sciencewise

UK Research and Innovation

NHS AI Lab Public Dialogue on Data Stewardship

Final report
November 2022

Ipsos, in partnership with the Open Data Institute and Imperial College Health Partners

open data institute

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Contents

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Finally, the Ipsos team would like to extend particular thanks to the forty-seven people who gave up their time to participate in the dialogue workshops. This dialogue would not have been possible without their thoughtful input.

Table 1.1: Members of the Oversight Group

Name	Role and organisation
Natalie Banner (Chair)	Director of Ethics, Genomics England
Kira Allmann	Former Public Engagement Researcher, Ada Lovelace Institute
Phil Booth	Coordinator, medConfidential
Sophie Brannan	Senior Policy Advisor (Medical Ethics), British Medical Association
Margaret Charleroy	Head of Strategy for Centre for Improving Data Collaborations, NHS Transformation Directorate
Vicky Chico	Senior Privacy Officer, Office of the National Data Guardian
Mark Halling-Brown	Head of Scientific Computing, Royal Surrey County Hospital
Ruth Keeling	Former Head of Data Strategy, NHS Transformation Directorate
Jasmine Leonard	Technology Consultant & Advisor
Sinduja Manohar	Senior Manager, Public and Patient Involvement and Engagement, Health Data Research UK
Joseph Savirimuthu	Senior Lecturer in Law, University of Liverpool
Susheel Varma	Head of AI & Data Science, Information Commissioner’s Office (ICO)
Joseph Watts	Head of Cross Government Data Strategy, NHS Transformation Directorate

Table 1.2: Members of the Stakeholder Group

Name	Role and organisation
Tim Davies	Research Director, Connected by Data
Ryan Dunn	Head of Data Science, DWP Digital Newcastle
Nikita Japra	Senior Manager, Data & Society Accelerator Program, The Patrick J. McGovern Foundation
Carly Kind	Director, Ada Lovelace Institute
Miranda Marcus	Global Mental Health Databank Product Lead, Wellcome Trust
Jessica Morley	Director of Policy, Bennett Institute for Applied Data Science, University of Oxford
Kasia Odrozek	Director, Mozilla Insights
Soujanya Sridharan	Research Analyst, Aapti Institute
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Wen Wha Lee	Chief Executive Officer at Action Against AMD & Chair, Data Trust Advisory Board at HDRUK INSIGHT Hub

01

Executive summary

Executive summary

This public dialogue was commissioned by the NHS AI Lab, with the support of UK Research and Innovation's Sciencewise programme. The aim of the dialogue was to understand participants' attitudes towards different approaches to data stewardship concerning access to health data for AI research, including their benefits and risks. The dialogue involved four online workshops, held throughout July 2022. Forty-seven members of the public took part in the dialogue, and they were joined at different points by specialists who provided additional information on the areas under discussion. A set of hypothetical scenarios for three decision-making approaches formed the core materials for the dialogue, developed to help bring these approaches to life. The three decision-making approaches were:

- Delegated decision-making: someone making decisions on your behalf and for other people like you
- Collective decision-making: people making decisions as part of a larger group
- Individual: people making decisions for themselves or on behalf of someone they care for.

The findings from this dialogue will hone the remit of a research competition to improve data stewardship approaches in the NHS AI Lab and more broadly in the NHS.

Initial views

Despite the participants' varying levels of prior knowledge and understanding of AI, and the way health data is used for AI research, they initially associated AI research with illness, treatment and cures as well as privacy, consent, statistics and trends. Early benefits identified regarding using health data for AI research included increased precision, reliability, cost-effectiveness and time saving. Through further discussion of case studies about different uses of health data in AI research, participants recognised additional benefits including improved efficiency and speed of diagnosis. However, they raised concerns about information being used to treat people differently, for example bias built into algorithms which can lead to less favourable treatment of people with protected characteristics such as ethnicity and sex, and the risk of data leaks. As well, when discussing AI research, and AI more generally, participants highlighted the importance of healthcare professionals, stressing that humans need to be involved when we are using machines. Levels of trust in organisations involved in using health data differed between individuals; some participants viewed commercial organisations in particular with scepticism.

Participants initially identified one benefit of delegated decision-making approaches (which were discussed first) as the involvement of specialists bringing the relevant knowledge to decisions about data access. As well, they were attracted to the perceived speed at which decisions could be made. They expected that there would be clinical, legal, ethical, data/data science and technical/AI specialists within delegated decision-making approaches, independent from commercial interests. The criteria used to make decisions within delegated approaches were also important, as well as transparency around these, and independent oversight to hold decision makers to account. Participants held mixed views on whether to involve the public in delegated decision-making approaches but where they are involved it was important that their voices are heard and given equal weight to those of specialists.

Developing perspectives

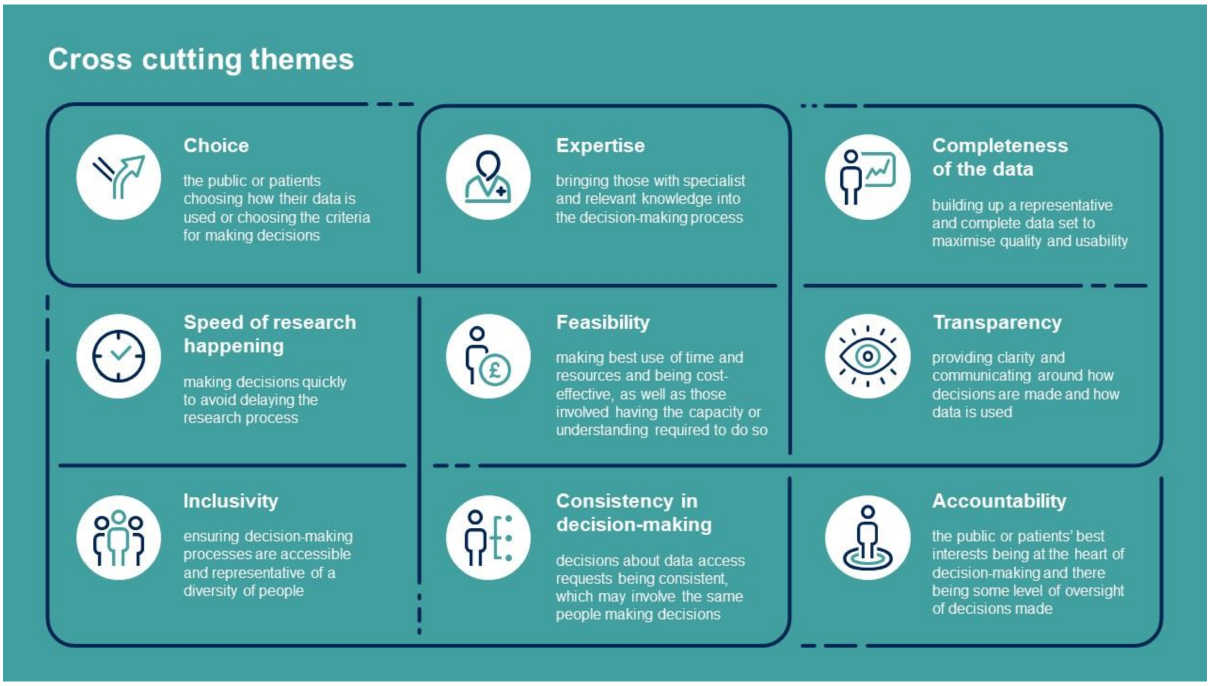
As the dialogue progressed, and as participants were introduced to and discussed alternative approaches to delegated decision-making (collective and, later, individual approaches), the lack of individual choice in the delegated approaches became apparent. Participants reacted positively to the opportunity to involve the public and patients in decision-making through collective decision-making approaches, though they raised concerns about the length of time needed for these approaches and how this may slow down research. Most dialogue participants thought specialists, as well as patients and/or members of the public, should be involved in the collective group.

Participants liked individual decision-making approaches for offering more comprehensive choice and transparency. They also saw the opportunity to educate the wider public about the benefits of using data for research using these approaches. However, participants cautioned against the overreliance on individuals within the individual decision-making approaches: the time it could take for individuals to make granular decisions and the knowledge needed to do so. They also questioned the feasibility – including the cost – of implementation within the NHS.

No single approach was seen as perfect, and participants suggested combining complementary data stewardship approaches.

Cross-cutting themes

Throughout discussions about the different decision-making approaches, and the scenarios used to bring these to life, participants generated a set of cross-cutting themes. These formed the basis of some of the deliberations about trade-offs. For example, participants appreciated that individual approaches allowed for personal choice about how data is used but also recognised that it may be costly to set up systems required to communicate with every individual, limiting the feasibility of these approaches. Other trade-offs discussed included expertise against choice, inclusivity against feasibility, and choice against completeness of the data.



Cross cutting themes

Choice
the public or patients choosing how their data is used or choosing the criteria for making decisions

Expertise
bringing those with specialist and relevant knowledge into the decision-making process

Completeness of the data
building up a representative and complete data set to maximise quality and usability

Speed of research happening
making decisions quickly to avoid delaying the research process

Feasibility
making best use of time and resources and being cost-effective, as well as those involved having the capacity or understanding required to do so

Transparency
providing clarity and communicating around how decisions are made and how data is used

Inclusivity
ensuring decision-making processes are accessible and representative of a diversity of people

Consistency in decision-making
decisions about data access requests being consistent, which may involve the same people making decisions

Accountability
the public or patients' best interests being at the heart of decision-making and there being some level of oversight of decisions made

Participants continuously returned to the importance of choice for those who want to be involved in granular decisions about access to their data, empowerment of patients and the public and their involvement in decision-making. However, at the same time, they valued expertise and involving specialists (healthcare professionals, legal, technical and AI specialists) within delegated and/or collective approaches for providing a level of accountability to the decision-making. Participants also recognised that patients with conditions relevant to the AI research in question could bring expertise to decisions about data access through their lived experience.

Participants recognised the importance of representative and complete datasets for AI research and cautioned against approaches that could compromise quality or impede the speed of research happening. The technological feasibility and cost of building and maintaining infrastructure mattered to participants, mostly in relation to the individual approaches, and were often considered as they weighed up the trade-offs.

Participants favoured collective and individual approaches for their increased transparency about the use of health data, which they felt have the potential to build trust. They also flagged that any decision-making approaches need to be inclusive, representative, and accessible to all. Importantly, participants wanted to see that patients' and the public's best interests were at the heart of decision-making and that there was some level of independent oversight of decisions made.

Participants deliberated about the consistency within the membership of collective decision-making approaches (i.e., the same patients or members of the public making decisions or mixing this up with new people), concluding that a blended membership is probably best.

Areas identified to explore within the research competition

Throughout the dialogue, questions emerged that will be important to consider within the subsequent research competition. Given the nature of these questions, it will be necessary to trial different decision-making mechanisms alongside real life people, data access requests, data and projects to evaluate how they work in practice and in the context of real-world constraints.

- Participants were interested in the technological feasibility and cost of implementing the data stewardship approaches, including the infrastructure needed to maintain them. They also wanted to explore how long it would take to deliver the different approaches, given the importance placed on the speed at which research could be conducted.

- Participants were interested in the levels of understanding required from the public or patients within the different decision-making approaches. They felt it was important to explore how individual decision-making approaches would work in practical terms, given the potential volume of requests (e.g., opt-out or opt-in).

- Participants were keen to include a range of digital as well as non-digital channels to engage individuals in data access requests and raised questions about ensuring inclusivity and the engagement of groups who tend to be less well represented.

- Additionally, they considered how the approaches would ensure public engagement is meaningful and impactful; how the dynamics between patients with lived experience, the public and specialists would be managed; and how the agendas of different stakeholders may impact the decision-making process.

- Participants were keen to explore the impact of incentivisation on participation and the types of people who would be involved in decision-making processes. They wanted to understand how adherence to the Five Safes framework (a set of principles which enable data services to provide safe research access to data) could be guaranteed and used to complement the decision-making approaches being used.

02

Introduction and methodology

Introduction and methodology

Chapter summary

This chapter outlines the aims and objectives of the dialogue as well as detailing the methodology used, the structure of the dialogue and summarises some of the key research materials.

Summary:

- This project involved a dialogue using deliberative techniques, in line with Sciencewise guiding principles, to engage a cross-section of the public in exploring different approaches to data stewardship. This will be used to hone the remit of an NHS AI Ethics Initiative research competition.
- Over a series of online workshops, participants were involved in: exploring the topic of AI and health data research; deliberating about different approaches and scenarios for managing data access requests; and co-producing principles to inform the Terms of Reference for the research competition.
- Whilst public dialogues are a robust approach for engaging the public with complex and technical subjects, this project involved a relatively small sample so is not intended to be generalisable to the wider public. These findings are used to illustrate *why* people hold particular views rather than *how* many people hold those views.

Context

Stewarding data is a foundational activity in the lifecycle of data. It involves collecting, maintaining and sharing data – and in particular, making important decisions about who has access to data, for what purposes and to whose benefit. How data is stewarded ultimately affects what types of products, services and insights it can be used to create, what decisions it can inform and which activities it can support.

In recent years there has been experimentation around new approaches to data stewardship. Many of these new approaches are designed to empower individuals and communities – usually those who have generated the data or whom the data is about – to play a more active role in deciding how it's used. In the US, for example, Open Humans enables people to explore, analyse and share data about their health, and make it available for collaborative research projects. Organisations such as the World Economic Forum have begun to promote 'data intermediaries', and in Europe, MyData has emerged as a quasi-trade body for a growing set of 'human-centric' data services and organisations. Governments, as well, are experimenting with approaches to make citizens 'the masters of their own data' (Flanders) and introducing new frameworks for 'data empowerment' (India).

The Ada Lovelace Institute argues that more actively involving people in the "design, development and deployment of data governance frameworks can help create the checks and balances that engender greater societal and economic equity, can help to rebalance asymmetries of power, and can contribute towards increased public confidence in the use of data". Their work on participatory data stewardship sets out five levels of participation, building upon Arnstien's 'ladder of citizen participation':

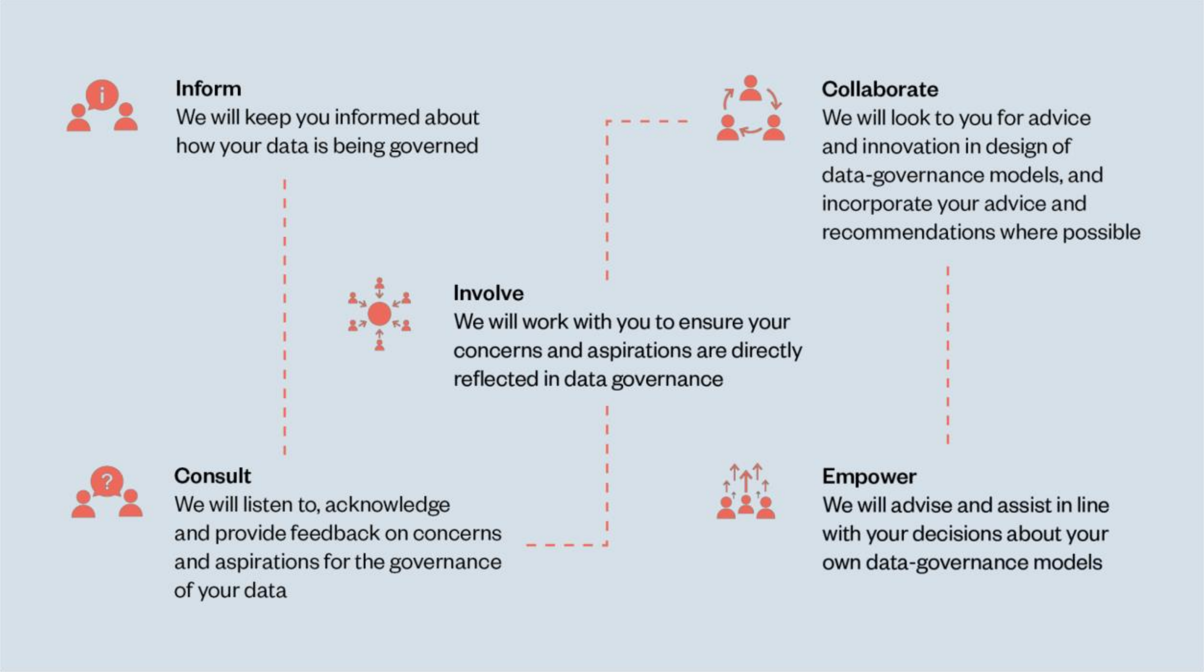


Figure 1.2: Framework for participation in data stewardship from the Ada Lovelace Institute

Recent research by the NHS AI Lab and the Ada Lovelace Institute has found that participation is central to adequately undertaking algorithmic impact assessments and recent publication of the Goldacre Review emphasised the need for greater public participation in the design and running of our health data infrastructure.

There is already evidence of participatory approaches to decision-making in some parts of the UK's health data research infrastructure. The Confidentiality Advisory Group (CAG) is an independent body, including members of the public, which provides advice on the use of confidential patient information to the Health Research Authority and the Secretary of State for Health. The Independent Group Advising on the Release of Data (IGARD), whose membership is a mixture of both specialist and 'lay' members, fulfils a similar role for NHS Digital.

However, while there has been considerable research into public attitudes towards the general use and sharing of patient data in the UK (summarised by the Understanding Patient Data library), this has not focused on particular methods of participation or those that extend beyond this status quo.

Aims and objectives

A consortium led by Ipsos, in partnership with the Open Data Institute (ODI) and Imperial College Health Partners (ICHP), was commissioned by the NHS AI Lab and UK Research and Innovation's Sciencewise programme to undertake a public dialogue about the benefits and risks of different approaches to data stewardship. The findings from this dialogue will ultimately hone the remit of a research competition that the AI Ethics Initiative will hold in 2022 to improve data stewardship approaches in the NHS AI Lab and more broadly in the NHS.

The project objectives, as set out by the NHS AI Lab, were to:

- engage a diverse and broadly reflective section of the public in exploring different approaches to stewardship;
- understand attitudes towards these different approaches, and which models are considered trustworthy;

- understand the values and principles that underlie dialogue participants' views on data stewardship approaches;
- guide the AI Ethics Initiative in prioritising the next tranche of research funding based on the findings; and
- inform the data stewardship approach to national [medical imaging] databases based on the findings.

The outputs of the dialogue will be used to:

- hone the remit of a research competition that the NHS AI Ethics Initiative will hold in 2022 to improve data stewardship approaches in the NHS AI Lab and, more broadly, in the NHS by informing the competition's Terms of Reference; and
- trial a participatory approach to exploring the public's views on data stewardship and understanding their appetite for such approaches.

