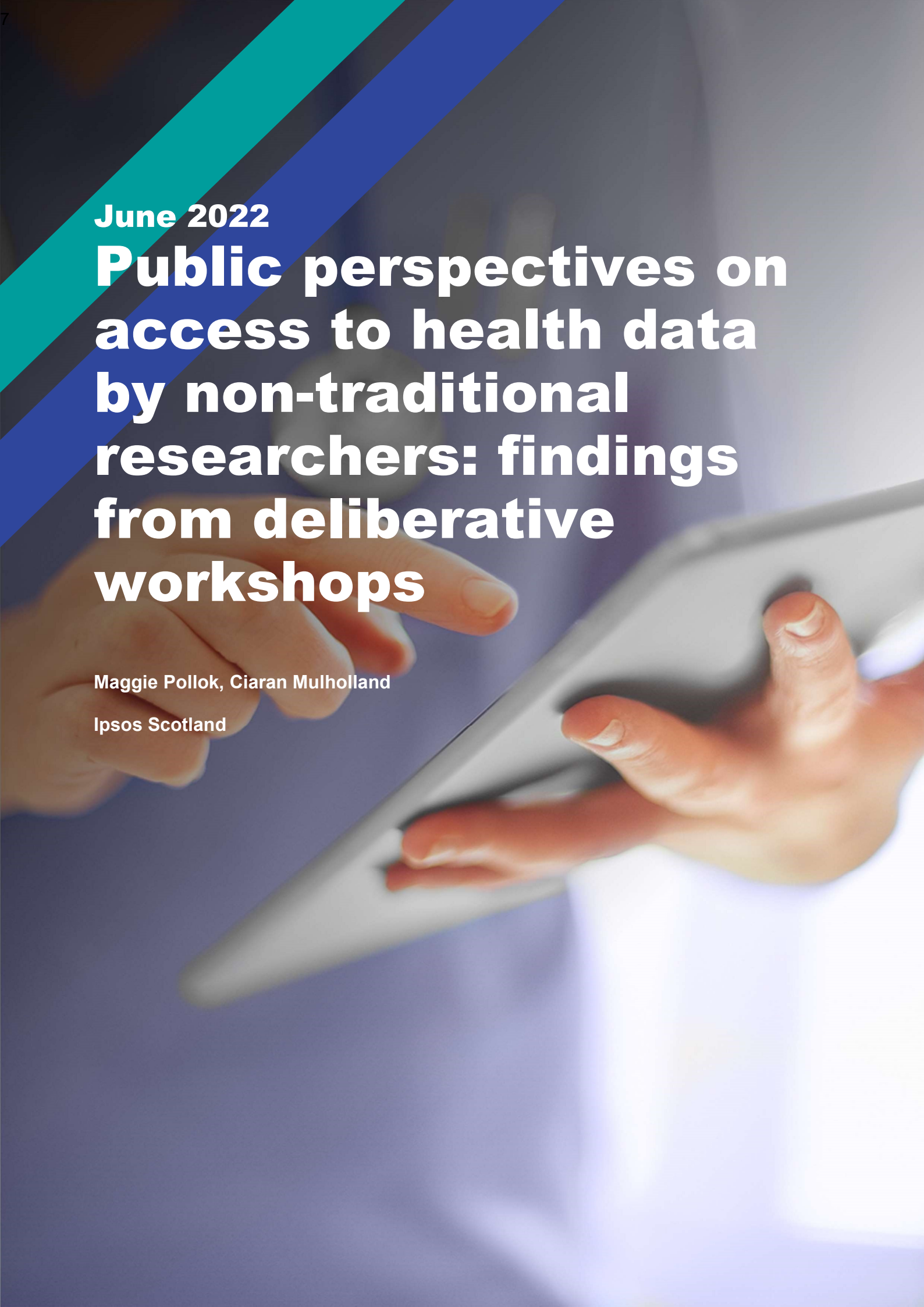

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Public perspectives on access to health data by non-traditional researchers: findings from deliberative workshops

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1 Executive summary

This report presents findings from deliberative workshops, commissioned by DataLoch[1] and carried out by Ipsos Scotland, to explore public perceptions on access to health data by non-traditional researchers. DataLoch is a data service that hosts local, regional, and national health and social care data that relate to residents in Edinburgh and South-East Scotland.

Public views about data access to support traditional researchers (e.g. academic and health care professionals) have been explored in-depth in previous engagement exercises. However, there is less understanding of public perspectives on the use of Trusted Research Environments (TREs[2]) by non-traditional researchers – such as software developers, Artificial Intelligence experts, and representatives from third- and private-sector organisations – in order to drive and realise improvements to health systems and opportunities for health and social care innovations.

The deliberative workshops therefore sought to provide insights from the public that would help support the design of DataLoch's governance framework for non-traditional users of TREs.

Methodology

A group of just over 40 residents of South-East Scotland met online across two three-hour deliberative workshops. The first took place on 26th April 2022, and the second on 30th April 2022.

