keep abreast of advances. IBM's Watson deploys natural language processing which allows computers to process written information.[75] Watson could process existing literature alongside patient data to aid diagnosis and then recommend treatment options to clinicians. This has the potential to standardise high-quality care as all health professionals have improved access to relevant research and guidance.

3.2.2 Improved diagnostics

For most conditions accurate and early diagnosing often provides the opportunity to start treatment earlier with the aim of reducing morbidity, mortality and complications. For example, women between 50 and 70 are advised to have mammograms every three years to screen for breast cancer.[76] Evidence shows that a high proportion of mammograms yield false positive results when interpreted by radiologists,[77] leading to one in two healthy women being told they may have cancer.[78] AI is enabling interpretation of mammograms 30 times faster than humans and with greater accuracy.[79] This is aiding early diagnosis from the time of the mammogram, reducing the need for unnecessary

68 Clustering is a form of machine learning (see Figure 1)
69 National Institute for Health and Care Excellence, *Data Science for Health and Care Excellence*, 2016.
70 Ibid.
71 NHS England, *Five Year Forward View*.
72 Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector.*
73 Ibid.
74 Mark Ware and Michael Mabe, 'The STM Report, An Overview of Scientific and Scholarly Journal Publishing', *STM*, no. 4 (March 2015).
75 IBM Watson Health, 'IBM Watson Health – Cognitive Healthcare Solutions', Webpage, 1 January 2017.
76 Cancer Research UK, 'Breast Screening', Webpage, 18 October 2017.
77 Archie Bleyer and Gilbert Welch, 'Effect of Three Decades of Screening Mammography on Breast-Cancer Incidence', *The New England Journal of Medicine*, no. 367 (November 2012); H. Gilbert Welch et al., 'Breast-Cancer Tumor Size, Overdiagnosis, and Mammography Screening Effectiveness', *New England Journal of Medicine*, no. 375 (October 2016).
78 Tejal A. Patel et al., 'Correlating Mammographic and Pathologic Findings in Clinical Decision Support Using Natural Language Processing and Data Mining Methods', *Cancer* 123, no. 1 (January 2017).
79 Sarah Griffiths, 'This AI Software Can Tell If You're at Risk from Cancer before Symptoms Appear', *Wired*, 26 August 2016.

biopsies and the concern of a misdiagnosis.[80] Interviewees for this paper explained that similar techniques to those described above are being deployed for the evaluation of eye imaging,[81] skin lesions, electrocardiograms, X-rays and cross-sectional imaging such as CT or MRI.

3.2.3 Treatment

Robotics is making inroads in surgery. Experimental studies have illustrated autonomous robots can perform better stitching than surgeons.[82] Verb is using AI to help surgeons interpret anatomical data, such as tumour boundaries, when operating.[83] Titan Medical is developing Single Port Orifice Robotic Technology in the hope it will allow surgeons to perform precision surgery through a single incision.[84]

AI can also be used in the treatment of common mental health conditions such as anxiety, depression and panic disorders. For example, the NHS is investing in the AI smartphone app Ieso to deliver online cognitive behavioural therapy.[85] So far, nearly 17,000 people have been treated and industry evidence shows it is reducing treatment time by 50 per cent.[86]

3.3 The efficiency and funding gap

The *efficiency and funding gap* addresses system inefficiency[87] and AI could be transformative in this domain as it automates tasks, triages patients to the most appropriate services and allows them to self-care.[88] As highlighted in the *Life Sciences Industrial Strategy*, AI can increase the efficiency of the NHS by reducing costs and improving outcomes.[89]

3.3.1 Right intervention at the right time

Treating individuals in the right location, at the right time, is key to delivering the *Five Year Forward View*.[90] To improve quality and control costs, it is vital that those who can self-care do so and those needing care in the community are not diverted into hospitals.[91] There are many AI applications in this domain.[92] One of these applications identifies where trauma patients – depending on the severity of the injury – should be treated on arrival to hospital with greater accuracy than out of hospital trauma teams.[93] The model uses specific pieces of data including demographics, type of trauma, pre-hospital fluid, medications, vital signs, and disposition.[94] Ensuring trauma patients are treated in the right location means that there is an efficient use of resources and delivery of appropriate care.[95]

80 Patel et al., 'Correlating Mammographic and Pathologic Findings in Clinical Decision Support Using Natural Language Processing and Data Mining Methods'.
81 Moorfields Eye Hospital NHS, 'Latest Updates – DeepMind Health', Webpage, 20 September 2016.
82 Arnold and Wilson, *What Doctor? Why AI and Robotics Will Define New Health*.
83 Tom Simonite, 'The Recipe for the Perfect Robot Surgeon', *MIT Technology Review*, 14 October 2016.
84 Titan Medical, 'SPORTTM Surgical System', Webpage, 2016.
85 Lynsey Barber, 'Ieso, an App for Managing Mental Health Used by the NHS, Lands £18m from Touchstone Innovations and Draper Esprit', *CityA.M.*, 12 September 2017.
86 Ibid.
87 NHS England, *Five Year Forward View*.
88 William D. Eggers and Paul Macmillan, *Gov2020: A Journey into the Future of Government* (Deloitte, 2015).
89 Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector*, 10.
90 NHS England, *Five Year Forward View*.
91 Ibid.
92 Anand Avati et al., 'Improving Palliative Care with Deep Learning', *Standford ML Group*, November 2017; DeepMind, 'Applying Machine Learning to Radiotherapy Planning for Head & Neck Cancer', 30 August 2016; Heather, 'Babylon Health to Power NHS 111 with "AI Triage" Bot'; Michelle Scerbo et al., 'Prehospital Triage of Trauma Patients Using the Random Forest Computer Algorithm', *The Journal of Surgical Research* 187, no. 2 (April 2014).
93 Scerbo et al., 'Prehospital Triage of Trauma Patients Using the Random Forest Computer Algorithm'.
94 Ibid.
95 Ibid., 5.

3.3.2 Freeing-up administrative time through automation

AI promises to reduce the burden of administrative work in many sectors[96] and healthcare[97] is no exception to this rule. The British Medical Association found that trainee doctors spend 15 per cent of their time on administrative work; others have put the figure as high as 70 per cent.[98] The Royal College of Nursing states that 17 to 19 per cent of nursing time is spent on "non-essential" paperwork.[99] Interviewees for this paper explained that intelligent virtual assistants, such as Amelia,[100] could also support medical staff by placing individuals on pathways, book appointments, automatically compose letters, and send patients reminders. In addition, the better scheduling enabled by AI could help address current inefficiencies.[101] It was recently found that 750 additional routine operations a day could be carried out if schedules were better organised.[102]

3.3.3 Chronic disease management and self-care

AI can empower individuals with chronic illnesses to improve their outcomes. Apps have been developed that use AI to process blood sugar readings from people with diabetes.[103] After learning about the individual, the programme sends guidance and information to help them manage their disease.[104] HbA1c is a blood test able to detect blood sugar concentration over a three-month period. It is the standard test to assess diabetic control, the target reading is <6.5 per cent. Company figures, for the Livongo app, show a mean HbA1c decrease from 8.0 per cent at registration to 7.1 per cent at 90 days and 7.0 per cent at 180 days.[105] For each 1 per cent reduction in HbA1c there is a 21 per cent fall in diabetes related deaths.[106] Evidence also shows that lower HbA1c reduces the risk of complications such as heart attacks, amputations and strokes.

As highlighted in this Chapter, there are many opportunities to improve service delivery and patient outcomes. Moreover, as highlighted by interviewees for this paper, AI algorithms can be expensive to develop, but are cheap to run and scale-up. The NHS has made the mistake in past of not embedding technology within service transformation plans[107] and has instead focused on technology for technology's sake.

Moving forward, the NHS should further explore which AI applications could be implemented in different local areas as the needs of patients and staff vary and so do the degrees of 'AI readiness' (e.g. access to machine-friendly data). AI has the potential to help deliver reforms that go beyond those expressed in the *Five Year Forward View*. The NHS should consider how to embed AI to deliver a more efficient system focused on achieving better outcomes for patients in its future service transformation plans. It should do so in an incremental fashion so as to test out which solutions work best on the ground and deliver the desired objectives.[108]

96 Vegard Kolbjørnsrud, Richard Amico, and Robert J. Thomas, *The Promise of Artificial Intelligence* (Accenture, 2017), 4; House of Commons Science and Technology Committee, *Robotics and Artificial Intelligence, Fifth Report of Session 2016–17*, 11–12; The Economist Intelligence Unit, *Advanced Science and the Future of Government* (The Economist Group, 2016), 17; Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 16.
97 The Economist Intelligence Unit, *Advanced Science and the Future of Government*, 22; House of Commons Science and Technology Committee, *Robotics and Artificial Intelligence, Fifth Report of Session 2016–17*, 11.
98 Laura Donnelly, 'Junior Doctors "Spend up to 70 per Cent of Time on Paperwork"', *The Telegraph*, 8 December 2015.
99 Royal College of Nursing, 'Nurses Spend 2.5 Million Hours a Week on Paperwork', 25 April 2013.
100 Gill Hitchcock, 'Robotics Revolution: Why Chatbots and AI Could Shake up Local Government', Webpage, PublicTechnology, 11 July 2017.
101 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 11.
102 Duncan Geddes, 'NHS Could Perform 750 More Operations a Day If It Were Better Organised', *The Times*, 25 October 2017.
103 Kevin Maney, 'How Artificial Intelligence Will Cure America's Sick Health Care System', *Newsweek*, 24 May 2017.
104 Ibid.
105 *Livongo Clinical and Financial Outcomes Report* (Livongo Health, 2016).
106 Irene M. Stratton et al., 'Association of Glycaemia with Macrovascular and Microvascular Complications of Type 2 Diabetes (UKPDS 35): Prospective Observational Study', *British Medical Journal* 321, no. 7258 (August 2000): 405–12.
107 Department of Health, *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England*, 2016, 14.
108 M. Lynne Markus, 'Technochange Management: Using IT to Drive Organizational Change', *Journal of Information Technology* 19, no. 1 (March 2004).

Recommendation 1

NHS Digital and the 44 Sustainability and Transformation Partnerships should consider producing reviews outlining how AI could be appropriately and gradually integrated to deliver service transformation and better outcomes for patients at a local level. Caution should be taken when embedding AI within service transformation plans. It should not be regarded as tool that will decide what objectives or outcomes should be reached. AI is an enabler not the vision.

To successfully embed AI in the NHS's service transformation plans several barriers will have to be overcome. The next Chapter will consider one of these barriers by looking at ways of improving the public's and healthcare professionals' perception of AI and data sharing.