Method

Sciencewise approach

Led and funded by UK Research and Innovation (UKRI), Sciencewise is an internationally recognised public engagement programme which enables policy makers to develop socially informed policy with a particular emphasis on science and technology, by supporting government bodies to commission deliberative public dialogue. This public dialogue took a deliberative approach in line with the Sciencewise guiding principles relating to the context for the dialogue, the scope and design, delivery, impact and evaluation.

Project governance and external input

Two groups were created to oversee and shape the project:

- Oversight group: a group of specialists eminent in the fields relevant to this dialogue were involved throughout, providing support to ensure all materials were accurate, balanced and held relevance to every part of the topics explored. The composition of this group is outlined in Appendix A.
- Stakeholder group: the ODI led stakeholder workshops, attended by representatives from a diverse network of specialist and civil society stakeholders who contributed towards the scoping of dialogue materials and framing of case studies. The composition of this group is detailed in Appendix A.
- Lay representatives: the Ipsos team engaged with three patient representatives who reviewed the workshop materials and provided feedback from a lay perspective.

Participants

Participants were recruited by a specialist recruitment agency based on quotas that were agreed with the NHS AI Lab. Originally, 55 participants were recruited (this included a target quota of 50 participants and five reserves who were prepared to participate if participants did not attend the first workshop). A few participants dropped out during the process due to a variety of reasons (e.g., illness or changes in personal circumstances), leaving a final sample of 47 participants (see Appendix A for a full sample composition).

The sample included a mix across: gender, ethnicity, age, socio-economic grade, location in the United Kingdom and attitudes towards how their data is used, as well as including a minimum quota for people with a long-term health condition such as asthma, bronchitis or COPD. Each participant was given £60 for each workshop to remove financial barriers from participating and as a thank you for their time and contribution.

An online dialogue

This dialogue took place exclusively online using Zoom. As the sample spanned the whole of the UK, this was a cost-effective and practical way for the participants to engage. This shaped the way the workshops were designed, including:

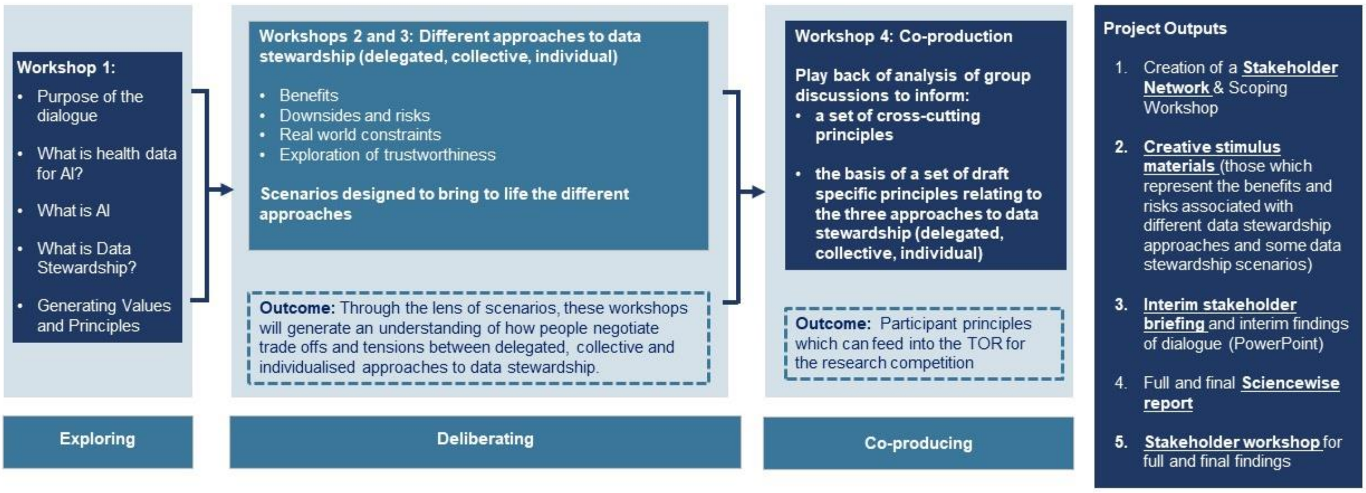
- Shortening workshops to three hours, rather than full day sessions, which is an approach Ipsos has honed throughout the pandemic, recognising that virtual workshops may be more tiring for participants than in-person ones.
- Using smaller group discussions (approximately six participants in each) to give everybody the opportunity to have their say and to make this process manageable for facilitators.
- Posting materials to participants in advance of the workshops so they all had hard copies to refer to.
- Offering support for participants joining the workshops: offering equipment and internet support; holding drop-in sessions on Zoom ahead of the workshops to familiarise people with the platform; having a dedicated team member on hand during the workshops to assist with any technical difficulties and supporting participants who were experiencing issues.

Dialogue structure

The dialogue was structured with the aim of equipping a diverse cross-section of the UK public with the information required to have informed discussions about the AI Ethics Initiative’s proposed data stewardship models and governance approach. The process consisted of four online workshops of three hours (12 hours in total) held throughout July 2022. During these workshops, participants engaged in dialogue with each other and specialists in this field.

The format of each workshop differed but the research team were responsible for providing introductions and summarising interim findings and specialists were responsible for delivering information sessions on relevant topics. These were followed by small breakout group discussions (with approximately six participants in each), led by a facilitator from the research team. In Workshop 2, there was also a short question and answer session with the specialist. As participants became more informed about the topic, the input of specialists reduced and the length of time for breakout group discussions increased.

Figure 1.3 below outlines the high-level content introduced at each stage. The process involved three key phases: 1) exploring the topic 2) deliberating about different approaches and then 3) co-producing a set of principles.



Workshop 1:

- Purpose of the dialogue
- What is health data for AI?
- What is AI
- What is Data Stewardship?
- Generating Values and Principles

Workshops 2 and 3: Different approaches to data stewardship (delegated, collective, individual)

- Benefits
- Downsides and risks
- Real world constraints
- Exploration of trustworthiness

Scenarios designed to bring to life the different approaches

Outcome: Through the lens of scenarios, these workshops will generate an understanding of how people negotiate trade offs and tensions between delegated, collective and individualised approaches to data stewardship.

Workshop 4: Co-production

Play back of analysis of group discussions to inform:

- **a set of cross-cutting principles**
- **the basis of a set of draft specific principles relating to the three approaches to data stewardship (delegated, collective, individual)**

Outcome: Participant principles which can feed into the TOR for the research competition

Exploring

Deliberating

Co-producing

Project Outputs

1. Creation of a **Stakeholder Network** & Scoping Workshop
2. **Creative stimulus materials** (those which represent the benefits and risks associated with different data stewardship approaches and some data stewardship scenarios)
3. **Interim stakeholder briefing** and interim findings of dialogue (PowerPoint)
4. Full and final **Sciencewise report**
5. **Stakeholder workshop** for full and final findings

Figure 1.3: Structure of the dialogue

Workshop materials

All the workshop materials are included in Appendix B. In Workshop 1, participants were introduced to the field of health data for AI research, which included details about the National Data Opt-Out and the Five Safes framework for ensuring the protection of health data. In Workshop 2 they were given information about three high-level approaches to managing data access requests, as well as a case study using a hypothetical database (the National Imaging Database). This was followed in the latter part of Workshop 2 and Workshop 3 by a set of hypothetical scenarios for each decision-making approach (delegated, collective and individual), developed to help bring them to life. These provide important context to the findings outlined in the rest of the report and so are detailed below.

National Data Opt-Out

This is a service that allows patients to opt-out of their confidential patient information being used for research and planning, noting that NHS Digital and all health and care organisations must comply. Participants were informed about the cases when the data opt-out does not apply (e.g., if there is a legal obligation to share data), and some of the limitations (e.g., that the data becomes less useful as more and more people opt out). See Annex B for the full detail.

Five Safes framework

Originating from the Office of National Statistics (ONS) and developed by other data providers, the Five Safes framework is a set of principles which enable data services to provide safe research access to data. The framework was presented to participants as:

- **Safe people**: only trained and accredited users and researchers access the data and they must not reidentify data subjects.
- **Safe projects**: data is only used once; it has ethical approval for projects with clear public benefit.
- **Safe settings**: secure technology is in place and the person-level data never leaves the secure environment.
- **Safe data**: data is de-identified to protect privacy.

- **Safe outputs**: all outputs are checked to ensure people cannot be identified.

Three approaches

In Workshop 2, participants were introduced to three approaches to making decisions about data access, based on the ODI's existing typology of participatory decision-making. These are:

- Individual decision-making: This involves people making decisions for themselves or on behalf of someone they care for. In a day-to-day context, this could look like someone making a decision about who they want to bank with. For example, in a data stewardship context, Schluss aims to ensure that people can share information however they want to, so whoever needs information about them sends them a request first.

- Collective decision-making: This involves people making decisions as part of a larger group. In a day-to-day context, this could be a housing co-operative making decisions about whether to spend collective reserves on a new roof. In a data stewardship context, Salus Coop is a citizen data cooperative that seeks to legitimise the 'right of citizens to control their own data' through sharing and governing data collectively.

- Delegated decision-making: This involves someone making decisions on another's behalf and for other people like them. In a day-to-day context, this could be a financial advisor choosing which stocks to invest a client's pension into. In a data stewardship context, Driver's Seat helps gig economy drivers to pool data about them to optimise their working hours and makes decisions about who else can access this data on behalf of the drivers.

At this stage they were presented at a high level, to introduce the approaches in an accessible way and to capture initial responses. These were presented (in the following order) as:

- **Delegated**: someone making decisions on your behalf and for other people like you.

- **Collective**: people making decisions as part of a larger group.

- **Individual**: people making decisions for themselves or on behalf of someone they care for.

National Imaging Database case study

Participants were prompted to explore the various approaches through the lens of a case study. This case study was centred on the hypothetical National Imaging Database (NID) being used to train and test AI screening technologies. NHS England would have legal responsibility for the NID and it would be a centralised, secure database consisting of de-identified, pseudonymised patient imaging data from a wide range of hospital trusts across the UK (see Appendix B for full details).

Hypothetical scenarios

A series of nine scenarios were developed that span the three decision-making approaches, which articulate hypothetical ways that people could be involved in deciding how medical imaging data should be shared.

While some of the scenarios are close to the status quo in terms of how decisions tend to be made about health data in an NHS context, others were more speculative and inspired by the ideas and proposals of others, such as MedConfidential's Data Usage Report and the Ada Lovelace Institute's work on Participatory Algorithm Impact Assessment for the NHS AI Lab.

The main differences between the scenarios are related to whether:

- people are able to make decisions as individuals, as part of a collective or are made on their behalf;
- people make decisions on a case-by-case basis or at a more abstract or general level;
- people are involved in the decision prior to the data access taking place or reflecting on data access that has been allowed to inform future decisions about access;
- people exert their control via workshops, phone calls, letters and/or digital services.

As well as enabling different types of involvement, some of these approaches have other benefits. For example, individualised approaches are also intended to give people greater visibility over their data in addition to a say in how it is used.

Participants started by looking at the delegated approaches, followed by those that represented collective and then individual decision-making approaches. These scenarios were described and participants were prompted to consider different elements, without boxing these into positives and negatives. To reduce the impact of possible order effects, each breakout group reviewed the scenarios in a different order.

Delegated decision-making scenarios

Expert Data Access Committee: A data access committee - made up of doctors, data scientists, legal and ethical experts from within, as well as independent to, the NHS, reviews every application to access the imaging data and decides whether access should be permitted. A patient or member of the public will also be asked to review applications alongside experts. The committee's decisions are made using a set of criteria focused on scientific, technical, legal and ethical merits. Some applications will meet the requirements and get approved, others will be rejected.

An Independent Group: The imaging data is under the control of an organisation independent of the NHS. The organisation is run by a group of doctors, AI experts (including from industry) and other stakeholders from the healthcare sector, who have a legal responsibility to make sure decisions about who gets access to the data are in the interests of patients. Given that the imaging data is outside the control of the NHS, the NHS and other interested parties must apply for permission from the independent organisation to gain access to the data.

Collective decision-making scenarios

Patient Panel: A representative group of the public and patients comes together as a panel to review and discuss every application to access the imaging data. The panel uses a set of criteria it created as a group to gain consensus and decide which uses should be approved. The outcomes of the data access and use are reported to the panel once the research is complete, and the panel can adjust their criteria over time.

Developing Data Access Principles: Before the imaging data can be used for research, a representative group of the public and patients take part in a series of workshops to develop high-level principles for how the data should be used. The group's views - such as on what types of researchers can access the data and what purposes it can be used for - are translated into detailed rules and criteria by doctors and other experts, who then apply them to requests to access the data as they come in.

Retrospective Review: Every three months, a representative group of the public and patients take part in a session with doctors, researchers and other experts who are responsible for giving access to the imaging data. The group sees which organisations have used the data over the last quarter, and can query why the experts made certain decisions. Over time, the experts may need to adjust their decisions to better reflect the group's expectations.

Case-by-Case Workshops: A representative group of the public and patients take part in a workshop with AI research teams before they are granted access to the imaging data. The group asks questions about what the researchers are seeking to find and why they need to use the data they've requested. At the end of the workshop, the group makes a recommendation as to whether access to the data should be granted or not, and can ask the researchers to adjust their approach.

Individual decision-making scenarios

Individual Preferences: Before allowing the data to be used for research, the NHS contacts every patient to ask how they would like their medical imaging data to be used. Some patients might allow for the data to be used for any research. Some patients might respond by saying that data can be used by NHS researchers to test the effectiveness of treatments they've received, but not for companies to build new AI products. Others might not want data to be accessed by any researchers at all. Patients could set their preferences by post, a phone call, using an NHS website or appointment with a healthcare professional.

Data Usage Reports: The NHS sends a letter, email or notification to every patient on a regular basis showing them how it has allowed their imaging data to be used for research. It shows each and every different project and researchers the data has been accessed and used by, and the outcomes from the research. Patients can respond to adjust how data about them is used in the next year, by post, a phone call, using an NHS website or appointment with a healthcare professional.

Personal Data Store: Patients use a digital interface to choose who can access their imaging data. Patients get notifications about upcoming research projects that have passed a legal and technical check, including information about the organisation conducting the research, what the researchers were looking to understand and how they plan to use the data. Patients can select which projects they'd like their data to be used for and for what purposes as well as setting default preferences. Patients can decide the frequency with which they receive notifications, the channel by which they receive them, or turn them off all together.

Approach to analysis

Findings in this report are presented thematically. The analysis approach was both inductive and deductive: many of the themes emerged from the data but were also shaped by the areas that would be most useful to focus on to feed into the Terms of Reference for the research competition (e.g., benefits/disadvantages of different approaches).

The themes and principles, both cross-cutting and specific to each approach, emerged as part of an interim thematic analysis. These were drafted and presented back to the participants in the final workshop to review and amend in real time. The principles detailed in this report either reflect the wording agreed with participants, or the final edits made by the research team in line with their suggestions from Workshop 4.

All discussions were transcribed by note takers and raw data was then summarised and organised using a thematic framework to aid analysis.

How to read this report

The findings of this report can be loosely separated into two sections, the first half (Chapters 3 and 4) covers attitudes towards the topic and the specific approaches, the second half (Chapters 5 and 6) outlines more practical implications for the Terms of Reference for the research competition.

Quotes are provided throughout the report in ***italicised green text*** with quotation marks around them. These are used to illustrate the points being made.

Terminology

Throughout this report, the following key terms and references are used.

- **Data stewardship:** this describes the process of collecting, maintaining and providing access to data. The focus of this dialogue was on the provision of access to data.
- **De-identified data:** information at a person-level, where identifiers have been obscured (e.g., replacing names with pseudonyms) so that it is not easily identifiable.
- **The National Data Opt-Out:** a service that allows patients to opt-out of their confidential patient information being used for research and planning.

One point to note on the terminology used by participants is that they often used the terms ‘patients’ and ‘members of the public’ interchangeably and not always consistently. Their language suggests they sometimes viewed themselves as patients, as users of NHS services. Therefore, this label was not always specifically used for referring to people with certain conditions (although this was sometimes the group being referred to). However, some participants were quite clear in making distinctions between patients and members of the public, making arguments about collective approaches based on this distinction. Where this is the case, it is noted.

Interpreting findings

Public dialogues are used to engage the public with complex questions and technical subjects, providing them with enough information to make informed decisions and judgements. The findings, therefore, can provide in-depth insight into citizens’ views, concerns and aspirations relating to specific issues. However, it is important to consider the following about the methodology when interpreting results:

- This is a qualitative approach, used to gain in-depth insights into the topic area. As it has a relatively small sample it is not intended to be generalisable to the views of the wider public. Findings are not intended to be statistically representative of the wider public.
- These findings are used to illustrate *why* people hold particular views rather than how many people hold those views.

Due to the small sample size, and the nature of public dialogues, findings are presented at a whole-sample level, rather than segmenting according to demographics. Where relevant, the language indicates whether views were shared by a majority or minority of participants, for example using words such as ’some', ‘many’ or ‘few’.

Key considerations about the topic area

It is also important to consider the following points about the topic area when interpreting the findings.

The database and scenarios presented were hypothetical and decisions had to be made about the level of detail provided.

Due to practical constraints, a hypothetical database of imaging data was developed instead of using a real-world example. Whilst a real-world programme is in development, at the time of conducting the dialogue there was not enough clarity about key aspects of it to use it as a case study. Therefore, specialists from the NHS and the Oversight Group helped develop a hypothetical database based on their experience and involvement with imaging databases for AI purposes.

Additionally, hypothetical scenarios were created to help bring the three key decision-making approaches to life and to aid participants' understanding of each approach. Real scenarios could not be used as many of these are theoretical concepts and haven't been tested in the real world, particularly within a healthcare context.

In designing this database and the scenarios, it was important to strike the right balance between not providing too much detail (e.g., to a point that constrains imaginative thinking about possible approaches to data stewardship) and providing enough information for participants to engage meaningfully with the case study and scenarios. Therefore, the findings may be constrained by the extent to which this balance was reached.

The discussions were broad and participants made sense of these new topics by discussing wider issues.

At points, participants appeared to make sense of the questions about health data for research by discussing other topics or raising broader points about AI and healthcare. Facilitators were not tasked with correcting misconceptions, as these were useful findings in themselves, but were expected to keep the conversation on track. Key areas to note included:

- Conflating decision-making about data access requests with decision-making about patients' care or use of AI in healthcare more broadly. This led to conversations about AI or technology making decisions about diagnoses or providing treatment.