Participants were recruited by telephone using a screening questionnaire designed to help ensure the group were reflective of the population of South-East Scotland. Quotas were set on age, gender, location, ethnicity, social grade and deprivation level. Ethnic minority participants were over-sampled to ensure sufficient representation of these groups.

Participants were posed two overarching questions:

- What are the benefits and risks of health data being used by non-traditional researchers?
- What needs to be in place for access to health data by non-traditional researchers to be considered trustworthy and acceptable?

In line with principles of deliberative public engagement, the sessions were broadly divided into two phases: the learning phase (session one), where participants got to know about the key concepts of importance, and the deliberation stage (session two) where they discussed the issues in detail and developed their conclusions.

[1] DataLoch is a data service. It is currently a partnership between University of Edinburgh and NHS Lothian, but it is expected that other NHS Boards and councils in South-East Scotland will join the partnership in future. DataLoch works to:

- Bring together health and social care data for the SE Scotland region
- Work with experts to understand and improve this data
- Provide safe access to data for researchers

[2] TREs are highly secure computing environments that provide remote access to health data for approved researchers to use in research that can save and improve lives. More information on TREs can be found here: https://www.hdruk.ac.uk/wp-content/uploads/2021/09/HDRUK_TRE-One-Pager.pdf

Key findings

- Participants were generally positive about the potential benefits of health data research. There was a feeling that access to the information contained in health data could help ensure that health care decisions were made based on the best evidence available.

- Overall, they felt positively about TREs and how health data was accessed and used for research purposes, but remained concerned about data breaches and the possible consequences of both data breaches and the research in general. Although feeling the current process was overly complex, they recognised the balance needed between protecting patients' data, and making sure access was possible for research that brought innovation and improvement in health services.

- Having learned about and deliberated on the range of different types of potential research requests, participants acknowledged the potential benefits of non-traditional researchers accessing health data. The main benefit was that research could ultimately help to improve the diagnoses and treatment of health conditions, which in some cases could mean saving lives.

- However, this did not mean there was blanket acceptance of non-traditional researchers accessing health data. Some types of non-traditional researcher, particularly those involving organisations operating outside of the health care field and those operating for profit, raised particular concern.

- In agreeing their principles (the conditions that would make it acceptable for health data to be accessed by non-traditional researchers) and "red lines" (that, if crossed, would make access unacceptable) some clear themes emerged. These were:

    - **Commercial interests** – while it was acknowledged that some research by private-sector companies may have public benefit, such as the development of medicines and improvements in treatment, there was concern about data being accessed by organisations where their sole motivation was to make profit. If profit was generated as a result of the research, there was a desire that some of this be put back into the NHS.

    - **Transparency of purpose** – it was felt that every researcher – either traditional or non-traditional – should be required to provide a clear justification for why they need data, what data they need and how they will use it. Making the purpose of the research clear would help to provide reassurance that it would have public value and was motivated by a desire to support or improve health care.

    - **Health-related impacts** – related to the principles above, there was a desire for non-traditional researchers to be able to demonstrate how their research would ultimately benefit the health care service or benefit research on health conditions.

    - **Ethics panel** – having an ethics panel to review research requests was seen as an effective way of providing scrutiny of research requests. It was suggested that the ethics panel should be made up of a combination of health care professionals, people with expertise in health data research, and members of the public.

    - **Quality standard or code of conduct** – it was suggested that there should be a quality standard, code of conduct or agreed set of terms and conditions for use of health data, that non-traditional researchers should be expected to meet. It was assumed that traditional researchers

were already subject to codes of conduct and that non-traditional researchers should be held to a similar standard.

- **Monitoring and review** – having a mechanism to review how researchers have used data, and checking whether that aligns with their original stated purposes, was seen as a way of providing reassurance about the ongoing level of scrutiny of the process.

Principles for access to health data by non-traditional researchers

Principles: ***'Access to health data by non-traditional researchers is acceptable if…'***
Data is kept safe and secure and is de-identified.
Researchers can only have access to the data that they request, and only for the purposes that they specify in their request for access.
They can demonstrate a clear public benefit for their use of the data, a positive intended outcome, and a clear reason why they need the data.
Research ultimately benefits the NHS (either through sharing of findings or outcomes from the research, or through financial contribution from any profit made).
Researchers agree the data is not going to be used solely for profit.
Pharmaceutical companies can agree the data will not be used to increase the price of the drugs they manufacture, and if they generate profit they contribute some back to the NHS.
Research requests are subject to review and scrutiny by an ethics panel.
Researchers can conform to meeting and adhering to a quality standard, code of conduct or an agreed set of terms and conditions.
Researchers are open to having their research and its outputs audited after being granted access to the data.
Breaches of terms and conditions are proportionately penalised, such as through fines or being prevented from accessing the data in future.
Traditional researchers from the NHS and universities continue to get free or at cost access to health data, and that any additional charges for access are targeted at private-sector / commercial organisations.