4
Improving buy-in

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For AI to support the delivery of a more efficient healthcare system which delivers better outcomes for the same or reduced cost, it must overcome concerns of both the public and healthcare professionals.[109]

4.1 Trustworthiness of AI

Dame Wendy Hall recognises that "building public confidence and trust will be vital to successful development" of AI.[110] Currently, public acceptance in healthcare is not particularly high. In a large survey[111] of public attitudes towards the use AI and robotics in healthcare, 47 per cent of the UK sample said it would be willing to use an 'intelligent healthcare' assistant via a smartphone, tablet or personal computer, with higher rates amongst younger generations.[112] Attitudes change, however, as procedures and monitoring touch on more sensitive areas. Only 37 per cent said they would use AI to monitor a heart condition and just 3 per cent said they would use it to monitor pregnancy.[113] Although more needs to be done to get the public onboard, it is important to recognise that the adoption of technology takes time and comes in phases.[114] As number of adopters grows, the more accustomed people become, eventually leading to full adoption.[115]

Winning the hearts of healthcare professionals is also an important factor. As interviewees for this paper explained, AI must show that it improves patient outcomes and that it is safe. Certification and regulation could address this and are discussed in section 6.2.2. Another aspect that might affect the buy-in of healthcare professionals is the user-friendliness of the AI systems. The interfaces used to interact with these systems should be intuitive for staff and simplify current processes rather than complicate them. As highlighted in the Wachter Review "training cannot compensate for poor usability."[116] Much work has been done in the field, of human-computer interaction to design visual systems that highlight important information, make information easily retrievable and work easier for medical staff and a better experience for patients.[117] Including clinicians in the process of the designing the interfaces they will use to interact with AI systems is extremely important.

Moreover, clinicians need some degree of transparency and interpretability over the results produced by AI systems to understand how the diagnostic, prognosis or treatment plan was reached. These elements are crucial to increase the buy-in of medical staff.[118] WatsonPaths has tried to create a system that interacts with clinicians in a way that is natural to them to improve engagement.[119] The system explains its decisions and attaches percentages to recommendations to illustrate its confidence in them.[120] However, this degree of explainability[121] might be technically difficult to achieve in some cases as some AI systems are 'black box' (see section 6.2.2 for further discussion).[122]

109 Johnson, 'AI Can Excel at Medical Diagnosis, but the Harder Task Is to Win Hearts and Minds First'.
110 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*.
111 PwC commissioned YouGov to conduct a survey of 12,000 individuals across 12 countries in Europe, the Middle East and Africa in 2016.
112 Arnold and Wilson, *What Doctor? Why AI and Robotics Will Define New Health.*
113 Ibid.
114 Geoffrey A. Moore, *Crossing the Chasm: Marketing and Selling Technology Products to Mainstream Customers*, Second Edition (Oxford: Capstone, 1998).
115 Ibid.
116 Department of Health, *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England*, 32.
117 Andreas Holzinger, Harold Thimbleby, and Russel Beale, 'Human–Computer Interaction for Medicine and Health Care (HCI4MED): Towards Making Information Usable', *International Journal of Human-Computer Studies* 68, no. 6 (June 2010); Erika S. Poole, 'HCI and Mobile Health Interventions', *Translational Behavioral Medicine* 3, no. 4 (December 2013); Ben Shneiderman, Catherine Plaisant, and Bradford W Hesse, 'Improving Healthcare with Interactive Visualization', *Computer* 46, no. 5 (May 2013).
118 Michael Veale, 'Logics and Practices of Transparency and Opacity in Real-World Applications of Public Sector Machine Learning', June 2017; Sandra Wachter, Brent Mittelstadt, and Luciano Floridi, 'Transparent, Explainable, and Accountable AI for Robotics', *Science Robotics* 2, no. 6 (May 2017); The IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems, *Ethically Aligned Design: A Vision for Prioritizing Human Well-Being with Autonomous and Intelligent Systems*, Version 2 (IEEE, 2017), 27.
119 IBM Research, 'WatsonPaths', Webpage, n.d.
120 Ibid.
121 David Gunning, 'Explainable Artificial Intelligence', Webpage, Defence Advanced Research Projects Agency, 2017.
122 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*, 2017, 93.

Recommendation 2

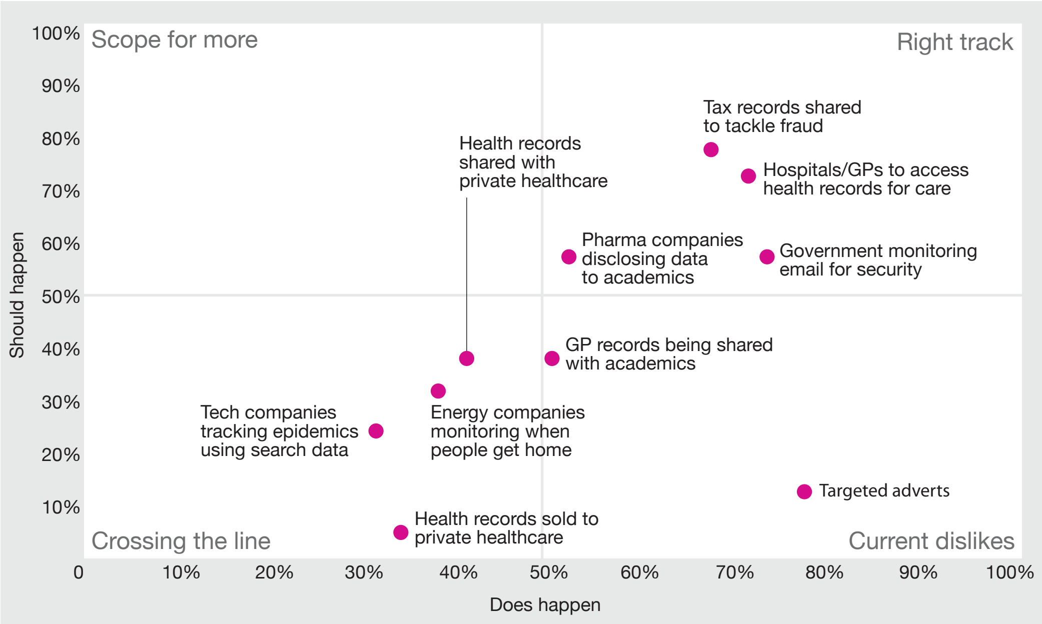
NHS England and the National Institute for Health and Care Excellence should set out a clear framework for the procurement of AI systems to ensure that complex to use and unintuitive products are not purchased as they could hamper service transformation and become burdensome of the healthcare professionals.

4.2 Data sharing

Applications of AI in healthcare are dependent on the access to individual or population datasets, however, accessing these datasets can be difficult because there is a "lack of public and patient engagement"[123] when it comes to sharing data. Individuals do not always understand what happens to their data, which might lead to reticence towards sharing it.[124] This is particularly true when sharing personal data for reasons beyond direct patient care (see Figure 2 and glossary for definition).[125] The third Caldicott review recognises the huge potential that could come from sharing this type of information. It recommends a clearer consent[126] and opt-out model to give people a choice and increase trust about how their personal data is used for purposes beyond their direct care.[127]

People's levels of reticence towards sharing data varies with type of organisation the data is shared with (see Figure 2). Commercial companies delivering health services are mistrusted by the public as they question their motivations.[128] Nevertheless, over 60 per cent would "rather that commercial research organisations have access to health data than society miss out on the benefits these companies could potentially create."[129] The NHS and industry must show patients that they can responsibly and securely use data to benefit the wider population.

Figure 2: Attitudes towards data sharing for specific purposes in health



Source: Ipsos MORI, 'Public Attitudes to the Use and Sharing of Their Data', July 2014.

123 National Institute for Health and Care Excellence, *Data Science for Health and Care Excellence*.
124 Ibid.
125 Ipsos MORI, 'Public Attitudes to the Use and Sharing of Their Data', July 2014.
126 See glossary for definition.
127 See glossary for definition. National Data Guardian for Health Care, *Review of Data Security, Consent and Opt-Outs*, 2016.
128 *The One-Way Mirror: Public Attitudes to Commercial Access to Health Data* (Ipsos MORI, 2016).
129 Wellcome Trust, *Public Attitudes to Commercial Access to Health Data* (Wellcome Trust, 2016).

Reticence towards data sharing is also fostered by a lack of public trust on how data is handled and stored. Only 41 per cent of people trust their GP surgery to use their data appropriately and 35 per cent trust the wider NHS in this regard.[130] Key reasons for concerns surrounding data usage include the risk hackers pose, institutions using data for other reasons, data not being used for personal benefit, data loss and inaccurate record keeping.[131] Following the recommendations in *Growing the artificial intelligence industry in the UK*, the *Industrial Strategy* recommends the use of data trusts to facilitate easy and secure data sharing with industry.[132] Upholding the data protection principle of data minimisation and providing a secure environment in which there is transparency over who has accessed which piece of personal data and for what purpose will be crucial to increase trust.[133]

Interviewees for this paper highlighted that the failure of the Care.data project had a negative impact on the willingness of healthcare professionals to share data. It was a scheme that aimed to improve health outcomes by increasing the amount of data available for experts to study.[134] It failed because of the poor safeguards in place to protect confidentiality and due to poor communication with staff and patients about the benefits of data sharing.[135] Furthermore, GPs were unsure over their legal responsibilities and this led to poor engagement.[136] Legislation surrounding data sharing can be hard to navigate[137] as will be highlighted in section 6.1.2.2. However, as highlighted by the Centre for Excellence of Information Sharing, there are some definite cultural barriers which prevent data sharing. Healthcare professionals and organisations can be quite risk-averse.[138]

The creation of a secure and transparent environment with clarity and visibility over who accesses data for which purpose will be key for the well-functioning of data-sharing ecosystem. The following Chapter will consider what systemic barriers needs to be overcome to successfully embed AI in the NHS's service transformation plans.

130 Ipsos MORI, 'Public Attitudes to the Use and Sharing of Their Data'.
131 Ibid.
132 HM Government, *Industrial Strategy: Building a Britain Fit for the Future*, 40.
133 Bryce Goodman and Seth Flaxman, 'European Union Regulations on Algorithmic Decision-Making and a "Right to Explanation"', *Working Paper*, August 2016, 6.
134 Colin Marrs, 'Care.Data – An In-Depth Check-up on NHS England's Controversial Bid to Join up Health Data', *Civil Service World*, 18 September 2015.
135 Ibid.
136 Ibid.
137 Law Commission, *Data Sharing between Public Bodies*, 2014.
138 Defined by the Information Commissioners Office as "a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be, processed."