- Assuming that, if a group of specialists included healthcare professionals, this would be somebody's own healthcare professional (e.g., GP). This led to conversations about personal levels of trust in individuals' GPs.

- The focus on medical imaging data may have shaped deliberations, as some participants discussed patients being involved in reviewing scans, as opposed to just considering their involvement in decision making. Some people noted that they would not be able to understand an X-ray or CAT scan so would need expert involvement.

> ***"I think I wouldn't know the first thing about it if I saw an X-ray, I wouldn't know really what I was looking for. So, I think the right people would have that job."*** (Female, 25-44, Workshop 2).

- Although participants received information about commercial organisations being involved in accessing and using data, at times they spoke about commercial organisations as an exception or caveated their responses to data access approaches with this in mind. For example, by indicating that they were comfortable with their data being accessed by those working in the NHS, but not by those within commercial organisations given perceptions around excessive profiting and fear of data breaches.

The stimulus focussed on imaging data, and linked data (i.e., including demographic and clinical data) so this may have shaped participants’ feelings about the topic.

There were few references specifically related to imaging data, though when it was mentioned, it was assumed that it was not easy to manipulate it, and that it might be less identifiable than other data.

It wasn’t always clear whether participants recognised that imaging data, in the hypothetical database, would be linked to other personal data for it to be of use, despite this being clear in the information about the hypothetical database.

“We keep talking about imaging data. I’m 100% behind it. Only an idiot or a fool would say you can’t use it. Sorry to word it that way.” (Female, 25-44, Workshop 2).

03

Awareness and understanding of health data

Awareness and understanding of health data

Chapter summary

This chapter outlines participants’ initial views of AI and the use of health data for research. It explores spontaneous thoughts about the benefits and risks of using health data for research and more considered responses in relation to specific case studies. It also outlines responses to prompts about ethical considerations and decision-makers.

Key findings:

- Initial understanding of AI and the way in which health data is used for AI was mixed, with varying levels of prior knowledge. Spontaneous views of health data for research tended to reflect associations with illness, treatment and cures as well as privacy, consent, statistics and trends.
- Some participants saw benefits in using health data for AI, such as increased precision, reliability, cost-efficiencies and time-saving and some were keen to ensure healthcare professionals had oversight of AI technology.
- Participants saw public sector bodies (e.g., government, health bodies, the NHS) as playing a role in decision-making about data usage, as well as the individuals that the data belongs to.
- When thinking about specific case studies involving the use of health data in AI research, participants saw improved efficiency and speed of diagnosis as a benefit but raised concerns about information being used to treat people differently, the risk of leaks and, again, cautioned against removing healthcare professionals from the process completely.
- Levels of trust in organisations involved in using health data differed between individuals and groups, however commercial organisations in particular were sometimes viewed with scepticism.

Spontaneous views of health data for research

At the start of the dialogue, and prior to receiving any information about this topic, participants were prompted to write down words that came to mind when they heard ‘health data for research’. They then discussed their initial thoughts as a breakout group, followed by discussions about AI and who they thought made decisions about health data usage.

There were varying levels of knowledge about health data for research. Initial spontaneous views were dominated by associations with illness, treatment and cures, with mentions of statistics, trends, technology and the NHS. There were also associations with personal information, privacy, consent, data storage, security and trust.

Figure 1.4 illustrates some of the words most commonly used in these discussions. Whilst the size of the word reflects the number of times it was mentioned, this does not indicate how important the topic was to people nor the words they most strongly associate with the topic. It merely reflects the topics that may be top of mind for people, before being presented with information.

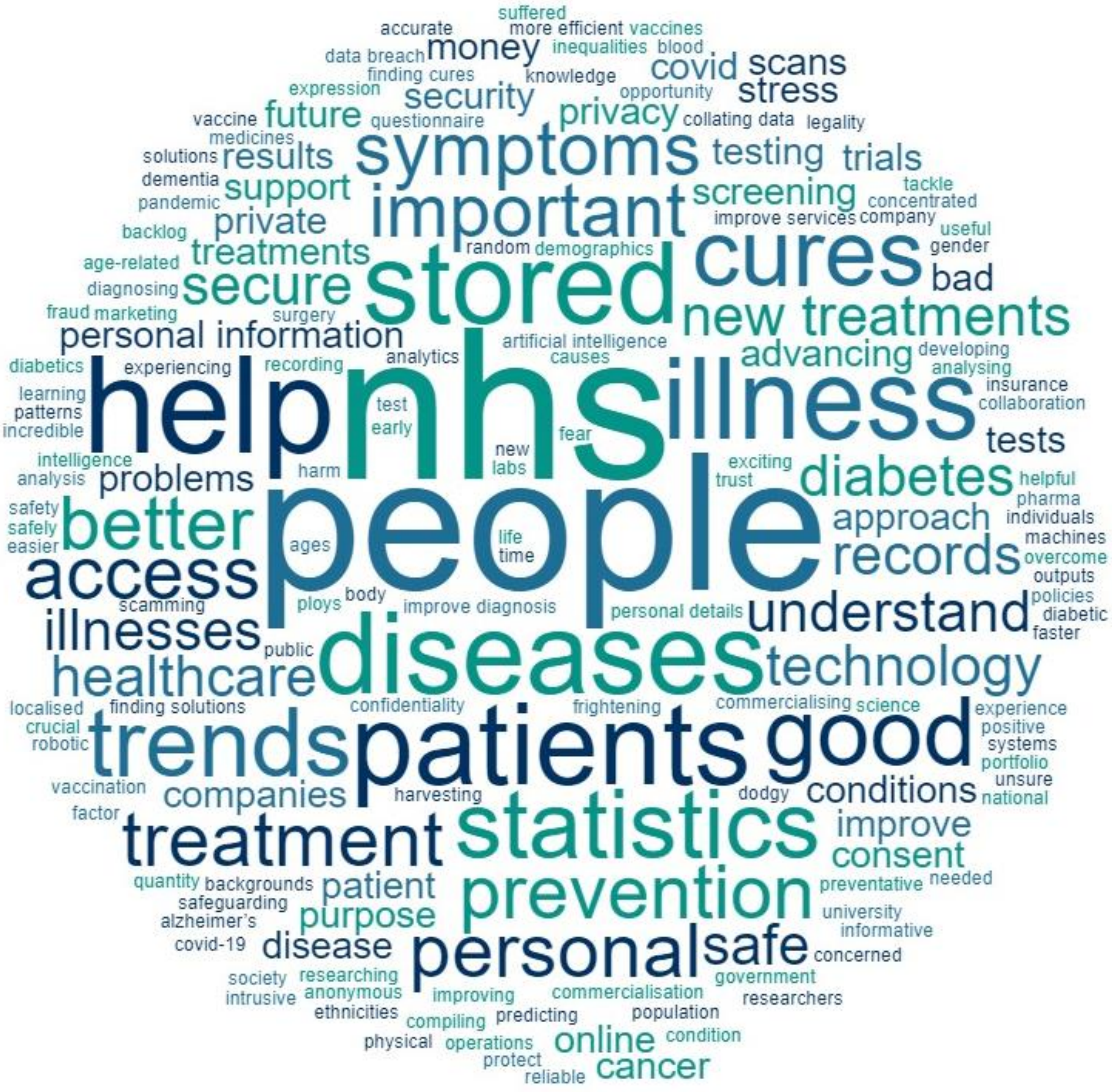


Figure 1.4: Word cloud showing common words used by participants when discussing health data for research. The size of the word indicates how many times it was used (larger words were mentioned more frequently).

The tone of discussions was generally mixed within groups. Often, participants framed their initial thoughts either in terms of improving services and overcoming problems or in relation to concerns or worries about how data is used. At this stage, the level of discussion about each other's points was limited as people were taking it in turn to explain what they had noted down.

When prompted to think about the type of health data that is used for health research, participants broadly discussed three types of data:

1) **Personal data**: including gender, ethnicity, weight, height, age, family history, the location people live/have lived in, and socio-economic status.

2) **Medical data**: including conditions and diagnoses, whether such conditions are hereditary, coronavirus records (whether people have had the virus and the number of vaccinations they've had), prescriptions, frequency of engagement with GPs/health services, outcomes of blood tests and genetic/DNA information.

3) **Health or lifestyle data**: including smoking, drinking, drug use, exercise and diet.

Participants drew on their personal experiences to understand which types of data might be used. For example, thinking about the data they give to their GP, identifying the demographics that may make them more susceptible to diseases or discussing hereditary diseases in their own families. One or two people across all the groups said they weren't sure, or this wasn't something they had ever thought about. In one group, coronavirus dominated the conversation which led to discussion about how somebody's GP used information about them having had coronavirus to change their treatment for another condition. In this group, coronavirus records were also used as an example of health data that may be used.

Participants spontaneously considered the fact that this data could be used for clinical trials as well as informing predictions about who may be susceptible to certain illnesses.

Initial awareness and understanding of AI and AI for health research

Levels of understanding about AI and AI for health research were mixed. Many participants had heard of AI but some had only heard about AI more broadly so extrapolated their understanding to make predictions about how AI would be used in health research.

"For health, I'm going to base it on other forms of AI which I assume they mean it's going to create algorithms to find trends and connect patterns together to form almost a data profile, that's what it makes me think of. Organising the information and sorting it out using a robot." (Male, 18-24, Workshop 1).

Participants described AI in terms of computer algorithms and machines learning to replicate human behaviour. This was also linked to decision-making and analyses of trends. They gave examples of AI they had heard about or were familiar with, including: facial recognition software, driverless cars and robots in factories.

Where some participants initially said they were unsure or that they didn't know anything about the topic, comments from other participants (e.g., somebody describing something they'd seen on TV) sometimes reminded them and prompted further conversation. At this stage, the people who did offer explanations of AI or AI for health research often made sense of this through things they had read, podcasts they had listened to and things they had seen on TV. Fewer understood this through a personal lens e.g., by considering their own personal experiences with healthcare professionals.

"I think when I visit the GP, they usually go online and are able to describe these things. AI can bring up any kind of information and solution." (Male, 25-44, Workshop 1)

The tone differed across the groups. For example, in one group the discussion opened with somebody calling AI 'amazing', followed by somebody else saying it is a 'great enabler' and another 'tremendous'. In contrast, in another group, initial reference to machines and AI led the subsequent conversation to be dominated by discussion of science fiction with a more ominous tone.

In these discussions, participants also spontaneously discussed where AI could be used in relation to healthcare such as identifying areas with higher incidence of cancer, forming profiles based on health data, and being used to diagnose conditions. Some participants noted benefits of using AI in health research, including increased precision and reliability, saving time, cost-efficiencies and having the capacity for remote use.

"It can also cut down on cost and can be more accurate where humans would make mistakes, so it would probably be very beneficial in the healthcare system." (Female, 45-64, Workshop 1).

Some participants were cautious about using AI to conduct research or inform decisions that would otherwise be made by healthcare professionals, given the likelihood of errors. For this reason, there were suggestions that healthcare professionals should still be involved and have oversight of any predictions made by AI. Other concerns related to the governance of AI and machine learning.

"You can rely on AI, and, at the same time, you can't make a final decision without a specialist. It makes robotic predictions which tells you their opinion. At the same time, this information gets passed to the professionals and you need professional people to make a final decision for final treatment. Robots are improving every day, but you can't rely on them 100%." (Male, 65+, Workshop 1).

Initial perceptions around who makes decisions about data usage and data access

When participants were prompted to discuss who currently makes decisions about uses of data, they mentioned the following groups:

- **Government and health officials or bodies**: including the Department for Health and Social Care (DHSC), health ministers, NHS England, and 'Health England'[1].
- **Individuals working within the NHS**: including people working with the data in hospitals and GPs.
- **The individuals the data belongs to:** participants suggested that individuals were decision-makers given they would need to consent to their data being used.
- **Joint decision-making groups**: one participant suggested that decisions are made jointly by specialists, scientists and people who know about AI.

There was little challenge within the groups. In some, the discussion remained broadly focussed on one group (e.g., government and health officials or the individuals the data belongs to).

Reflections on initial stimulus

Participants were then presented with information about the applications of AI in healthcare, including potential risks and benefits, the Five Safes framework, the National Data Opt-Out and ethical considerations. They were then given an opportunity to reflect on this information and raise any questions which they would like to ask the specialists.

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[1] This could be referring to Public Health England or Health Education England

Levels of familiarity with the information presented was mixed. It ranged from people saying it was all new to them, through to some people saying they were aware of the opt-out and could remember choosing to opt-out, and others who said they were familiar with the topic and how the data is used.

"To be honest, it was actually all new to me. I didn't know much about AI. It was actually very educational and very helpful. Me as a person, I don't really delve into these kinds of things. I did like when they were talking about the ethical side as well. I did study ethics in my A-levels. I can kind of find some link between the two." (Male, 18-24, Workshop 1)

"I was familiar with what the data would be used for and how algorithms collate it together to generate findings." (Male, 25-44, Workshop 1)

Table 1.3 below summarises some of the questions which participants had at this stage. This indicates areas of particular concern or interest, or where things were unclear in the stimulus. Many of these were long-running themes throughout the workshops and therefore appear, in more detail, later in this report.

Risk of data breaches and storage of data	Participants raised questions about how data would be stored and accessed, the consequences of data breaches, how/whether these would be communicated with the people whose data had been breached, and steps that would be taken to prevent data breaches.
Opt-out vs opt in	The mechanisms about opting out were questioned, including: whether people can opt out once they've opted in (and vice versa) and the impact of opting out on the data available for research/the conditions that can be researched.
Accountability and ethics	Questions related to who would be responsible for developing the AI, who decides when AI will be used to inform decisions, who would own the data, how to minimise the chance of bias in the system, how ethical frameworks would be built into AI, how to determine capacity to consent to data use (e.g. taking into account mental capacity/age), and if operating at a national level – how to ensure equality of access to the benefits of using the AI across NHS Trusts.
Practical considerations	Participants asked how cost-efficient it would be to collect so much health data.

Table 1.3: Questions raised in response to initial stimulus applications of AI in healthcare

Benefits and risks of health data for AI research

Participants were then presented with two case studies to explore how health data could be used for AI in practice (the order in which they were presented was mixed up across the groups to limit the impact of order effects). Facilitators prompted participants to consider the benefits and risks of using health data in these examples, the acceptability of doing so, and who they thought should make decisions about how this data is accessed. These case studies were:

- **Reviewing eye scans**: An NHS hospital partnering with a globally recognising technology company to see if machines could help review eye scans at the same level of accuracy as a doctor (see Appendix B for detail).

- **Screening for causes of dementia and stroke**: Academic researchers in a university partnering with an NHS hospital to develop and test an AI algorithm which can help screen for signs of stroke and dementia on a brain scan (CT). This would be done using de-identified brain scans, linked to health records from primary and social care (see Appendix B for detail).

Whilst participants were asked to consider the benefits/risks of the use of data in these examples, the focus in many of the groups tended towards considering the broader benefits/risks of AI within healthcare. These conversations were often framed by a comparison of humans (healthcare professionals, researchers) versus 'machines'. Therefore, consideration of the risks and benefits were situated within the context of what a human could do well, and what a machine could do well. In some cases, participants discussed the two as though they were mutually exclusive and considered the risks associated with a machine being totally in control. Other participants noted the need for the two to work together.

"I think I prefer doctors to the machines they have now. I might just be old-fashioned." (Female, 45-64, Workshop 1)

Benefits of using health data in these case studies

The benefits identified of using health data in these case studies broadly relate to improved efficiency and speed of diagnosis, as well as increased accuracy.

Participants' discussions were often framed by the assumption that if AI could be used to identify conditions quicker and enable faster diagnosis, this could lead to conditions being treated more quickly, reducing waiting times and minimising pressures on doctors. They often anchored this to their own personal experiences of waiting a long time for results of scans or for treatment and therefore appeared to view an improvement to this as a tangible benefit. It was also seen to be able to free up doctors' time.

The ability to diagnose signs of dementia earlier was particularly popular amongst participants, who noted that the earlier you catch this, the more that can be done to improve quality of life. Although some people suggested that learning about a potentially heightened risk of diseases could scare a person or cause them to worry.

"If somebody predicts that you'll have a stroke in 10 years' time, that'll affect a lot in your life, which is the negative side. On the positive side, you can prepare yourself and do a lot of things before you get the diagnosis." **(**Male, 65+, Workshop 1).

Most people felt that the use of health data in this context could help improve accuracy and could be used to identify diseases or conditions that a doctor may miss. In the case of screening for dementia and stroke participants also broadly understood the need to link this data to other health records. This is because they recognised that diagnosing a complex condition like dementia may require contextual information, so linking this in could increase the chance of an accurate diagnosis. One participant suggested that a feedback loop should be put in place to ensure the AI algorithms could learn from mistakes or errors to continually improve diagnoses. In the case of the eye scans, the inclusion of a figure ('94%') to indicate accuracy received mixed reviews:

"Anything that can assist medically is a good thing. My only slight concern is speed versus accuracy. Some people would think 94% is good but as someone who is short-sighted, if I had a problem and I fell into the other 6% then that would not have been picked up." (Male, 45-64, Workshop 1).

"I'm happy with this. It's good because it's got 94% accuracy. It's really reassuring. A very high number and the fact that it's the same as the accuracy of leading eye experts. That technology is just assisting them. For the other 6%, they might be able to notice that. They might be able to see if the scan missed anything." (Male, 18-24, Workshop 1).

Risks/downsides of using health data in these case studies

In terms of risks identified in relation to the use of health data in this case study, participants were often quick to caution against removing doctors/humans from the process completely due to risks of malfunctions and the need for oversight. Some noted concerns about the information being used to treat people differently and some discussed the risk of leaks or data breaches.

Many participants expressed a preference for a doctor to review scans in addition to using AI and felt uncomfortable with the prospect of the whole process being carried out by AI (although this was never presented as part of these case studies and participants who raised this did so of their own accord). Some saw the potential for a collaborative approach in which two levels of review could provide extra reassurance. Participants took this thinking beyond just using AI to analyse scans, noting that they wouldn't want to lose the personal consultation they currently have with healthcare professionals. Some noted practical implications, with one person suggesting this could enable the input of doctors working abroad. Others suggested that current pressures on the NHS and staff shortages could lead to delays if doctors still have to review all the scans.