Red lines that would make access by non-traditional researchers unacceptable

Red Lines: *'Access to health data by non-traditional researchers becomes unacceptable if…'*
It is solely for commercial gain.
There is any use of the data beyond its stated purpose (for instance using the data to target people).
Researchers cannot agree to comply with the terms and conditions for access.
Researchers are unable to demonstrate that they, or the organisation they are part of, have the track record, skills and expertise to research with health data.
The organisation has a history of misuse of data or unethical practices.
Researchers cannot demonstrate the potential benefits to the NHS from the research.
The research doesn't serve a health purpose (e.g. an insurance provider changing their cover).
Public sector agencies, such as housing providers, use health data to monitor individuals' behaviours without their consent.

2 Introduction and method

Background

DataLoch is a data service that hosts local, regional, and national health and social care data that relate to residents in Edinburgh and South-East Scotland. It was established as part of the Edinburgh and South East Scotland City Region Deal, under the Data-Driven Innovation (DDI) programme. The DDI programme aims to develop innovative and financially sustainable models of health and social care that improve lives. As part of DDI, DataLoch supports research, innovation and NHS service management, to facilitate the use of data for improvements in health and social care.

Public views about data access to support traditional researchers (e.g. academic and health care professionals) have been explored in-depth in previous engagement exercises. However, there is less understanding of public perspectives on the use of Trusted Research Environments (TREs) by non-traditional researchers – such as software developers, Artificial Intelligence experts, and representatives from third- and private-sector organisations – in order to drive and realise improvements to health systems and opportunities for health and social care innovations.

Against this background, DataLoch commissioned Ipsos Scotland to design and deliver deliberative workshops to explore public perceptions on access to health data by non-traditional researchers. The deliberative workshops sought to provide insights from the public that would help support the design of DataLoch's governance framework for non-traditional TRE users.

Findings from quantitative research

As part of its governance framework planning process, DataLoch also commissioned a quantitative survey of public attitudes to health data being shared for innovation purposes (also carried out by Ipsos, just prior to the workshops). The survey was administered through Ipsos' KnowledgePanel, a random probability online panel. The achieved sample was 595 adults aged 16+ based in South-East Scotland.

The survey found that the public in South-East Scotland were broadly positive about data sharing in health care:

- A majority (72%) agreed more with the statement 'We should share all the health data we can because it benefits health services and me', than 'We should not share health data as the risks to people's privacy and security outweigh the benefits'.
- Looking at access to health data by type of research organisation, traditional researchers (NHS and universities) received higher support than non-traditional researchers (commercial organisations, charitable organisations, private health care companies and pharmaceutical companies). However, access to health data for all types of researchers, whether traditional or non-traditional, was supported by over half of the public.
- Respondents were asked which conditions they would want to see in place before researchers could access health data about them. For both traditional and non-traditional researchers, the most popular conditions were the removal of personally identifying information, strict rules that data

could not be passed on to any other organisation, contracts put in place so data could only be used for agreed purposes, and data only being accessible in a secure IT environment.[3]

Aims and objectives

Building on the findings from the quantitative research, the deliberative workshops aimed to answer the following questions:

1. What is expected from non-traditional researchers and/or organisations to be considered trustworthy and credible?
2. What public concerns exist about non-traditional researchers accessing health and social care data in general, as well as through TREs?
3. What user accreditation standards are required to provide reassurance about the public value of projects requiring data access through TREs?

Method

A group of residents from across South-East Scotland met online across two three-hour deliberative workshops. The first took place on 26th April 2022, and the second on 30th April 2022. The aim was to achieve a sample of at least 40 participants, with some over-recruitment to account for potential cancellations or drop-outs. In the end, there were 43 participants in attendance at the first session and 41 at session two[4].

Recruitment

Participants were posed two overarching questions:

- **What are the benefits and risks of health data being used by non-traditional researchers?**
- **What needs to be in place for access to health data by non-traditional researchers to be considered trustworthy and acceptable?**

Participants were recruited by telephone using a screening questionnaire. The questionnaire captured demographic information about the participants, designed to help ensure the group were reflective of the South-East Scotland population. Quotas were set on age, gender, location, ethnicity, social grade and deprivation level. Ethnic minority participants were over-sampled to ensure sufficient representation of these groups.

Once recruited, participants were onboarded by the Ipsos research team. To support and enable participation in all workshops, and in line with industry standards, participants were each paid £120 for their participation. Where necessary, participants were supported with training on how to use the technology and access the meeting platform. This allowed Ipsos to increase the diversity of those taking part. Workshops were also arranged to take place outside of regular office hours to increase participation.

[3] The full survey report can be found through the DataLoch website at https://dataloch.org/insights/news/node/232

[4] The small decrease in the number of participants between the two sessions related to unexpected illness and work commitments rather than any negative experience of the process.