5
Overcoming system challenges

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Interviewees for this paper highlighted that enthusiasm for AI in healthcare should be contained at this early stage, as the NHS needs to consider the barriers to implementation. Two main challenges will be discussed in this Chapter: the availability of appropriate data on which AI systems can be developed and the certification of these systems.

5.1 Data

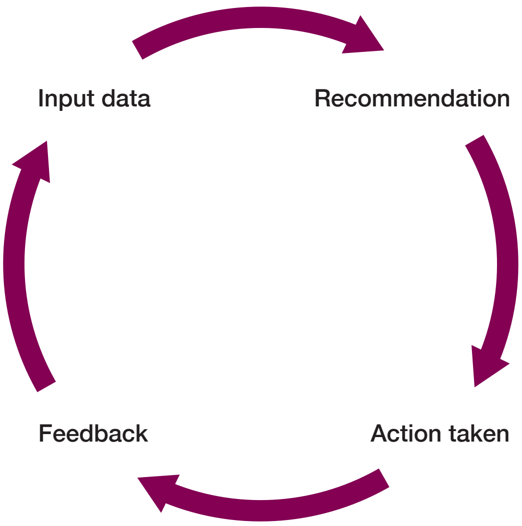
Sir Gordon Duff, former Chairman of the Medicine and Healthcare Products Regulatory Agency (MHRA) argues that "almost all conversations on AI quickly go back to data".[139] Getting data right is crucial for the increased adoption rate of this technology within the NHS. This means collecting the right type of data in the right format, increasing its quality and securely granting access to it.

5.1.1 Getting data right

5.1.1.1 Learning health systems

Data is the fuel of AI[140] as many algorithms learn by using examples found in the data that is used to train them.[141] However, it is important to note that not all AI systems have the same type of data requirements, some are more 'data-hungry' than others. Machine learning is a subset of AI that allows computer systems to learn by analysing huge amounts of data and drawing insights from it rather than following pre-programmed rules.[142] It requires a relatively specific type of data environment to function as illustrated in Figure 3. A feedback loop is necessary to learn, reinforce positive actions and not repeat negative ones, providing a 'virtuous circle' of data use, application and learning.

Figure 3: Virtuous circle of data and AI



Source: *Reform* interviews.

A common theme across the interviews for this paper was that the NHS does not currently provide the most amenable environment for this virtuous circle. In many cases, it would require collecting data in a new kind of way as the NHS does not currently collect data in this manner. However, this shift could enable "continuous and real-time improvement in both the effectiveness and efficiency of care."[143]

139 All-Party Parliamentary Group on Artificial Intelligence, *Ethics and Legal: Data Capitalism*, 2017, 10.
140 Clifton Leaf, 'The Real Limitations of Big Data', *Fortune*, 2 August 2017.
141 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*, 49.
142 The Economist Intelligence Unit, *Advanced Science and the Future of Government*.
143 Mark Smith et al., *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* (Institute of Medicine of the National Academies, 2012), 17.

5.1.1.2 Machine-friendly data

As highlighted by the *Life Sciences Industrial Strategy*, the most "important changes in healthcare will emerge with the increasing digitisation of a wide range of information."[144] This means moving away from paper systems and developing "a 'machine-friendly' data environment" meaning that data can be easily processed by a computer.[145] The NHS has still some way to go to achieve this as the government's healthcare digitisation agenda delivered patchy results.

The digitisation of primary care was successful supported by financial incentives from the Department of Health. Electronic Healthcare Records (EHRs) in primary care are now deployed universally.[146] In contrast, the digitisation of secondary care has been "far from smooth".[147] The system still relies heavily on paper files.[148] This limits the application of AI in secondary care.

Nevertheless, the Government's digitisation programme had some successes. Its legacy is the mandated use of a single national patient identifier, the NHS number,[149] which offers unique possibilities to link data across the healthcare system. In addition, it rolled out the Picture Archiving and Control System (PACS) across the NHS meaning that all X-ray images and reports are digital.[150] This is an extremely valuable resource for AI. The NHS is pursuing its efforts to digitise the healthcare system. In its report *Personalised Health and Care 2020*, it prioritised a paper-free NHS with fully interoperable health and social care records.[151] However, as highlighted in the Wachter Review these are potentially overly ambitious plans and these goals should be first reached at a regional level.

Recommendation 3

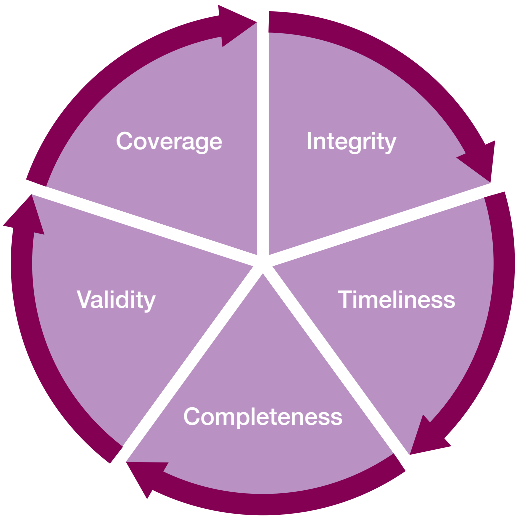
The NHS should pursue its efforts to fully digitise its data and ensure that moving forward all data is generated in machine-readable format.

5.1.1.3 Data-quality issues

The Academy of Medical Sciences highlights the importance of high-quality data for the accuracy of AI algorithms.[152] The quality of the input data will dictate the quality of the output or as the adage says: "garbage in garbage out".[153] Several factors affect the quality of healthcare data[154] as shown by Figure 4.

144 Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector*, 9.
145 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*.
146 Department of Health, *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England*, 15.
147 Ibid., 8.
148 Department of Health, *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England*.
149 Ibid.
150 Ibid., 11.
151 National Information Board, *Personalised Health and Care 2020: Using Data and Technology to Transform Outcomes for Patients and Citizens*.
152 The Academy of Medical Sciences, *Response the House of Commons Science and Technology Committee Inquiry into Algorithms in Decision-Making*.
153 William Warwicka et al., 'A Framework to Assess Healthcare Data Quality', *European Journal of Social and Behavioural Sciences* 13, no. 2 (2015): 1730.
154 DAMA UK, *The Six Primary Dimensions for Data Quality Assessment*, 2013; Data Services for Commissioners, *Data Quality Guidance for Providers and Commissioners* (NHS England, 2016); Nicole Gray Weiskopf and Chunhua Weng, 'Methods and Dimensions of Electronic Health Record Data Quality Assessment: Enabling Reuse for Clinical Research', *Journal of the American Medical Informatics Association* 20, no. 1 (1 January 2013): 144–51; Hong Chen et al., 'A Review of Data Quality Assessment Methods for Public Health Information Systems', *International Journal of Environmental Research and Public Health* 11, no. 5 (May 2014): 5170–5207.

Figure 4: Dimensions of data quality



Source: Adapted from Data Services for Commissioners, *Data Quality Guidance for Providers and Commissioners*, 6-7.

Inaccuracies in data-collection processes can affect the integrity of the data and occur for various reasons. An example can be found in the mechanisms for coding vital data, diagnostics and procedures used in primary care, known as Read-codes. They are like a coded thesaurus of clinical terms. Although, Read-codes will be retired and replaced by a single terminology, SNOMED CT,[155] a lack of standardisation of Read-codes across IT systems can have an impact on the integrity of data. Read-code differences, caused by differences in coding by clinicians,[156] have a large impact on the quality of the data available for research. The literature has highlighted that "code set differences could induce nearly a sevenfold difference in estimates of the incidence of rheumatoid arthritis."[157] The replacement of Read-codes by a single terminology system will not solve the issue of misclassification and inaccuracies in legacy data.[158] This could have a negative impact on the findings produced by AI algorithms using historic data.

Data quality can also be affected by the timeliness of the data entry. All information entered into an IT system is timestamped. These timestamps are used by algorithms in numerous ways. In other words, it is important that information is recorded at the time of the event, and not delayed.[159]

Coverage and completeness of information can also impact data quality. Within the NHS, coverage relates to the degree "to which data have been received from all expected data suppliers".[160] For example, this can relate to the proportion of GPs who submit data to NHS Digital for the Quality and Outcomes Framework. Completeness relates to certain variables, such as gender, age or other, not having any missing values. In some datasets, it might not be a mandatory requirement to collect such information, which means that they might be affected by a high number of missing values. This can be problematic for

155 National Information Board, *Personalised Health and Care 2020: Using Data and Technology to Transform Outcomes for Patients and Citizens*.
156 Wendy Rollason, Kamlesh Khunti, and Simon de Lusignan, 'Variation in the Recording of Diabetes Diagnostic Data in Primary Care Computer Systems: Implications for the Quality of Care', *Informatics in Primary Care* 17, no. 2 (October 2009); Simon de Lusignan et al., 'Call for Consistent Coding in Diabetes Mellitus Using the Royal College of General Practitioners and NHS Pragmatic Classification of Diabetes', *Informatics in Primary Care* 20, no. 2 (February 2012); Samuel Seidu et al., 'Prevalence and Characteristics in Coding, Classification and Diagnosis of Diabetes in Primary Care', *Postgraduate Medicine Journal* 90, no. 1059 (2014).
157 Richard Williams et al., 'Clinical Code Set Engineering for Reusing EHR Data for Research: A Review', *Journal of Biomedical Informatics* 70, no. 1 (June 2017): 2.
158 de Lusignan et al., 'Call for Consistent Coding in Diabetes Mellitus Using the Royal College of General Practitioners and NHS Pragmatic Classification of Diabetes', 109.
159 Data Services for Commissioners, *Data Quality Guidance for Providers and Commissioners*, 7.
160 Ibid., 6.

the accuracy and fairness of AI algorithms.[161] In other contexts, coverage and completeness of data often relate to the representativeness of the sample. This is of crucial importance for the accuracy of AI algorithms as they can be more prone to error on sub-populations that have low representation within a sample.[162]

5.1.1.4 Increasing data quality

The NHS recognises that high-quality data is not optional and should be at the centre of every organisation.[163] Actions need to be taken to ensure this vision gets put into practice. Good quality data is crucial for AI algorithms to produce accurate results.

The design of data-collection systems and their user-friendliness can have an impact on the quality of data.[164] As highlighted in the Wachter review, "without user-centred design" IT systems have been shown to create "opportunities for new types of error".[165] IT systems should not create an extra burden for the user and should be intuitive enough that no intensive training is required. Currently, this is not the case.

Interviewees for this paper also highlighted the importance of interface design and having a rigorous understanding of human-computer interaction as a way of creating user-friendly data collection software.[166] The "less onerous and more user-friendly you make the data collection process, the more you decrease the chances of getting bad data" as highlighted by an interviewee for this paper.

