Our data-driven future in healthcare

People and partnerships at the heart of health related technologies

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The Academy *of* Medical Sciences

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Contents

Executive summary

New data-driven technologies, powered by novel ways of linking and analysing patient data, are set to transform the way that health and social care is delivered as well as the ways in which we manage our own health. Technologies such as wearable devices, mobile apps and intelligent monitoring devices that use machine learning, provide an opportunity for the NHS to harness the breadth and depth of patient data that it holds to support a healthier future for patients and the public. This report outlines a set of principles based on our dialogues with patients, the public and healthcare professionals, for the development, evaluation and deployment of data-driven technologies in healthcare. Embedding these principles will be essential if we are to realise the anticipated benefits of these innovative technologies whilst maintaining trust in their use in health and social care sectors. Central to this are meaningful partnerships with patients and the public and their health and care professionals.

Data-driven technologies provide an extraordinary opportunity to deliver significant benefits for patients, the NHS and society. They have the potential to improve individual care, NHS services and public health, and to advance medical research and innovation. For example, they could help prevent illness by identifying those at higher risk of certain diseases or by enabling earlier diagnoses; empower patients with long-term conditions in self-management, including through self-monitoring; and improve outcomes by personalising, fine-tuning or automating treatment. Furthermore, they may increase the efficiency of healthcare services and drive research and innovation to develop new interventions, with potential patient benefit in both the near- and longer-term.

Despite these major opportunities, the rising use of data-driven technologies also brings challenges. These include the continued protection of privacy, as well as the consequences for decision-making and communication, for example, when the outputs from these technologies cannot easily be explained. As these technologies depend on accessing and analysing patient data for their effective development and utility, it is critical that they are designed and used in ways which align with the expectations and needs of patients and the public, and also retain trustworthiness in the uses of patient data. The right balance is needed between maintaining confidence in the safeguarding of data and enabling appropriate access for data-driven technologies. An approach that is unnecessarily risk averse may impede the development and evaluation of these technologies for health and care to the detriment of patients and the NHS. Clarity is needed around when, where and how data-driven technologies access patient data and are collectively deployed in the NHS and social care. In addition, there should be clear information about their potential impact and the responsibilities surrounding their use.

Actionable principles

To address the challenges of using data-driven technologies in health and social care, the Academy of Medical Sciences developed a framework of actionable principles to guide their development, evaluation and use. These build on, and add value to, the work of others in this field. The principles are informed by the findings of a series of structured dialogues with patients, the public and healthcare professionals, followed by further engagement and evidence gathering across key stakeholder groups.

These principles, based on five core themes, propose that data-driven technologies should be designed and used for health and care in ways that:

1. **Support clearly defined purposes that uphold the social values of the NHS and benefit individuals, the NHS, or society.**

2. **Respect and protect the privacy, rights and choices of patients and the public.**

3. **Include patients and the public as active and meaningful partners.**

4. **Maintain trustworthiness in the responsible and effective stewardship of patient data within the NHS.**

5. **Incorporate mechanisms for evaluation and regulation that build public understanding, confidence and trust in these technologies, and guide their use in the NHS.**

Underpinning these principles are three key responsibilities for those accountable for determining the purposes and uses of patient data and of data-driven technologies, and their evaluation and regulation. The responsibilities are:
- Involving and actively partnering with patients and the public.
- Effective and accountable stewardship of patient data and data-driven technologies in the NHS.
- Establishing robust processes for the evaluation, regulation and continued oversight of the use of patient data and data-driven technologies.

Next steps

Novel data-driven technologies will create new opportunities as well as new issues for debate as they evolve, and as experience and knowledge are gained from their development, evaluation and use. Ongoing and meaningful engagement of patients, the public and healthcare professionals as active partners is a *key* requirement to ensure the successful realisation of these opportunities. This will enable a sustained dialogue about the use of these technologies, which are likely to evolve in ways that may not be predicted at present, potentially raising wider questions about their implications for individuals, health and social care and society. The principles outlined in this report place patients, the public and healthcare professionals at the heart of this dialogue.

Coordinated actions across multiple stakeholders are required to put these principles into practice. This collaborative approach will help fulfil the ambition to keep the NHS at the global forefront of healthcare and cement the UK's position as a world-leading environment for the trusted development and use of data-driven technologies in healthcare. This will demand:

- UK-wide improvements in the digital capabilities and competencies of NHS and social care staff and systems. An integrated data infrastructure is needed across the NHS with a workforce that is able to use it.
- A cultural shift within the NHS and across healthcare professionals that balances respect and protection of patient data with enabling data access. This will facilitate the development, evaluation and adoption of data-driven technologies that demonstrate health benefits.
- The development of robust evaluation mechanisms and an appropriate regulatory framework to guide the effective and safe deployment of these technologies.

The Academy will work with others to ensure that the principles outlined in this report are put into practice so that we do not miss out on the significant potential benefits of these technologies for the health and wellbeing of the population.

Principles for using data-driven technologies

The principles set out below have been developed to maximise the potential benefits for patient and public health from new and emerging data-driven technologies. In particular, they have been developed to ensure that these uses reflect the values and expectations of patients, the public and healthcare professionals for individual care, for the NHS and for society more broadly.

For this report, 'patient data' means health-related information about patients that is created or used as part of their NHS care. It may also be linked to information they have collected themselves, or to information collected as part of their related social care.

References

1.   Department of Health & Social Care (2012). *The NHS Constitution for England.* www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england 'Social values' are outlined in the NHS Constitution for England and similar documents for Scotland, Wales and Northern Ireland.

Principles

Theme	Principle
A. Purpose, value and benefits	**Data-driven technologies should be designed and used for clearly defined purposes that uphold the social values[1] of the NHS and benefit individuals, the NHS, or society.** *In doing so, they should* 1. Enable fair access to their benefits by all social groups. 2. Realise the value of patient data created as part of NHS care. 3. Not be used for direct marketing or similar commercial activities. *and, depending on their purpose, they should* 4. Preserve and enhance direct contact between healthcare professionals and patients. 5. Enable safe and effective health and social care. 6. Support people to manage their own health. 7. Enable research and innovation.
B. Privacy and rights	**Data-driven technologies should be designed and used in ways and settings that respect and protect the privacy, rights and choices of patients and the public.** *Their design and use should* 1. Meet all ethical, regulatory and legal requirements. 2. Enable patients to know and decide when and where data about them are collected. 3. Be transparent about how, where, why, when, and by whom, patient data are collectively used and accessed. 4. Respect patient privacy and confidentiality. 5. Protect a person's right to choose to be in a state of less than optimal health. 6. Maintain rights to access health and social care and insurance. 7. Not discriminate unfairly based on genetic or other information.
C. Public engagement and partnership	**Those determining the purpose and uses of data-driven technologies should include patients and the public as active partners.** *This means that patients and the public* 1. Are active partners in agreeing priorities for, and determining the acceptability of, data-driven technologies as part of an ongoing process. 2. Have easy access to clear information communicated in a way that raises awareness and understanding of these technologies.
D. NHS data stewardship and responsibilities	**The NHS, and those acting on its behalf, should demonstrate their continued trustworthiness by ensuring responsible and effective stewardship of patient data and data-driven technologies in the NHS.** *They should* 1. Retain overall responsibility for where patient data and data-driven technologies are used. 2. Make sure those accessing patient data to develop data-driven technologies use it for agreed purposes (see theme A). 3. Ensure data access agreements are for defined purposes (see theme A), and set out how benefits will be shared fairly across the NHS. 4. Assure the consistency, accuracy and quality of patient data used by data-driven technologies. 5. Build skills and capacity in the NHS workforce to enable the use of data-driven technologies. 6. Introduce into the NHS data-driven technologies that have evidence about their effectiveness and safety, being clear about where responsibility lies for any harmful health or other consequences of their use.
E. Evaluation and regulation	**Data-driven technologies should be evaluated and regulated in ways that build understanding, confidence and trust, and guide their use in the NHS.** *The use of data-driven technologies should be* 1. Supported by timely evidence on their benefits, accuracy, effectiveness, safety and security in line with regulatory, ethical and commissioning requirements. 2. Reviewed and periodically audited.

Glossary

Algorithm
The set of rules used by a technology to analyse and process data to produce a specific output.

Anonymised data
Data where identifying details/information have been removed or encrypted. There are two types of anonymised information – depersonalised and anonymous, which carry different risks of re-identification.[2]

Anonymous
Where it is not possible to identify an individual from the data as information has been combined from multiple individuals.[3]

Artificial intelligence (AI)
Technologies that have the ability to perform tasks that would otherwise require human intelligence, or which conduct analyses which are either too complex or laborious for a human to carry out, such as visual perception, speech recognition or language translation. They usually have the capacity to learn or adapt to new experiences or stimuli.[4]

Black box systems
Systems or technologies that have limited technical transparency around the processes by which they reach their output, as the algorithms they use are complex and dynamic.

Cost-effectiveness analysis
Evaluation of the effectiveness of two or more interventions relative to their cost to inform decision-making. The aim when assessing new interventions is to identify those that maximise outcomes and minimise costs.

Data-driven technologies
Technologies that work by collecting, using and analysing patient data to support the care of individuals, NHS services, public health, or medical research and innovation. For example, using AI and machine learning to analyse patient data collected in the course of NHS care, which may also be linked to social care data or to data collected by patients themselves such as through wearable technologies and mobile apps.

Data governance
The management of data throughout the life cycle, including ways to ensure data integrity and security, and managing access.

Data integrity
The overall quality and validity of data, which depends on factors including provenance, accuracy, reliability and consistency over its life cycle.

Data life cycle
The different stages of the patient data journey. This involves various organisations and processes, including the generation and collection of data, curation, storage, access, use and its eventual destruction or legacy.

Data processing
The processing or curation of data to allow them to be used more effectively or linked with other datasets.

Depersonalised data
Data which have had any personal identifiers removed or encrypted. There is still a risk of re-identification of an individual if other potential identifiers remain or if the data are linked with other data sources.

Digital literacy
The capabilities and understanding required to allow an individual to effectively engage with a data-driven technology or the processes that surround its use.

Digital maturity
The extent to which an organisation makes use of digital technology to achieve a health and care system that is paper-free at the point of care. This includes consideration of the extent to which providers are able to plan and deploy digital services, have the capability to use digital technology to support delivery of care, and have the underlying infrastructure in place to support these capabilities.

Electronic Health Records (EHRs)
Digital records of a patient's medical history, health and care.

Healthcare professional
A person who is qualified and allowed by regulatory bodies to provide healthcare to a patient. They include: medical and dental staff; nurses, midwives and health visitors; professionals allied to medicine such as clinical psychologists, dieticians and physiotherapists; ambulance staff and paramedics; and other professionals who have direct patient contact, such as pharmacists.

Individual care
Healthcare processes or services (such as diagnosis, treatment, management or monitoring) directed at an individual for their care or treatment. 'Individual care' is commonly termed 'direct care'.

Internet of Things
Technologies and platforms embedded in everyday objects that are connected to each other via the internet, which enables them to interact through collecting, linking and exchanging data.

Machine learning
A specific type of algorithm which enables technologies to learn from experience as well as data, and so evolves over time as it learns without human input.

Natural Language Processing
A type of AI which extracts, processes, analyses and interprets written and spoken language.

NHS data stewards
Individuals in NHS organisations, or those acting on their behalf, who are responsible for the stewardship and curation of patient data, including controlling how, when and by whom it is collected, stored, accessed or otherwise used.