Structure of the workshops

In line with principles of deliberative public engagement, the sessions were broadly divided into two phases: the learning phase (session one), where participants got to know about the key concepts of importance, and the deliberation stage (session two) where they discussed the issues in detail and developed their conclusions. Table 1 provides a summary of the format and coverage of each of the sessions.

Table 1: Overview of deliberative sessions

	Date/ time	Objective	Session description	Presentations
Session One	Tuesday 26th April, 18:00-21:00	Introduction to the process and aims. Introduction to key concepts.	Participant introductions. Introducing participants to the process and to key concepts: health data and how it can be used, data services like DataLoch, findings from past public consultations, and an introduction to TREs. Q&A with expert speakers.	Introduction to health data research. Data services for health data research. Public engagement about health data for research. Introduction to TREs.
Session Two	Saturday 30th April, 10:00-13:00	Deliberation exploring pros/cons and necessary conditions of access by different types of researchers.	Small group discussions on a mix of case studies to show the range and diversity (i.e. organisations involved, purposes, outputs and benefits). Deliberation and decision-making on recommendations and red lines.	Talking heads presentation – short clips from six different non-traditional researchers who would like access to health data.

In session one, expert speakers delivered presentations to introduce key concepts (health data, data services, and TREs). After each presentation, members moved into small breakout groups to discuss and reflect on what they had learned. In the breakout discussions, participants agreed on clarification questions which were then answered by the speakers in the main plenary, or via a Question and Answer (Q&A) document with written responses provided by the speakers, DataLoch and Ipsos prior to session two.

Materials

Discussion guides and stimulus materials were developed by Ipsos and approved by DataLoch. Presentations were developed by expert speakers (in consultation with Ipsos) and these presentations were either given live or recorded in advance and played back live during the main plenary sessions. The speakers then joined the sessions to answer questions from participants. Any questions that were not answered during the session were compiled in the Q&A document. Presentation recordings that were made in advance were hosted on YouTube and shared via private links for members to watch again in their own time.

Interpretation of qualitative data

The principles set out and discussed in this report are intended for consideration in the possible future use of health data by non-traditional researchers via a TRE.

This exercise supported participants to express a range of views on different types of research, and of their expectations and understanding of considerations in relation to using public health data in this way. This report synthesises those diverse and sometimes inconsistent expressions to draw out major themes of discussions and to draw attention to the way that participants – individually and collectively – described what mattered to them and why. On occasion, the report refers to verbatim assertions by participants and their understanding of the issues. These are not intended as authoritative statements of fact, but they tell us something valuable about how key messages, support, or services can been perceived and understood by members of the public.

Further, it should be noted that whilst the method of qualitative analysis is systematic and rigorous and the conclusions robust (being based on groups that are reflective of the diversity of the wider public), the analysis does not seek to quantify findings nor does it indicate statistical significance from a representative sample. This report offers a valuable insight into public perspectives on the key questions posed to them after receiving and deliberating on key information relevant to the questions.

3 Attitudes towards current access to health data

This chapter explores participants' views on the current systems in place for access to health data by researchers. It is based largely on participants' discussions during the first session. Participants were presented with information on concepts such as data services and Trusted Research Environments (TREs) and asked to reflect on their risks and benefits.

Views on health data

Presentations given on this topic (in session one)

- Professor Nick Mills (University of Edinburgh and Consultant Cardiologist) on how health data has been used in research, with specific examples including measurement of outcomes following heart attacks or strokes.
- Professor Sarah Cunningham-Burley (Professor of Medical and Family Sociology, University of Edinburgh) on what previous public engagements have found about public views on health data being used for research.

Health data was a relatively new topic for participants. While a few had previously been asked by researchers to take part in studies related to their own health (for example, in relation to an existing health condition or as follow-up to an operation they had), most were fairly unfamiliar with what health data was and how it had been used for research.

Having learned more about the use of health data in research, participants were generally positive about its potential benefits. There was a feeling that access to the information contained in health data could help ensure that health care decisions were made based on the best evidence available. In particular, they felt that health data could help researchers and health services better understand serious conditions such as heart disease or stroke (as explained in the first presentation) and therefore help improve treatment.

Because of those perceived benefits, one group even felt that the current process for data sharing seemed overly bureaucratic and time-consuming, and required simplification.

> Ultimately, it's for a good cause. The only negative was that the whole process [sounds] so slow. You get the impression that there might be too much bureaucracy and red tape holding the system back. Results could be reached a lot quicker if not for the red tape.
>
> (Session one, Group two)

On the other hand, participants were also conscious of the risks associated with health data being accessed for research purposes. Some discomfort was expressed about private-sector, commercial organisations using public health as a means of generating more profit and this prompted early calls for regulation and safeguarding of data access requests (this was discussed in more depth later, as outlined in chapters 4 and 5).