Better designed IT systems that have a greater focus on data visualisation "can reveal data quality problems",[167] which can then be corrected. This view was shared by many interviewees for this paper who suggested that intelligent data-collection systems could flag up errors or inconsistencies as data is being collected. This would allow the user to immediately see the problem and correct it, thus increasing data quality.

Monitoring data quality and being aware of the limitations of datasets are extremely important. NHS Digital produces a Data Quality Maturity Index which aims to do just that, however, it depends on voluntary data submissions.[168] This means there is no consistent oversight of the quality of data collected by primary and secondary-care providers.

Recommendation 4

NHS England and the National Institute for Health and Care Excellence should consider including the user-friendliness of IT systems in the procurement process of data collection systems and favour intelligent systems that flag-up errors in real-time.

Recommendation 5

NHS Digital should make submissions to the Data Quality Maturity Index mandatory, to have a better monitoring of data quality across the healthcare system.

161 Michael Veale and Reuben Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data', *Big Data & Society* 4, no. 2 (December 2017): 2.
162 Osonde Osoba and William Welser IV, *An Intelligence in Our Image: The Risks of Bias and Errors in Artificial Intelligence* (RAND Corporation, 2017), 19; Veale and Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data', 2; Moritz Hardt, 'How Big Data Is Unfair', *Medium* (blog), 26 September 2014.
163 NHS Digital, *SUS Essentials Secondary Uses Service – Essential User Guide*, 2016, 6.
164 Department of Health, *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England*, 32.
165 Ibid.
166 Vimla L. Patel and Thomas G. Kannampallil, 'Cognitive Informatics in Biomedicine and Healthcare', *Journal of Biomedical Informatics* 53, no. Supplement C (February 2015).
167 Shneiderman, Plaisant, and Hesse, 'Improving Healthcare with Interactive Visualization', 61.
168 NHS Digital, 'Improving Data Quality Assurance', Webpage, 9 May 2017.

5.1.2 Access to data

The ease of access to NHS data is context dependent, meaning that access might be more or less difficult depending on the type of data that is needed and for what purpose. The linking of data sources can be difficult as there can be both technical and legal barriers. This section will highlight these barriers and the solutions that have emerged to address them.

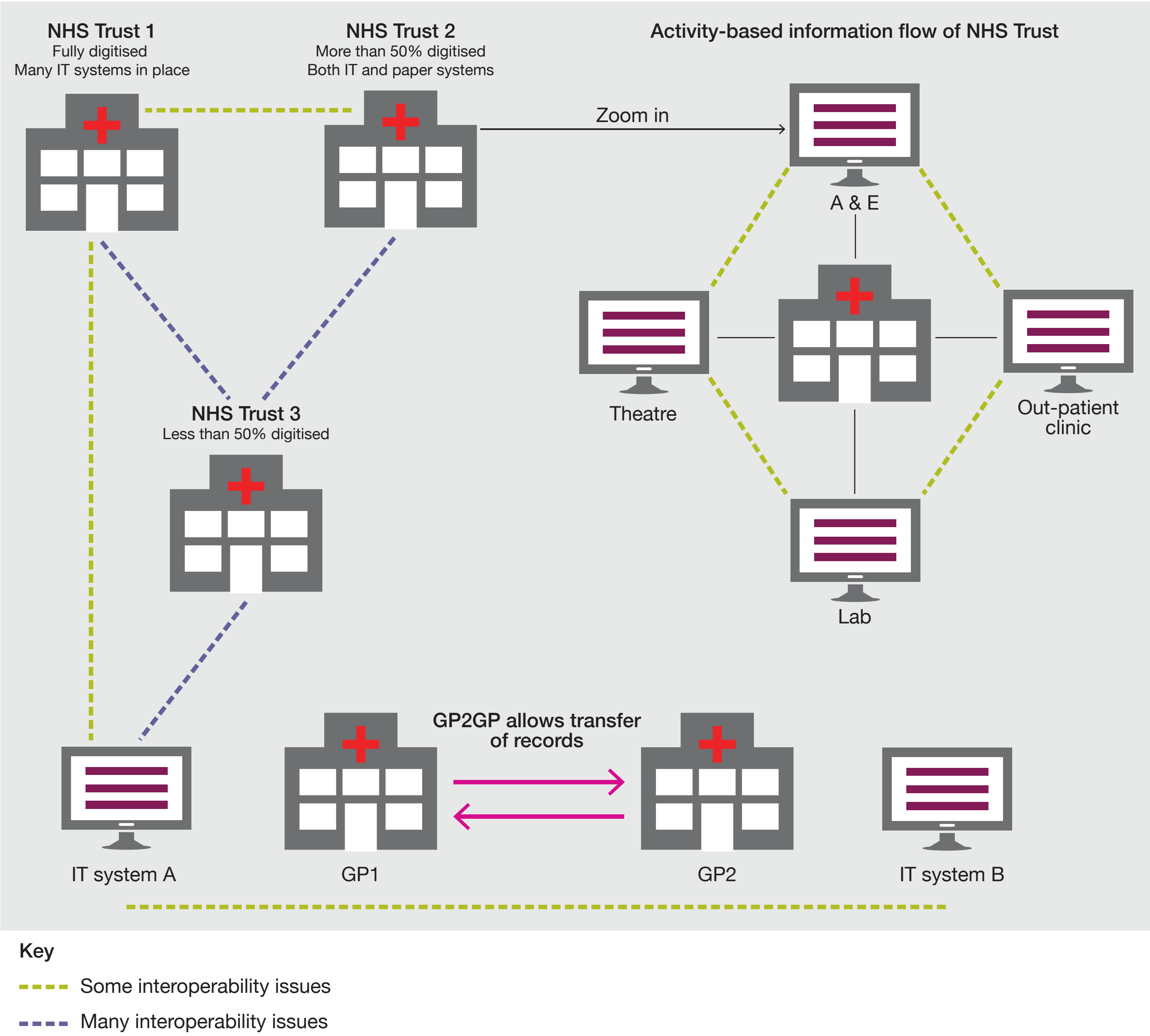
5.1.2.1 Linking data

The Law Commission argues that linking data together "unearths correlations that would otherwise remain invisible and thereby helps tackle multi-dimensional challenges."[169] The Central New York Care Collaborative integrated more than 75 electronic health record systems for their "cognitive population health platform".[170] The linking of the health and social-care records helped to build "holistic patient insights incorporating clinical history, social determinants, and behavioural health."[171] This allowed the AI platform to identify high-risk individuals and engage them with their health by providing care plans.[172]

One of the main technical barriers to linking data sources together is the lack of interoperability of IT systems in healthcare – defined as "the ability of systems to exchange and use electronic health information from other systems without special effort on the part of the user."[173] Figure 5[174] highlights some the interoperability issues within and between healthcare stakeholder organisations. For example, secondary-care trusts use a range of different IT systems which collect and store information about different types of activities, such as imaging, A&E and in-patient admissions. The different IT systems do not always properly communicate with each other – meaning the process of linking data is more cumbersome.

169 Law Commission, *Data Sharing between Public Bodies*, 5.
170 Christine Douglass, 'Central New York Care Collaborative (CNYCC) Chooses IBM Watson Care Manager to Improve Health Across the Region', Press Release, IBM, 20 February 2017.
171 Ibid.
172 Ibid.
173 Department of Health, *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England*, 49.
174 It is not meant to be a perfect depiction of reality, but a high-level representation of some of the issues.

Figure 5: Interoperability issues



Source: *Reform* interviews.

Solutions to interoperability issues are starting to emerge. In the short term, interoperability standards for the exchange of healthcare information such as Fast Healthcare Interoperability Resources (FHIR)[175] which enables "the exchange, integration, sharing and retrieval of electronic health information",[176] should be used. Looking forward, adherence to open standards will be crucial to ensure the interoperability of IT systems. The NHS recognises this and highlights that the focus of interoperability strategies should be on creating an "open environment for information sharing".[177] Open standards were strongly supported by interviewees for this paper as a solution to interoperability issues and to general problems with the data architecture of the NHS. Greater interoperability of healthcare IT would allow for compliance with the EU's General Data Protection Regulation principle of data portability.[178] This means that "patients have a right to take

175 NHS England, *Interoperability Handbook*, 2015, 29.
176 Margaret Rouse, 'What Is FHIR (Fast Healthcare Interoperability Resources)?', *SearchHealthIT*, 30 October 2017.
177 NHS England, *Interoperability Handbook*, 9.
178 Jennifer Trueland, 'Special Report: Interoperability', *Digital Health*, 22 November 2017.

their data with them between different organisations – meaning that these health bodies will have to make sure that they can a) find the information, and b) make it available in a transparent format."[179]

The conversation around the linking of data in the NHS should not remain confined to the data that already exists and is routinely collected. It is also crucial to acknowledge the opportunity offered by linking health and care data with data from personal devices and technologies (such as apps on smartphones, wearables, sensors in the home and medical devices). As highlighted in section 4.1.1, wearable devices offer the possibility for a new type of data to be collected. Data is often continuous, instead of being collected at a given point in time. In addition, it would reflect the state of the patient when they are away from a care setting. Linking this new information with that currently collected in the system could present many opportunities for AI and the furthering of medical knowledge.

Recommendation 6

In line with the recommendation of the Wachter review, all healthcare IT suppliers should be required to build interoperability of systems from the start allowing healthcare professionals to migrate data from one system to another. This would allow for compliance with the EU's General Data Protection Regulation principle of data portability.

Recommendation 7

NHS Digital should commission a review seeking to evaluate how data from technologies and devices outside of the health-and-care system, such as wearables and sensors, could be integrated and used within the NHS.