Ethical concerns were also highlighted. In approximately half of the groups, participants discussed concerns that this data being gathered and stored, and with the potential for people to access it, could lead to information being used to treat people differently. Specifically, they noted concerns that this information could impact somebody's chance of getting a job or records of health conditions (such as diabetes), could lead to increased life insurance premiums. Another group suggested this could impact who would get treatment for conditions.

"With social care, would the data be a disadvantage in the sense that certain pre-conceived notions about certain people, like people with a history of mental illness, would they be treated differently because of that? …If you were going to decide who was going to get treatment, like the post code lottery, would you then look at them and see they'd been in and out of institutions, but this person had never had a problem, could looking at someone's full history be a disadvantage for someone's chances of treatment." (Female, 45-64, Workshop 1)

Some participants were concerned about the risk of leaks and data breaches. They suggested that if data was being shared with a technology company, these may be more susceptible to hacking. Others noted that somebody would have to be accountable for any leaks or breaches. One group discussed the possibility that, if there was a data leak or breach, this data could be used to identify vulnerable people or people with certain conditions to be targeted with sales.

"If you've got a certain condition, if any data is leaked they can try selling you things. Because I'm a diabetic, it might be the latest blood glucose detector. If you're older and have a condition

like dementia, your thought process won't be as clear. People could be robbed." (Female, 45-64, Workshop 1).

Views of involvement of partner organisations

The eye scan case study involved the NHS working with a globally recognised technology company, whereas the dementia and stroke screening case study involved the NHS partnering with academic researchers at a university.

Participants generally felt that universities being involved in AI research was acceptable. This was often anchored to positive views of the universities that developed the coronavirus vaccines.

"It was the university that developed vaccines, Oxford, they are the ones who were looking into potential vaccines and put in a lot of the work. Then Government and others got involved, but the universities did all the initial tests. It's the same with a lot of medicines as well, a lot of it comes from universities." (Female, 45-64, Workshop 1).

In relation to the eye scan case study, whilst some people felt the fact the company involved was credible because it was globally recognised, others raised concerns about the involvement of commercial companies.

Some felt concerned about involvement of countries based outside of the UK (specifically mentioning American and Chinese companies), as they were seen as being less well-regulated than companies in the UK. Participants wanted transparency about their motivations for being involved, as well as assurance that they wouldn't be making large profits, that they would be vetted for information security and would be upholding safeguarding procedures.

"A globally recognised company, their ultimate goal is profit. Ulterior motives when you're dealing with something as sensitive as personal health data." (Male, 45-64, Workshop 1).

However, some grounded these conversations in the reality of constraints on the NHS and recognised that sharing data with these organisations may help to advance research.

"I heard a great interview towards the end of the pandemic saying as they developed the vaccine for Covid they learned a lot about other diseases. They were saying that it's taken the NHS 10 or 15 years ahead on other things like heart disease, because they've been able to share that data, from a private company, to the NHS." (Male, 45-64, Workshop 1).

Views of decision makers around access to health data for AI research

Participants were prompted to think about who currently makes decisions about whether health data should be accessed for AI research in these case studies and, later on, more broadly. They suggested the following:

- Healthcare professionals, such as: GPs, nurses, consultants, authorities that run hospitals, opticians or medical administration staff.
- The NHS.
- Independent authorities, such as: regulatory bodies, a governing board (which could involve members of the public) or governing body (akin to Ofwat or Ofgem), an ethics committee or advisory committees.

- The government/government departments and arm's length bodies, including: the Office for National Statistics, health ministers or the Health Research Authority.
- The World Health Organisation.
- Technical experts, such as: medical specialists or legal specialists.
- The organisation that owns the AI system.
- The researchers or academics/universities.
- The organisation responsible for collecting the information.
- Financial investors.
- The individuals the data belong to.

In discussions, some participants conflated this with the organisations who would be involved in delivering the work, so mentioned private companies.

Response to ethical considerations in relation to health data for AI research

As part of gathering spontaneous views on this area, a Senior Data Scientist from the NHS AI Lab delivered an introduction to how health data is used in AI. The two case studies were used to illustrate possible uses (responses to these above). The Data Scientist outlined the Alan Turing Institute's FAST Track principles for the ethical design and use of AI systems. These were presented to participants as:

- **Fairness**: to be fair, an AI system should not lead to discrimination or unjust impacts across different groups, like people of different race or sex.
- **Accountability**: to be accountable, an AI system should have clear options for redress, and that legal responsibility will be assumed for any harms.
- **Sustainability**: to be sustainable, an AI system should be secure and reliable. The people who develop the system should try to minimise any negative impacts on communities and the environment.
- **Transparency**: to be transparent, those who develop an AI system should be able to explain how outcomes were reached in plain language. Those who develop and use the system should make clear the processes they followed to design and deploy it.

Participants discussed these ethical considerations. They engaged with these topics by asking questions about how these principles could and would be ensured. These often began with hypothetical or 'what if' questions which allowed them to play out scenarios and think about the consequences.

"If your data was breached, would you be informed, or would you just not know anything about it?" (Female, 65+, Workshop 1)

Fairness

Participants valued fairness and noted that these systems should not be used to marginalise people. Some raised concerns about the risks of AI systems being prone to biases and 'learning' prejudices. Some raised broader issues relating to data sets themselves being biased and certain people being less well represented, in part, due to lesser engagement with services.

"Historically, how black and brown people have been treated by healthcare systems has been horrific, so they may reluctantly opt-in[2] to these data collecting services for healthcare research, so how will they be well represented in training the AI?" (Female, 25-44, Workshop 1).

Participants raised questions about who would be accountable for governing or ensuring fairness, such as who would check samples within data sets to ensure representativeness. They also questioned what fairness would mean in practice, noting that people define fairness in different ways.

Accountability

Whilst participants felt accountability was important, how this would work in practice raised a lot of questions. They questioned how this would be controlled and who would be accountable (e.g., the person processing the data or the NHS). They expressed a lack of trust in machines and technology, often feeling that humans needed to be involved to be accountable. If something were to go wrong, they wouldn't want errors to be blamed on technology.

Sustainability

Many dialogue participants questioned the extent to which it could be ensured that AI systems are secure and reliable, and breaches and errors were often a focus of conversation, with people often viewing them as inevitable. They noted that there are always risks involved and that it may be hard to enforce security if lots of different entities are trying to get hold of the data. One participant also noted the costs of collecting data, which they imagined would be high.

Transparency

Participants didn't discuss transparency very much during the first workshop. Whilst the stimulus presented transparency in terms of clearly articulating how a decision is made, one participant suggested transparency would lead to the data being available to other people, which may reflect a misunderstanding about what transparency means in this context (i.e., transparency about the decision-making process itself).

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[2] Note that whilst this talks about these groups reluctantly opting in, the wider point is about these groups being less well represented in datasets so the participant may have meant to say 'opt out' however this cannot be confirmed.

04

Attitudes towards the different approaches to data stewardship

Attitudes to data stewardship approaches

Chapter summary

Participants were introduced to three broad ways in which decisions about health data access for AI research can be made in ways that involve the public.

- **Delegated decision-making:** someone making decisions on your behalf and for other people like you.
- **Collective decision-making:** people making decisions as part of a larger group.
- **Individual decision-making:** people making decisions for themselves or on behalf of someone they care for.

This chapter discusses dialogue participant views towards these different approaches and responses to the scenarios used to bring these to life. Participants revisited the approaches, and scenarios, in the final workshop. The aim of this was to further interrogate the benefits and risks and debate the trade-offs. This result was a set of principles for each approach to decision-making.

Key findings

- Participants were initially keen on delegated decision-making approaches because of the presence of specialists, bringing the relevant knowledge to decisions about data access, and the perceived speed at which decisions could be made. However, when they compared delegated approaches to collective and individual decision-making approaches later in the dialogue, the lack of individual choice in these approaches became apparent.
- There was an expectation that there would be clinical (from within the NHS), legal, ethical, data/data science and technical/AI specialists within delegated decision-making approaches, independent from commercial interests. The criteria used within delegated decision-making approaches was important, as well as transparency around this, and oversight to hold decision makers to account. There were mixed views on whether to involve the public in delegated decision-making approaches but where they are involved it was important that their voices were heard and given equal weight to those of specialists.
- Participants reacted positively to the collective decision-making approaches, given the opportunity to involve the public and patients in decision-making, though they raised concerns about how long it would take to deliver these approaches and how this could slow down research. There was a steer from most dialogue participants to also involve specialists in these processes, rather than patients and/or members of the public only.
- Individual decision-making approaches were liked for the more comprehensive choice and transparency they were seen to offer. Participants also saw the opportunity to educate the wider public about the benefits of using data for research using these approaches.
- However, there was caution about the overreliance on individuals within the individual decision-making approaches. For example, the time it could take for individuals to make granular decisions and the knowledge needed to do so. They also questioned the feasibility – including the cost - of implementing them within the NHS.

Delegated decision-making scenarios

Expert Data Access Committee: A data access committee - made up of doctors, data scientists, legal and ethical experts from within, as well as independent to, the NHS, reviews every application to access the imaging data and decides whether access should be permitted. A patient or member of the public will also be asked to review applications alongside experts. The committee's decisions are made using a set of criteria focused on scientific, technical, legal and ethical merits. Some applications will meet the requirements and get approved, others will be rejected.

An Independent Group: The imaging data is under the control of an organisation independent of the NHS. The organisation is run by a group of doctors, AI experts (including from industry) and other stakeholders from the healthcare sector, who have a legal responsibility to make sure decisions about who gets access to the data are in the interests of patients. Given that the imaging data is outside the control of the NHS, the NHS and other interested parties must apply for permission from the independent organisation to gain access to the data.

Attitudes towards delegated decision-making approaches

Participants were able to relate to delegated decision-making, given this is how decisions are made across society more generally. For example, within businesses (i.e., a board of directors), schools (i.e., a board of governors), and public services (i.e., elected councillors). There was an assumption across most participants that this is how decisions are currently made within the NHS regarding access to health data for research, but there was mixed reaction to the acceptability of this.

There were participants who were comfortable with delegated decision-making, noting that decisions were not about them, but rather about the NHS using data to help other people. Some participants saw the benefit of involving patients with expertise gained through experience of relevant conditions. However, others questioned the expertise of the public to be involved in such decisions (see 'expertise' below). Some participants highlighted the National Data Opt-Out, which they saw as a form of 'individual' decision-making within a current system which is dominated by delegated decision-making approaches, and how important it is to retain this. For these participants, the National Data Opt-Out was a mechanism which offers individual choice and control to people.

Other participants were far less comfortable with decisions being made on their behalf despite the National Opt-Out in place, flagging the lack of consultation and how this might lead to decisions that people would disagree with. In one of the question-and-answer sessions with specialists, a group asked whether, within delegated decision-making, they had a choice to consent or whether this choice was delegated, representing the group's discussion on the relative levels of choice within these approaches.

The 'who' became important for participants as they discussed delegated decision-making approaches, and the scenarios they were presented with. Participants expected those involved in delegated decision-making to represent a blend of skills and knowledge, have patients' and the public's best interests at the heart of decisions, and be held to account.

"I was just wondering who the people are that are delegating decisions on your behalf. Is it a collective of many people or one organisation that's delegating that decision? Or is it various organisations or institutions? I want to know who these people are that are making these delegated decisions, and also the collective one as well. Who are these people? Do we get to know who they are?" (Female, 25-44, Workshop 2).

Delegated approaches were presented first, before collective and then individual approaches. In most groups there were participants who viewed these approaches as sufficient, viewing this as the status quo. Positive views of delegated approaches were often framed by assumptions about the people making decisions – that these are experts who know what they are doing, how to use the data and will act in people's best interests.

"I would be able to trust someone who knows more about how my data can be beneficial to research to make the decision for me, and they know more about it… They know what they're doing." (Male, 18-24, Workshop 2).

However, over the course of the workshops, participants were presented with, and deliberated about, more options. Through this process, delegated approaches began to be viewed as less sufficient and the benefits and risks were weighed up against the collective and individual approaches, often highlighting the lack of individual choice in these approaches.

"I think it's been a good discussion, I've really liked hearing other people's perspectives. When we looked at the previous workshop, I was all about delegated but I've actually changed my mind now that it's somewhere between delegated and collective, more so collective perhaps. But there needs to be that balance." (Female, 25-44, Workshop 3).

Expertise

Participants were keen on delegated approaches because of the presence of specialists. The blend of different voices was seen as a major advantage. Some voiced an expectation that GPs, doctors and other healthcare professionals working within the NHS would need to be involved and were reassured by this given the trust they had in these individuals. For others - who spoke of a sense of waning trust in the NHS, some mentioning the COVID-19 pandemic and in the context of increased waiting times – the presence of GPs and healthcare professionals was less reassuring. Some wondered if the NHS would be biased and overly permissive when it came to data access because they would want to see AI research going ahead.

There was an expectation that there would be clinical, legal, ethical, data/data science and technical/AI specialists within a delegated decision-making approach, and that there would be independence from commercial interests.

(When discussing the 'Expert Data Access Committee') "The committee is made up of experts in their fields. They've also got legal and ethical experts to make sure everything is done correctly. They come together and review the data. They've got a mixture of everything in one, which is good." (Male, 16-24, Workshop 2).

When presented with two alternative scenarios: one with representation from the NHS (an 'Expert Data Access Committee') and one which was independent ('An Independent Organisation'), most participants tended to favour the involvement of the NHS. This was due to the perception that the NHS would be focussed on innovation and healthcare improvement, and this would ensure the interests of patients and the public were at the heart of decision-making (as reflected in the first and third delegated decision-making principles).

Some favoured the involvement of the public in delegated decision-making approaches (i.e., a patient or member of the public as part of the 'Expert Data Access Committee' scenario), recognising that this would open the process to enable transparency. In some cases, participants distinguished between the public and patients, recognising the expertise that patients could bring through their experience of relevant conditions.

"It's really important because potential patients or past patients, there is no one who knows better about their condition than those who are going through it." (Female, 45-64, Workshop 4).

Others, however, saw public involvement as unnecessary. They felt the right expertise was in place with the group of specialists, or they were opposed to this idea because they assumed a patient or public representative would not have the technical knowledge required to meaningfully contribute. Hence, the second delegated decision-making principle about discussions being at a lay level so they do not exclude people. The potential risk of overreliance on one voice was also discussed: raising questions about how a patient or member of the public would be chosen.

"As a patient sitting in on it, that's good but I think you'd sit in the background as you wouldn't have a clue looking in." (Female, 65+, Workshop 2).

During discussions about the merits and downsides of public involvement in delegated decision-making approaches, participants questioned whether their voice(s) would have equal weight in the decision-making process and how this would be assured. They also wondered when their views would be considered (e.g., would specialists bring them in at the end of the discussion about a data access request?), and what proportion of the decision-making group would be made up of members of the public.

"Whatever decision they want to make, they will make it whether a member of the general public agrees or not. It's good to have the variety there but I just wonder whether it's a box for them to tick." (Male, 25-44, Workshop 2).

Transparency and trust

The criteria used within delegated decision-making was important to participants and there was some discussion around the transparency of this (hence, the fourth delegated decision-making principle representing an expectation to publish these criteria). When discussing the 'Expert Data Access Committee' scenario, participants asked about the criteria being used to make decisions and how these would be developed.

(When discussing the 'Expert Data Access Committee' scenario) "You need to be really clear on what the criteria are, who's in the committee. To trust the system, they need to be transparent, to let you know exactly what's going on." (Male, 16-24, Workshop 2).

During the final workshop, when participants were ratifying the principles, as well as the requirement to publish the criteria used in decision-making, some groups added the requirement for the criteria to be periodically reviewed with an auditable trail. This would allow the opportunity for learning, and for the criteria to evolve over time, as well as ensuring accountability and further transparency.

Trust dominated discussions around the acceptability of delegated approaches. Trustworthiness was related to expertise and retaining a level of objectivity when deciding whether to grant access to data for AI research. Some participants were also interested in whether diversity would be represented within delegated decision-making approaches, as this was also important from the perspective of trust.

"At the end of the day you have to have the trust in these people that they are acting in your best interests and if they've got the experience that we haven't to make these sorts of decisions." (Male, 65+, Workshop 2)

Apart from a few people who saw the value of involving industry, participants were against the involvement of representatives from pharmaceutical companies or industry given commercial interest and conflict of interest. Additionally, the independence described in the 'Independent Organisation' scenario heightened concerns about the motivations, commercial interests and assumed financial gains of those involved.

(When discussing the 'Independent Organisation' scenario) "Most companies only after just money. They don't really care for people. Otherwise, they would do more about alternative medicine, alternative therapies. So, I would stick to expert analysis committee [expert data access committee] within the NHS being governed by the governing body, supervising what they are doing. Rather than subcontracting day by day, where the business is money oriented." (Male, 45-64, Workshop 2)

Another aspect of transparency and trust related to the need to inform the public that such delegated groups are making decisions on their behalf, and to reassure people that those making decisions are credible to do so.

"For me, personally, I have no issue with data being shared for the greater good. If we can prevent or recognize trends or something that will pick up a trend that can prevent something in the future, I'm all for it. My only concern about delegated decision-making is there's a lack of transparency and awareness about how and why." (Male, 25-44, Workshop 2).

Accountability and governance

There was an expectation, voiced by some, that delegated decision-making processes would need to be audited to ensure that those involved are not diverging from the agreed criteria, and that the voice of public representatives are being considered (see 'transparency and trust'.) Participants highlighted the importance of holding those involved in delegated decision-making processes accountable, especially for when things go wrong. The sixth delegated decision-making principle was strengthened during workshop four to include a suggestion that a legal body or regulator might fulfil this role.

"Quality assurance that the people making these delegated decisions that there's people above that, who are looking at whether those decisions be made are viable, ethical as well…. So, I feel that people who are making the delegated decision, there should be people above them, overseeing the decision-making process." (Male, 45-64, Workshop 2)

Questions were also raised over how accountable an independent organisation would be, when reviewing the 'Independent Organisation' scenario. Participants were worried about the NHS losing control of the data, and there was also a sense of an increased risk of data breaches and hacking if data access was managed by an independent organisation (even though it was explained to participants that the National Imaging Data base would be used in the context of the Five Safes Framework).

Speed of decision-making and research happening

Participants remarked on the speed at which decisions could be made through delegated decision-making approaches, considering the need to act fast during COVID-19 as an example. In early discussions some cautioned how long it might take to reach consensus among a group of delegated decision makers. Later in the dialogue, however, when participants compared these approaches to collective and individual decision-making approaches, they viewed delegated decision-making approaches favourably as quicker.