> If this helps them [understand more] about what's killing people in Scotland, would [companies] then double the price of medicine? I wonder how they safeguard against big commercial interests.
>
> (Session one, Group one)

Participants felt strongly about the need to remove all identifying information about individuals from the data – a theme that would continue throughout the deliberations in sessions one and two. Although it was explained that this already happened (and that data available through a TRE would have personal information removed) it emerged early on as a key principle for participants.

> I feel personal data should be personal… it includes my medical history, my illnesses, my medication…I wouldn't want it to be shared. Unless it's anonymised and I'm just a number. But I don't want it to be attached to me as a person.
>
> (Session one, Group three)

A few participants also took issue with data being accessed at all, without the explicit consent of patients each time. While this was a more exceptional view, the issue of consent continued to be raised by these participants throughout both workshops. When it was explained that gaining consent from patients for each use of their data would not be possible, and that Scotland does not currently have a single, central mechanism for individuals to opt-out of health research, their views on the importance of consent did not shift. This highlights that the topic of consent may continue to be a concern for some members of the public when they make judgments on the acceptability or otherwise of health data being used.

Another concern related to the idea of becoming too reliant on insights from data to the detriment of direct care from health care professionals, or to reduce the number of NHS staff. Related to this was a feeling that data should be used to ultimately improve health care treatment for the wider population, and participants were therefore interested in finding out more about how an assessment of public benefit would be applied.

> How effective is [the research] going to be for improving the NHS? I know a lot of people have a problem with a lack of workers in the NHS. Will that data be used to have even less workers? Or to get rid of specialists in that area?
>
> (Session one, Group one)

Data services

Presentations given on this topic (in session one)

- Dr Atul Anand (University of Edinburgh and Consultant Geriatrician), on the role played by health data services, why they are important and some of the challenges with their role.

The role of data services, as described by the presentation, includes checking and sorting health data, ensuring it is representative of the population, improving data quality and creating a data dictionary / metadata catalogue (a set of agreed definitions for what the data shows). These steps maximise the potential for good-quality health-data research, and mean that the cleaning and improving of data is carried out once rather than multiple times.

On the whole, participants reacted positively to the concept of data services. They saw the value of data being managed by one organisation, thereby increasing the consistency and efficiency of the process.

Opinion was split, however, on the security of the data. On the one hand, it was felt that data being held by one organisation might minimise the risk of data breaches, as it would avoid risks associated with data being transferred between organisations. On the other hand, it was felt that a single organisation holding health data could make the data more susceptible to risk, if that organisation did not have adequate security processes in place. While data services were described as being safe and secure organisations, there were still some doubts around how secure they might be.

> There is this risky aspect of it. No matter how much you protect it, once it's compromised… if they can hack into the account, then they might get everything.
>
> (Session one, Group three)

Although it was explained that personally identifying information would be removed from the data before researchers had access, participants expressed worries that it would still be possible for individuals to be targeted through their health data (for example, targeted via advertising or increased insurance costs). There was also a concern that although the data accessed by researchers through data services like DataLoch might be de-identified, this data could still be combined with other data sources, thereby making it possible to identify individuals from the data. Another worry was that although data might be considered to have all identifying information removed now, advances in technology could make it possible for it to be made identifiable again in the future – raising the question of how data services can be future-proofed.

> Most people are happy to give data knowing it will benefit research or get a new drug from it or something. But if it went in the wrong hands and you are being targeted for having an illness, and lots of people know about it and you didn't want to tell the world, that's not the reason you gave the information in the first place.
>
> (Session one, Group five)

More broadly, participants emphasised the importance of data service organisations, as gatekeepers of data, having a system in place to determine whether a request for access to data is appropriate or not. They further felt that the vetting process used by data services should be objective and not influenced by the commercial interests of organisations seeking access to the data.

Trusted Research Environments (TREs)

Presentations given on this topic (in session one)

- Dr Susheel Varma (Health Data Research UK) on what a TRE is, why they are important, and the ways in which they safeguard data. This included explanation of the 'Five Safes' framework: Safe People, Safe Projects, Safe Settings, Safe Data and Safe Outputs. Examples were given of the process researchers would have to go through to access health data.

It was explained to participants that a TRE is a secure digital environment that holds data and allows access to that data for analysis purposes, that data remains secure in the TRE and approved researchers access the data they need by connecting to it remotely. Those researchers cannot export

data, and – after undertaking their analysis – any outputs they want to export go through careful checks to make sure they are in line with the research purpose and that individuals cannot be identified.

Initially, participants had difficulty understanding the concept of a TRE, and it was something that they had not been aware of before the workshop. However, once they got deeper into the discussion, the idea became clearer to them. They were reassured to hear that the data never leaves the TRE, and that researchers need to be approved before they gain access.

> I found it really reassuring that ultimately, the data isn't moving anywhere. We're just using it in a more efficient and proactive way.
>
> (Session one, Group six)

It was felt that it made sense to streamline systems so that data could be accessed in a safer and more consistent way, with better oversight. There was a view that having the data in one defined, secure environment could reduce the risk of unapproved researchers having access, as might be possible if the data were held in different places.