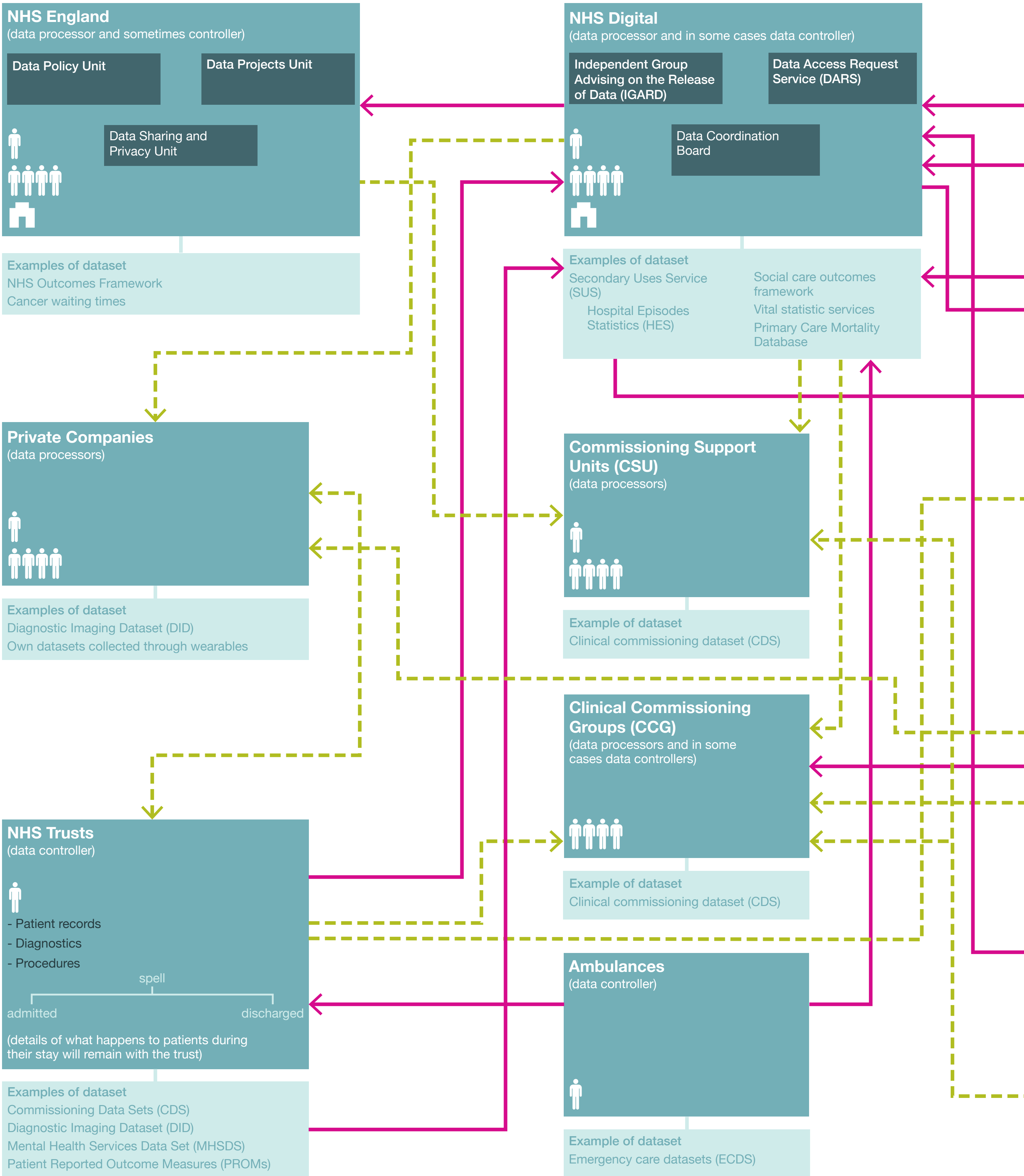
5.1.2.2 Confusing data flows

As highlighted in the Government's Review, *Growing the Artificial Intelligence Industry in the UK*, organisations trying to deal with the NHS to access data find it is an "unfathomable task".[180] This is not only due to the issues addressed in the previous sections, but also due to the fact that it can be confusing for them to understand where is the data they would like to access and who they need to speak with to gain access.[181]

Figure 6 depicts part of the complexity organisations face when trying to understand the information flows within the NHS. It is not meant to be a perfectly accurate description of reality, as it does not capture regional and actor-level variation. Rather, it is designed to show the stakeholders within the healthcare system, the type of information they collect, the type of information that they share with the rest of the system and the type of information which is not shared, to give an insight into the confusion felt by those needing access to linked datasets.

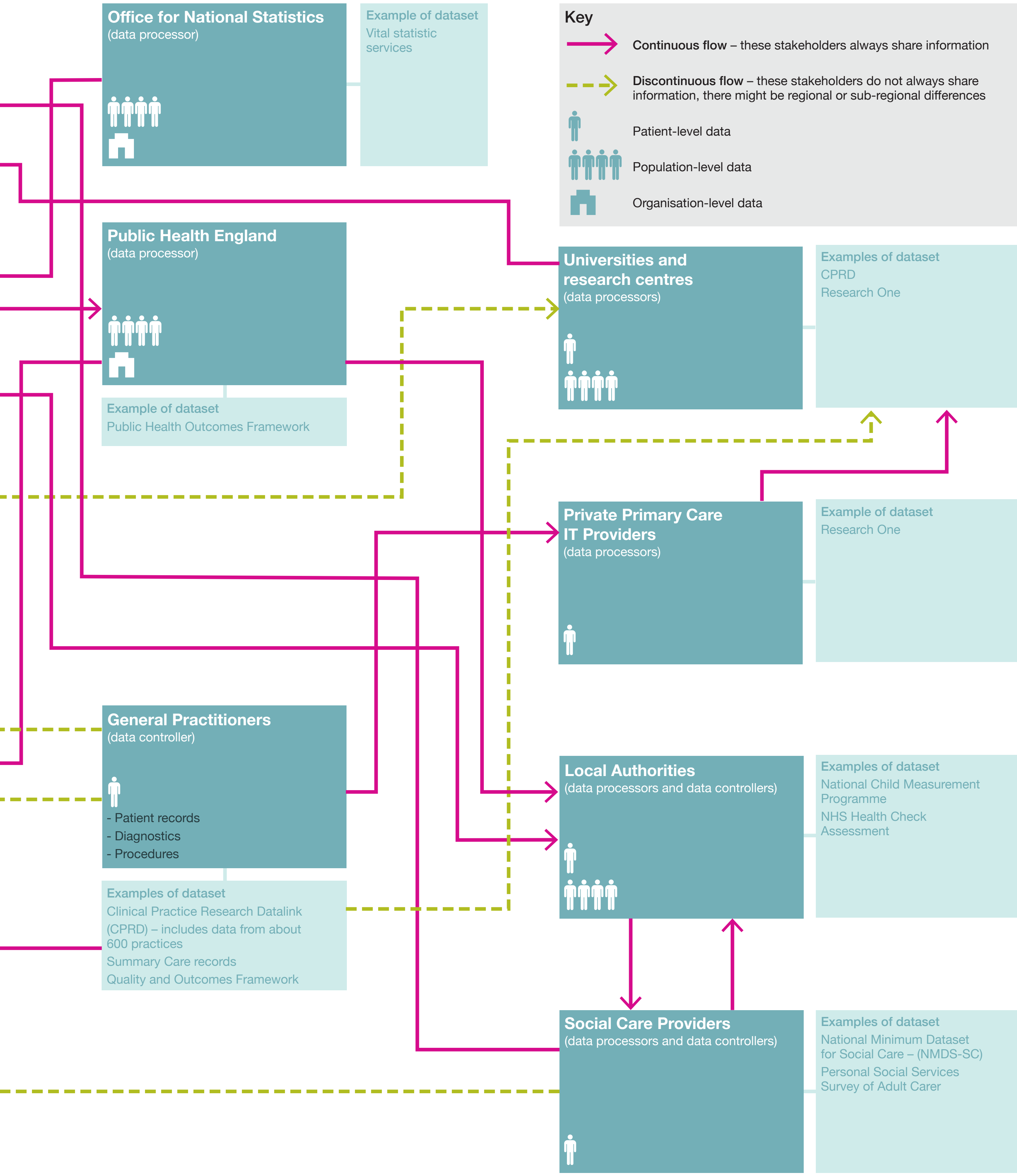
179 Ibid.
180 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*, 44.
181 Ibid.

Figure 6: Data flows within the NHS



Note: This data flow map is not a perfectly accurate depiction of reality. It does not take into account regional variations and various other local particularisms. It is meant to give a general overview of the data flows within the NHS.

Source: *Reform* interviews and research.


Office for National Statistics
(data processor)
Example of dataset
Vital statistic services
Key
Continuous flow – these stakeholders always share information
Discontinuous flow – these stakeholders do not always share information, there might be regional or sub-regional differences
Patient-level data
Population-level data
Organisation-level data
Public Health England
(data processor)
Example of dataset
Public Health Outcomes Framework
Universities and research centres
(data processors)
Examples of dataset
CPRD
Research One
Private Primary Care IT Providers
(data processors)
Example of dataset
Research One
General Practitioners
(data controller)
- Patient records
- Diagnostics
- Procedures
Examples of dataset
Clinical Practice Research Datalink (CPRD) – includes data from about 600 practices
Summary Care records
Quality and Outcomes Framework
Local Authorities
(data processors and data controllers)
Examples of dataset
National Child Measurement Programme
NHS Health Check Assessment
Social Care Providers
(data processors and data controllers)
Examples of dataset
National Minimum Dataset for Social Care – (NMDS-SC)
Personal Social Services Survey of Adult Carer

5.1.2.3 Legal barriers?

Accessing healthcare data can be complex due to the legal and information governance (IG) frameworks. As highlighted in section 5.2, how healthcare data is used and governed is a growing concern for the public.[182] IG provides the frameworks to alleviate these concerns and guidance as to what can be done with different types of data and for what purpose.[183] IG is highly intertwined with what the public feels about how their personal data should be used and societal values.[184]

Different types of patient data (i.e. identifiable to anonymised) come with different implications for the duties and responsibilities of data controllers[185] and processors.[186] Some types of patient data are easier to access than others (see Figure 7).

Figure 7: Data type and consent needed

Data type	Definition	Consent needed
Identifiable data	Any data that could potentially identify a specific individual, either on its own or combined with other information	Requires the explicit consent of the patient to be shared for other purposes than direct patient care
De-personalised data	Data that is stripped from identifiers e.g. name, address, postcode, NHS number or date of birth, and replaced by one or more artificial identifiers, or pseudonyms	No need to obtain consent, as long as there is no likelihood of the data causing unwarranted damage or distress
Anonymous data	Data that does not itself identify any individual and that is unlikely to allow any individual to be identified through its combination with other data	No need to obtain consent, as long as there is no likelihood of the data causing unwarranted damage or distress

Source: *Understanding patient data brief*, April 2017

The NHS's IG framework is very complex and stems from various international information security standards, EU, UK and NHS-specific legislations and codes of practices (see Appendix Figure 8). The Law Commission has highlighted that IG and legislation surrounding data sharing has been described as hard to navigate.[187] This was also echoed by interviewees for this paper. However, as highlighted by the Centre for Excellence of Information Sharing, some of these barriers are more due to a culture of risk-aversion rather than real legal barriers.