“It makes the process much quicker instead of going out to each individual to ask whether they’re happy for information to be shared. Depending on the severity of what they’re researching, I’d automatically assume they’d be taking my information anyway, if I had decided to opt-in. I wouldn’t expect them to reach out to me individually whether or not it’s okay.”
(Female, 45-64, Workshop 2)

The fifth delegated decision-making principle reflects the importance of speedy decision-making which does not slow down research from going ahead. In the final workshop, where groups ratified the principles, some participants suggested removing the word ‘fast’, which was in the draft principle, because they did not want speed of decision-making to compromise the quality of the decisions.

“I agree. I connotate fast with rushed. They need to make the right decision but not rushed.”
(Male, 25-44, Workshop 4)

Delegated decision-making principles

1. Delegated groups should have representation from the NHS (healthcare professionals, specialists in the fields being discussed) and educated patients/public [3] as well as technical expertise (i.e., AI) relevant to the likely data access requests (expertise).
2. Discussion should be at a lay level to avoid excluding patient and public representatives.
3. Delegated groups and experts should keep patients' best interests in mind at the heart of their decisions, be thinking of the greater good [4] and be accountable to ensure that data is not abused (inclusivity, transparency, and accountability).
4. The criteria delegated groups use to make decisions about access to data for AI research should be publicised (transparency) and periodically reviewed with an auditable trail.
5. Delegated groups should make decisions about access so that research can go ahead without delay (speed of research happening) [5].
6. There should be some level of oversight of decisions made by delegated groups (accountability) for example by a legal body or regulator, and legal repercussions.

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[3] As noted, some participants used the terms 'patient' and 'public' interchangeably. At times they were referring to patients as people with lived experience of the health condition in question. At other times, they referred to patients as recipients of NHS services. In this principle, participants suggested that, if people are involved in making decisions about data access requests, they should have enough information about the topic and be informed and educated to enable them to be involved.

[4] Please note that the question of 'greater good', 'public good' and 'public benefit' is complex, and a previous Sciencewise dialogue has explored this issue in greater depth in the context of health and care data – commissioned by the National Data Guardian's Office: https://sciencewise.org.uk/2020/04/good-enough-assessing-public-benefit-in-data-driven-health-and-care-research-and-innovation/ . This is usually defined as generating a clear return that can be evidenced back to either the NHS and/or patient/publics.

[5] However, some participants did note that decisions should not be rushed or compromised by the speed. One group noted that this is reflected in the use of language 'without delay' as opposed to just stating it should be fast.

Collective decision-making scenarios

Patient Panel: A representative group of the public and patients comes together as a panel to review and discuss every application to access the imaging data. The panel uses a set of criteria it created as a group to gain consensus and decide which uses should be approved. The outcomes of the data access and use are reported to the panel once the research is complete, and the panel can adjust their criteria over time.

Developing Data Access Principles: Before the imaging data can be used for research, a representative group of the public and patients take part in a series of workshops to develop high-level principles for how the data should be used. The group's views - such as on what types of researchers can access the data and what purposes it can be used for - are translated into detailed rules and criteria by doctors and other experts, who then apply them to requests to access the data as they come in.

Retrospective Review: Every three months, a representative group of the public and patients take part in a session with doctors, researchers and other experts who are responsible for giving access to the imaging data. The group sees which organisations have used the data over the last quarter, and can query why the experts made certain decisions. Over time, the experts may need to adjust their decisions to better reflect the group's expectations.

Case-by-Case Workshops: A representative group of the public and patients take part in a workshop with AI research teams before they are granted access to the imaging data. The group asks questions about what the researchers are seeking to find and why they need to use the data they've requested. At the end of the workshop, the group makes a recommendation as to whether access to the data should be granted or not, and can ask the researchers to adjust their approach.

Attitudes towards collective decision-making approaches

Involving the public and patients in decision-making was seen as a positive step. Participants warmed to these approaches the more they were discussed. Before collective decision-making approaches were introduced in the dialogue, there were participants who had been comfortable with delegated decision-making (the status quo, a perceived feasible solution). Though as participants discussed collective decision-making, they identified many benefits. Those who lacked trust in government, the NHS and how health data is used (including participants who had previously opted out), were drawn to collective decision-making approaches, especially when compared to individual ones. They perceived this as an opportunity to build trust among the public by opening up processes that are otherwise closed and involve the public in shaping decisions.

Collective decision-making approaches, when later compared to individual decision-making approaches, also felt more feasible for the NHS to implement. However, there was a steer from most dialogue participants to also involve specialists in these processes, rather than the public only (see 'expertise' below).

Participants, including those from ethnic minority backgrounds, raised concerns about underrepresentation of ethnic minorities in datasets used for AI research, and therefore bias. For this reason, the idea of involving patients and the public more in decision-making through collective approaches was appealing and seen as preferable to individual approaches which might create further opportunities for individuals to opt-out.

Inclusivity, balance and accountability

Participants valued the involvement of patients and the public in more collective decision-making approaches, which was seen to provide a level of accountability to the public. The inclusion of a mix of people, who bring different perspectives, was viewed as providing more balance to decision-making and was a major benefit of this form of decision-making.

"I think it's as honest as it can be. Without consulting everybody, you'll have a wide range of views, a snapshot of people. It's a bit like a jury overseeing a trial. It's a bit like that. The collective people with their experience of what they're talking about, they'll be able to come to some agreement." (Male, 45-64, Workshop 2).

However, some expressed concern about dominant agendas and voices, with the risk that decisions may not be made sensibly and in line with what others would want. This was of particular concern when dialogue participants considered the role for patients with conditions relevant to the AI research.

"It's obviously really good for the general public to have their views on things. Especially those that may have an added interest in the decision-making because they've got a particular illness or things like that. I worry that perhaps decisions will be made based on from-the-heart decisions rather than sensible, logical, from-the-head decisions." (Female, 25-44, Workshop 2).

Additionally, there were participants who flagged that there would need to be a level of compromise within this form of collective decision-making, to enable a group to reach decisions about whether to approve data access or not. This was viewed as a potential downside of this approach to decision-making.

In all scenarios discussed there was a strong feeling that patients and public representatives would need to be reimbursed for any expenses incurred (hence, the third collective decision-making principle), though participants were not aligned on whether they should be paid for their time. In the fourth workshop, as participants ratified the principles, most groups removed the reference to 'paid' involvement from the draft principle.

Choice

As mentioned, the involvement of patients and the public in collective decision-making approaches was viewed as progressive and positive. Through exploring the scenarios, participants recognised the importance of patient and public voice and choice.

(When discussing the 'Developing Data Access Principles' scenario) "It's the right idea if they are working with the patients and it's the patient's data getting used, so they should have a say." (Male, 44-64, Workshop 3).

Although there were perceived benefits of including patients and the public, participants also raised potential risks. There was a sense that patient and public voice could be misinterpreted in some of the scenarios discussed (e.g., the 'Developing Data Access Principles' scenario), meaning that decisions might not always be made in line with the values expressed by the public. As well, some questioned what would happen if the views of specialists misaligned with those of the public.

While many saw the opportunity to learn from mistakes and hold professionals to account when discussing the 'Retrospective Review' scenario, some participants were particularly uncomfortable with the reflective nature of the patient and public input, and choice, given that decisions will have already been made.

(When discussing the 'Retrospective Review' scenario) "I don't know how I feel about this one, or whether I like this. I like the fact that there is public and patient input, but I don't like the fact that it's retrospective. The fact that the data has already been released to whatever organisations need it, so I guess it's possibly too late then. This one doesn't sit as easily with me." (Female, 25-44, Workshop 3).

As participants discussed the extent of choice in the scenarios representing collective decision-making approaches in the final workshop, there was some discussion about the role of the public. While there were participants who perceived the scenarios to offer choice, as they involved patients or members of the public and not just specialists, there were others who were less satisfied with the extent of choice.

- Some noted that these groups only included the opinions and preferences of a sample of patients or members of the public, not everyone (hence, this is not individual choice). They reiterated the importance of these collective decision-making groups being representative (age, geography, ethnicity).

  (When discussing the 'Retrospective Review' scenario) "I'm not sure about the patient choice because it depends obviously on the range of patients. I've always been told, and I agree totally, no two people are the same." (Female, 65+, Workshop 4).

- Participants also noted that the extent of choice was dependent on whether it was the same group of people involved or whether this was changed. This linked to the theme around consistency in decision-making (see below).

  (When discussing the Patient Panel scenario) "I would think it had to be a different group. If you want patient choice you can't say it will just be the same 10 patients forever, which makes the consistency very difficult." (Male, 44-64, Workshop 4).

- In some of the scenarios discussed, and where specialists are involved (i.e., 'Developing Data Access Principles', 'Retrospective Review'), patient and public preferences, and choice, would be informing (not specifying) the decision. They recognised that this might not sit well with those who would want to specify the decision.

  (When discussing the Developing Data Access Principles scenario) "Patient choice is the number 1. But then you have to look on the other side. It's about patient choice but they don't get the final say. It's only informed by it. It may seem about patient choice, but it's more inclusivity. It's got elements where it's the choice of the patient and the choice that they're creating these principles, but it's not their final choice. I think it's got patient choice but it's more inclusivity." (Male, 16-24, Workshop 4).

Expertise

Prior to discussing examples of how collective decision-making could work in practice (through the scenarios), many participants assumed that these approaches would only involve patients affected by the disease(s) at the heart of the AI research. Later in discussions, there was a debate about the merits of involving patients with lived experience of the conditions or diseases relevant to the research being conducted. Including such patients could be beneficial given they would be classed as experts by experience, and there were participants who felt strongly about the need to involve patients with lived experience.

“A group of people who have had an illness do have some insight. If they haven’t had any experience, how do you move forward? For me that would work better than someone* [a member of the public] *who is a so-called expert.” (Female, 45-64, Workshop 2).

However, some challenged this idea. While they recognised the advantage of involving patients with lived experience of the conditions or diseases at the focus of the AI research, they were also concerned about the potential for bias, the difficulty involved and time it might take to reach consensus (hence, the fourth collective decision-making principle which emphasises the need to bring in broader perspectives to discussions by involving members of the public.).

The absence of specialists with the knowledge needed to make decisions regarding data access for AI research (clinical, technical, legal, ethical) concerned many participants as they discussed the collective decision-making scenarios where this was the case. While some flagged the potential for specialists to bias decision-making, the involvement of specialists was viewed as essential by most participants, given the perception that the public would lack specialist knowledge about the data and research (as reflected in the first collective decision-making principle). Having specialists involved would also create some accountability, which would otherwise be absent if only patients and/or the public were involved.

“I would say there is no accountability. You’re asking patients to make decisions on something that they have no knowledge of, so how can you make them accountable when they’ll say they didn’t understand?” (Female, 65+, Workshop 4).

Some participants assumed specialists would be involved in collective decision-making approaches when they described how the approaches would work. This reflects the ongoing discussions around the relative merits of bringing in patients and the public compared to bringing in specialists.

“This patients’ panel which involves public and patients, is there anybody who would oversee on the top of these people? Somebody as a professional must be overseeing this panel group. People can’t get together and say, ‘Let’s have a group’. Someone must oversee it, who are they? AI people? Professional people? If they are professional people, fine, they have some kind of input, and it might be alright. Unless we know who’s overseeing this group, it’s a bit risky to me.” (Male, 25-44, Workshop 3).

It was also suggested that the involvement of specialists would benefit situations where a collective group of patients and/or the public struggled to reach consensus, which was noted as a particular risk when participants discussed the ‘Patient Panel’ scenario.

“I like this one a lot because the public and patients don’t make the final decision, there’s someone overseeing it. You’ve got an expert view and you’ve got clinicians and doctors making the final ultimate decision.” (Female, 25-44, Workshop 3).

The involvement of specialists could also avoid the risk of patients and the public being persuaded or misled by the merits of the research by those wanting access to the data. In the ’Case-by-Case Workshops’ scenario, some participants wanted specialists to have the final say once the public had judged whether access to data should be given.

(When discussing the ‘Case-by-Case Workshops’ scenario) “I’d be wary that if you see the AI research team as a sales team, you’re missing out the professionals that can qualify the need here and they can be misled. It’s quite easy to hoodwink people I think.” (Male, 25-44, Workshop 3).

Speed of research happening

Participants felt that collective decision-making approaches would take time to work effectively, and thought that the challenge of reaching a consensus, with multiple people involved, may hamper, or slow down the research process. At the same time, this idea was challenged by others who cautioned decisions being made too quickly, favouring a more considered process.

“I said that was a good thing, as we aren’t in a rush to hand that data over.” (Female, 45-64, Workshop 2).

“The collective would be more difficult because there would be a lot of voices and people from various backgrounds involved. I think it would be quite challenging to make decisions from that. There would be people wearing different hats and coming from different areas.” (Female, 45-64, Workshop 2).

During the final workshop, as participants ratified the principles, participants in one group were keen to add a principle to specify that collective decision-making approaches should not introduce delays and allow for fast and effective decision-making.

Trust

Participants likened collective decision-making approaches to the dialogue workshops they were participating in. They recognised the journey they had been on, becoming more informed about how health data is used in AI research, and pointed out that these approaches offered the opportunity to build trust in research among the public and patients. This point was particularly pertinent, for example, as participants discussed the ‘Case-by-Case Workshops’ and the ‘Retrospective Review’ scenarios.

Some participants – particularly those who had indicated that they were less trusting of the government and the NHS – were encouraged by the prospect of empowering people and patients to make decisions. Involving people more in decision-making could aid in building trust.

(When discussing delegated decision-making) “We have no trust in the GPs and no trust in the government. Some of our data is out there already. We don’t know where it is. Will it be the right decision if somebody else makes the decision for you?” (Female, 65+, Workshop 2).

At the same time there were participants who would not trust themselves, nor other members of the public or patients to make decisions about data access (as is the case in the ‘Patient Panel’ scenario). For this reason, they favoured the scenarios which were seen to achieve a balance of patient and public involvement, alongside the expertise of specialists, as already mentioned (and is the case in the ‘Developing Data Access Principles’ scenario for example).

Consistency in decision-making

There was discussion about the relative merits of involving the same people in collective decision-making processes, and rotating involvement of different patients and members of the public. There was no clear consensus on this, and it tended to depend on the scenario. For example, participants saw the value of keeping the same people involved in the ‘Retrospective Review’ scenario, so that they could learn and develop their views over time.

“In this one, I think it would be better to keep the same people. If they’re making decisions with experts and researchers, they can help the public and patients in coming to an agreement. It would be more work and time consuming to bring new people and explain it all over again. It would be

more hassle for them. It should be kept under one sheet and keep the same people and help them understand, rather than adding new people and taking time to explain.” (Male, 16-24, Workshop 4).

However, participants raised concerns around having the same people as part of the ‘Patient Panel’ scenario, given the risk that the group could become stagnant. The fifth collective decision-making principle reflects the fact that participants saw the benefits of consistency within collective decision-making groups, as well as mixing this up to bring in new perspectives.

Feasibility

Collective decision-making approaches were viewed as more feasible than individual approaches as they would not require consulting every single individual. However, at the same time, participants noted the demands on those involved and the feasibility of these groups reviewing many data access requests. Some scenarios were seen to be more feasible than others, however. The ‘Developing Data Access Principles’ and ‘Retrospective Review’ scenarios were favoured over the other scenarios discussed. This was because specialists are ultimately driving decision-making using patient preferences, whereas in the ‘Patient Panel’ and the ‘Case-by-Case Workshops’ scenarios the public and patients are involved in granular decision-making about every data access request.

(When discussing the ‘Developing Data Access Principles’ scenario) “It’s probably more efficient timewise. I think it will streamline things.” (Male, 45-64, Workshop 3).

As well, the ‘Patient Panel’ and the ‘Case-by-Case Workshops’ scenarios were viewed to be more costly for the NHS. There was also a feeling that it would be impractical to bring patients or public together to review every single data access request, some also describing this as overly onerous for the individuals involved. There were suggestions of using these approaches for more complex research or specialist subjects/disease areas only.

“Case-by-Case Workshops could be used for more specialised topics that the public could have more feelings on. It shouldn't be used for everything because it might just be an additional layer of resources. It could just be for top tiers or something very specific. Not a blanket approach.” (Male, 45-64, Workshop).

Transparency

As noted above, participants were keen to understand the makeup of collective decision-making groups and called for transparency around how the membership is chosen, who this consists of and how decisions are made (hence, the first principle). There was also some discussion, mostly in the final workshop, about the extent to which collective decision-making approaches offer transparency around how data is used. When discussing the ‘Retrospective Review’ scenario, for example, some participants picked up on the fact that the group sees which organisations have used the data over the last quarter and can query why the experts made certain decisions. The perceived transparency and feedback loop in this example was viewed positively, and as such the second collective decision-making principle was created.

(When discussing the ‘Retrospective Review’ scenario) “I think transparency is one that comes to mind. The whole retrospective review is a form of being transparent. It’s showing the public you are what you’ve done with the data.” (Male, 16-24, Workshop 4).

As well, when discussing the ‘Case-by-Case Workshops’ in Workshop 4, some flagged that this scenario offers transparency in terms of the intended purpose of the data use. However, some noted that full transparency would only be achieved if the AI research team disclosed what they used the data for.

(When discussing the ‘Case-by-Case Workshops’ scenario) “I think ‘transparency’ should be green. We get to put questions to the team and then decide whether that team should be granted access, so it’s completely transparent, providing they’re truthful with what they want to use the data for.” (Male, 25-44, Workshop 4).

Collective decision-making principles

1. Patients and the public should be involved alongside specialists (accountability and expertise) and there should be transparency about how decisions were reached (transparency) and publish these.[6]
2. There should be a feedback loop whereby the collective sees the outcomes of the research, so that they know that they are moving in the right direction.[7]
3. Patients and the public should be reimbursed for their involvement to retain commitment (inclusivity). Like Jury service.
4. There are benefits to involving patients with conditions relevant to the AI research being done, but at the same time we need to consider involving other members of the public to bring a broader perspective to decisions (expertise). These groups should be representative of the public as a whole (inclusivity).
5. There are benefits to keeping collective groups consistent, so that they develop expertise, but at the same time fresh new perspectives are important (consistency) or a mix (i.e., 50/50 consistent people and fresh people)

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[6] Discussion indicates participants wanted to see transparency about both *how* the decisions were reached and also about the decisions themselves.

[7] This also links to discussions around transparency.