> It confused me but it sounds like the whole system is confusing. It needs to be put into some kind of coherent system so it all works better.
>
> (Session one, Group two)

Again, participants were concerned that data breaches remained a risk. They wanted to know more about the possible consequences for patients if their data was breached, as well as what the consequences would be for those responsible for data breaches.

> It's a great idea in theory. To my understanding the data is held with the data custodians, and when they have a request for data, it's minimised datasets, so they can remove certain elements. … But I think they're being a bit naïve about data protection…Rather than talking about how secure their datasets are, what are the consequences if that data gets out?
>
> (Session one, Group three)

Some participants were encouraged by the level of public involvement in the development of TREs, as this aligned with their general support for the public to be involved in decisions that might ultimately impact on them. However, again there were participants for whom consent emerged as a key issue. These participants took issue with the idea that patients would not have a say in the research projects which use health data about them.

Overall, participants felt positively about TREs and how health data was accessed and used for research purposes, but remained concerned about data breaches and the possible consequences of both data breaches and the research in general. Although feeling the current process was overly complex, they recognised the balance needed between protecting patients' data, and making sure access was possible for research that brought innovation and improvement in health services.

4 Attitudes towards access to health data by non-traditional researchers

Having learned about and discussed health data, data services and TREs, participants were asked to consider potential access to health data by researchers. This chapter outlines their views on the use of health data for different types of research, including non-traditional researchers specifically.

General attitudes towards traditional and non-traditional research

To help explore their views on non-traditional researchers, in session one participants were presented with examples of three broad types of research (both traditional and non-traditional) and asked to reflect on each. These are shown below:

Stimulus provided (in session one)
Descriptions of three hypothetical types of research:

1. Health data being used by Scottish universities to help researchers understand more about a disease, such as diabetes. This would be research led by a traditional academic or a health care professional.

2. Health data being used to develop a medical device, using Artificial Intelligence (AI) to help identify a condition like diabetes in patients earlier. This would be innovative research, which could involve traditional researchers such as academics or clinicians, but also non-traditional researchers from commercial organisations (like Google) or third-sector organisations (like Diabetes UK).

3. Health data being used by a pharmaceutical company to develop or improve a medication to help treat a disease, such as diabetes.

Generally, participants were accepting of some non-traditional researchers accessing health data. However, their support varied depending on a number of factors, primarily the extent to which organisations were motivated by commercial interests and the nature of the organisation itself. These considerations are outlined below.

Motivations of organisations and purpose of the research

Much of the discussion about non-traditional research centred around private-sector companies and whether or not they were motivated solely by commercial interests. This was raised as a concern in session one and it continued through the deliberations in session two (and into the suggested conditions on future access, explored in the next chapter). These concerns about commercial interests reflected a sense of mistrust in organisations that wanted to make a profit and a perception that their desire for profit may mean they were unlikely to be accessing health data for public value. Indeed, accessing health data for commercial gain was a sticking point for many – there was a general sense that research should benefit the NHS and that organisations should not be able to access people's data if the ultimate goal was solely to generate profit.

> I don't think commercial organisations have any right to [access health data], because they're going to use it for monetary gain, not for our benefit… if it's to do with improving public health, I don't mind [data being accessed], but people who turn it in to a business and make it profitable for them, I think it's very wrong.
>
> (Session one, Group three)

In contrast, participants were broadly supportive of traditional researchers (academics or health care professionals), partly because they felt they were motivated by a desire to enhance learning or to improve public health, rather than for profit. There was also an inherent sense of trust in academic and health care professionals, who participants assumed would have codes of practice governing their research, which provided comfort that there would be control over their access and use of data.

> The words 'academic or health care professional' give me comfort. I have concern about data being given to companies or used for commercial purposes, that's an inherent worry of mine all the time. But the word 'traditional' … is reassuring for me.
>
> (Session one, Group six)

While overall there was a general sense of distrust about profit-making in the field of health research, there was some acceptance that commercial organisations could add public value and help to advance innovation in medical research due to their scale and the financial resources they have at their disposal. However, in light of the concerns about data being accessed for commercial gain, it was suggested that organisations that made profits as a result of their research should be required to give some of that to the NHS or to a charity that works within the health care setting. Some also raised the possibility of a charge for commercial organisations getting access to health data, as a way of helping provide income for the NHS. However, these did not supersede the need for these organisations to provide a clear reason for accessing health data or for their request to be subject to scrutiny in terms of their motivations and intended use of the data.

> Certain companies aren't [motivated by] the greater good, they are out for their own good. But they have the money and power to be able to help the greater good. Those companies should have to go through the same safeguards as everybody else has to, and transparency is absolutely key to enable [those companies] to access data.
>
> (Session one, Group six)

As well as the organisation's motivations, the purpose of the research itself was also seen as important. Participants felt that organisations should be able to clearly demonstrate the reason they need access to health data, and be transparent about their purpose. As with motivations, participants were generally supportive of research that was intended to improve public health or health care provision. Where the sole purpose of the research was to create profit for the organisation, and there was no public health benefit, the research was considered an unacceptable use of health data.