Solutions should be developed to facilitate the navigation of the NHS's IG frameworks to help stakeholders be more risk-aware and not risk-averse. The Industrial Strategy announced the creation of new bodies that might help overcome these IG barriers such as Data Trusts and the Centre for Data Ethics and Innovation. However, the Government should clarify the exact remit of these institutions as it is unclear what the difference will be between the role of the Centre for Data Ethics and that of the Information Commissioner's Office.[188]

182 Benedict Rumbold, Geraint Lewis, and Martin Bardsley, 'Access to Person-Level Data in Health Care', *Nuffield Trust*, 2011.
183 NHS England, *Information Governance Policy*, 2016, 6.
184 Rumbold, Lewis, and Bardsley, 'Access to Person-Level Data in Health Care'.
185 The Information Commissioner's Office defines a data controller as a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be, processed.
186 The Information Commissioner's Office defines data processor as any person (other than an employee of the data controller) who processes the data on behalf of the data controller.
187 Law Commission, *Data Sharing between Public Bodies*.
188 Daniel Zeichner, 'Data Will Change the World, and We Must Get Its Governance Right', *The Guardian*, 15 December 2017.

Currently, the access and linking of existing NHS datasets is made difficult by the lengthy processes in place for access.[189] Interviewees highlighted that more datasets should be made readily available with faster approval processes or even in an open source manner. These pseudonymised training datasets would allow the development of more effective AI algorithms, which would in turn allow for the delivery of better care. Encouragingly, Simon Stevens has announced that NHS England is working with NHS Digital to identify three to four regional 'data innovation hubs' each covering 3 to 5 million people.[190] The hubs are to "share anonymous and identifiable patient data regionally, and in some cases nationally, for direct care and care improvements."[191] *The Life Sciences Industrial Strategy* also supports this view as it recommends digitising and making available training datasets for pathology images.[192]

Recommendation 8

NHS Digital, the National Data Guardian and the Information Commissioner's Office, in partnership with industry, should work on developing a digital and interactive solution, such as a chatbot, to help stakeholders navigate the NHS's data flow and information governance framework.

Recommendation 9

NHS Digital should create a list of training datasets, such as clinical imaging datasets, which it should make more easily available to companies who want to train their AI algorithms to deliver better care and improved outcomes. It should also develop a specific framework specifying the conditions to securely access this data.

5.2 Building AI algorithms

There are many ethical questions surrounding the applications of AI in healthcare. Some concern the building of AI systems, who should bear the costs and reap the benefits; others focus on safety and the certification procedures for AI.

5.2.1 Who builds them and who reaps the value?

The NHS could benefit from investing in AI and develop its own AI unit for example, within NHS Digital. As highlighted previously, the development of AI systems is expensive, but the scaling is cheap. However, given the NHS's budgetary constraints this solution seems unlikely. The NHS will thus have to find ways to benefit from public-private partnerships.

NHS data is a hugely valuable asset.[193] This has fostered a lot of debate over who should reap the economic benefits of products that would not have seen the light of day without the use of patients' data.[194]

The *Life Science Industrial Strategy* outlines that most NHS data-sharing agreements have been completed locally, predominantly by powerful larger companies that may not share profits equitably.[195] The strategy promotes a clear "framework to better realise the true value for the NHS of the data at a national level".[196] The Government's Review, *Growing the Artificial Intelligence Industry in the UK*, also highlights the role that Data

189 NHS Digital, 'Data Access Request Service (DARS)', Webpage, 22 January 2015; NHS Digital, 'DARS Process', Webpage, 17 December 2015.
190 Heather, 'NHS England Will Invest in Artificial Intelligence, Says Stevens'.
191 Ibid.
192 Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector*, 17.
193 The Economist, 'The World's Most Valuable Resource Is No Longer Oil, but Data', 6 May 2017.
194 Christina Aperjis and Bernardo A. Huberman, 'A Market for Unbiased Private Data: Paying Individuals According to Their Privacy Attitudes' (Rochester, NY: Social Science Research Network, 2012); Jathan Sadowski, 'Companies Are Making Money from Our Personal Data – but at What Cost?', *The Guardian*, 31 August 2016; Billy Ehrenberg, 'How Much Is Your Personal Data Worth?', *The Guardian*, 22 April 2014.
195 Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector.*
196 Ibid.

Trusts Support Organisations could have in making sure there is a trusted framework of data sharing that is “secure and mutually beneficial” for those wanting to share and use data.[197] This includes agreements on the conditions upon which commercial value should be generated from data.[198]

If industry is to use NHS data to design AI, as it does now, the NHS should make sure that it can reap the benefits in the long term. Government should explore mutually beneficial arrangements such as profit and risk-sharing agreements.

Recommendation 10

The Department of Health and the Centre for Data Ethics and Innovation should build a national framework of conditions upon which commercial value is to be generated from patient data in a way that is beneficial to the NHS. The Department of Health should then encourage NHS Digital to work with STPs and trusts to use this framework and ensure industry acts locally as a useful partner to the NHS.

5.2.2 Certification of AI

Regulation of AI is a thorny issue. Some feel that regulation would stifle innovation[199] whilst others strongly advocate that the public and government should not simply view these tools as “just machines processing cold numbers”[200] without paying attention to their fallibility and biases. It is crucial to highlight that “a great deal of subjective human labour is involved in system design and deployment”[201] of AI systems. Healthcare is a high-risk area, where the impact of a mistake could have profound consequences on a person’s life.[202] Public safety and ethical concerns relating to the usage of AI in the NHS should be a central concern for healthcare regulators such as NICE, the MHRA and Government.

5.2.2.1 Verification and validation

Herbert Simon argued that “we must make sure, in AI design and application, that it serves reliably the desired purposes.”[203] This means that methods must be put in place to “verify that the system is functioning correctly.”[204] It is critical that people developing AI algorithms be able to prove, test and validate the accuracy and performance of their algorithms. In addition, as highlighted by the Science and Technology Committee, preventing unwanted or unpredictable behaviours should be one of the goals of the verification and validation procedure.

Fox and Das, follow Boden’s model, and highlight that there are four main reasons why intelligent agents might have hazardous or “unintended side effects”:[205]

> An agent’s knowledge base might be wrong or biased. This mostly relates to the quality of the input data.

> Even if the knowledge base is correct the “inferences drawn from it maybe be wrong”[206] because the inference procedure is unsound. This relates to the possibility of a technical flaw in the AI algorithm.

> Even if the knowledge base is correct the agent’s reasoning might not be able to adapt “when presented with unusual contingencies”.[207]

197 Hall and Pesenti, *Growing the Artificial Intelligence Industry in the UK*.
198 Ibid.
199 Andrea O’Sullivan, ‘Don’t Let Regulators Ruin AI’, *MIT Technology Review*, 24 October 2017.
200 Cathy O’Neil, *Weapons of Math Destruction* (New York: Crown, 2016), 20.
201 Hardt, ‘How Big Data Is Unfair’.
202 Michael Anderson and Susan Leigh Anderson, ‘Ethical Healthcare Agents’, in *Advanced Computational Intelligence Paradigms in Healthcare – 3*, Ed. Margarita Sordo, Sachin Vaidya (Berlin: Springer, 2008), 233.
203 John Fox and Subrata Das, *Safe and Sound: Artificial Intelligence in Hazardous Applications* (Cambridge, Massachusetts: American Association for Artificial Intelligence Press and MIT Press, 2000),x.
204 House of Commons Science and Technology Committee, *Robotics and Artificial Intelligence, Fifth Report of Session 2016–17*, 16.
205 Fox and Das, *Safe and Sound: Artificial Intelligence in Hazardous Applications*, 132.
206 Ibid.
207 Ibid.

- The decision criteria built into the system "may not be universally acceptable".[208] For example, given the input data the AI algorithm might recommend certain medical procedures that could end up having "a side effect that is unacceptable to the patient."[209]

The authors highlight that it is not sufficient to prove that AI algorithms are "technically sound",[210] but it is vital to understand how it deals with "hazards that might arise unexpectedly".[211] This highlights the importance of truly stress-testing these systems before applying them in healthcare.

The UK's regulatory framework in healthcare acknowledges that "all medical treatments or approaches come with an element of risk"[212] and that regulation should "ensure an acceptable level of risk in proportionate manner without stifling innovation".[213] Currently, the MHRA provides guidelines and medical directives that all developers of healthcare algorithms and apps need to comply with. Some interviewees felt that many current regulatory procedures for medical devices could be used for the regulation of AI algorithms without need for too much adaptation.

However, AI algorithms can sometimes differ from other forms of medical software or devices.[214] Firstly, their degree of autonomy may vary compared to other medical devices.[215] Is their purpose to make a clinical decision or is it to provide advice to a medical practitioner or patient? Currently, AI algorithms are considered as decision support tools, thus simply providing advice instead of making clinical decisions on behalf of doctors. However, this might change in the future, as their diagnostic accuracy rates surpass those of humans in certain medical fields, as shown in the Chapter 4.

Secondly, AI algorithms differ from existing forms of medical devices as they continuously evolve. Some algorithms, also known as 'online' or 'live' algorithms, are not immutable. These will continuously update with new data.[216] This presents a greater regulatory challenge than offline AI algorithms that are trained on a dataset and are then fixed once the training is done.[217] Developing a continuous monitoring system would be necessary to ensure that with new data inputs the safety of the patient is protected and the quality of care does not deteriorate.[218] The US Food and Drugs Administration (FDA) has recently approved the first cloud-based online deep learning algorithm (see glossary) in healthcare.[219] The medical imaging platform is meant to help doctors diagnose heart conditions.[220] The FDA approval process included amongst other things that the deep neural nets could "produce results at least as accurately as humans are currently able to".[221]

Currently most clinical software falls into class 1 (see Appendix Figure 9), which is subject to only light touch regulation.[222] Developers are required to self-declare if they are compliant with a list of requirements to get the CE marking. However, understanding where many decision-support tools fit within the current purpose-oriented regulatory framework of medical devices is not straightforward. As Luxton highlights "rapidly changing technology can get ahead…and thus laws and guidelines have to catch up with technology."[223]

208 Ibid., 133.
209 Ibid.
210 Ibid., 167.
211 Ibid.
212 The British Academy, 'Algorithms, Data and Regulation Workshop – Summary Note', 23 March 2017.
213 Ibid.
214 Ibid.
215 Ibid.
216 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*, 20.
217 Ibid.
218 The British Academy, 'Algorithms, Data and Regulation Workshop – Summary Note'.
219 Bernard Marr, 'First FDA Approval For Clinical Cloud-Based Deep Learning In Healthcare', *Forbes*, January 2017.
220 Arterys, 'Medical Imaging Cloud Platform', Webpage, 2017.
221 Marr, 'First FDA Approval For Clinical Cloud-Based Deep Learning In Healthcare'.
222 The British Academy, 'Algorithms, Data and Regulation Workshop – Summary Note'.
223 David D. Luxton, 'Recommendations for the Ethical Use and Design of Artificial Intelligent Care Providers', *Artificial Intelligence in Medicine* 62, no. 1 (September 2014): 1.