Individual decision-making scenarios

Individual Preferences: Before allowing the data to be used for research, the NHS contacts every patient to ask how they would like their medical imaging data to be used. Some patients might allow for the data to be used for any research. Some patients might respond by saying that data can be used by NHS researchers to test the effectiveness of treatments they've received, but not for companies to build new AI products. Others might not want data to be accessed by any researchers at all. Patients could set their preferences by post, a phone call, using an NHS website or appointment with a healthcare professional.

Data Usage Reports: The NHS sends a letter, email or notification to every patient on a regular basis showing them how it has allowed their imaging data to be used for research. It shows each and every different project and researchers the data has been accessed and used by, and the outcomes from the research. Patients can respond to adjust how data about them is used in the next year, by post, a phone call, using an NHS website or appointment with a healthcare professional.

Personal Data Store: Patients use a digital interface to choose who can access their imaging data. Patients get notifications about upcoming research projects that have passed a legal and technical check, including information about the organisation conducting the research, what the researchers were looking to understand and how they plan to use the data. Patients can select which projects they'd like their data to be used for and for what purposes as well as setting default preferences. Patients can decide the frequency with which they receive notifications, the channel by which they receive them, or turn them off all together.

Attitudes towards individual decision-making scenarios

Over the course of the dialogue, participants were introduced to alternative approaches to the status quo (delegated decision-making). As they discussed the merits of these in terms of public and patient involvement and elements of choice, participants increasingly argued for what they saw as the benefits of approaches which enable people to make decisions about data access for AI research individually. As well as increased choice for those who want to be involved in granular decisions about how their data is accessed, they also felt that individual approaches offered full transparency and the potential to build trust in how data is used for research. In the earlier dialogue workshops, some indicated a preference for delegated approaches (given their perceived feasibility), or perceived these to be an adequate form of decision-making, and finished the workshops championing individual approaches.

"Initially I thought only experts should make the decision but at the end of the third workshop I did change my mind and felt there needs to be some kind of a balance." (Female, 25-44, Workshop 4).

In some cases, the tone of the conversation had shifted from viewing these decisions as belonging within the realm of experts at the beginning of the dialogue process, to more of a focus on individuals having a say towards the end. This may reflect participants' own journey of learning and understanding more about the subject.

Individual decision-making approaches were particularly appealing to those who lacked trust in government, the NHS and how health data is used.

"Yes, I think for me, I will focus on the way forward on the individual decision-making process because it's all done to consent, trust, reliability, and transparency. I'll be more comfortable with my GP if he asked, are you happy for me for him or her, for the GP to pass information around so

you can help people of different race ethnicity…rather than just delegating it to some people who you don't know what they will do with your data.” (Male, 45-64, Workshop 2).

For other participants, while these approaches were perceived as ideal – in terms of choice, transparency and trust – they recognised the risks involved. These related to the overreliance on individuals: the time it could take for individuals to make decisions and the knowledge needed to do so, and the potential for datasets to be compromised because they are incomplete. They also questioned the feasibility of implementing some of these approaches within the NHS. For these people, the risks outweighed the perceived benefits.

Choice

Participants praised individual decision-making approaches for the opportunity for individuals to have more comprehensive choice, especially when compared to collective and delegated decision-making approaches which had been previously discussed. The ‘Personal Data Store’ scenario in particular was viewed as flexible in terms of the ability for individuals to set and express preferences. Participants felt individual decision-making could be particularly beneficial in engaging those who lack trust and could appeal to those who currently feel removed from decisions about their data.

“I like it. I think everyone should have a choice whether they want their data being used for research. Irrespective of being anonymous, or semi anonymous. We all have a choice. We all have a choice to vote or not. Voting is good and you’re deciding who you want to run the country. A lot of people don’t vote. But having the freedom of choice whether you want that data there or not. Whether it is anonymous or not. I don’t mind it. I am not against it, but I can see why people would be.” (Male, 16-24, Workshop 3).

At the same time, some struggled with the practicalities of involving people in granular decision-making, often using parallels such as consenting to internet cookies time and time again. This led to participants questioning the feasibility of this and the effort involved from the perspective of the public.

“That’s the parallel I used in the first session, if you’re asked repeatedly then you can delve into it. If you were given the option to click 1 button and accept all cookies, they need a way to water down the whole process, as it’s become too much for us all. The practicality of being asked every time, is there a way of streamlining it a bit?” (Female, 45-64, Workshop 2).

Discussions returned to the National Data Opt-Out, as a means for individuals to express their choice while delegating granular decisions about data access (see ‘opt out or opt in?’ below).

Expertise

Participants highlighted that not all patients and members of the public, some including themselves, could be assumed to have the knowledge required, nor be trusted, to make informed decisions about access to their data for AI research. There were parallels drawn here to the Brexit vote, a referendum where “people did not understand what they were voting for” (as reported by a few participants). Some identified an additional and related risk here, that people would not understand what the data was going to be used for and why and could be wary about approving access accordingly (i.e., through setting preferences as would be the case in the Individual Preferences scenario).

“I can’t see how people will understand what they are talking about if they get a letter once they are contacted. A bit about Brexit, people didn’t know what was going on. People just opted in or out.” (Female, 65+, Workshop 3).

A few participants made comparisons between individual and collective decision-making approaches, with respect to knowledge needed to make decisions, and felt that collective decision-making approaches offered the opportunity for selected individuals to discuss data access requests with others, which was seen as beneficial given the perceived difficulty of understanding this information by themselves.

For these reasons, many participants were clear that individual approaches need to sit alongside the involvement of specialists so that expertise is brought to decision-making. This reflects the tension, which participants often came back to, around the benefits of individual choice as well as the benefits of involving specialists with expertise. This was emphasised further in the final workshop, as participants ratified the principles (hence, the second individual decision-making principle was added).

(When discussing the 'Individual Preferences' scenario) "I quite like this scenario. But I don't think this scenario works on its own. I like it because the patient gets to choose what they want their data to be used for. But I think that the decisions on who accesses the data has to be made by experts, because the public don't have the expertise to know about research." (Female, 65+, WS4).

Opt-out or opt-in

Discussion about how some of the individual decision-making scenarios would work in practice raised questions about whether the system would function as an opt-out. This became a key debate underpinning deliberations about individual approaches, as participants were keen to find ways to ensure completeness of data sets, recognising the risk of relying on all individuals to consent for each granular data access request, and the opt in/opt out mechanisms were linked to this. This opt-out would be an additional opt-out, above and beyond the National Data Opt-Out, and would allow participants to opt-out of individual access requests for example. The scenarios which prompted this discussion, in particular, were those which inferred individuals can choose how they would like their data to be used, such as the 'Individual Preferences' and 'Personal Data Store' scenarios.

There were participants who felt that such individual decision-making approaches should be set up to work as an opt-out in practice. This would mean that people could choose to opt-out from the use of their data for each access request, but if they did not take action their data would be automatically included. This would counteract the risk that many people will not engage and avoid compromising the quality and completeness of the data (hence, the fourth individual decision-making principle).

(When discussing the 'Individual Preferences' scenario) "With that one, the patient decides before the project is started or analysed, so if most patients say no there won't be enough info for AI to do any analysis. So obviously the data could be too biased. That could be a disadvantage." (Male, 25-44, Workshop 3).

Those who held this view were very clear that an opt-out system would need to sit alongside wide-reaching communications, and a period of time for people to opt-out of individual access requests if they wanted to. In the final workshop, five of the eight break-out groups expressed their desire for individual decision-making approaches to be opt-out by default by adding this in as a principle, some caveating this with the need for wide reaching communications.

"Probably a national campaign telling people that everyone is opted in but there is the option to opt out at a later date and explain to them what it's being used for. I think if more explanation is told to the general public, they might go ahead with it." (Female, 65+, Workshop 4).

There were also participants who felt that the default setting for individual decision-making approaches should instead be an opt-in system, expressing the importance of seeking the permission of people before their data is used for each individual access request and so that individuals feel in control.

(When asked whether people should be automatically opted in unless they opted out, when discussing the 'Personal Data Store' scenario) "No. That person still has to make that decision… I don't think you should be able to use data without their consent." (Male, 45-64, Workshop 3).

Comparisons were made here with the change in law for organ donation, which caused suspicion among some.

"If I opted in to be an organ donor, you can be an organ donor and choose which organ, and for what purpose, but now that has been superseded where we are all opted in. I have a feeling that whatever we decide, a decision has been taken that we're all in unless you say out." (Male, 65+, Workshop 3).

Recognising the challenge that there will be people who will not engage, participants called for flexibility. For example, one participant suggested a more sophisticated version of the process within the 'Personal Data Store' scenario:

- an option where the individuals' data is automatically included in the dataset unless they opt-out of individual access requests or research studies (i.e., an opt-out system by default)
- an option where the individual can set their preferences, so that after this they are not required to engage in any individual requests.
- an option where the individual is asked each time for consent to share data for AI research studies.

The first individual decision-making principle reflects participants' steer that individual approaches must recognise that not everyone will engage in decisions about data access requests.

In the final workshop, where participants ratified the principles, some groups tightened up the draft principles by adding references to cut off dates, as reflected in the sixth individual decision-making principle.

Feasibility, speed of research happening and completeness of the data

There was a live tension in most groups' discussions as participants discussed the provision of choice to individuals alongside the feasibility of individual approaches. As mentioned already, many responded positively to individual approaches initially. However, when participants explored the scenarios, and the way in which these would be carried out in practice, they raised a number of questions about the feasibility of doing so. Ideally individuals would be given comprehensive choice around how their data is used, however this did not always feel feasible. Participants considered the prospect of contacting individuals to request their preferences (as is the case in the 'Individual Preferences' scenario) and relying on individuals to make decisions about every single data access request (although it would not necessarily have to work like this in practice). This felt overly laborious and might slow down research.

(When discussing the 'Individual Preferences' scenario) "I think feasibility does come into it, as the cost will be phenomenal to contact everybody, and will take a heck of a long time as well, to

contact people and for people to get back to them with their choice. It's going to be very time consuming." (Female, 65+, Workshop 4).

For some, the risk that individual decision-making approaches would either encourage people to opt-out of data sharing, or mean their data was not included if the system was opt-in by default, thus compromising the quality and completeness of the data, outweighed the perceived benefits of choice and transparency.

"I think it is encouraging people to opt out. I can understand if it was Netflix and they said they had 3 million customers and asking them to sell data to Google. But this is data being used for good. To help cure things and make medical research better and they're telling people they're anonymised too. I don't get why you'd want to opt out and it's encouraging more people to opt out. As there is 60 plus million people involved, you're creating a lot of paperwork and hassle, for what? I don't get it." (Male, 45-64, Workshop 3).

They recognised that there will be many individuals who will not engage and many who will not be bothered about having a granular level of control over their data and how it is accessed. Additionally, participants felt that many may not have the time nor inclination to make these decisions, and that these factors could compromise the speed at which the research could be delivered. The risk that individual approaches might increase the chances that some people's data would not be included in the dataset was a worry, given the importance of high quality and complete datasets for AI research.

"It's important to remember that not everybody cares. If somebody has no interest in this topic they might choose the wrong decision because they don't have any information or they don't care. It could impact the research or the goal." (Female, 16-24, Workshop 2).

Some participants raised concerns about building the infrastructure required to enable individual decision-making, flagging the cost and time involved in creating and managing this. For example, when discussing the 'Individual Preferences' and 'Data Usage Report' scenarios, the cost and resource involved in contacting every individual patient (i.e., man hours working out how data had been used, formulating letters and postage), was queried in terms of feasibility for the NHS currently. Some questioned how this was going to be paid for.

(When discussing the 'Individual Preferences' scenario) "In an ideal world, this would be great because then every single person has been contacted and made their preferences and that way, the NHS will know each individual, what they want it used for. But realistically, I don't see this happening. I don't even know if this would be logistically possible. In an individual one, every single person consulted, that's my initial thought." (Female, 25-44, Workshop 3).

There was challenge to this view, however, with some participants suggesting that it would not be impractical to manage. When discussing the 'Individual Preferences' and 'Data Usage Report' scenarios, they thought about how existing systems could be utilised, such as blood test feedback mechanisms or the NHS App, and how individual preferences could be set within the 'Personal Data Store' scenario.

(When discussing the 'Individual Preferences' scenario) "It's a brilliant idea because every individual is given the opportunity to tell the NHS whether they want their personal data to be divulged. You've got consent and approval of individuals. I don't think it's going to be difficult logistically – in this age and time, you can go online, give feedback, like a survey. That way it can be, with the use of technology, patients can give their opinion on whether their data is taken or

not. This gives the opportunity for different backgrounds, ethnicity, culture, all these sorts of things. It's a good idea." (Male, 45-64, Workshop 3).

Many participants favoured individual decision-making approaches which sought to understand participants' preferences (i.e., the 'Individual Preferences' scenarios), rather than those which involved people in each and every data access request (i.e., the 'Personal Data Store' scenario). These felt more feasible and would not interfere with the speed of research happening.

(When discussing the 'Individual Preferences' scenario) "Get it done at the start then you don't have to worry about it down the line. You tick your preferences, you pick what you want it to be used for and it's out of the way. It's definitely the one I'd choose." (Female, 65+, Workshop 3).

Transparency, education, and trust

A key benefit of individual decision-making approaches noted by participants was the opportunity to be transparent with people about how their data is used. Participants felt it was important to inform people of how their data was being used at an individual level, even if they themselves would not need or want to know about every research project that had involved their data. Participants liked the 'Data Usage Report' scenario, for example, because this could educate people about the benefits of research, how their data had been used and the outcomes of research.

In contrast to the concern that individual approaches could increase the chances that individuals will opt-out, or that their data will not be included within a dataset because they have not directly consented for this to happen (as reported above), there was suggestion from some participants that these also have the potential to positively influence those who had previously opted out through the National Data Opt-Out. And those from certain ethnic groups who might lack confidence in data use. This was due to the opportunity to inform people, through these approaches, about how their data was being used and the associated benefits.

"If I see data that is used, like some ethnic groups don't have enough people come forward to give blood and bone marrow, and I see this company is using these scans and data for that purpose, it will help people have more confidence in using that data." (Female, 65+, Workshop 3).

Participants suggested that there would need to be a great deal of awareness raising and education, in the form of information campaigns for example, targeted at the public, which would sit alongside individual decision-making approaches (hence, the fifth individual decision-making principle). This transparency could build trust in data use for AI research, which was important. There were occasional parallels made to the GP Data Planning and Research extract in 2021[8].

"Last year there was a great big hoohah about opting in or out. I actually opted out because I thought [it] would be used by private companies. But if a public ad came on TV I would say, OK I didn't realise that and would be more likely to opt in." (Female, 45-64, Workshop 3).

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[8] About the GPDPR programme - NHS Digital

Inclusivity

During discussions about the individual decision-making approaches, participants referred to inclusivity, in terms of the extent to which processes are accessible and representative of a diversity of people.

Technology dominated discussions about the 'Personal Data Store' scenario, given the digital interface described in the scenario. Participants were quick to raise concerns about those who are not online, or those who are not as confident online. There was a strong feeling that there would need to be alternative means for individuals to engage, for example by letter or by phone (hence, the fourth individual decision-making principle).

(When discussing the 'Personal Data Store' scenario) "I think we touched on that last time. Not everyone has access to an electronic device and even if they do they don't know how to use it. For example, my mum just about manages to use a phone to call me and she still gets it wrong sometimes. She's from a different generation and many people are like her out there. They wouldn't even know where to begin. There's a question on inclusivity there. You're giving people the patient choice but taking away elements as well. You've not factored in that there are people whose first language isn't English or can't use certain devices." (Female, 25-44, Workshop 4).

Conversely, the 'Data Usage Report' scenario felt very inclusive given the range of mechanisms that would be used to inform people. Though, as well as the privacy implications associated with sending letters to people's homes (see below), some were wary of the huge volumes of paper that would be needed for such an exercise and the environmental impact of this.

As well, where there are different systems for different populations (as would need to be the case for an approach to be inclusive), some highlighted the need to bring all of the systems together and the potential complexity of doing so.

Privacy and a perceived greater risk of data hacking

During discussions about the individual decision-making scenarios, and in particular the 'Data Usage Report' scenario, participants spontaneously highlighted the increased risk of privacy breaches and hacking due to information about how people's data have been used being posted to people's homes. This was because the scenario referenced sending a letter, email or notification to every patient on a regular basis showing them how it has allowed their imaging data to be used for research. This, for some, challenged the perception that they were otherwise unidentifiable within datasets used for research.

(When discussing the 'Data Usage Report' scenario) "The other thing about notifications sent to patients. Doesn't that increase the chance of a data breach? What if my post is intercepted or my email is one wrong letter, and suddenly I am not anonymous? I wouldn't be happy with that." (Male, 45-64, Workshop 3).

Given these concerns, they suggested electronic solutions or including this information within GP/health records which people could access if they wanted to find this out. This was also seen to help with the unnecessary large volumes of paperwork, which could be overwhelming and even off-putting to some. However, in some groups, when discussing the 'Personal Data Store' scenario, there were participants who questioned where information would be stored and assumed that the system for managing consent would be an open database, easily compromised and open to hacking.

(When discussing the 'Personal Data Store' scenario) "When something is in a national database, presumably it is already in a secure structured environment. If this personal data store sounds like something openly accessible for everyone to be able to set preferences to opt in and out, it sounds easily comprisable." (Male, 25-44, Workshop 3).

Individual decision-making principles

1. Individual approaches should recognise that there will be many people who will not want to engage in every decision about how their data is accessed (inclusivity, completeness of the data)
2. These approaches need to sit alongside specialist involvement (expertise)
3. It is important that effort is made to ensure that individual approaches do not compromise research from going ahead (speed of research happening)
4. Where digital individual approaches are developed, there always needs to be viable alternatives for people so that they don't exclude people, for example post, telephone, text message, email, speak to GP/healthcare professional (inclusivity)
5. People should be informed about how their data was/is used (transparency) and there should be a national campaign and well publicised cut-off dates for opting out/opting in.

Summary of attitudes towards each scenario

Expert Data Access Committee (Delegated)

Benefits

- Expertise of specialists
- Speed of these approaches, quality, and completeness of the data
- NHS involvement, assumed to align with patients' best interests

Limitations

- Potential for a lack of transparency about how decisions are made
- Lack of patient and public involvement and individual choice

- Who makes up the committee?
- What criteria is the group using to make decisions, and will this be updated over time?
- How can we hold those involved to account and audit decision-making?
- If patients or members of the public are involved, how do we ensure they have an equal voice in decision-making?
- How do we ensure that those involved (inc. those within the NHS) retain independence from commercial interests?