Patient data
Health-related information about patients that is created or used as part of their NHS care (such as a healthcare professional's notes and care records, vital signs, laboratory test results, medical images and letters). For the purposes of this report, this may also be linked to information they have collected themselves, or to information collected as part of their related social care. These data may be personally identifiable or anonymised. Anonymised data may comprise depersonalised or anonymous data.

Personally identifiable data
Data that contain personal information that could identify an individual.[5]

References

2.   Understanding Patient Data (2017). *Identifiability briefing.* http://understandingpatientdata.org.uk/sites/default/files/2017-07/Identifiability%20briefing%205%20April.pdf

3.   Ibid.

4.   House of Lords Select Committee on Artificial Intelligence (2018). *AI in the UK: ready, willing and able?* https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/100.pdf

5.   Understanding Patient Data (2017). *Identifiability briefing.* http://understandingpatientdata.org.uk/sites/default/files/2017-07/Identifiability%20briefing%205%20April.pdf

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The challenge is to find ways to turn data into knowledge that can be used to improve patient outcomes and safety, for research and innovation, and to help with planning of services in the NHS.

1. Introduction

The increasing digitisation of health and social care is enabling real-time access to patient data in ways that were not previously possible. This has the potential to transform patient care by enabling decision-making in health and care to be more timely, safe and effective. In addition, it is opening up opportunities to use new types of data, such as lifestyle data collected or reported by patients themselves, or data collected in different settings such as care homes. The challenge is to find ways to turn these data into knowledge that can be used to improve patient outcomes and safety, for research and innovation, and to help with the planning and operation of services in the NHS.[6]

For the purposes of this report we have used the following definitions:

Data-driven technologies
Data-driven technologies work by collecting, using and analysing patient data – for example by using machine learning or other types of artificial intelligence (AI) – to support the care of individuals, NHS services, public health, or medical research and innovation. For example, 'intelligent' devices are emerging for the management of diabetes that use an algorithm to administer insulin in response to glucose levels, by pairing insulin pumps with smart glucose monitors.[7]

Patient data
Health-related information about patients that is created or used as part of their NHS care. For the purposes of this report, this may also be linked to information they have collected or reported themselves, or to information collected as part of their related social care.

Much of the language used throughout this report has been informed by work such as that of Understanding Patient Data, and a glossary of definitions can be found on pages 10-11.

Data-driven technologies can help to meet that challenge. For individual care, their use may result in faster and more accurate diagnoses or access to treatment, offer new care pathways or treatments, support shared decision-making and empower individuals to manage their health. While many of these benefits will be immediate for patients, others may take longer to be realised. For the NHS and its workforce, the use of data-driven technologies may lead to improvements in the systems, operation and efficiencies of the NHS, freeing up time and resources for individual care as well as potentially changing the way that individuals can interact with healthcare professionals. Information derived from new, linked data sources can also support population health management, as well as the planning and commissioning of health and social care services. Analyses of these data by technologies can also drive research that increases our understanding of human health and disease. This could result in longer-term patient benefit through supporting the development and evaluation of new interventions, diagnostics, medical devices and digital health tools.

Innovative data-driven technologies are already starting to be used in healthcare and devices that continuously capture patient data have been used for some time. More recently, developments have been in different forms of AI such as machine learning, deep learning and natural language processing, which hold significant opportunities for patient benefit. These powerful methods are capable of quickly processing large volumes of different patient data in real-time, adding to the information already available for care and research.

The use of data-driven technologies in healthcare is accompanied by a set of risks and challenges.[8] Some relate to the use of patient data, such as data privacy, confidentiality and stewardship, and some to the security, reliability and effectiveness of the technology itself. Specific risks of data-driven technologies that use AI or similar analytic approaches relate to their relative lack of 'explainability'. This can potentially impact the healthcare professional-patient interaction when making shared decisions about care as well as the regulation of these technologies.[9] This lack of 'explainability' is either due to low awareness of how technologies are collecting, processing and using data, or limited transparency around how the technologies arrive at an outcome or decision. Recent controversies involving access to, and the use of, patient data by commercial developers, have confirmed the need for continued dialogue with patients and the public and greater transparency in the decision-making processes surrounding uses of patient data. Moreover, lessons learned from the introduction of other innovative technologies suggest that meaningful partnership and engagement with patients and the public are key to realising their full benefits.[10]

This project by the Academy of Medical Sciences was designed to explore the use of data-driven technologies with the public, patients, healthcare professionals and wider stakeholders, to create principles for their development and use for health. As these technologies are developing rapidly, it is difficult to predict those that might emerge in the future or their impact.[11] Therefore the principles are intended to have broader relevance to emerging, and as yet unknown, data-driven technologies, and are not tied to specific technologies or applications. In addition, experience of accessing and using social care data in the UK is very limited, meaning there may not have been the same opportunity for public deliberation around the integration and use of social care data as there has been for healthcare data. Further research is needed to understand the context for using these technologies in social care, and whether it may echo the findings of this report or raise new challenges.

The Academy's project and the principles complement the *'Initial code of conduct for data-driven health and care technology'* recently set out by the Department of Health & Social Care, and its policy paper on *'The future of healthcare: our vision for digital, data and technology in health and care'*, which was published in October 2018.[12] A draft of this report was shared with the Department during the preparation of the code.[13] It provides essential evidence about the expectations of patients, the public and healthcare professionals, and how these can be met when using data-driven technologies in healthcare. The report also provides important detail on patient and public perspectives on the 'value proposition' for data-driven technologies as described in the code, and aligns with the code on the need for transparency around their development, deployment and evaluation. The principles in this report are relevant to the different stakeholders involved with data-driven technologies in healthcare, including NHS data stewards, and how they can effectively engage with developers working to the code. Furthermore, they will support developers, researchers and others to design and develop data-driven technologies in a way that fulfils patient and public expectations of being active partners in this process.

Conduct and scope of the project

This project started with a series of dialogue workshops with the public, patients and healthcare professionals, carried out by Ipsos MORI on behalf of the Academy.[14] A policy workshop was then held to discuss the findings of the dialogue programme with a wide range of key stakeholders including the NHS, regulators, funders, policymakers and researchers, as well as pharmaceutical, medical technology, data and digital health companies. Evidence from these, together with reports published by other organisations (Annex I), was considered by a project steering group comprising experts from a range of backgrounds (see Annex II). From this, the group developed actionable principles aimed at ensuring public and patient expectations and values are considered and respected by those using and making decisions about data-driven technologies in healthcare. The findings and principles were discussed with a variety of key organisations and individuals working in this field to maximise their relevance and usefulness (see Annex III). Finally, the project was reviewed by an external review group appointed by the Council of the Academy and was approved by the Academy's Council.

Dialogue programme

The objective of the dialogue programme was to explore awareness, expectations, aspirations and concerns of patients, the public and healthcare professionals around future technologies that use patient data.[15] To do this, Ipsos MORI convened three initial one-day workshops in Sheffield, London and Cardiff with patients and the public. Some of each of these groups were then re-convened in three evening workshops with healthcare professionals the following week. The design of the dialogue sessions was informed by a development workshop involving key stakeholders, as well as with input from the Academy's project steering group. Workshop attendees were selected to ensure a geographical spread (for example, across England and Wales, and recruitment from both rural and urban areas) and diversity of ages, gender, ethnicity, stages of life and sociodemographic factors.

Scope of the project

At the outset, the scope of the project was defined to be:
- Based on evidence about the values and perspectives of the public, patients and healthcare professionals, obtained directly from the Academy's dialogue workshops or external reports.
- Focused on data-driven technologies that work by collecting, using and analysing patient data to support the care of individuals, NHS services, public health, or medical research and innovation.
- Addressing only those data-driven technologies that use patient data. This is health-related information about patients that is created or used as part of their NHS care, and which may also be linked to information they have collected themselves, or to information collected as part of their related social care. For example, daily physical activity data collected by a patient using a wearable technology that is not linked to NHS patient data would be out of scope.
- Considering the different organisational structures across UK regions and nations in order to be applicable to all UK countries.
- Relevant and applicable to a wide range of technologies, including those that are not yet mainstream or have yet to emerge. Robotics, such as those used in surgery, were out of scope.
- Not seeking to reconsider the legal or ethical basis of consent to use patient data, assuming that any uses of patient data by data-driven technologies will comply with data protection and privacy laws, and the ethical and regulatory standards governing research and care.

Who are the principles for?

The principles are intended to be relevant to the following audiences who may use, or be responsible for developing, evaluating, regulating, or commissioning data-driven technologies in different contexts and settings:
- **Healthcare professionals –** those who may use data-driven technologies or enter and provide data into systems.
- **Patients –** those who may use data-driven technologies or provide data into systems.
- **NHS managers and commissioners –** individuals within the NHS who are responsible for planning and purchasing services, including data-driven technologies that use patient data.

- **Developers and researchers –** those who access or receive NHS-held patient data for use in research or to develop tools, apps, devices, algorithms, technologies or other interventions.
- **Regulators –** those responsible for determining the appropriate regulation for data-driven technologies.
- **NHS data stewards –** individuals in NHS organisations, or those acting on their behalf, who are responsible for the stewardship and curation of patient data, including controlling how, when and by whom it is collected, stored, accessed or otherwise used.
- **Data processors –** those commissioned by a data controller to process, store or curate data on behalf of the controller, for example cloud service providers or other IT service providers.
- **Research funders –** those who are responsible for determining funding priorities and awarding grants for research associated with patient data and/or data-driven technologies.

References

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7. Bekiari E, *et al*. (2018). *Artificial pancreas treatment for outpatients with type 1 diabetes: systematic review and meta-analysis.* BMJ **361**, k1310.

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13. Department of Health & Social Care (2018). *Initial code of conduct for data-driven health and care technology.* https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology

14. Ipsos MORI (2018). *Future data-driven technologies and the implications for use of patient data.* www.acmedsci.ac.uk/datadialogue

15. *Ibid.*

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Patients, the public and healthcare professionals are supportive of technologies where they have demonstrable benefits to patients or the health and social care system.

2. The purposes, benefits and value of developing and using data-driven technologies

A. Purpose, value and benefits

Principle

Data-driven technologies should be designed and used for clearly defined purposes that uphold the social values[16] of the NHS and benefit individuals, the NHS, or society.

In doing so, they should

1. Enable fair access to their benefits by all social groups.
2. Realise the value of patient data created as part of NHS care.
3. Not be used for direct marketing or similar commercial activities.

and, depending on their purpose, they should

4. Preserve and enhance direct contact between healthcare professionals and patients.
5. Enable safe and effective health and social care.
6. Support people to manage their own health.
7. Enable research and innovation.

There is increasing evidence that health services that are research- and data-enabled deliver safer and higher-quality care, and that patients taking part in research have better outcomes than those who do not.[17, 18, 19] Data-driven technologies such as artificial intelligence (AI) and machine learning have the potential to transform healthcare across the patient journey, from personalising or automating treatments and predicting outcomes for prevention, through to empowering patients by self-monitoring.[20] The Academy's public dialogue workshops identified patient and public expectations and values about the purposes and context in which such data-driven technologies should be developed and used. These expectations inform the first set of principles set out here.