Interestingly, the FDA has recently assembled a team to "oversee and anticipate future developments in AI-driven medical software."[224] The MHRA should follow in the FDA's steps and create such a team to provide clarity as to the verification and validation process of AI systems in healthcare. As highlighted by interviewees there is a need for clarity in terms of what the certification would include (i.e. testing protocols, discrimination test, data pre-processing protocols, training data). Currently, FDA approval for machine learning systems analysing medical imaging includes: information about the algorithm and its training, information on the features analysed and the model and classifiers used.[225]

Recommendation 11

The Medicine and Healthcare Products Regulatory Agency and NHS Digital should assemble a team dedicated to developing a framework for the ethical and safe applications of AI in the NHS. The framework should include what type of pre-release trials should be carried out and how the AI algorithms should be continuously monitored.

5.2.2.2 Transparency and explainability

The transparency and interpretability of AI algorithms is important for their verification and validation as it allows for better scrutiny. Transparency can relate to the 'technical transparency' of AI algorithms. In other words, understanding how the AI system is making sense of input data. This can be difficult depending on the selected technique. The more complex the AI methods the harder it is to interpret.[226] The Royal Society has highlighted that "many machine learning systems are 'black box'".[227] Although it is possible to verify the statistical reliability of the results produced by AI algorithms, it may not always be possible to explain how these results have been generated.[228] This inherent opacity relates to deep learning neural nets.[229] However, it is important to highlight that not all AI algorithms are inherently opaque. In addition, research is currently advancing to make these 'black box' algorithms less opaque, with researchers in natural language processing trying to develop algorithms that can write rationales for the decision they have made.[230] Research has also come up with ways to provide explanations for the decisions made by AI algorithms without having to open-up the black box.[231]

Transparency can also relate to the disclosure of the 'code' underpinning the algorithm. This type of transparency might be problematic in terms of the commercial sensitivity or intellectual property law. However, it is important that during the certification procedure sufficient information be given about the AI algorithm so that it can be appropriately stress-tested. Some interviewees suggested that making algorithms explainable might be more important than achieving transparency. However, standard machine learning algorithms have "no concern for causal reasoning or "explanation" beyond the statistical sense in which it is possible to measure the amount of variance explained by a predictor."[232] This means that it is not yet technically possible to really answer the question of why an algorithm reached a certain decision.

224 Jeremy Hsu, 'FDA Assembles Team to Oversee AI Revolution in Health', *IEEE Spectrum*, 29 May 2017.
225 Editorial Team, 'FDA's Next Frontier: Regulating Machine Learning in Clinical Decision Support Software', *InsideBIGDATA*, 18 March 2017.
226 Goodman and Flaxman, 'European Union Regulations on Algorithmic Decision-Making and a "Right to Explanation"', 6.
227 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*, 93.
228 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*; Sandra Wachter, Brent Mittelstadt, and Chris Russell, *Counterfactual Explanations Without Opening the Black Box: Automated Decisions and the GDPR* (Rochester, NY: Social Science Research Network, 2017).
229 Information Commissioner's Office, *Big Data, Artificial Intelligence, Machine Learning and Data Protection*, 2017, 10.
230 Gunning, 'Explainable Artificial Intelligence'; Cliff Kuang, 'Can A.I. Be Taught to Explain Itself?', *The New York Times*, 21 November 2017.
231 Wachter, Mittelstadt, and Russell, *Counterfactual Explanations Without Opening the Black Box: Automated Decisions and the GDPR*.
232 Goodman and Flaxman, 'European Union Regulations on Algorithmic Decision-Making and a "Right to Explanation"', 6.

Recommendation 12

NHS Digital, the Medicines and Healthcare Products Regulatory Agency and the Caldicott Guardians should work together to create a framework of 'AI explainability'. This would require every organisation deploying an AI application within the NHS to explain clearly on their website the purpose of their AI application (including the health benefits compared to the current situation), what type of data is being used, how it is being used and how they are protecting anonymity.

5.2.2.3 Minimising bias

As highlighted by Mittelstadt et al., one of the ethical concerns that can arise from the use of algorithms is that evidence is inscrutable.[233] This means that there is lack of knowledge about the data being used, how it has been pre-processed and how the algorithm has used it to reach its conclusion which limit the possibility of understanding algorithmic decision-making. The process of cleaning and transforming data before use implies many subjective decisions which will have an impact on the output of AI algorithms.[234]

The disclosure of the data pre-processing procedure and training data used are important principles to take into account in the context of healthcare. A careless approach to AI in healthcare could further entrench healthcare inequalities through the reinforcement of biases found in healthcare data.[235] The goal is to use AI to tackle challenges such as variations in healthcare outcomes not make them worse.

Debiasing data can be extremely difficult.[236] It would require correcting for sampling disparities for example which is not an easy feat. Every decision to correct biases carries its load of subjectivity. However, techniques have been developed to detect and prevent biases from occurring in machine learning methods.[237] Furthermore, some of these approaches allow for the detection of bias without holding sensitive data about individuals.[238] Implementing these methods might have a positive impact on the external validity of these AI systems, meaning that a system trained on data from hospital A might provide accurate results for hospital B.

Recommendation 13

The Medicine and Healthcare Products Regulatory Agency should require as part of its certification procedure access to: data pre-processing procedures and training data.

Recommendation 14

The Medicine and Healthcare Products Regulatory Agency Review in partnership with NHS Digital should design a framework for testing for biases in AI systems. It should apply this framework to testing for biases in training data.

5.2.2.4 Accountability

Given the current state of technology the applications of AI in medical decision-making are described as augmenting a doctor's cognitive capacities, not replacing them.[239] They are decision-support tools, not agents making decisions for people. This means that currently, accountability and legal liability remains on the doctor's shoulders. In case of a

233 Brent Daniel Mittelstadt et al., 'The Ethics of Algorithms: Mapping the Debate', *Big Data & Society* 3, no. 2 (November 2016): 4.
234 Veale and Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data', 2.
235 Robert Hart, 'If You're Not a White Male, Artificial Intelligence's Use in Healthcare Could Be Dangerous', *Quartz*, 10 July 2017.
236 Hardt, 'How Big Data Is Unfair'; Osoba and Welser, *An Intelligence in Our Image: The Risks of Bias and Errors in Artificial Intelligence*, 19.
237 Veale and Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data', 3; Katie Cramer, 'How Can We Reveal Bias in Computer Algorithms?', *The Regulatory Review*, 10 October 2017.
238 Veale and Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data', 5.
239 Marr, 'First FDA Approval For Clinical Cloud-Based Deep Learning In Healthcare'.

failure, current regulatory frameworks set out by the MHRA should be followed. Nevertheless, it is important to be aware of the fact that "clinical staff can be influenced by a machine's recommendation, even against their judgement."[240] This can be hugely problematic in cases where the machine makes a wrong recommendation. Clear guidelines should be established as to how medical staff is to interact with AI tools, machine should be seen as decision-support tools.

Recommendation 15

Tech companies operating AI algorithms in the NHS should be held accountable for system failures in the same way that other medical device or drug companies are held accountable under the Medicine and Healthcare Products Regulatory Agency framework.

Recommendation 16

The Department of Health in conjunction with the Care Quality Commission and the Medicine and Healthcare Products Regulatory Agency should develop clear guidelines as to how medical staff is to interact with AI as decision-support tools.

240 The British Academy, 'Algorithms, Data and Regulation Workshop – Summary Note'.

Conclusion

AI presents a great opportunity to help the NHS deliver its service transformation plans. It could help narrow the gaps identified in the *Five Year Forward View* by increasing the quality of care, helping the NHS move from a system focused on acute care to one that focuses on prevention and improving patient outcomes.[241] It could also make processes within the healthcare system more efficient and reduce costs. The NHS must consider gradually embedding this technology in future service transformation plans.

Nevertheless, the NHS "has a long way to go before AI can be effectively leveraged".[242] Both buy-in from patients and healthcare professionals needs to improve. This will be a factor of time for people to trust this technology and will also partly depend on the AI interface design and explainability. Increasing the user-friendliness and having a clear understanding of human-computer interaction can influence the adoption rate of this technology amongst healthcare professionals.

As highlighted by Matthew Swindells, National Director for Operations and Information at NHS England, one of the main barriers to the implementation of AI systems in healthcare is the "lack of access to 'good quality data'". The NHS needs to move forward with its digitisation agenda, increase the interoperability of its current IT systems and make sure that in the future they all adhere to open standards. It should also develop a plan for the integration of new forms of data generated by wearables and sensors at home. AI is not the panacea for these back-end implementation challenges and it will not be possible to reap the benefits of this technology at scale if these barriers are not overcome.

It is crucial that the Department of Health creates a framework to ensure the NHS enters into truly mutually beneficial agreements with the private sector developing these AI systems. It must safeguard the NHS from unfair situations where private companies could charge extremely high fees for the use of algorithms that would have never been developed without the use of NHS patient data.

The MHRA will also have to update its certification procedures as new AI tools based on machine learning techniques present challenges for current regulation. They are very different from 'old-school' AI such as expert systems (see glossary) as highlighted by John Fox. These newer AI tools will need a different certification procedure and closer oversight compared to older AI systems. This will be crucial to ensure that they are explainable and minimise bias to reduce healthcare inequalities.

241 Bell, *Life Sciences Industrial Strategy – A Report to the Government from the Life Sciences Sector.*
242 British Journal of Healthcare Computing, 'Is an AI-Driven Health System a "Realistic" Vision?'; Johnson, 'AI Can Excel at Medical Diagnosis, but the Harder Task Is to Win Hearts and Minds First'.