Questions or areas for exploration identified

Independent Organisation (Delegated)

Benefits

- Expertise of specialists
- Speed of these approaches, quality, and completeness of the data
- Could relieve the burden on the NHS if decision making is outsourced

Limitations

- Questions over motivations of those involved (commercial, for example)
- Potential for a lack of transparency about how decisions are made
- Lack of patient and public involvement and individual choice
- Potential for NHS to lose control of the data, as well as perceived increased risk of data breaches

- Who makes up the committee?
- How accountable would an 'independent' organisation be?
- Will decision-making be audited?
- What criteria is the group using to make decisions?
- Could there be a place for a patient or member of the public, like the 'Expert Data Access Committee'?
- How do we ensure that patients' best interests are at the heart of decision-making, particularly if this organisation has independence from the NHS?

Questions or areas for exploration identified

Patient Panel (Collective)

Benefits

- Empowerment of patients and members of the public to be involved in decision-making, accountability to the wider public
- People with lived experience of the conditions or diseases relevant to the AI research could be useful

Limitations

- Absence of specialists, overreliance on the knowledge of patients and the public
- Questions about feasibility – costly and time consuming to implement (bringing people together, reaching consensus)
- Experience of patients could be biassing

- How do we ensure the panel is representative?
- How do we motivate the right people to be involved (not just the most interested) and stay committed?

- How can specialists also be involved, to bring clinical and/or technical knowledge to decision-making?
- Would the panel need to be the same people or be rotated so that new perspectives are incorporated?

Questions or areas for exploration identified

Developing Data Access Principles (Collective)

Benefits

- Empowerment of patients and members of the public to be involved in shaping criteria used in decision-making
- Appears more streamlined than some of the other collective options (‘Patient Panel’, ‘Case-by-Case workshops’), thus time efficient
- Specialists still involved in final decisions

Limitations

- Potential for a lack of transparency about how criteria have been applied
- Potential for difficulty in the group reaching consensus when formulating the principles
- Potential for specialists to not always follow patient/public preferences or misinterpret their values when making decisions

- How do we ensure the group is representative?
- How can we audit the decision-making process (i.e., specialists applying the developed criteria)?

- Would the panel need to be the same people or be rotated so that new perspectives are incorporated?

Questions or areas for exploration identified

Retrospective Review (Collective)

Benefits

- Empowerment of patients and members of the public to be involved in shaping criteria used in decision-making
- Appears more feasible than other collective approaches; would not delay decision-making or slow down research from happening
- Specialists still involved in final decisions
- Opportunity to build trust through transparency about data use

Limitations

- Retrospective nature of the approach means that there will be decisions made that people are not necessarily comfortable with (though there is potential to influence future decision making)
- Feels more like a tick box exercise, compared to other collective approaches which involve the public more upfront

- How do we ensure the group is representative?
- Would the group need to be the same people or be rotated so that new perspectives are incorporated? In some ways, consistency is more important here

Questions or areas for exploration identified

Case-by-Case Workshops (Collective)

Benefits

- Empowerment of patients and members of the public to be involved in decisions, alongside specialists
- Provides an opportunity for patients and members of the public involved to ask questions about the data access request
- Increased transparency in the process, which has the potential to build trust in AI research and data use

Limitations

- Too much responsibility and burden on patients and members of the public involved
- Potential for those involved to be persuaded by the AI research team
- Potential for difficulty in the group reaching consensus
- Appears less feasible: Time consuming to bring patients and the public together, and costly

- How do we equip patients and members of the public who are involved with the knowledge needed to make decisions about data access?
- Would the panel need to be the same people or be rotated so that new perspectives are incorporated?
- Would the patients involved need to have experience of the conditions or diseases in question?

Questions or areas for exploration identified

Data Usage Report (Individual)

Benefits

- Increased transparency around data use and potential to highlight the benefits of AI research, building trust
- Accessible and inclusive solution, does not exclude people who are less digitally capable
- Does not compromise the speed of research happening or slow down decisions

Limitations

- Seems unfeasible given the huge costs and time associated with writing to everyone
- Could be overwhelming or even off putting to the public to receive such a report
- Might encourage people to opt-out, meaning that the quality and completeness of the data could be compromised
- Less of an opportunity for individuals to influence granular decisions (i.e., if they have already been made)
- Privacy concerns: potential for intercepted post, increased chances of a data breach

Questions or areas for exploration identified

- Could this information instead be published on a website somewhere?
- Could this information only be provided to those who would like to see it, and in different forms? This could save paper/postage costs

Individual Preferences (Individual)

Benefits	**Limitations**
• Allows for comprehensive individual choice in how data is accessed and used • Appears less time consuming and more feasible than some of the other individual scenarios (‘Personal Data Store’) and less costly than others (‘Data Usage Reports’)	• Will still be costly for the NHS, and still feels unfeasible to ask everyone • Might encourage people to opt-out, meaning that the quality and completeness of the data could be compromised • People might not engage, and therefore their data might not be used
• Would this work as an opt-out or an opt-in?	• How would this be communicated to people so that they knew that this was an option for them?

Questions or areas for exploration identified

Personal Data Store (Individual)

Benefits	**Limitations**
• Allows for comprehensive individual choice in how data is accessed and used, feels the most comprehensive of all options	• Overreliance on technology, potential to exclude certain groups (such as those who are not online, people whose first language is not English) • Might encourage people to opt-out, meaning that the quality and completeness of the data could be compromised • People might not engage, and therefore their data might not be used. Appears time consuming for patients and the public • Appears very costly
• Would this work as an opt-out or an opt-in? • What options would be in place for those who are not online or are less confident with technology?	• Could this be set up flexibly so that only those who want to have to be involved in granular decisions about how their data is accessed?

Questions or areas for exploration identified

05

Focus and priorities for the research competition

The focus and priorities for the research competition

Chapter summary

This chapter brings together the findings from the previous chapters into themes which are relevant to the focus and priorities for the research competition. It discusses how participants grappled with some of the trade-offs and weighed up the benefits and risks of different approaches to decision-making regarding access to health data for AI research. Here we bring in relevant findings from other public engagement exercises to contextualise what we found in this public dialogue.

Key findings

- A combination of complementary data stewardship approaches was often suggested given that no single approach is perfect.
- Participants continuously returned to the importance of choice for those who want to be involved in granular decisions about access to their data, and empowerment of patients and the public and involvement in decision-making
- However, at the same time, expertise also mattered and involving specialists was perceived to have other benefits
- High-quality and complete datasets were seen to be important, and as such participants cautioned approaches which have the potential to compromise quality or impede the speed of research happening
- The technological feasibility and cost of building and maintaining infrastructure mattered to participants, and was mostly in relation to the individual approaches, and this was often considered as they weighed up the trade-offs
- Participants felt that transparency about the use of health data has the potential to build trust
- They also flagged that decision-making approaches need to be inclusive, representative, and accessible to all
- There was some debate around consistency within collective decision-making approaches (i.e., the same patients or members of the public making decisions or mixing this up with new people) and participants often concluded that a blend is probably best
- The involvement of specialists, within delegated and/or collective decision-making approaches, was perceived to provide a level of accountability to the decision-making.
- Importantly, participants wanted to see that patients' and the public's best interests were at the heart of decision-making and that there was some level of oversight of decisions made and to ensure that this was always the case.

A combination of complementary approaches

Given the tensions outlined around the desire for the involvement of specialists in decision-making alongside the importance of patient and public involvement (through collective approaches) and choice (through individual ones), as well as tensions concerning the provision of choice alongside the motivation of the public, participants often concluded that no single approach was perfect. As such, some participants suggested combining elements from each approach and the different scenarios.

"I think a three-pronged approach covers many bases. Individual, collective and delegated. A multifaceted approach." (Male, 18-24, Workshop 3).

"Collective with delegate expert as well, just to balance it." (Female, 25-44, Workshop 4).

"Personally, a hybrid of delegated and individual would enable decisions to be made with a knowledge background and people can opt in and opt out as they please." (Male, 18-24, Workshop 3).

They saw value in using different approaches at different points in the decision-making process, in ways which would complement one another. For example, allowing the public to select their individual preferences concerning how they would like their medical imaging data to be used, and then using a Patient Panel to decide whether access is granted for individual data access requests.

"Yeah, I mean, you can see the strengths of all three coming together, see how they might all be used in a blend to make everybody happy, I think." (Male, 25-44, Workshop 3).

"There are elements of every single one we should be using like we need the experts but at the same time individuals should be asked how their data should be used and it's not right for a group of people to be speaking on behalf of everyone else. So, individuals using the data, opting in and opting out, and then how data should be used, using Science and knowledge and real foundations to get the best outcomes rather than people who don't know what it's about." (Male, 18-24, Workshop 3).

"For me, I am stuck on three. Patient panel, developing data access principles and retrospective review. They make sense. Before, during and after." (Female, 65+, Workshop 3).

Some participants flagged that the choice of approach might depend on the research in question. Where the research is very technical, requiring specialist knowledge to understand it, a delegated approach might be more appropriate.

"I'm open to all three really. It depends on what the research is trying to investigate and the appropriate decision-making method has to be applied." (Male, 45-64, Workshop 3).

As well, where decisions need to be made quickly.

"The delegated decision making happened during covid with the vaccine. In some cases, there might not be a choice or time for collective decision making. The natural choice is to delegate decision making because of what is going on, like a pandemic." (Female, 18-24, Workshop 4).

Whereas if the impact of the disease area is very specific, the knowledge of patients with lived experience might add value. And where the impact of the disease/research is wide reaching, a collective group of members of the public might feel more appropriate.

"It would be collective and individual depending on the severity. If it weren't severe I would like to have a say. If it were cancer or dementia I would like a collective group of people coming together to make a decision." (Female, 45-64, Workshop 3).

Combining complementary approaches were seen to offer the right balance of allowing individual choice for those who want this or involving patients and the public via collective decision-making, while also retaining expertise and accountability, especially in more complex situations. Participants wanted flexibility here and talked about how individuals might be able to make certain decisions, however, they may not always have the right amount of knowledge to do so hence the decision could revert to the expertise of specialists.

"It's probably a mix with myself. I really like the individual. I think it's important whether it's us or someone close to us. We know ourselves and them well. Then there's something about the delegated; it's thinking of NHS people being involved for situations whereby you might not have the right amount of knowledge. If it's a scenario that's a bit different to the norm or something. I wouldn't mind a bit of delegated but I do like the individual." (Female, 45-64, Workshop 3).

Cross-cutting themes

Across the group discussions about the three different decision-making approaches, a set of cross-cutting themes emerged, summarised in Figure 1.5 and discussed throughout this chapter.

These themes formed the basis of some of the deliberations about trade-offs. For example, participants appreciated that individual approaches allowed for personal choice about how data is used but also recognised that it may be costly to set up systems required to communicate with every individual, limiting the feasibility of these approaches. Other trade-offs include expertise vs choice, inclusivity vs feasibility, choice vs completeness of the data and these are discussed below.

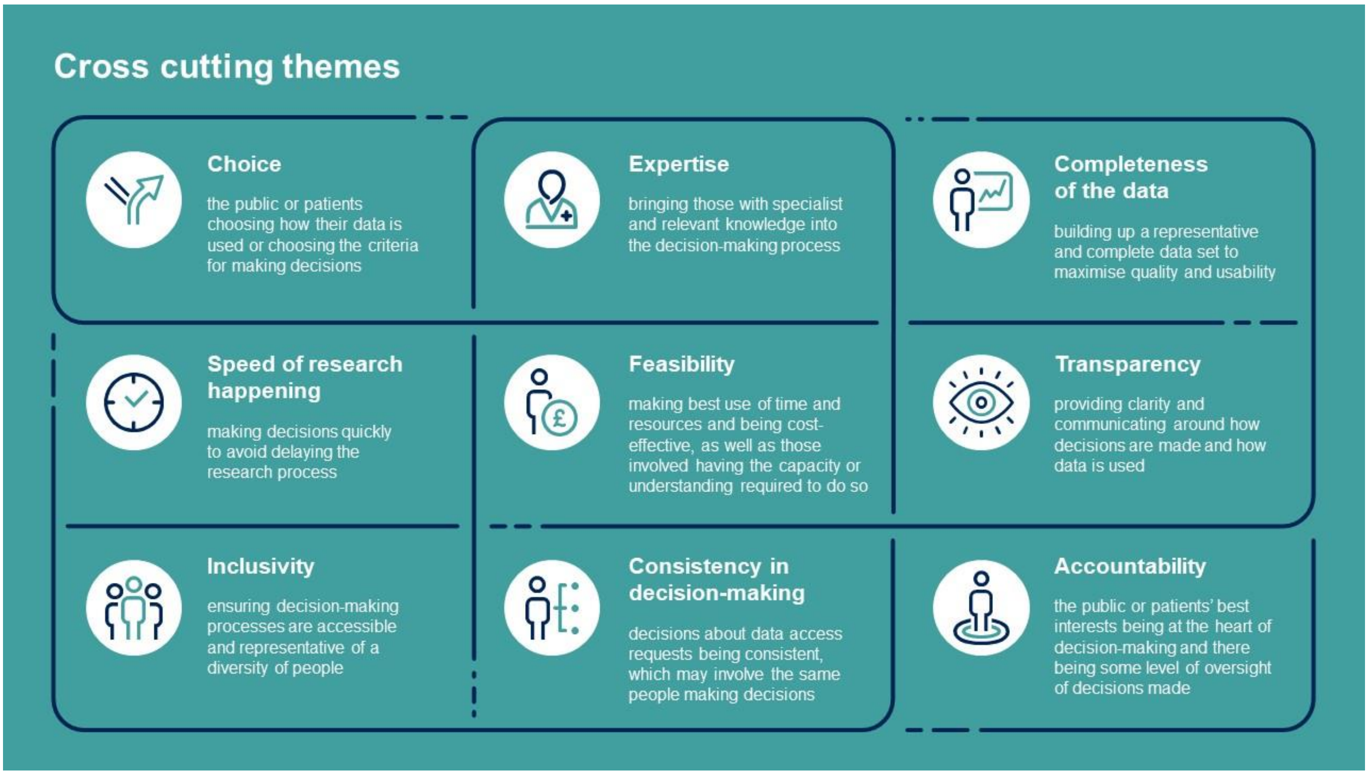
These themes were often related, for example feasibility and speed of research happening and/or feasibility and completeness of the data. **Trust** cut across all themes and was often co-dependent on these; for example, there were links between expertise and trust, choice and trust and transparency and trust.

The nine cross-cutting themes are:

- **Choice –** the public or patients choosing whether their data is used, how their data is used and with whom, and/or choosing the criteria for making decisions. Choice was discussed in terms of a spectrum: little or no individual choice, patients and/or the public making choices on behalf of others, to individuals having different levels of choice.
- **Expertise** – bringing those with specialist and relevant knowledge into the decision-making process. For the most part this related to the expertise of specialists (such as those with clinical, technical and/or ethical expertise); however, participants also discussed the expertise of patients (i.e., those with lived experiences of diseases relevant to the AI research) in decision-making.
- **Completeness of the data** – building up a representative and complete data set to maximise quality and usability. Participants recognised that incomplete and/or biased datasets would be less appealing to use in AI research and could also lead to decisions being made which are based on unrepresentative data.
- **Speed of research happening –** making decisions quickly to avoid delaying the research process. Participants discussed the speed of decision-making processes, as well as how quickly research could happen as a result of decision-making.
- **Feasibility –** making best use of time and resources and being cost-effective, as well as those involved having the capacity or understanding required to do so. Participants were interested in understanding the costs associated with different decision-making approaches, and in particular the

specific scenarios used. They were also interested in the technical feasibility of building and maintaining the infrastructure to support the scenarios. Additionally, they were interested in the feasibility of engaging individuals and groups regarding access to data.

- **Transparency** – providing clarity and communicating around how decisions are made, who is involved and how data is used. It is worth noting that given the focus of the dialogue was on data access, transparency was viewed to be around this: *how* decisions are made around data access which also included what data was going to be used for. Participants tended not to focus on transparency around the outcomes of AI research using health data, however they did appreciate transparency around the impact of decisions.
- **Inclusivity** – ensuring decision-making processes are accessible and representative of a diversity of people. Inclusivity was discussed in relation to representation of the wider public and patients within decision-making structures and how inclusive and accessible information and/or systems are.
- **Consistency in decision-making** – decisions about data access requests being consistent, which may or may not involve the same people making decisions about how data is used or choosing the criteria for making decisions.
- **Accountability** – the public or patients' best interests being at the heart of decision-making and there being some level of oversight of decisions made.



Cross cutting themes

Choice
the public or patients choosing how their data is used or choosing the criteria for making decisions

Expertise
bringing those with specialist and relevant knowledge into the decision-making process

Completeness of the data
building up a representative and complete data set to maximise quality and usability

Speed of research happening
making decisions quickly to avoid delaying the research process

Feasibility
making best use of time and resources and being cost-effective, as well as those involved having the capacity or understanding required to do so

Transparency
providing clarity and communicating around how decisions are made and how data is used

Inclusivity
ensuring decision-making processes are accessible and representative of a diversity of people

Consistency in decision-making
decisions about data access requests being consistent, which may involve the same people making decisions

Accountability
the public or patients' best interests being at the heart of decision-making and there being some level of oversight of decisions made

Figure 1.5: Cross-cutting themes that dialogue participants referred to through the discussions about different approaches to decision-making.

The importance of choice and empowerment of patients and the public and involvement in decision-making

Overall, there was interest in, and appetite for, involving patients and the public more in decisions about data access for AI research. Participants recognised the benefits of collective and individual approaches, including the provision of choice which can empower patients and the public to have a say in how their information is used.

"One thing I've taken from these workshops is that we are asked to be included in decision-making about access to data and I find that very interesting." (Male, 45-64, Workshop 4).

For those less trusting of government and data use more generally, these approaches felt more trustworthy and individual decision-making approaches were seen as preferable over delegated and collective decisions.

"Delegated is a very old-fashioned way. I go back to my late father, he never made a decision, it was made for him right? That takes me back to years ago. I like the idea of mixing collective and individual." (Female, 65+, Workshop 3).

However, dialogue participants highlighted that it should not be assumed that all individuals will want to express a choice in granular decisions about access to their data. As such, systems and approaches should be set up to avoid reliance on individuals, while retaining the option (where possible) for those who want to exercise individual choice. They were worried about whether people would engage in individual decision-making, and if they did whether this would encourage some to opt-out at the risk of compromising the quality and completeness of the data, which was important to participants and reflected a tension between choice and quality of data sets.