Purpose of use

The Academy's public dialogue workshops identified an expectation that new technologies will be used in ways that benefit patients either individually or collectively, the NHS or wider society, and uphold the values of the NHS.[21] We found that patients, the public and healthcare professionals are supportive of technologies where they have demonstrable benefits to patients or the health and social care system. These included system improvement (e.g. NHS operations) or research and innovation, as well as individual care. The purpose of using technologies that utilise patient data for their development or deployment should therefore be clearly defined so it is apparent that they meet these expectations. The Digital Assessment Questions for the NHS Apps Library, for example, require evidence on *'clarity of purpose and intended use'*.[22]

Upholding the social contract and ethos of the NHS

Society expects that the NHS, and those working for it, will act in the interests of 'public good'. This may be characterised as a 'social contract' between the NHS, patients and society that reflects social values.[23] This is consistent with the NHS Constitution in England and similar legislation in Wales, Scotland and Northern Ireland.[24, 25, 26, 27]

The Academy's public dialogue workshops and other work have found that patients and the public are strongly supportive of the NHS as a public service and are encouraging of new approaches that may:[28, 29]
- Improve patient experience or outcomes.
- Improve health and care through research and innovation.
- Enhance or add value to NHS systems and operations.
- Support fair distribution of potential benefits and minimise potential harms to individuals, the NHS and society. Technologies should not be used for purposes that may unfairly disadvantage certain individuals or groups.

This is consistent with the principles governing the National Institute for Health and Care Excellence's (NICE) social value judgements developed by its Citizens Council.[30]

Commercial access to patient data: purposes and benefit-sharing

Patients, the public and healthcare professionals do not support the use of patient data by data-driven technologies *solely* for commercial activities such as direct marketing, which are not perceived to offer patient, system or societal benefit. In the Academy's public dialogue workshops, patients and the public distinguished between the acceptability of *purposes* for using data-driven technologies and *who* was using the data.[31] However, it was clear that tensions around these uses remain and that technology developers are expected to deliver societal benefit in line with the ethos of the NHS, and should be accountable and trustworthy in this respect.

More broadly, it is important to patients and the public that the benefits afforded by using data-driven technologies are shared with and returned to the NHS, and this is integral to the value of deploying a data-driven technology.[32] This is part of a wider desire to ensure that maximum value is derived from the use of patient data and that advances arising from data-driven technologies are available to patients and the NHS. While it has been shown that patients and the public understand the value, and are generally supportive, of using patient data for research, particularly when it is depersonalised, they have also been shown to be more divided in views on research which entails commercial access to patient data.[33] Where patient data are used for a data-driven technology with potential commercial applications, patients and the public expect the NHS to realise some benefit from contributing to its development. This should be approached in a way that ensures 'fair reward' for all.[34] A number of benefit-sharing models are being used or proposed, including those that offer low or no-cost access to the technologies developed, or equity in companies or royalties from sales. As experience is gained with using these models, it is likely that patient and public perspectives on their relative merits will evolve, and these will inform 'best practice models' and the contracts and data access agreements that underpin them.

Supporting patients' relationships with their healthcare professionals

The relationship between patients and healthcare professionals and their direct (usually face-to-face) interactions at the point of care are a highly valued and important part of NHS care.[35] Where relevant to their purpose, data-driven technologies should be designed and implemented in ways that support and enhance, rather than replace, this relationship.[36, 37] This was deemed important as it was perceived that technologies may not have access to all the information that a healthcare professional has about an individual, and that they do not possess the human experience, understanding, compassion and communication skills needed for shared decision-making.[38] At the Academy's public dialogue workshops, empathy and human perception were felt to be particularly essential to the patient-healthcare professional interaction for those with mental health conditions, and it was felt this would be lacking with automated diagnosis or treatment. Depending on the context and outcomes, patients also generally prefer a human to communicate information about their diagnosis with them at the point of care – the 'human factor'.[39] They may perceive humans to be better at tailoring information to their level of understanding or for delivering difficult news. Data-driven technologies which support the work of healthcare professionals and release time for interaction with patients were welcomed, including those which may, for example, identify or triage patients who urgently need to speak to a clinician.

Perceived risks to using these new technologies included the loss of human contact and opportunity to discuss options for care, errors arising from a lack of access to relevant or accurate information, and the inability to explain how and why a technology has arrived at a specific outcome. Technologies can act as a mediator or bridge in the healthcare professional-patient interaction, with AI referenced as the *'third participant in the previously binary patient-healthcare professional dynamic'* in a report by the Wellcome Trust.[40] However, more work will be needed to understand the impact on the patient-healthcare professional relationship as these technologies evolve and healthcare delivery shifts.

What constitutes value?

Data-driven technologies have great potential to support the 'triple aims' of the NHS as set out in the Five Year Forward View: improve health and outcomes; enhance care delivery; and enable more effective use of NHS resources.[41] Decisions around their design, development and use should be informed by the value that they offer to patients individually and collectively, to the NHS or to society. Individual or collective benefit, or NHS or societal value, may be in tension and such tensions will need to be debated in an open and transparent manner.[42, 43] Determination of the value of a data-driven technology should take account of its effectiveness compared with alternative options and consider potential harms or unintended consequences. It should also take account of potential risks, for instance to privacy and confidentiality, as well as reliability in real-world settings. Building on the importance of defining a 'value proposition', as outlined in the Department of Health & Social Care's code of conduct for data-driven health and care technology, the following dimensions were identified at the Academy's public dialogue workshops and through work by others as important values when considering uses of data-driven technologies:[44, 45]

- **Adding to the quality and experience of individual care –** for example by:
  - ○ Providing decision support or otherwise adding to the information available in order to improve patient safety and outcomes and to predict, diagnose, treat or manage illnesses at the point of care through novel analyses.
  - ○ Supporting faster, more efficient care pathways. This may involve earlier diagnosis, as well as enabling more effective use of healthcare professionals' time for individual care by reducing the administrative burden on them and other staff. For example, a telecare initiative in Scotland to support dementia patients has both improved their experience by enabling better patient management in the community, and reduced admission of these patients to care settings.[46]
- **Empowering patients –** technologies may motivate and enable patients to manage their own health and provide greater autonomy in doing so by supporting self-management and shared decision-making. For example, patients and the public felt positive about linking data from wearable devices to their clinical data to enable them to monitor their own health.
- **Improving healthcare systems –** in addition to supporting and freeing up time for interaction between patients and their healthcare professionals, patients and the public recognised the significant opportunity for technologies to improve NHS operations, systems and efficiency, including workforce experience. This may be achieved through better integration of, and access to, data across different services within the NHS and social care. There is already an expectation that different NHS services should have a mechanism by which they are able to view or access patient data from one another for individual care. While data-driven technologies might support a more efficient NHS, patients and the public considered that overall this should not result in reduced resources for the NHS.
- **Supporting medical research and innovation –** for example, to develop new health interventions that may improve patient outcomes. This could include increasing personalisation of treatments so that care can be better targeted to the patient.
- **Protecting public health –** for example, evaluating the health effects of air pollution or strategies to reduce it.[47] Similarly, data-driven technologies can be useful for monitoring or controlling infectious diseases, and in prevention.[48]
- **Ensuring equity –** enabling equitable access for all patients and healthcare professionals irrespective of, for example, location, age, sex, socioeconomic status, ethnic group, health behaviours, or health status.

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Case study 1. AI assisted ultrasound examination of pregnant women

Background

Ultrasound examinations of a pregnant woman and her fetus are carried out to monitor the pregnancy and identify potential health problems which may be relevant to the future health and wellbeing of the woman or fetus. As well as providing assurance, some women value information on the sex of the fetus and may regard the examination as a significant milestone in their pregnancy to be shared with friends and family members.

The scans are usually carried out by a skilled sonographer who can give immediate feedback. If any problems with the pregnancy or fetus are suspected – and depending on their nature – the sonographer can request immediate or subsequent review by a senior colleague, who may undertake further scans or investigations.

How might this change with new technologies?

The 'automation' of antenatal ultrasound examinations (for example, through simplification of the scan procedure to a single sweep and image interpretation by AI) could confer a number of benefits such as:
- Speeding up the process of acquiring and interpreting images, more accurate identification of any problems, and avoiding false alarms or false reassurance concerning the health of the fetus.[49, 50]
- Enabling antenatal scans to be carried out in low resource or remote settings, and by less experienced staff, by simplifying the scan procedure and interpretation.
- Facilitating research to identify new imaging biomarkers – alone or in combination with results from other tests – that predict clinically important problems that may be present or develop later in the pregnancy, and in time to take effective action.[51]

However, they may also have potential disbenefits such as:
- Identifying features of the pregnancy which are of uncertain clinical importance, thereby creating unnecessary anxiety for women whose pregnancy or fetus is likely to be 'healthy'.
- Constraining opportunities for face-to-face human interaction between a sonographer and mother due to increased automation.
- De-skilling sonographers and others whose expertise may be crucial to other services.

How might these new technologies be evaluated with reference to the principles set out in this report?

A research group has developed and tested automated methods to obtain and analyse antenatal ultrasound images, and confirm the presence of a fetal heartbeat and position of the fetus in the womb, with the intention to develop low-cost ultrasound technologies suitable for low-income countries with high maternal mortality.[52] The group analysed antenatal ultrasound videos obtained by trained obstetricians from over 300 pregnant women. They developed and tested methods to identify different anatomical regions of the fetus in the videos and reported acceptable accuracy in detecting a fetal heartbeat. They propose to apply these methods to a larger number of women to confirm and extend their early findings.

This case study is an example of the early stages of developing an innovative data-driven technology which requires access to patient data. In Annex IV, we set out the stages envisaged to take this technology all the way through to its potential adoption in clinical practice. These illustrate the requirements around data access at each stage and reflect where the different principles for data-driven technologies will apply and who may be responsible for applying them at these different stages.

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The public expects the NHS to use patient data in their individual and collective interests as well as for the NHS, and to take all necessary steps to keep patient data safe.

3. Transparency, privacy, rights and choice

B. Privacy and rights

Principle

Data-driven technologies should be designed and used in ways and settings that respect and protect the privacy, rights and choices of patients and the public.

Their design and use should

1. Meet all ethical, regulatory and legal requirements.
2. Enable patients to know and decide when and where data about them are collected.
3. Be transparent about how, where, why, when, and by whom, patient data are collectively used and accessed.
4. Respect patient privacy and confidentiality.
5. Protect a person's right to choose to be in a state of less than optimal health.
6. Maintain rights to access health and social care and insurance.
7. Not discriminate unfairly based on genetic or other information.

Trust in healthcare professionals and the NHS is high but this needs to be actively maintained and reinforced, particularly with the introduction of innovative data-driven technologies.[53, 54, 55] Transparency is central to achieving this through demonstrating trustworthiness.[56] Therefore robust frameworks are needed that provide clarity about why and how data-driven technologies and associated patient data are being used, by whom, for what, and how decisions about these uses are arrived at.

The public expects the NHS to use patient data in their individual and collective interests as well as for the NHS, and to take all necessary steps to keep patient data safe.[57] There is evidence that, while patients and the public recognise the benefits of data-driven technologies, these should not be at the expense of their access to healthcare, their privacy or their rights to make personal choices about their health and lifestyles.[58] If properly deployed, these technologies can enhance patient choice and the potential suite of healthcare options, whilst also protecting their autonomy. In this chapter we set out some principles that reflect public and patient views on privacy and rights.

Transparency around the use of data-driven technologies and patient data

There are strong expectations from patients and the public for transparency around the use of data-driven technologies, and evidence from multiple public dialogues suggests that five key pieces of information are required to fulfil them.[59, 60]

- **When and where** data are being collected and data-driven technologies are being used, including in clinical and non-clinical settings, and the level of patient awareness and control over this. Patients and the public felt that this was especially important when continuous observations or pervasive monitoring are involved.
- **What** data the technologies are collecting and whether these are in a personally identifiable or depersonalised form.[61] Patients and the public felt more strongly about the need for further information or controls around data perceived as personally identifiable, including videos and photographs, compared to numerical data such as blood pressure readings, blood test results or aggregate or anonymous data.[62]
- **Who** will curate, have access to, or use the data.
- **Why** data-driven technologies are being used **and the value of doing so** (as discussed in Chapter 2).
- **How** data are collected and how they are used for decision-making, and when this is with the knowledge of the patient and when it is not.