Types of organisation

When discussing different types of organisation that may want access to health data, level of trust in organisations was a clear theme that emerged. As noted above, both the NHS and universities were described as "trustworthy" because they were seen to have legitimate reasons for wanting to access health data and were not motivated by profit. There was also a sense of trust in universities because they were long-established and were likely to have codes of conduct that governed their research. In contrast, there was a sense of mistrust about access to health data from organisations that did not work within the field of health care or academia, particularly insurance and technology companies, as

participants felt that the purpose of their access to health data was likely to be profit-driven and not related to health care. Views on these specific types of organisation are outlined below.

Insurance and technology companies

There was particular push back against the idea of insurance companies accessing health data, as they were viewed as being entirely motivated by commercial interests and likely to use the data to help them increase premiums. This caused participants to emphasise the need for safeguarding against misuse of the data.

> So many aspects of your life can cause your insurance company to ask for a premium… the only reason they would have to access that data is to make more money, and that's not ethical at all.
>
> (Session one, Group one)

Participants were similarly negative about technology companies accessing health data (specifically Google, as mentioned in the research example provided in the stimulus). Like with insurance companies, participants questioned why technology companies would want to access health, as they were not obviously associated with health care.

Specific concerns relating to Google (or other technology companies) was that there may be misuse of the data, leading to breaches of security and privacy. One group felt there was a risk that data could be used to create profiles of individuals based on their health and other characteristics, which might get sold on to insurance companies for profit. This group was concerned that technology companies would have access to other personal data via smart devices, social media accounts and search engines, and that having access to health data may allow those companies to link information about individuals. Data being de-identified did not provide enough reassurance on this, as it was suggested that technology companies could still find some ways of linking data.

> I don't see a need or a purpose for someone like Google to access health data. What would they bring to the table? They aren't researchers or scientists looking for the greater good, they are looking at this data for some other reason.
>
> (Session one, Group five)

As a counter to this sense of distrust, some found reassurance in the description of TREs provided in the session one presentations – they felt that, if TREs were as secure as they had been described, then commercial organisations would be unable to access identifiable data, and that identities would be safeguarded.

Pharmaceutical companies

There were mixed views on pharmaceutical companies having access health data. On the one hand, there was a sense that health data could help these companies to develop new drugs that would ultimately help with treatment (such as for diabetes as described in the third stimulus example). One group cited the development of the COVID-19 vaccines as an example of pharmaceutical companies being involved in helping to drive forward improvements in public health.

On the other hand, there were some questions about the extent to which pharmaceutical companies can be trusted, and concerns that they might use research to help them increase the prices of drugs. Again, the sense of trust or mistrust came back to the motivations behind the access to health data, leading to a desire for transparency with research access requests.

> It's an issue of transparency and who's funding what, and how the research is being used. If it's used to price people out of treatment then that's not a good thing. I'd be wary of that.
> (Session one, Group six)

Third-sector organisations

Through it was not immediately clear to participants why a third-sector organisation might want to access health data, on reflection and discussion they generally felt this would be justifiable if the organisation was conducting research for the purpose of helping with health care treatment or prevention. No specific concerns were raised about third-sector access to health data – although, for a few participants, there were ongoing concerns about data security and privacy which applied regardless of the sector or organisation involved.

Use of Artificial Intelligence (AI)

There were limited comments made about use of Artificial Intelligence (AI) and few concerns raised about health data being accessed by researchers that might use AI. Overall there was support for the advancement of technology for medical research, and participants could see benefits of this type of approach in helping to find new ways of identifying and treating health conditions.

> I think saying the term 'Artificial intelligence' makes me go, 'Oh, that's weird,' just because it's so new and it's like stepping into the unknown in terms of medicine. But there's so much scope to do so much good, so I don't think it would stop me supporting this.
> (Session one, Group four)

However, there was also an element of the unknown associated with AI, which raised some questions around how AI would be used alongside health data. For example, one participant suggested that technology companies might be able to use AI as a way of accessing other types of personal data that they could use for commercial gain (though the participant did not specify what types of data that might be). Discussions about use of AI also led to some concerns about its possible use within a health care setting, with the feeling that if AI was used too much then the human connection between clinicians and patients might get lost, which participants felt would be detrimental to treatment.

Type of data

It was explained to participants that researchers may want to access different types of data, including GP records, hospital records, information about prescriptions or laboratory data. Participants' views on the acceptability, or otherwise, of access to health data did not vary much by the type of data – they felt that the same principles should apply.

However, it was felt that the impact of research using health data, particularly data related to rare conditions, was important to consider. For example, one group discussed how health data on rare conditions might lead to individuals being discriminated against or treated differently as a result of that research. This caused participants to emphasise the need for data to be de-identified and for published outputs to not be identifiable.