Expertise also matters and involving specialists has related benefits

At the same time, participants valued expertise in decision-making and the involvement of specialists (healthcare professionals, legal, technical and AI specialists), cautioning that, if complete control was handed over to patients and the public, the quality and completeness of the datasets might be compromised. Participants also raised concerns about delaying the research process, because of the need to engage with patients and the public.

"What's really stuck out to me is the way I've changed my mind from always wanting to have a say, but now I've realised that's going to take up time and delay research." (Female, 65+, Workshop 4).

The scenarios that were perceived to lack the involvement of specialists and place too much emphasis on patients and the public to make decisions about data access requests, such as the 'Patient Panel' and the 'Personal Data Store', appealed less to some participants for these reasons.

(When discussing the 'Personal Data Store' scenario) "I think one thing you can't compromise on is expertise. I know for the formal decision-making, expertise it's particularly important… I think I would rather have an expert than heavy patient choice. I just think expertise is a lot better. I'm not particularly fond of this system. I think expertise is more important. Could it work if you didn't have expertise? It could, but how effectively? This system works on its own without the expertise, but how good of a choice will that be by the general public? I don't particularly think that a patient could even have expertise on something. You gain that thorough knowledge, not just experience. It's difficult." (Male, 16-24, Workshop 4).

This caution around overreliance on the public knowledge and view, given the technical nature of health research and AI, and the need for specialists to also be involved and have the final say, was also observed during deliberative engagement on behalf of the OneLondon Local Health and Care Record Exemplar exploring different uses of health and care data. As well as during engagement on behalf of the Discover-NOW health data research hub to explore how the public should be involved in oversight and development of policy relating to the use of health and care data. Additionally, similar themes were found in the Citizens Juries to address policy questions about data sharing initiatives introduced in the COVID-19 pandemic, funded by the National Institute for Health Research Applied Research Collaboration Greater Manchester (NIHR ARC-GM), NHS Transformation Directorate (formally NHSX) and the National Data Guardian for Health and Social Care.

Approaches which combine patients and the public with the expertise of specialists

Given the tensions outlined above, dialogue participants saw a benefit in approaches which combine patients and the public and specialists. This will ensure that patients' and public choice is considered, which will build trust, while ensuring that the expertise of specialists is still included in granular decision-making. This will provide a level of accountability to the public too.

"Initially, I thought only experts should make the decision but at the end of the third workshop I did change my mind and felt there needs to be some kind of a balance. Not sure what that would look like but there needs to be a balance for experts or **[and]** ***people."*** (Female, 25-44, Workshop 4).

Some of the combinations that were suggested included:

- Patients and the public informing the development of decision-making criteria (through a collective decision-making approach such as 'Developing Data Access Principles' and/or via 'Retrospective Review'), while delegating decisions about which data access requests are approved and which are not to specialists.
- Individuals expressing their preferences through an individual approach (such as the 'Individual Preferences' scenario, or via the function within the 'Personal Data Store'), while delegating the decision about each specific data access request to specialists, through an 'Expert Data Access Committee', for example.
- Patients and the public discussing individual data access requests through a collective approach (such as through the 'Patient Panel' scenario), with the final decisions being made by specialists.

"Surely the individual preferences that we're looking at, at the moment aren't doing away with the other things further down the line. You're just making your choice about what you want your data to be used for. You tick your boxes of what you want your data to be used for. But surely this isn't doing away with the panel **[group of specialists]** ***down the line who decides who gets to access everything. This is just the patient deciding what their data should be used for. I wouldn't want this to be the only one. I still think that there needs to be accountability down the line as to who's getting access to what and why."*** (Female, 65+, Workshop 3).

Support for investing in engagement approaches that shape decision-making

Dialogue participants commonly placed more importance on the need to understand people's preferences around how they want their data to be used or giving them the opportunity to decide the criteria by which data could be accessed, as opposed to involving them in every decision. Similar findings were observed in citizen engagement around NHS health data partnerships commissioned by Understanding Patient Data and the Ada Lovelace Institute.

Participants tended to favour approaches which achieved this (i.e., the 'Individual Preferences' and 'Developing Data Access Principles' scenarios*),* particularly if this involvement was ongoing so that people could be involved in refining access criteria, providing the opportunity to learn from mistakes (i.e., the 'Retrospective Review' scenario*).* Some participants also perceived retrospective options as being easier to understand and would allow the public to judge what went well/less well within the decision-making process.

Some participants also felt that approaches which seek to understand patients' general preferences, rather than involving them in every decision, seemed more feasible and less likely than individual approaches to compromise the quality and completeness of the data. They felt that the involvement of specialists in decision-making was fundamentally important.

High quality and complete datasets are important, and approaches should not compromise quality nor impede the speed of research happening

As previously noted, participants were quick to caution against the risk of over burdening the public with technical decisions (although concerns were also raised in relation to other approaches about overburdening the NHS and GPs), especially as there will be many people who would not want to be involved in such detailed decision-making. Some were additionally concerned that creating the opportunity for people to have a say in how their data is used – particularly via the individual approaches - might encourage people to opt-out.

"The more data, the more complete the data set, and the more useful it is. My worry is if you prompt people with any of these solutions, you have made them aware. By making them aware that you have opted them in, they might prompt out, which makes the data less valuable, so whatever you do, there is a danger." (Male, 65+, Workshop 3).

For these reasons, participants were keen to avoid any decision-making approach that could compromise the quality and completeness of the data. This reflected the tension between achieving a complete data set, whilst still allowing individual choice, which often underpinned their deliberation around the different approaches. A possible solution to this, which came about as part of the later discussions, could involve combining approaches which balance involving people in shaping decision-making criteria while ensuring that specialists make the final decisions about each access request, with the aim of avoiding delays to the research process (i.e., 'Developing Data Access Principles' scenario), assuming that there is oversight and auditing of the decisions made by specialists. Another solution could include transparently informing people about how their data is used (i.e., through 'Data Usage Reports'*)* while relying on specialists to make access decisions (i.e., through an 'Expert Data Access Committee').

The technological feasibility and cost of building and maintaining infrastructure matter

Some participants suggested that some approaches may be limited in terms of feasibility, noting the effort and cost involved in bringing people together to make decisions through collective approaches. Some noted that individual approaches could overburden individuals, many of whom may not be able or motivated to engage in decisions, and questioned the cost of setting up new systems to engage with every individual. Concern about the cost implications of different models is a common finding from other public engagement around attitudes to health data use, and a similar finding was observed during the OneLondon health and care data deliberation.

While participants found some elements of these approaches appealing, as they provide the opportunity for people to exercise choice either collectively (as is the case with the 'Patient Panel' scenario*)* or individually (through setting individual preferences or through a personal datastore for example*),* the perceived feasibility and cost implications of implementing them was a key concern. Additionally, where patients and the public are more involved, participants were concerned about delaying the speed at which research could be conducted.

"How do you ensure that individual approaches don't compromise the research? By it being individual you are depending on the speed of everybody moving to enhance the speed of your research. It's just not going to work." (Female 65+, Workshop 4).

Transparency about the use of health data has the potential to build trust

Participants noted that some of the scenarios discussed provided an opportunity to raise awareness about and build trust in how data is used. They felt this would highlight the benefits of using health data for AI research. This was discussed in relation to the 'Data Usage Reports' and 'Individual Preferences' scenarios, as well as the 'Case-by-Case Workshops' scenario. They noted that 'Case-by-Case Workshops' could provide the opportunity for those involved to ask questions of the AI teams seeking access to the data, which could generate trust in AI research more widely.

Communicating with individuals about how their data has been used (for example, through data usage reports) could also provide an opportunity to educate those who would otherwise opt-out of their data being used for research. The dialogue process itself highlighted the potential benefit of communicating with the public about data access and usage, as well as emphasising the purpose of sharing this data, as it could encourage people to see the benefits of sharing their data.

"At the beginning I was very wary of including my information for the AI. But I've become more confident for what it's going to be for. Now I feel more confident it's going to be for the good for mankind and definitely the world is going towards that area whether we like it or not." (Male, 45-64, Workshop 4).

There were also participants who reported that they had previously opted out, through the National Data Opt-Out, and were planning to opt back in – or were considering this - having been involved in the dialogue.

"I opted out last year. One of the reasons I opted out was because I assumed my personal data was going to a private sector and could be exposed. This workshop has made me reconsider **[the decisions around]** ***opting out."*** (Female, 45-64, Workshop 4).

Participants' views on the benefit of making detailed information available to the public about how their individual data had been used, as is the case with the 'Data Usage Report' scenario, are consistent with those within the OneLondon health and care data deliberation. In that work, the participants involved also weighed up the benefits and downsides of sharing specific information with individuals and concluded that given the number of people expected to look at it, and those with the ability to make sense of the information, more general information about how data is used in research would be sufficient. There were, as well, participants in the dialogue who were concerned about the cost, feasibility, and environmental impact (assuming paper copies would be used) of providing this level of detail to individuals, despite the importance of transparency.

Decision-making approaches need to be inclusive, representative, and accessible to all

As participants discussed approaches which involved people more in decision-making, and in particular collective approaches, they flagged the importance of ensuring that the right people were in the room. This might involve patients with conditions relevant to the research in question, or equally it might include a representative group of members of the public. Participants discussed the importance of compensating those involved for their time and input.

During discussion about the individual approaches, accessibility was key, especially since some of the scenarios discussed inferred the use of digital platforms. While paper (and other alternative) solutions will be necessary to use, so that people are not excluded, there were a different set of risks that came with this (such as privacy concerns related to posting personal information to people's homes, and the environmental impact of doing so).

Consistency in decision-making

Related to ensuring a good representation of patients and/or the public in collective decision-making approaches that were discussed, participants debated whether these groups should remain the same or be mixed up. There were perceived benefits to retaining the same people – they would become more educated as time went on – but at the same time there is a risk that groups become stagnant. Where they often landed was to include a mix within these collective decision-making structures.

Accountability

As mentioned above, the involvement of experts in decision-making, either in a delegated approach or within collective decision-making approaches, as suggested by participants, was perceived to provide a level of accountability to the decision-making. Importantly, participants wanted to see that patients' and the public's best interests were at the heart of decision-making and that there was some level of oversight of decisions made and to ensure that this was always the case.

06

Questions or areas identified to explore within the research competition

Questions or areas to explore within the research competition

Chapter summary

Throughout the dialogue, questions emerged that will be important to consider within the research competition. Given the nature of the questions that dialogue participants had, it will be necessary to trial different decision-making mechanisms alongside real life people, data access requests, data and projects to evaluate how they work in practice and in the context of real-world constraints. The key questions arising from this research are discussed in this chapter, however in no particular order.

Key findings

- Participants were interested in the technological feasibility and cost of implementing the approaches, including the infrastructure needed to maintain them.
- Participants wanted to explore how long it would take to deliver the different approaches, given the importance placed on not compromising research from happening.
- They were also interested in the levels of understanding required from the public or patients within the different decision-making approaches discussed.
- Participants felt it was important to explore how individual decision-making approaches would work in terms of individuals involved in granular decisions about access to their data (e.g., opt-out or opt-in). They discussed time-bound access windows too.
- They were keen to include a range of digital and supplementary channels to engage individuals.
- Participants raised questions about how the approaches would ensure inclusivity and how groups who tend to be less well represented would be engaged in decision-making processes.
- Additionally, they considered how the approaches would ensure public engagement is meaningful and impactful; how the dynamics between patients with lived experience, the public and specialists would be managed; and how the agendas of different stakeholders may impact the decision-making process.
- Participants were keen to explore the impact of incentivisation on participation and the types of people who would be involved in decision-making processes.
- Finally, participants were interested to understand how adherence to the Five Safes framework could be guaranteed and used to complement the decision-making approaches being used.

The feasibility and cost effectiveness of implementing the proposed approaches

Despite being presented as hypothetical scenarios, the feasibility of different approaches dominated some discussions and was often questioned and considered by participants, especially as they weighed up some of the trade-offs (patient choice and feasibility, for example). This was particularly the case for the individual approaches, but also when participants discussed some of the collective approaches too.

Through the research competition, the scenarios presented in this research could be further refined and strengthened, detailing how these would work in practice. For example, drawing on pre-existing templates for developing data access principles or outlining how patients would be able to indicate their individual preferences for how their data is used.

The cost of delivering different approaches and technological feasibility

Participants had questions about the relative cost and feasibility of approaches, considering whether there would be sufficient resources or the right infrastructure to deliver them. These were situated within the current context of the NHS being under substantial pressure. However, the level of importance participants placed on cost varied between groups and individuals.

In terms of technological feasibility, some questioned how the NHS would identify which research projects individuals had been involved in and communicate this to them (as is the case in the ‘Data Usage Report’ scenario). And how the NHS would manage the dataset, and access to this, if some had opted out of individual access requests and others had not.

The time required to deliver different approaches and levels of understanding required from the public or patients

Participants raised questions about the time required to deliver approaches, from those managing the data, using the data, or stakeholders involved in the decision-making process. They voiced concerns about factors that may slow down the research process and expertise was often linked to an ability to deliver things quickly. However, they were also apprehensive about decisions being made too quickly as this could result in errors or decisions being compromised.

There was interest in exploring how efficient decisions could be made within some of the collective approaches (for example, the ‘Patient Panel’ scenario and ‘Case-by-Case Workshops’). This was due to the perception that these formats would take time to convene, decision-making would be slow, and the processes would thus have the potential to slow down the starting of research.

The need for transparency about individual data rights and involvement mechanisms

Discussions often returned to a discussion about awareness and consent for data use and how this would be achieved within the context of some of the decision-making approaches discussed.

Opt-out vs opt-in

Broadly, it was felt that if the public had a role in decision-making around data access requests, they should be aware of this (e.g., that they have the option to opt in or out) and should be informed about how their data would be used. Dialogue participants raised concerns that an opt-in would have the potential to compromise the quality and completeness of the data given the reliance on members of the public to engage. Additionally, when thinking about opt-out vs. opt-in, they questioned whether any opt-out system would be ongoing or if there would be a cut-off date.

Whether digital or alternative channels would be used

Participants discussed the benefits and risks of different methods of communicating about data access requests (e.g., whether data usage reports would be sent via post or electronically). They raised concerns about physical postal channels being associated with risks of interception or accidental disclosure as well as noting higher administrative costs. However, they noted that digital channels could be inaccessible for those who are digitally excluded. Participants suggested that it would be useful to explore the best ways to contact and engage with patients, while being very mindful of minimising the risk of excluding certain groups of people.

Time-bound access windows

Participants were concerned that involvement of the patients and the public in data access decisions could delay the research process. As such, many participants suggested the idea of time-bound access windows, whereby (regardless of whether the mechanism was an opt-out or an opt-in) there would be a set amount of time for patients to input.

The importance of ensuring equitable involvement and inclusivity

Throughout discussions participants consistently returned to the importance of inclusivity; thus, these were areas which felt important to understand further as part of the research competition.

How proposed approaches would ensure inclusivity

As well as being interested in the steps that would be taken to prevent bias within systems and datasets, participants wanted to ensure a diversity of people are represented within the decision-making process (e.g., as part of a ‘Patient Panel’), recognising that some groups might have higher or lower levels of trust in, and engagement with, health systems. Some participants noted that certain groups may be less represented in datasets themselves, linking this to levels of trust and engagement with health services.

When thinking about how representative a collective decision-making approach might be, some were keen to understand how large a ‘Patient Panel’ or representative group of patients and the public (as is the case in the ‘Case-by-Case Workshops’ scenario) would need to be.

How groups who tend to be less represented would be engaged in decision-making processes

Participants highlighted some groups within society which might struggle to engage with decision-making processes, such as ethnic minorities; younger people who may engage less with health services; older people; those experiencing digital exclusion; people who do not speak English; people experiencing homelessness; and those who are less engaged, or deliberately disengaged (possibly due to a lack of trust), with health services.

As such they were keen to understand how decision-making approaches would be designed so that they do not exclude such groups.

Creating and managing a collaborative dynamic between the public, patients, specialists and independent organisations

Given that some of the approaches discussed included both specialists and patients and the public, participants were interested in how these groups would work together to achieve the desired end goal.

How the approaches would ensure public engagement is meaningful and impactful

This is especially relevant when both specialists and the public would be involved (i.e., ‘An Expert Data Access Committee’ or ‘Case-by-Case Workshops’), some participants questioned whether the views of the public may be downplayed or even disregarded in lieu of specialist opinion.

How the dynamics between patients with lived experience and the general public would be managed

Whilst some participants emphasised the need for public involvement, some participants placed more weight on the input of patients with lived experience of relevant conditions. They would feel more confident in their decision-making than the general public, who could be seen as less informed. Participants raised questions about what the relative contribution of these groups would be.

"I think it would be interesting to see. We've already written about interaction with the public, what level of interaction with the public. One of the things I remember seeing was it's not so clear how much level of interaction there is. When doing the research projects, it would be interesting to see what level of public interaction it actually did have." (Male, 18-24, Workshop 4).

How the agendas of different stakeholders may impact the decision-making process

Some participants questioned the extent to which different stakeholders, as well as patients with lived experience, would be objective, sometimes viewing the motivations of independent commercial organisations with suspicion, or feeling concerned that patients would be biased. They felt the trustworthiness of a given approach would depend on the specific organisation involved, their funding and their motivations. Therefore, this should be a key consideration as part of any proposed approach.

Exploring ways to enable broad, diverse and ongoing participation in collective and individual approaches

Some participants questioned the impact of incentives on engagement, suggesting it could result in individuals participating solely for the money and not engaging fully with decisions around data access requests. To combat this, they discussed different approaches to incentivisation, such as only reimbursing expenses or paying vouchers instead of cash. Others recognised that continued engagement, with a representative sample, may require incentivisation and noted that some may not be able to afford to participate without this. Participants were interested in the impact of incentivisation on the types of people who might come forward and remain committed to decision-making processes.

Ensuring the Five Safes framework is adhered to and complements the decision-making approaches being used

The Five Safes framework tended to frame discussions and participants assumed that this would underpin any approach used. However, they raised questions about how proposed approaches would incorporate the principles of the framework in practice**.** For example, how re-identification of de-identified data or data breaches would be prevented. While outside of the scope of this dialogue and its aims, and the research competition which will be run by the NHS AI Lab more generally, the expectation that the Five Safes framework would underpin any decision-making approach for data access and the concerns raised around data security are important to note. Participants had questions related to data storage and where the central data will be stored (i.e., in the UK or elsewhere).

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