In general, it is important to note that often patients and the public do not distinguish between identifiable and depersonalised or anonymised data. However, irrespective of the level of depersonalisation (or anonymisation), patients and the public retain an interest in how data about them are used and expect patient data to be used with respect and in line with their expectations.

The views and preferences of patients and the public on the use of data-driven technologies differ depending on the criteria outlined above. The Academy's public dialogue workshops highlighted that analyses of data involving, for example, images of the face or body, are deemed particularly sensitive.[63] They also demonstrated that views vary according to the context or setting in which data are being collected. Hence clarity about this is crucial. For instance, continuous monitoring might be acceptable in a hospital or other healthcare setting, but regarded as intrusive in a home setting.[64] One case study discussed involved the use of a finger sensor to record tremor and the risk of Parkinson's disease whilst the patient was in hospital for unrelated medical reasons. This is an example where patients may be aware that data are being collected during the hospital stay but not 'what' data are being collected[65] 'Pervasive surveillance techniques' that collect and analyse data about them as citizens or patients also raised concerns for patients about their privacy, especially if citizen data are linked to data collected about them as patients, and without their knowledge. It has also been noted that *'non-sensitive data can hold sensitive insights'*.[66] The acceptability of using such data will depend on the purpose, anticipated benefit, context (e.g. hospital or home setting), who might have access, and how it is protected.

Clear and transparent answers to the five criteria outlined above should be provided to patients and the public, enabling them to understand the dimensions of any decisions on the use of data-driven technologies. In addition, answers to these criteria will vary depending on the specific technology in question as they will have differing levels of health 'impact' or risk. For example, answers in relation to a diagnostic tool that guides treatment will be different to those for a service improvement technology.

Expectations of privacy, rights and choice

Choice on data collection and disclosure
Data-driven technologies are expanding the ability to interrogate and interpret linked data collected from a wide range of different services and sources, including data collected outside of clinical settings. For example, many individuals use devices to collect information on their health-related behaviours such as physical activity. In addition, patients are being encouraged to enter valuable information about their health outcomes, wellbeing or for their care plans directly into a medical record.[67] For example, the patient portal

developed by University Hospitals Birmingham NHS Foundation Trust (myhealth@QEHB) enables patients to access their clinical information and submit information directly to their healthcare professionals.[68] Data-driven technologies can create meaningful summaries of these large volumes of data for patients and healthcare professionals to share. They may also reduce the burden of reporting and biases in what is reported. Analyses of this information can generate new insights into an individual's health or into disease risks and outcomes that might otherwise not be identified.

While appreciating these benefits, patients and the public felt strongly that they should retain their right to withhold such information and to maintain control over when and by whom it can be accessed, even if this may have implications for their individual care. Patients and the public thought it was important to be able to choose whether a data-driven technology collects data about them or not and to be aware when such data are being collected. Therefore patient privacy and confidentiality should be respected at all stages of using data-driven technologies in healthcare.

Rights to choose lifestyles
Patients and the public felt strongly that they should retain their individual right to choose certain lifestyles or care choices, even where these might result in less than optimal health.[69] For example, they felt that linkage of information about health-related behaviours or lifestyles (such as on diet, alcohol and tobacco use, or physical activity) to patient data should not lead to unreasonable or unfair decisions on determining or rationing access to care, or restrict rights to choose less healthy lifestyle options. A case study used at the Academy's dialogue workshops explored the possibility of a smart insulin device for diabetes which monitors blood glucose and automatically administers treatment, and also records the patient's health 'state' through an app for patients and healthcare professionals. This information could then be linked in the future via the app to lifestyle data or social media data.[70] A key message was that patients should not be penalised should they choose not to contribute such lifestyle data, and that those who do choose to contribute such data should not be discriminated against as a consequence of the data that they provide.

Rights to healthcare
Data-driven technologies should not unfairly restrict opportunities or rights of access to health and social care or other services such as insurance.[71, 72, 73] Circumstances where some healthcare options may be reasonably targeted for some – and hence constrained for others – are those where there is robust evidence that they afford the most effective and safe treatment options, and that the efficiencies of care pathways are increased as a consequence. For example, genetic sequencing technologies or triaging tools are being increasingly used to identify the cancer patients most likely to benefit from treatments, and those unlikely to significantly benefit so that side-effects can be avoided. Patients and the public felt strongly that these data-driven technologies should only be deployed where there is evidence of benefit and that they should not unreasonably reduce opportunities to receive or access healthcare, result in discrimination or inequitable access to care.

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Developers and service providers should involve patients and the public in co-development or 'co-creation' of data-driven technologies.
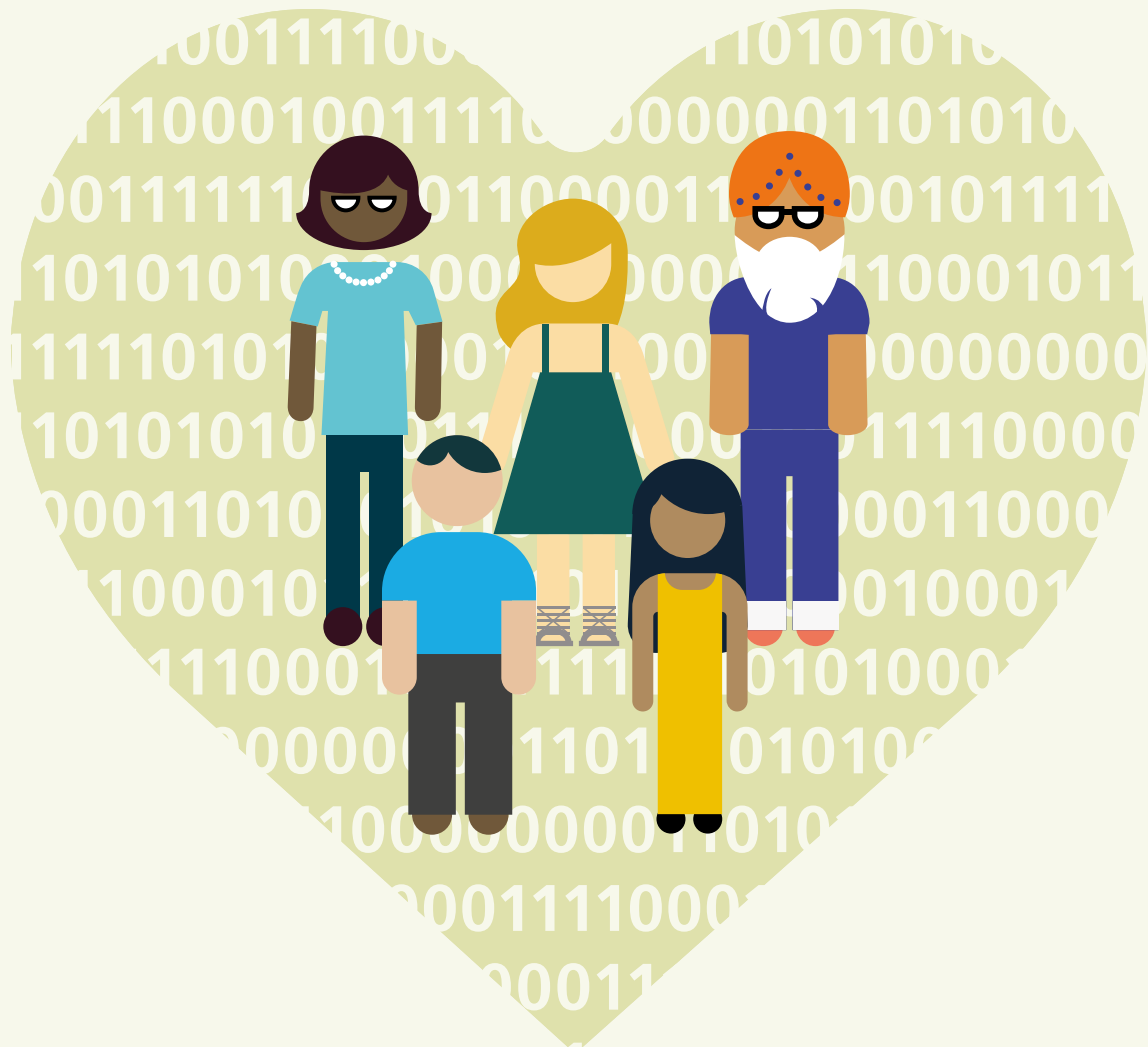
4. Developing active partnerships with patients and the public

C. Public engagement and partnership

Principle

Those determining the purpose and uses of data-driven technologies should include patients and the public as active partners.

This means that patients and the public

1. Are active partners in agreeing priorities for, and determining the acceptability of, data-driven technologies as part of an ongoing process.
2. Have easy access to clear information communicated in a way that raises awareness and understanding of these technologies.

To date, patients and the public have had little opportunity to collectively engage with and co-produce data-driven technologies. However, there are successful examples of engagement with other health technologies and research.[74] Early and ongoing public and patient involvement in the development, evaluation and deployment of new technologies is, however, considered essential to maximise their impact.[75, 76, 77] Building on this, the Academy's project on data-driven technologies has highlighted that as these technologies and applications emerge, continuous engagement of, and active partnership with, patients and the public is needed in setting priorities for these technologies. This ensures that patient and public perspectives are included when examining the acceptability and uses of such technologies, and provides assurance to the public that their views are being taken into account. It is important that this is ongoing as new information comes to light on how data-driven technologies and patient data are, and will be, used.

Patient and public engagement in decision-making

Dialogue and active partnership with patients and the public are cornerstones to ensuring that their perspectives and voices are included in decisions regarding the scope, development, evaluation and adoption of data-driven technologies.[78] For example, the James Lind Alliance Priority Setting Partnerships recently identified ten research priorities for digital technology in mental health that reflect the perspectives and needs of people with lived experience of mental health problems.[79] The need for active and meaningful partnership with patients and the public as a foundation for decision-making in health and research has also been repeatedly highlighted.[80, 81, 82] This includes their involvement in setting priorities and agreeing policies for the evaluation, adoption and use of these technologies. It is critical that

this is an ongoing process as it is a rapidly evolving field where data-driven technologies are continuously emerging and therefore views on these are constantly evolving. Developers and service providers should involve patients and the public in this co-development or 'co-creation' of data-driven technologies so that they better meet their needs. This co-creation will also help to build trust in data-driven technologies as well as ensuring their utility and subsequent adoption.[83] It also enables the NHS to take appropriate responsibility for the deployment of data-driven technologies in line with public interests.

Such involvement needs to include patients and the public from all sectors of society, allowing representation of those living in different settings and of different backgrounds. This enables a breadth of views to be expressed and will ensure that data-driven technologies are developed and implemented equitably.