Appendix

Figure 8: Information governance in the NHS

EU regulation	EU Data Protection Directive (1995)	Regulates the processing of personal data within the EU and is based on a set of rights for individuals and principles that organisations must follow.
	Database Directive (1996)	Creates a new exclusive and unique right for database producers to protect their investment of time, money and effort, irrespective of whether the database is in itself innovative. The Directive also harmonises copyright law applicable to the structure and arrangement of the contents of databases.
	Human Rights Act (1998)	Article 8 of the Convention – the right to respect for private and family life.
	General Data Protection Regulation (GDPR) (2018)	Builds on existing rights and principles, but will bring in a stronger accountability principle, strengthen existing rights and introduce some new ones – for example, 'data portability'. It also seeks to harmonise the data protection regime across the EU.
UK regulation	Common law of confidentiality and consent	Not codified in an Act of Parliament but "built up from case law through individual judgement".[243] The key principle is that information given in confidence "should not be used or disclosed further, except as originally understood by the confider, or with their subsequent permission."[244] However, "some judgements have established that confidentiality can be breached 'in the public interest', these have centred on case-by-case consideration of exceptional circumstances."[245]
	Data Protection Act (1998)	The main piece of legislation that governs the protection of personal data in the UK. It implements the 1995 EU Data Protection Directive. It will be replaced by the Data Protection Bill.
	Freedom of Information Act (2000)	Provides public access to information held by public authorities. It does this in two ways: public authorities are obliged to publish certain information about their activities and members of the public are entitled to request information from public authorities.
	Re-use of Public Sector Information Regulations (RPSI) (2015)	Intended to encourage re-use of public sector information and is about permitting re-use of information and how it is made available.
	Digital Economy Bill (2017)	Implements several government commitments on the digital economy made in the Conservative Party Manifesto, such as rules concerning data sharing and statistical data.
	Data Protection Bill	Meant to give people more control over their data. It will replace the 1998 Data Protection Act with a new law that provides a framework for data protection in the UK with stronger sanctions for malpractice. It will implement GDPR standards.

243 Health & Social Care Information Centre, *A Guide to Confidentiality in Health and Social Care*, 2013, 7.
244 Ibid.
245 Ibid.

NHS specific	NHS Act 2006 – Confidentiality Policy	Lays down the principles that must be observed by all who work within the NHS and have access to personal or confidential information. All staff must be aware of their responsibilities for safeguarding confidentiality and preserving information security in order to comply with common law obligations of confidentiality and the NHS Confidentiality Code of Practice. Section 251 of the NHS Act provides a basis in law for patient identifiable information to be disclosed for specific purposes.
	Information sharing policy	Ensures that all information held or processed by NHS England is made available subject to appropriate protection of confidentiality and in line with the terms and conditions under which the data has been shared with NHS England. This policy sets out what is required to ensure that fair and equal access to information can be provided and is supported by a range of procedures.[246]
	Health and Social Care Act 2012	Enables the health and social care Information Centre to “establish systems to collect and analyse health and social care information where directed or requested to do so”.[247]
	NHS Constitution	“Sets out rights for patients, public and staff. It outlines NHS commitments to patients and staff, and the responsibilities that the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively.”[248]
	Caldicott principles	1 Purpose specification – Justify the purpose(s) for using or transferring confidential data. 2 Only use personal confidential data if it is absolutely necessary. 3 Data minimisation – Use the minimum necessary personal confidential data. 4 “Only those individuals who need access to personal confidential data should have access to it, and they should only have access to the data items that they need to see.”[249] 5 “Everyone with access to personal confidential data should be aware of their responsibilities.”[250] 6 Comply with the law. 7 The duty to share information can be as important as the duty to protect patient confidentiality.[251]

Sources: The British Academy and The Royal Society, *Data Management and Use: Governance in the 21st Century*, 2017; NHS England, ‘Information Governance’, Webpage; NHS England, *Information Governance Policy*, 2016; Health & Social Care Information Centre, *A Guide to Confidentiality in Health and Social Care*, 6

246 NHS England, Information Governance Policy.
247 Health & Social Care Information Centre, *A Guide to Confidentiality in Health and Social Care*, 35.
248 Department of Health, ‘NHS Constitution for England’, 14 October 2015.
249 Health & Social Care Information Centre, *A Guide to Confidentiality in Health and Social Care*, 6.
250 Ibid.
251 Ibid.

Figure 9: MHRA regulation of medical devices

Classification of medical device	Definition	Regulation
Class I: low risk	This class contains all non-invasive devices, unless one of the rules set out in the other class definitions states otherwise. Generally, it includes accessories but excludes devices intended for clinical investigation.[252]	Regulation is based on self-declaration by the manufacturer. The Medical Device Directive (MDD) stipulates that devices must draw up the European Community (EC) declaration of conformity. If the software producer is satisfied that the medical device complies with the requirement in the MDD, they must: 1 Write a statement to declare this. 2 Apply to a notified body to approve and certify the parts of the manufacturing that relates to sterility or metrology, if applicable.[253] Once completed, the product can receive a CE mark.
Class IIa: medium-low risk	This class contains all non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for eventual infusion, administration or introduction into the body[254] e.g. allow direct diagnosis of vital physiological processes.[255]	Manufacturers must: 1 Declare the device conforms to the requirements in the MDD. 2 Apply to a notified body to carry out a conformity assessment to approve your declaration.[256] The type of assessment can either be: 1 An examination and testing of each product or; 2 An audit of the production quality assurance system or; 3 An audit of final inspection and testing or; 4 An audit of full quality assurance system.[257] Once completed, the product can receive a CE mark.

252 European Union Law, *Council Directive 93/42/EEC Concerning Medical Devices*, 1993.
253 GOV.UK, 'Medical Devices: Conformity Assessment and the CE Mark', Webpage, 27 January 2015.
254 European Union Law, *Council Directive 93/42/EEC Concerning Medical Devices*.
255 Medicines and Healthcare products Regulatory Agency, *Guidance: Medical Device Stand-Alone Software Including Apps*, 2017.
256 GOV.UK, 'Medical Devices: Conformity Assessment and the CE Mark'.
257 Ibid.

Class IIb: medium-high risk	This class contains all non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body[258] e.g. contraception or the prevention of the transmission of sexually transmitted diseases.[259]	Manufactures must carry out either: 1 An audit of full quality assurance stem. 2 Provide assurance from a notified body that a representative sample of the production covered fulfil the provisions of the MDD **plus** either option 1, 2 or 3 given for Class IIa devices. Once completed, the product can receive a CE mark.[260]
Class III: high risk	This class contains all devices incorporating a substance which can be a remedial product and which is liable to act on the human body with action supplementary to that of the devices e.g. used to monitor or correct a defect of the heart.[261]	Manufacturers must carry out either: 1 An audit of the full quality assurance system including a design dossier examination or; 2 Provide assurance from a notified body that a representative sample of the production covered fulfil the provisions of the MDD plus either option 1, 2 or 3 given for Class IIa devices.[262] Once completed, the product can receive a CE mark.

258 European Union Law, *Council Directive 93/42/EEC Concerning Medical Devices*.
259 Medicines and Healthcare products Regulatory Agency, *Guidance: Medical Device Stand-Alone Software Including Apps*.
260 GOV.UK, 'Medical Devices: Conformity Assessment and the CE Mark'.
261 European Union Law, *Council Directive 93/42/EEC Concerning Medical Devices*.
262 GOV.UK, 'Medical Devices: Conformity Assessment and the CE Mark'.

Glossary

Algorithm: set of rules and instructions that an agent (e.g. computer, robot…) follows to solve a problem.

Anonymous data: data "about individuals but with identifying details removed".[263]

Artificial Intelligence: any manmade agent (i.e. computer programme or robot) who exhibits intelligence. Intelligence is defined as an "agent's ability to achieve goals in a wide range of environments."[264]

Artificial Neural Networks: are defined as a collection of artificial neurons that can be activated by the input data. The neurons then communicate messages about the input to each other which contributes to the output.

Consent: "approval or agreement for something to happen after consideration. For consent to be legally valid, the individual must be informed, must have the capacity to make the decision in question and must give consent voluntarily."[265] **Explicit Consent**: "It can be given in writing or verbally, or conveyed through another form of communication such as signing."[266] **Implied consent**: "applicable only within the context of direct care of individuals. It refers to instances where the consent of the individual patient can be implied without having to make any positive action, such as giving their verbal agreement for a specific aspect of sharing information to proceed."[267]

Data controller: "a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be, processed."[268]

Data processor: "any person (other than an employee of the data controller) who processes the data on behalf of the data controller."[269]

Data processing: "obtaining, recording or holding information or data or carrying out any operation or set of operations on the information or data."[270]

Data subject: "means an individual who is the subject of personal data".[271]

Deep neural net: is a similar computing system to Artificial Neural Networks, but has multiple layers of neurons. It uses its layered design so that outputs from one layer are used as the input for the next.

Deindentified data: it is the same as pseudonymised data except that the date of birth of the patient is removed. In addition, there is no way of knowing if a same person has, for example, received treatment several times as it appears as a single entry each time.

Direct care: "is a clinical, social or public health activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of individuals (all activities that directly contribute to the diagnosis, care and treatment of an individual)".[272]

Expert systems: computer system that emulates the decision-making ability of a human expert through complex pre-programmed rules.

Identifiable data (or patient identifiable data): "containing details that identify individuals".[273]

263 NHS Digital, 'How We Look after Information', Webpage, 2017.
264 Legg and Hutter, 'A Collection of Definitions of Intelligence', 8.
265 Health & Social Care Information Centre, *A Guide to Confidentiality in Health and Social Care*, 7.
266 Ibid.
267 Ibid.
268 Information Commissioner's Office, *Guide to Data Protection*, 2017, 8.
269 Ibid., 9.
270 Ibid., 8.
271 Ibid.
272 Health & Social Care Information Centre, *A Guide to Confidentiality in Health and Social Care*, 27.
273 NHS Digital, 'How We Look after Information'.

Indirect patient care: "activities that contribute to the overall provision of services to a population as a whole or a group of patients with a particular condition, but which fall outside the scope of direct care. It covers health services management, preventative medicine, and medical research."[274]

Machine learning: is a subset of AI that allows computer systems to learn by analysing huge amounts of data and drawing insights from it rather than following pre-programmed rules.[275]

Offline machine learning systems: these systems are trained and tested static datasets models are then "'frozen' before being deployed in a live setting."[276]

Online machine learning systems: these systems continuously update with new data.[277]

Population data: "anonymised information grouped together so that it doesn't identify"[278] individuals.

Pseudonymised data: "about individuals but with identifying details (such as name or NHS number) replaced with a unique code."[279]

Sensitive data: refers to personal data consisting of information as to the ethnicity, religion, physical or mental health, sexual orientation and practices, political beliefs, being member of a trade union, offending history (even alleged commission of crime).[280]

274 Health & Social Care Information Centre, *A Guide to Confidentiality in Health and Social Care*, 27.
275 The Economist Intelligence Unit, *Advanced Science and the Future of Government.*
276 The Royal Society, *Machine Learning: The Power and Promise of Computers That Learn by Example*, 20.
277 Ibid.
278 NHS Digital, 'How We Look after Information'.
279 Ibid.
280 Information Commissioner's Office, *Guide to Data Protection*, 6–7.

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