Involving patients and the public in governance processes

A recent report published by NHS England, the Department of Health & Social Care and the AHSN Network identified the need to build transparent governance structures and an ethical framework to support decision-making around artificial intelligence (AI) and to build trust.[86] Governance that is inclusive of patients and the public is required to ensure that decisions about data-driven technologies are made in line with their views. There are growing examples of good practice for involving patients and the public in decision-making and co-production, including as members of panels who direct funding for health research, or those that determine uses of data and data access.[87, 88, 89] There are opportunities for involving patients and the public in governance at multiple different levels. At a higher level, the Board of NICE includes patient representatives as partners in its governance, and the NICE Citizens Council, Scottish Medicines Consortium's Public Involvement Network and Citizens' Juries are examples of mechanisms for incorporating the views of these groups into broader discussions and decisions about data-driven technologies and uses of patient data.[90, 91, 92] From this project, we believe there is a clear requirement for actively engaging patients and the public as partners in ongoing dialogues about data-driven technologies, and so governance processes will need to be adapted to ensure that this is enacted. These dialogues may need to go beyond determining the potential benefits and risks of adopting these technologies by also considering any specific ethical and social implications of their use. This could be guided at a national level by the government's new Centre for Data Ethics and Innovation. Although not specific to the healthcare sector, it is proposed that this body will look to review and guide innovative uses of data and AI in a safe and ethical manner, including identifying appropriate governance measures.[93]

Accessing clear information about data-driven technologies

Patients, the public and healthcare professionals require access to clear information about data-driven technologies. Analytical methods underlying new uses of patient data such as AI, natural language processing and machine learning are, in general, not well understood by them.[94] For example, the Academy's dialogue workshops included a case study of the potential to use natural language processing to flag episodes of, or diagnose, psychosis, and there was little belief that this could usefully monitor or identify a complex mental health condition. In part, this was due to a lack of awareness and understanding of the technique, which greatly limited the level of confidence in this technology.[95] As levels of understanding may vary across different social groups, there is also a risk of increasing the 'digital divide' between those who are informed and/or able to access technologies, and those who are not.[96] For example, there may be instances when socioeconomic background limits awareness or understanding of data-driven technologies or their associated requirements.[97] This divide will limit the ability for data-driven technologies to be used equitably and effectively across the health and social care system.

Clear and accessible information should be developed for patients and the public on how data-driven technologies work and how they might be used to benefit them. This includes clear communication on the various applications of data-driven technologies and their methods, as well as evidence on their benefits and potential risks. This will raise awareness and enable engagement and societal dialogues about the role of data-driven technologies in shaping and transforming healthcare.

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Case study 2. Data-driven technologies to support people with dementia in their home

Background

There are over 800,000 people with dementia in the UK, half of whom currently receive care at home. By 2040, this number is expected to double.[98] Primary carers enable a person with dementia to live well at home and help them to avoid or delay admission to other care settings or hospital.

Innovative approaches to providing support for people with dementia, their carers, and the health and social care teams providing community services are needed to meet this rising demand, to improve patient care and to make the most effective use of limited resources. These approaches might include using a number of data-driven technologies, which can be linked and used jointly to give a holistic assessment of the movements and health of a person with dementia. The intention is to provide reassurance on their health and safety, and enable early identification of any concerns.

How might data-driven technologies contribute?

Data-driven technologies could confer the following benefits for people with dementia and their carers:
- Helping them to maintain confidence and independence.
- Alleviating pressure on carers who may not live in the same home by supporting improved remote monitoring.
- Enabling health and social care professionals to be more effective.
- Allowing people to be cared for safely in their own homes for longer.
- Avoiding hospital admissions and the associated stress and adverse effects on health.

However, depending on their approach, they may also result in the following disbenefits:
- Replacing rather than supporting relationships between people with dementia and their health and social care team.
- Leading to incorrect decisions about care because data are not accurate or complete.
- Intruding on, or failing to safeguard, personal privacy and confidentiality, or to protect patient data.

How might these new technologies be evaluated with reference to the principles set out in this report?

A randomised clinical trial is underway to test technologies that aim to support people with dementia, which exemplifies many of the principles set out in this report.[99] This major NHS study, called TIHM (Technology Integrated Health Management) for dementia, aims to transform support for people with dementia and their carers by using smart devices sited in the home or worn by the person with dementia. These are connected to the 'Internet of Things' and enable analysis and monitoring of a person's environment, behaviour patterns and vital signs such as blood pressure, temperature and hydration.

The study is led by Surrey and Borders Partnership NHS Foundation Trust and involves a collaboration of partners including the Alzheimer's Society and the University of Surrey. It is funded by the Department of Health & Social Care, NHS England and Innovate UK. Its design was informed by a dialogue held with patients and their carers to identify the issues that they considered important.[100] This included establishing what people with dementia, their carers and healthcare professionals want and need from technologies, including the hopes, fears and opportunities that need to be considered when using technology in the home. The trial has been designed to evaluate these aspects and to determine whether there is sufficient evidence to introduce these technologies into routine health and care.

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Data access is essential for the effective development and utility of data-driven technologies.

5. NHS stewardship

D. NHS data stewardship and responsibilities

Principle

The NHS, and those acting on its behalf, should demonstrate their continued trustworthiness by ensuring responsible and effective stewardship of patient data and data-driven technologies in the NHS.

They should

1. Retain overall responsibility for where patient data and data-driven technologies are used.
2. Make sure those accessing patient data to develop data-driven technologies use it for agreed purposes (see theme A).
3. Ensure data access agreements are for defined purposes (see theme A), and set out how benefits will be shared fairly across the NHS.
4. Assure the consistency, accuracy and quality of patient data used by data-driven technologies.
5. Build skills and capacity in the NHS workforce to enable the use of data-driven technologies.
6. Introduce into the NHS data-driven technologies that have evidence about their effectiveness and safety, being clear about where responsibility lies for any harmful health or other consequences of their use.

A strong theme which emerged from the Academy's public dialogue workshops was that the public expect the NHS to be *'in control of patient data'* in relation to the deployment of data-driven technologies. However, patients and the public are not always aware that NHS services are delivered by different provider organisations, including private contractors. In this chapter, we consider the collective responsibilities of those individuals in NHS organisations, or acting on their behalf, who are either responsible for stewardship of patient data (including the collection, recording or curation of patient data) for data-driven technologies, or the commissioning or adoption of data-driven technologies themselves.

As discussed in Chapter 2, the NHS has a pivotal role to play in enabling the full benefits of data-driven technologies to be evaluated and realised. To fulfil that role, the NHS and its organisations need to develop transparent and accountable partnerships and agreements with developers and third parties (such as researchers) in accordance with patient and public expectations. These will provide assurances to patients and the public that data are secure, while ensuring appropriate access to patient data by technologies which is key to their use. Furthermore, the NHS will need to ensure the appropriate capacity and capabilities of its workforce to engage with data-driven technologies, for example, through building digital literacy, instigating culture change around views and application of data-driven technologies, and supporting evidence-based commissioning of these tools.

Digital maturity in the NHS

It is important to recognise that at present, NHS organisations have not fully implemented digital technologies to achieve an integrated health and care system that is universally paper-free at the point of care. Therefore at present, there remains considerable variation in digital maturity across the NHS.[101] This limits the extent to which providers can plan and deploy emerging digital services including data-driven technologies.[102] Strategies are starting to be put in place that may help to raise UK-wide levels of digital maturity, and better integrate IT systems and data across health and social care.[103, 104, 105, 106]
Further plans for infrastructure or investment in this area will be critical to realising the potential of data-driven technologies in healthcare. The importance of improving IT and digital infrastructure to enable this is recognised in the Department of Health & Social Care's policy paper on technology and data in healthcare.[107]

The Wachter review on health information technology highlighted that both technical and human aspects need to be developed to advance the digital maturity of the NHS.[108] Clinical leadership and training of the NHS workforce are crucial to this task and are the focus of the current Topol Review into digital capabilities of the healthcare workforce.[109] For example, clinicians with expertise in clinical informatics provide important leadership in NHS organisations, as recognised through the recently established Faculty of Clinical Informatics.[110] However, as highlighted by Wachter, more needs to be done in terms of resourcing and supporting the stewardship of, and access to, patient data and the deployment of data-driven technologies. The employment of computer and data scientists within the NHS may also need to be considered.

Data curation for data-driven technologies

The data used or generated by data-driven technologies will be collected, stored and accessed either by, with or on behalf of the NHS, in line with NHS rules and guidelines and relevant UK ethical and legislative requirements and standards.

The quality, reliability and safety of data-driven technologies depend on the accuracy and integrity of the data entered. As a steward of patient data, the NHS has a responsibility to ensure that patient data meet these needs and remain accurate, up-to-date, accessible and a reliable reflection of a patient's status. This applies equally to data that may be collected or created by third parties contracted to deliver NHS services.

For the NHS to retain oversight of data-driven technologies and the patient data that they use, it needs to retain overall responsibility for uses of data-driven technologies and patient data in the NHS, and to determine accountability for their use. This includes: data creation or acquisition, linkage, curation, analysis, retention, security, deletion, access, and any legacy uses, as well as the deployment of the technologies themselves.

Data curation
Data curation involves the acquisition, maintenance, preservation and disposal of data throughout the data life cycle to ensure the quality and value of the data are actively maintained.[111] If improperly curated, important data may be lost or corrupted or erroneous interpretation by a data-driven technology might arise. Once this has occurred, it may be very difficult to detect and/or rectify the issue.

The availability of systems for data curation in the NHS is key to ensuring the integrity and quality of patient data for individual care and use by data-driven technologies. It is clear that the NHS will need to grow its data curation and access capabilities in order to capitalise on data-driven technologies. For example, patients and healthcare professionals are aware that they do not currently have access to a complete and integrated electronic health record (EHR) at the point of care. This reflects a number of factors including a lack of a fully digitised health system, limited capabilities to link different data types, different siloed systems used for recording data and their lack of interoperability, and until recently, different systems for coding data leading to a lack of standardisation. There are initiatives seeking to tackle this by developing innovative approaches to integrating and annotating diverse types of patient data collected from multiple sources.[112]

In addition, patient data can become outdated due to changes in the patient's circumstances or health status. As such, it is important that data-driven technologies have access to the most up-to-date data

available. Systems should be in place to identify substantive changes to patient data, for example in coding or format, that may have occurred since the data were collected and which might reduce the reliability of the technology.

Ensuring the quality of patient data

Data-driven technologies require consistent and high-quality data that comply with external standards for collection and curation, and also allow data from different sources to be combined. This is especially relevant for technologies that depend on data directly entered by a healthcare professional. Data collected and entered in this way should conform to agreed standards.[113, 114] Developers of data-driven technologies should also be clear about data and technical standards employed by their technologies so that these can be aligned with those used in the NHS. This can build on the recent introduction of the SNOMED Clinical Terms in the NHS, which will be in use across the entire NHS by 2020.[115]

The NHS cannot be responsible for the accuracy of information generated outside of the NHS, such as from wearable devices. It will be important to ascertain responsibility for any decisions arising from the integration of this information with NHS data. Patients may also generate data, for example, from self-monitoring devices or by entering outcomes and other information using mobile apps. It is important that systems aimed at enabling patients to collect or input data are designed to support the quality of the data contributed.[116]

Data access for data-driven technologies

Data access is essential for the effective development and utility of data-driven technologies. Those charged with the stewardship of patient data therefore need to balance safeguarding of patients, including respecting the wishes of patients who opt out, with enabling data access for data-driven technologies.[117] An approach that is too risk averse may impede the development and evaluation of data-driven technologies to the detriment of patients and the NHS.

There are national mechanisms for approving and providing access to depersonalised or anonymised patient data in the UK.[118, 119] However, these mechanisms for data access by third parties are largely lacking *within* NHS provider organisations that are being approached by technology developers for access, with some specific exceptions.[120, 121, 122] Transparent and accountable processes are needed to support NHS organisations to review and approve data access requests for data-driven technologies in line with the expectations of patients and the public. Trusted research environments are also needed to provide assured access to large volumes of data. A number of approaches to this have been proposed, including access to federated or distributed data held in a number of safe havens, 'data enclaves' or data trusts.[123, 124, 125, 126, 127] The intention is to provide a secure and controlled environment for data access to minimise the risks associated with data access and enable the NHS to maintain control, enabling all parties to focus on realising the benefits of agreed uses of patient data.

Data access or processing agreements are an important element for managing access to patient data for data-driven technologies. They can ensure that risks are minimised and that access addresses the expectations of patients and the public of the purposes and value of employing such technologies, as well as how the benefits of the technologies developed as a consequence are returned to the NHS. These agreements should clarify expectations for the privacy and security of data, including accountability and liability, as well as expectations around the deployment of the technology itself. This includes ensuring robust mechanisms for the deletion or return of data upon completion of its intended use.

Deployment of data-driven technologies in the NHS

Implementing data-driven technologies will require a broader culture change to enable full and informed participation by the NHS and social care workforce, to allow their effective use and to understand their benefits and mitigate potential risks. This is particularly important where data-driven technologies may cause a paradigm shift in the way that health and social care is delivered,

which has particular implications for the healthcare workforce. For example, the accountability and responsibilities of the workforce when evaluating and using data-driven technologies may change, and training to ensure they have the necessary capabilities and capacity to engage with these new technologies will be important.

The shifting role of healthcare professionals

The use of data-driven technologies in healthcare settings may create new responsibilities for those involved in their deployment, creating a need to clarify roles and responsibilities.[128] This is especially true when these technologies are used in decisions about care, where patients and the public feel that healthcare professionals should retain the right to use their clinical experience and reasoned judgement to disagree with or overrule a conclusion made by a technology.[129]

Where the accountability lies for an error made through using a data-driven technology will vary on a case-by-case basis, and whether it is a technical error caused by a fault in the equipment or analyses, or a clinical error made using information provided by the technology. Accountability for errors (by the developers, healthcare professionals or commissioners) will depend on the data-driven technology itself, the context for its use and how it was used by a healthcare professional. For example, the responsibility of a healthcare professional using a 'black box' technology – where there is limited or no information on how it analyses data or comes to a conclusion, also known as 'explainability' – will be markedly different compared to a healthcare professional interpreting raw data from a monitor or wearable device. Clarity is needed on the expectations of the healthcare professional when using a data-driven technology and their liability for any consequences such as adverse health outcomes.

Skills and capacity in the NHS workforce

There is a need to prepare the NHS and its workforce for these technologies which may be truly disruptive to traditional clinical pathways, both in terms of skills and behaviour around data curation and access, as well as how they are deployed in the NHS, which will create demand for new expertise, systems and training. This preparation can be supported, in part, through:

- Embedding digital literacy and competency throughout the NHS, as highlighted by the Wachter review and the Topol Review.[130, 131] It is important that these efforts involve patients to enable their active and informed participation.
- Raising awareness and understanding of the benefits of data-driven technologies and highlighting their potential as complementary tools for healthcare delivery, public health, biomedical research and service improvement.
- An evolution of the NHS into a 'learning health system', where the benefits and learnings from data-driven technologies are fed back into the system to drive system-wide improvement, whether for individual care, research or planning.[132]

Digital literacy is defined by Health Education England as: *'the capabilities which fit someone for living, learning, working, participating and thriving in a digital society'*.[133] Patients and healthcare professionals should feel able to make informed decisions on when and how data-driven technologies are used based on an understanding of how they have been evaluated and how they work. Education and training of the NHS workforce in digital literacy will be key to developing this confidence. For example, this could build on the work of the NHS Digital Academy to ensure that digital knowledge and skills are disseminated more widely to the entire healthcare workforce and patients.[134]

Digital literacy will also help ensure that data-driven technologies are used as effectively as possible by healthcare professionals and patients. This not only guarantees that they are operated correctly, but also aids the effective use of their outputs and support for shared decision-making.[135]

Commissioning decisions on data-driven technologies

For commissioners, healthcare professionals and patients to make informed decisions about the use of data-driven technologies, they need to have access to clear information on their effectiveness and safety. For example, new health apps are 'kitemarked' by their inclusion in the NHS Apps Library, which ensures technology developers have considered and supplied a certain level of information around utility, quality, safety and other factors through completing a set of Digital Assessment Questions.[136] However, as of August 2018, only 71 apps had been vetted in this way despite there being a vast number of potential health

and fitness apps available.[137] Furthermore, this 'kitemarking' does not provide evidence of effectiveness and safety as is the case for other healthcare interventions approved by the National Institute for Clinical Excellence (NICE) and similar UK organisations. Given the rapid growth in data-driven technologies, appropriate processes for this need to be developed within existing systems for evaluation and guidance, and communicated clearly to the end users.[138, 139]

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Healthcare professionals and their patients require access to trusted evaluations of data-driven technologies and transparency around their decision-making processes.
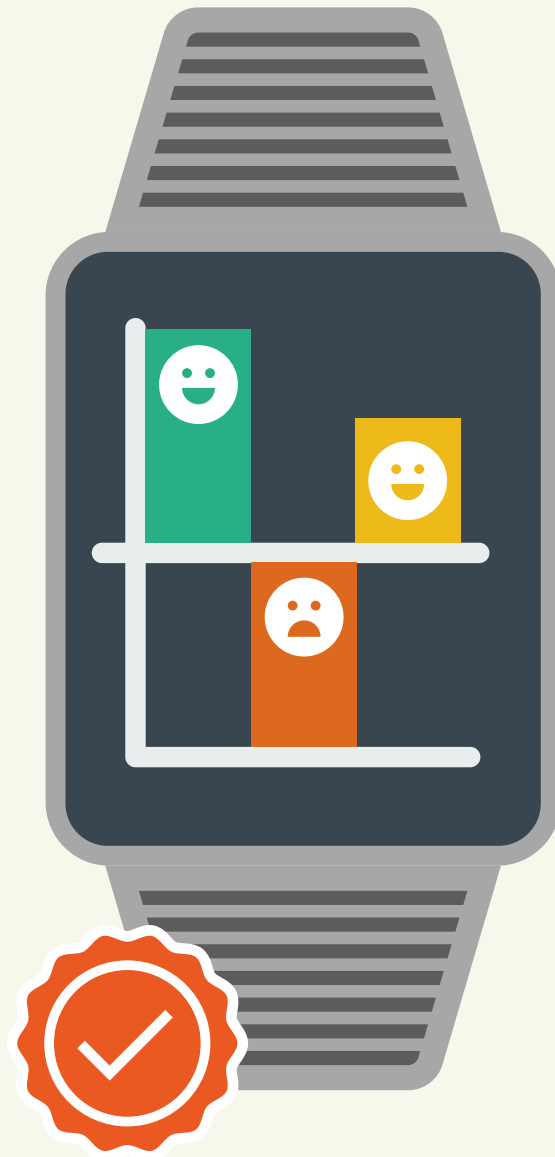
6. Evaluation of data-driven technologies and their regulation

E. Evaluation and regulation

Principle

Data-driven technologies should be evaluated and regulated in ways that build understanding, confidence and trust, and guide their use in the NHS.

The use of data-driven technologies should be

1. Supported by timely evidence on their benefits, accuracy, effectiveness, safety and security in line with regulatory, ethical and commissioning requirements.
2. Reviewed and periodically audited.

The Academy's public dialogue workshops highlighted the importance of assessing and understanding the benefits, effectiveness, cost-effectiveness and risks of data-driven technologies. It is essential that they are fully evaluated on these factors, as with any other health intervention or diagnostic test. Evaluation and improvement of these technologies will rely on effective data access processes.

Frameworks for the approval and regulation of data-driven technologies are not currently fully articulated or established.[140] Once deployed, ongoing scrutiny will be essential to assure their quality and performance to agreed standards, minimise risks associated with their use and protect them against external interference. In addition, their evaluation should be continuous and updated as they are iterated and improved. Many of these aspects are similar to those used to assure the quality of other devices and processes, such as pathology tests and their reporting in the NHS by the independent UK National External Quality Assurance Service.[141] Clarification around the regulation and evaluation of data-driven technologies should build upon work already being undertaken to support developers in understanding the regulatory checkpoints along the route to market.[142]

As discussed previously, the reliability of data-driven technologies can be supported by ensuring the integrity and quality of the patient data that the technology uses, that the technology is used in the right way, and that the minimal requirements for a technology's usefulness, effectiveness and accuracy are met.

Evaluating data-driven technologies

A robust evidence base is needed on the effectiveness and safety of data-driven technologies in line with current regulatory criteria, as well as their cost-effectiveness and guarantee of security or privacy when deployed in real-world settings. This evidence should be generated with effective patient involvement.[143] It is important that regulators identify and clarify any additional evidence requirements for data-driven technologies employing analytical techniques, such as artificial intelligence (AI) or

machine learning, over and above those in place for medical devices and apps that collect or analyse patient data, so that they can be fulfilled during development.[144] In addition, these evidence needs may differ based on the type or purpose of the technology (and its relative level of 'impact' or risk in healthcare). For example, whether it is a health service improvement tool, health monitoring or surveillance device, or a digital therapy or behavioural change technology. The initial code of conduct for data-driven health and care technology explores some of the differences in clinical impact and risk of harm between the different types of these technologies, and the evidence standards that may accompany them.[145]

It is also important that evidence is continually reviewed and updated with technology improvements or as they evolve. For example, it is expected that a machine learning algorithm will change over time due to the increasing volume of data for it to learn from. It is also likely that data-driven technologies will be iterated and improved based on user experience. Therefore, they will need to be periodically audited to ensure they continue to meet expected standards. Given that technologies using methods such as AI may evolve over time, it will be important to retain information about the version of a technology that was approved and used for healthcare decisions. Retaining this breadth of information will allow comparisons and updates to previous information produced by the technology.

It is also important to note the provenance of data that a technology uses and when these data were used, as this will affect the reliability of the technology itself. Discrimination or bias may arise if technologies are developed or deployed using incorrect, biased or skewed population data or assumptions. In addition, a lack of equitable access across the country or a lack of available data from certain sub-populations may result in discrimination.[146]

Transparency of decision-making by data-driven technologies

Healthcare professionals and their patients require access to trusted evaluations of data-driven technologies and transparency around their decision-making processes in sufficient detail to determine their effectiveness, reliability and safety, and to interpret and apply this information for individual care. As well as transparency on decision-making processes, it is also helpful for those evaluating and regulating data-driven technologies to clarify the potential for unconscious bias to be introduced through training data. A layered approach incorporating different levels of information may be needed to enable variation in the level of detail provided on how data-driven technologies have been evaluated.[147]

There are likely to be circumstances where the exact nature of the way a data-driven technology works is not easily explainable because it operates as a 'black box'. In this situation, the reasons for being unable to disclose information should be apparent. Developers of technologies that operate in this manner may encounter challenges from patients, healthcare professionals or regulators in terms of validating their outputs and their reliability and trustworthiness. Developers should anticipate these issues and provide sufficient information and assurance to support their evaluation and use, for example, through audit mechanisms and independent scrutiny.

Security of data-driven technologies

It is important that there are processes in place to safeguard data-driven technologies against external interference, and mechanisms to monitor and detect such interferences. Developers should be responsible for taking steps to detect and prevent such interference, and be able to demonstrate that these steps are in place to the user. Regulators also have a role in reviewing the security processes in place for a technology to identify expected practice and to monitor compliance.

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Collective working and coordinated action across all key stakeholders are needed to uphold these principles.

WORKFORCE

DIGITAL MATURITY

NHS CULTURE

REGULATION

EVALUATION
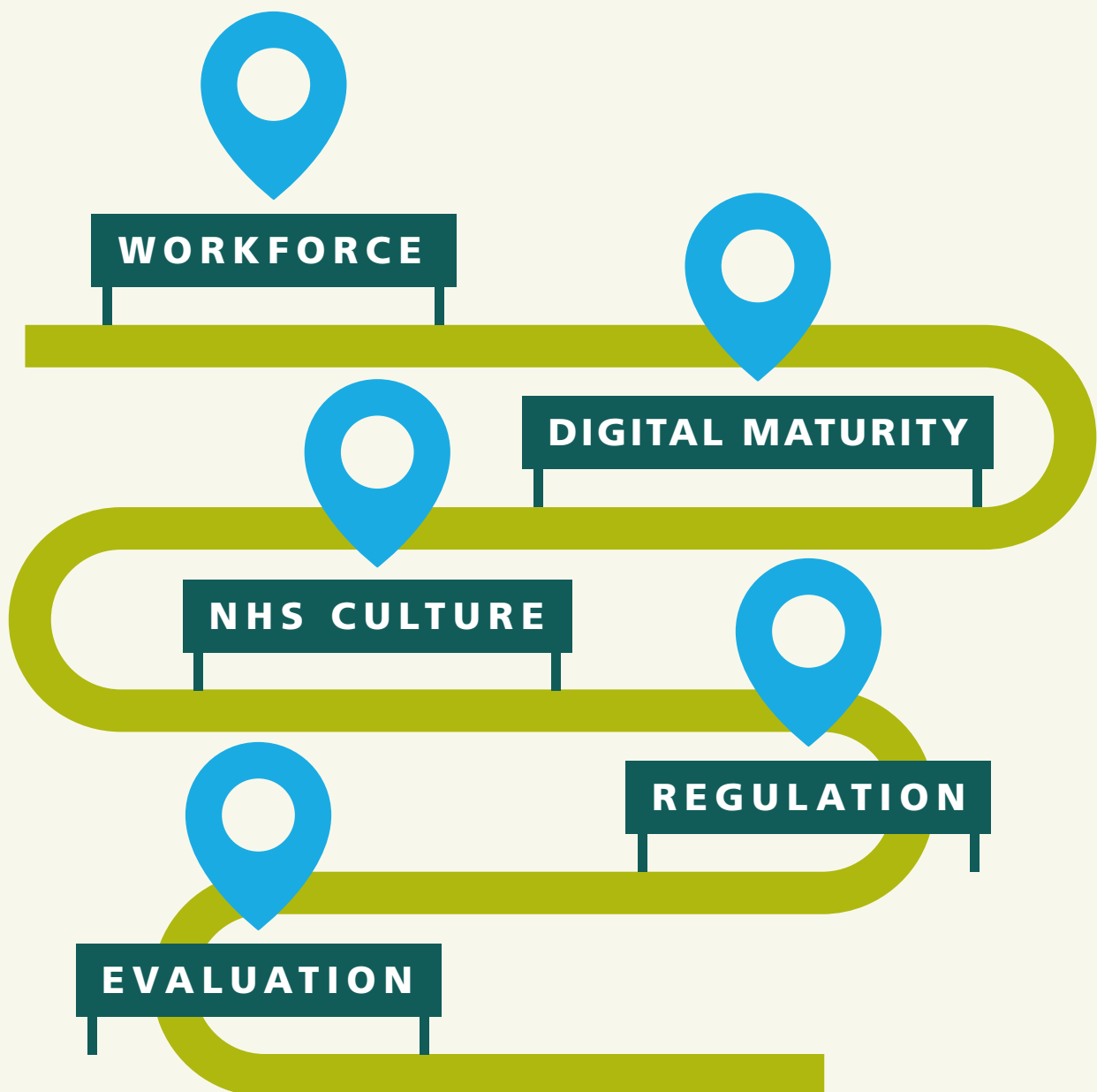
7. Putting principles into practice

Maintaining trustworthiness in the NHS and in its use of patient data to develop and deploy data-driven technologies requires honesty, reliability and competence on the part of the NHS as stewards of patient data, as well as on the part of academics, developers and others with whom they partner. The findings of this project have highlighted the expectations of patients, the public and healthcare professionals, and the importance of making them meaningful partners in this process in order to fully realise the potential benefits of data-driven technologies in health and social care and mitigate their potential risks. This contribution will need to be ongoing as technologies evolve in ways that may not be anticipated. It will also need to recognise existing tensions around patient data and any new issues that emerge for debate. Transparency, accountability and communication are also essential, but will be insufficient if patients and the public are not included and involved as active partners from the outset.

We have set out actionable principles that build on prevailing concepts of co-production in research and healthcare, and are consistent with other frameworks for responsible data use and governance.[148, 149] They also usefully extend upon the principles of data governance proposed in a report by the British Academy and Royal Society, which included protection of *'individual and collective rights and interests'* and enhancing *'existing democratic governance'*.[150] The audiences for these principles have a responsibility to consider how they can act in ways that align with them, thereby engaging with and reflecting the values and perspectives of patients, the public and healthcare professionals, which are likely to evolve over time.

New processes and infrastructure are essential to underpin the enactment of these principles, including:

✔ **UK-wide improvements to the digital capabilities and competencies of NHS and social care systems.**[151] This includes processes for safe data storage and access; data standardisation, curation and linkage; and the security of data-driven technologies. The Wachter review on health information technology highlights the need to secure an integrated data infrastructure across the NHS and a workforce able to use it, in order to capitalise on more innovative digital technologies.[152]

✔ **A cultural shift within the NHS and across healthcare professionals.** Clear lines of accountability and responsibility which reward and encourage innovation are needed for NHS organisations and providers, developers, funders and others. At the same time, these need to ensure that data-driven technologies are used in ways that meet the expectations outlined in this report, and that mitigate and clarify responsibilities for any risks that the technologies may bring. In addition, behaviour change across healthcare professions will be key to ensuring the uptake of new technologies, and that they are deployed in the most effective and informed way to benefit patient health.

✔ **Robust evaluation mechanisms** in the health and social care system that allow data-driven technologies to be rapidly adopted on a national scale, and their potential benefits and risks to be reviewed by the NHS to facilitate appropriate prioritisation and uptake. Evaluation and assurances are needed around reliability in two respects: the reliability of the patient data that data-driven technologies use, and how the technology itself processes the data. The challenges around reliability of patient data and data-driven technologies are inextricably linked. Failure to have transparency or governance in either one of these areas will lead to failure of the technology.

✔ **An appropriate regulatory framework** that is clear about the evidence requirements for data-driven technologies and promotes technologies that meet the expected standards set out within this report and by others.

Collective working and coordinated action across all key stakeholders are needed to build the underlying supporting processes and infrastructure, and uphold these principles in the development, evaluation and use of data-driven technologies in healthcare. We recognise that a single set of clear guidance is fundamental to achieving this, and the Academy will continue working to integrate and embed the principles outlined within this report with the work of others, including the Department of Health & Social Care. We will explore different possible mechanisms for doing this, including a potential framework or concordat for those organisations involved with patient data and data-driven technologies in healthcare.

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Annex I. Key background reports on patient data and data-driven technologies in healthcare

Below is a list of key reports and public dialogue programmes that helped to inform the Academy's project on data-driven technologies.

Public dialogue programmes

- **Ipsos MORI (2016).** *The One-Way Mirror: Public attitudes to commercial access to health data.* https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf
  A public dialogue programme commissioned by the Wellcome Trust that explores public perspectives on commercial access to health data.
- **Ipsos MORI (2017).** *Public views of Machine Learning.* https://royalsociety.org/~/media/policy/projects/machine-learning/publications/public-views-of-machine-learning-ipsos-mori.pdf
  A public dialogue programme commissioned by the Royal Society to explore the views of the public on machine learning.
- **Ipsos MORI (2018).** *Future data-driven technologies and the implications for use of patient data.* http://www.acmedsci.ac.uk/datadialogue
  A dialogue programme with patients, the public and healthcare professionals commissioned by the Academy of Medical Sciences to explore perspectives and expectations on the use of data-driven technologies in healthcare.

Reports

- **National Data Guardian for Health and Care (2016).** *Review of Data Security, Consent and Opt-Outs.* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF
  A review of data security and consent for access to identifiable patient data in the NHS with the aim of building public trust.
- **National Advisory Group on Health Information Technology in England (2016).** *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England.* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/550866/Wachter_Review_Accessible.pdf
  The Wachter review identifies steps to creating a fully digitised NHS.
- **Royal Society (2017).** *Machine learning: the power and promise of computers that learn by example.* https://royalsociety.org/~/media/policy/projects/machine-learning/publications/machine-learning-report.pdf
  Exploring the opportunities afforded by advances in machine learning and ways to harness its potential.
- **Hall W & Pesenti J (2017).** *Growing the Artificial Intelligence Industry in the UK.* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/652097/Growing_the_artificial_intelligence_industry_in_the_UK.pdf
  An independent review of how AI can be grown in the UK to capitalise on its potential benefits.
- **House of Lords Select Committee on Artificial Intelligence (2018).** *AI in the UK: ready, willing and able?* https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/100.pdf
  An inquiry into the current environment in the UK for development and use of AI, and recommendations to capitalise on its potential.

- **Nuffield Council on Bioethics (2018).** *Bioethics briefing note: Artificial intelligence (AI) in healthcare and research.* http://nuffieldbioethics.org/wp-content/uploads/Artificial-Intelligence-AI-in-healthcare-and-research.pdf
  Outlining developments in the use of AI and its potential for healthcare and medical research and the associated ethical and social challenges.

- **Future Advocacy & Wellcome (2018).** *Ethical, social, and political challenges of artificial intelligence in health.* https://wellcome.ac.uk/sites/default/files/ai-in-health-ethical-social-political-challenges.pdf
  Identifies the key ethical, social and political challenges raised by the use of AI in healthcare.

- **House of Commons Science and Technology Committee (2018).** *Algorithms in decision-making.* https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/351/351.pdf
  An inquiry into the potential challenges of using algorithms and how this might be managed by a new Centre for Data Ethics and Innovation.

- **Health Education England (2018).** *The Topol Review: Preparing the healthcare workforce to deliver the digital future, Interim Report June 2018 – A Call for Evidence.* https://www.hee.nhs.uk/sites/default/files/documents/Topol%20Review%20interim%20report_0.pdf
  The interim report of a review into how advances in technology may impact the clinical workforce.

- **Academy of Medical Sciences (2018).** *New technologies that use patient data.* http://www.acmedsci.ac.uk/dataworkshop
  A report of a policy workshop to explore the findings of the Ipsos MORI dialogue programme on data-driven technologies in healthcare (*'Future data-driven technologies and the implications for use of patient data'*) with a range of key stakeholders.

- **Association of Medical Research Charities (2018).** *Promoting more effective partnerships in digital health.* https://www.amrc.org.uk/Handlers/Download.ashx?IDMF=2adb157a-c385-49e7-92cd-d03882001172
  A draft discussion paper from the AMRC member charities on creating effective and meaningful partnerships with patients in digital health innovation.

Annex II. Project steering group

All members of the steering group declared any potential conflicts of interest and these were considered as part of their membership of the group. This report was prepared by the steering group for the project and a summary of the members and their relevant expertise can be found below.

Steering group

Professor Carol Dezateux CBE FMedSci [Chair], Professor of Clinical Epidemiology and Health Data Science, Queen Mary University of London
Professor Dezateux is a professor at Queen Mary University of London, accredited paediatrician, NHS Consultant in Clinical Informatics at Barts Health NHS Trust, as well as Associate Director of the London site of Health Data Research UK. Her research aims to improve the health of children by identifying and evaluating opportunities to prevent childhood obesity and improve outcomes and care for children with long-term conditions and their families. As a member of the Discovery Data Service, she supports the development of an integrated health and care record and a learning health system. She was made a Fellow of the Academy of Medical Sciences in 2006 and awarded a CBE in 2010 for services to science.

Dr Natalie Banner, Lead, Understanding Patient Data
Dr Banner leads the Understanding Patient Data (UPD) initiative, hosted at the Wellcome Trust, and set up to support better conversations about how patient data is used for care and research. UPD works with patients, charities and health professionals to champion responsible uses of data, including exploring emerging data-driven technologies and the ethical and governance frameworks for these in healthcare and research. She formerly led Wellcome's policy work on data protection, seeking to ensure UK legislation and regulation creates a supportive, trustworthy environment for health research.

Dr Kambiz Boomla, General Practitioner and Clinical Senior Lecturer, Queen Mary University of London
Dr Boomla has been a GP in Tower Hamlets since 1982, and is a founding member of the east London Clinical Effectiveness Group at Queen Mary University of London. This group has established a trusted relationship with all east London practices and for three decades has conducted quality improvement and research using patient data for whole populations. He is Primary Care Clinical Lead for Discovery Data Service, a collaboration of NHS and social care organisations creating an integrated health and care record to support a learning health system.

Professor Mandy Chessell CBE FREng, Distinguished Engineer and Master Inventor, IBM
Professor Chessell is a Fellow of the Royal Academy of Engineering and IBM Distinguished Engineer. She is an expert in data management and governance and leads the ODPi (an organisation that aims to simplify and standardise the big data ecosystem) initiatives to create open standards and technologies for metadata and governance.

Professor Susan Michie FMedSci, Professor of Health Psychology and Director of the Centre for Behaviour Change, University College London
Professor Michie has worked in the NHS as a clinician, an organisational consultant, a trainer and a researcher. Her research investigates innovative methods for developing, evaluating and implementing behavioural interventions in three main health domains: preventing ill health, managing long-term conditions and promoting evidence-based professional practice. Her research covers population, organisational- and individual-level interventions, including digital interventions.

Professor John Naughton, Emeritus Professor of the Public Understanding of Technology,
Wolfson College, University of Cambridge
Professor Naughton is a systems engineer with a strong interest in the social impacts of networking technology.
He is currently a Senior Research Fellow in the Centre for Research in the Arts, Social Sciences and Humanities
(CRASSH) at the University of Cambridge and Director of the Press Fellowship Programme at Wolfson College,
and Emeritus Professor of Public Understanding of Technology at the British Open University.

Dr Amara Nwosu, Medical doctor and Clinical Lecturer in Palliative Medicine, University of Liverpool
Dr Nwosu is a consultant and Honorary Senior Clinical Lecturer in Palliative Medicine. His research involves
the evaluation of health technology to study symptoms, quality of life and physical function in advanced
disease. He is the Clinical Lead for Palliative Care projects conducted as part of the Global Digital Exemplar
(GDE) programme of the Royal Liverpool and Broadgreen University Hospitals NHS Trust.

Professor Jill Pell CBE FRSE FMedSci, Director of the Institute of Health & Wellbeing,
University of Glasgow
Professor Pell is the Henry Mechan Professor of Public Health and Director of the Institute of Health &
Wellbeing, University of Glasgow. She is a Fellow of the Royal Society of Edinburgh and a Fellow of the
Academy of Medical Sciences. Jill has been using routine data and record linkage as a resource for research
for more than 20 years. She was Deputy Director, then Director, of The Farr Institute's Scotland Centre and
is currently a member of HDR UK in Scotland. She was awarded a CBE in 2017 for services to public health
research.

Jonathan Sellors, Legal Counsel and Company Secretary, UK Biobank
Mr Sellors is the Legal Counsel of UK Biobank, a partner at Howard Kennedy LLP and Senior Fellow at the
Nuffield Department of Public Health at Oxford University. He is also a board member of the European
Society of Cardiology.

Professor Lionel Tarassenko CBE FREng FMedSci, Professor of Electrical Engineering and Head,
Department of Engineering Science, University of Oxford
Professor Tarassenko is the Head of the Engineering Science Department at the University of Oxford, and an
expert in the application of signal processing and machine learning in healthcare. Working with clinicians, he
has led the engineering development of four digital health products in the last decade such as GDm-Health,
a digital therapeutic for the management of gestational diabetes, and SEND, a system for monitoring patient
vital signs in hospital and identifying deterioration early.

Dr Mary Tully, Director of Public Engagement for Connected Health Cities and Reader of Pharmacy
Practice, University of Manchester
Dr Tully is a pharmacist by background and is Director of Public Engagement at Connected Health Cities, as
well as Reader in Pharmacy Practice, both based at the University of Manchester. She is interested in both
investigating public values and concerns about health data use (so that data initiatives, such as Connected
Health Cities, understand what they need to do to be seen as trustworthy), and maintaining public trust
through awareness-raising.

Professor Dame Til Wykes DBE FMedSci, Professor of Clinical Psychology and Rehabilitation, Institute of
Psychiatry, Psychology and Neuroscience, King's College London
Professor Wykes is Consultant Clinical Psychologist at the South London and Maudsley NHS Foundation
Trust. She co-produces digital technology with people with mental health conditions including evaluations of
e- and m-health interventions, and workshops to overcome the digital divide.

Review group

The report was reviewed by an independent review group who were asked to consider whether the report met the terms of reference and whether the evidence and arguments presented in the report were sound and supported the principles. The review group comprised:

Professor Philippa Saunders FMedSci [Chair], Director of Postgraduate Research, College of Medicine and Veterinary Medicine, University of Edinburgh

Professor Corri Black, Co-Director, Aberdeen Centre for Health Data Science, University of Aberdeen

Professor Jonathan Mant FMedSci, Professor of Primary Care Research, University of Cambridge

Hilary Newiss, Chair, National Voices

Secretariat

Liberty Dixon [Lead secretariat], FORUM Policy Manager, Academy of Medical Sciences
Dr James Squires, Policy Officer, Academy of Medical Sciences
Dr Naho Yamazaki, Head of Policy, Academy of Medical Sciences
Holly Rogers, Communications and Engagement Manager, Academy of Medical Sciences
Nick Hillier, Director of Communications, Academy of Medical Sciences

We are grateful for the coordination of the independent review by Elizabeth Bohm, Head of International and Sophia McCully, Policy Officer, both from the Academy of Medical Sciences.

We are also particularly grateful for the input and contributions from:

Professor Bobbie Farsides, Professor of Clinical and Biomedical Ethics, Brighton and Sussex Medical School
Professor Jonathan Montgomery, Chair, Health Research Authority
Professor Andrew Morris CBE FRSE FMedSci, Director, Health Data Research UK

Annex III. Organisations consulted for this project

In addition to the Academy's dialogue programme and policy workshop, we further consulted the following organisations on the principles within the report:

- Alzheimer's Research UK
- Association of British HealthTech Industries
- Association of Medical Research Charities
- British Heart Foundation
- British Standards Institution (BSI Group)
- Cancer Research UK
- Care Quality Commission (CQC)
- Centre for Data Ethics and Innovation
- DeepMind
- Department of Health & Social Care
- Diabetes UK
- Digital Catapult
- Evergreen Life
- Health Data Research UK
- Health Education England
- Health Research Authority
- House of Lords Select Committee on Artificial Intelligence (Chair)
- Information Commissioner's Office (ICO)
- INVOLVE
- Medical Research Council
- Medicines & Healthcare products Regulatory Agency
- MQ
- MS Society
- National Data Guardian's Panel
- National Institute for Health and Care Excellence (NICE)
- NHS Digital
- NHS England
- Office for Life Sciences (Department for Business, Energy & Industrial Strategy)
- Office for Strategic Coordination of Health Research (Health Informatics Sub-Group)
- Pinnacle Health Partnership
- Royal Academy of Engineering
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal College of Paediatrics and Child Health
- Royal College of Physicians
- Royal Society
- SAIL Databank Wales
- SAIL Databank Wales Consumer Panel
- TechUK
- The King's Fund
- The Topol Review
- Wellcome Trust
- Use MY data

Annex IV. Case study 1. Stages of technology development

Stages of technology development	Type of patient data required	Data access	Principles	Who
1. Develop and test automated methods of technology on a training dataset of anonymised images previously collected in a research setting.	Antenatal ultrasound videos from women at different stages of pregnancy and with different presentations (e.g. head or breech); limited clinical information about pregnant woman needed with scans.	Third-party permission to access videos for defined purposes, with appropriate ethical and legal permissions. Access formally provided by a data access agreement and IP sharing defined.	A2 A3 A5 A7 B1 B3 B4 C1 C2 D1 D2 D3 D4	Researchers Developers Research funders Clinicians Patients Data controllers
2. Test the performance of automated methods on a larger sample of anonymised images previously collected in routine care.	As above; images may be selected to test other characteristics of the woman, her pregnancy, or fetus, for example, pregnant women with more than one fetus, or with other information suggesting the fetus is at high risk.	As 1. above	As 1. above	As 1. above
3. Evaluate performance in a study carried out in a clinical setting using images prospectively collected for the study.	As above, with more information about short-term outcomes but without influencing clinical care.	Research collecting new data with consent and appropriate legal, regulatory and ethical permissions; may require CE approval to enable these methods to be applied in a clinical setting; sponsor of research study to clarify liability; IP arrangements agreed.	A1 A2 A3 A4 A5 A7 B1 B2 B3 B4 C1 C2 D1 D2 D3 D4 D5	Researchers Developers Research funders NHS data stewards Clinicians Patients Regulators

Stages of technology development	Type of patient data required	Data access	Principles	Who
4. Evaluate performance and outcomes in a study carried out in more than one clinical setting and with women with different demographic and clinical features to obtain real-world evidence about performance and clinical outcomes (including potential harms), using images prospectively collected for the study.	As above and with information used to inform clinical care in real-time and to evaluate pregnancy outcomes, as well as patient reported experience and outcome measures.	Research study collecting new data conducted in a clinical setting with consent and appropriate legal, regulatory and ethical permissions; may require CE approval to enable these methods to be applied in a clinical setting; sponsor of research study to clarify liability; IP arrangements agreed.	As 3. above	As 3. above
5. Synthesise evidence from this and other evaluations to inform recommendations to introduce into clinical care.	Patient-level data including on longer term outcomes for individual patient data meta-analysis and/or economic analysis, e.g. for medical technology guidance by NICE.	Research study using existing research study data and/or routine NHS data, but not requiring the collection of new data.	C1 E1	Researchers Regulators Commissioners Patients Clinicians
6. If recommendation is to introduce into clinical care or, for example, as part of an antenatal screening programme, develop training and guidelines, patient information and arrangements to monitor performance and quality assure the technology in the NHS.	Aggregated data to develop quality assurance (QA) measures and performance indicators.	Establishing and implementing NHS systems for implementation, workforce training and quality assurance and performance monitoring.	A1 A2 A3 A4 A5 B2 B3 B5 B6 B7 C2 D4 D5 D6 E1 E2	Commissioners NHS data stewards Clinicians Patients Regulators

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- More people have a say in the future of health and research.

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