> Data could be published and it could lead to discrimination from insurance companies or employers…even in 2022 people can be discriminated against for the conditions they have. People might not employ someone with HIV, even with everything that we know about it.
> (Session one, Group one)

On a related point, one participant described research being carried out on their family member that suffered from a very rare condition. They felt that research could help to treat patients in similar circumstances, therefore felt that there was benefit in health data being accessed even for rare conditions.

Location of the researcher

Though the three examples shown to participants did not mention the location of the researcher, participants were asked to consider whether location would make a difference to the acceptability of these types of research. There were mixed views on whether the location of the researcher made a difference. Some felt that priority for access to data should be given to organisations based in the UK, as they felt their research was more likely to directly benefit the NHS. Trust was also raised as a consideration, with the suggestion that the public might know and therefore trust UK-based organisations more so than those in other countries.

> If the [researcher] is based in a country that has no public health ethos then access should be guarded more suspiciously than practitioners who come from a public health culture that isn't about making money or saving money.
>
> (Session two, Group three)

A less common view was that access should only be given to organisations within Scotland, and not those in the rest of the UK. This view was driven by a sense of distrust in the UK Government and a feeling that the ethical standards of organisations in the rest of the UK may not be as robust as those in Scotland. Others, however, felt that the purpose of the research mattered more than the location – and even felt that collaboration between researchers in different countries could lead to advancements in health care treatment, and should not therefore be restricted on the basis of location.

Attitudes towards specific types of research request

To help understand views on non-traditional researcher access in more depth, participants were shown videos from six different real-life researchers, representing organisations that want to access health data in future. The videos were supported by written case studies. Participants discussed their views on all six researchers, with each smaller breakout group then discussing two of these in more detail. The case studies are summarised below:

Stimulus provided (in session two)
Videos and written case studies representing potential requests for access to health data.

1. The Centre for Cardiovascular Science at University of Edinburgh using AI to make more accurate heart attack diagnoses, based on factors like age and sex.
2. The NHS Lothian innovation team analysing health data to create a tool that can help health care staff manage diabetes in their patients.
3. University of Edinburgh using synthetic health data to help students learn about real-life health and social care data and practice their skills.
4. A housing society combining health data with data they collect on vulnerable tenants' routines, so that they can intervene with support sooner.
5. A new mental health app accessing data that will help them improve the app's ability to screen for mental health issues and provide support.
6. A cancer research centre making it easier for cancer pharmaceutical companies to access NHS data (in the NHS environment) to help provide evidence that their medicine is worth buying.

Initial reflections on case studies

Before discussing the case studies in detail, participants were asked to briefly give their 'top of mind' first impressions. Overall, participants found the examples a useful way of illustrating the different types of researchers that might want access to health data. In these initial discussions, two of the case studies (examples 4 and 5) raised the most initial questions and concerns.

Participants questioned why the housing association (in example 4) would want to access health data from their tenants, and felt they should already have systems in place to alert them to tenants' health risk (such as heart monitors, alarms, and face-to-face interaction with their tenants). There was also a sense of unease at the idea of housing associations being able to find out more about tenants' routines and health risk factors – which some felt was an encroachment on their privacy.

The case study involving the new mental health app (example 5) raised questions around what type of health data was being accessed and what the benefit would be for the public. One group expressed some concern about the trustworthiness of the organisation, linked to the fact that it was new and therefore may not have a track record in research or be able to demonstrate its credibility. Participants generally felt they needed more information and reflection before deciding their view on this example.

On the other end of the scale, the case studies that were presented by universities and NHS (using AI to predict heart disease and creating a tool to manage diabetes) stood out as being more appealing due to being linked with academics and the NHS, and generally trusted organisations (the University of

Edinburgh and NHS Lothian respectively). Use of synthetic data by University of Edinburgh was also generally viewed in positive terms, with a feeling that it had a worthwhile purpose – for learning.

The example on cancer medicine had few spontaneous mentions. Those that did mention it generally felt it sounded like an acceptable use of the data, though one group raised some concern about the organisation being motivated by commercial interests (as it aimed to provide evidence that the medicine was worth buying).

Each case study is explored in more detail below, based on more in-depth group discussion.

1 The Centre for Cardiovascular Science at University of Edinburgh using AI to make more accurate heart attack diagnoses, based on factors like age and sex.

This example was viewed positively. Perceived benefits were that it could help to improve detection of heart attacks and therefore reduce pressures on the NHS and ultimately avoid people having serious outcomes from a heart attack.

The name of the organisation itself (the Centre for Cardiovascular Science) provided some reassurance about its trustworthiness – it gave confidence that the data would be used for the purposes of treating cardiovascular disease, rather than for profit. As noted earlier, there was also a sense of implicit trust in a university.

> In a research institute you're going into it for a greater good, not because you want to be a millionaire. Its purpose, the people and the ethics behind it all tie up properly. That isn't always the case with commercial companies.
>
> (Session two, Group five)

One aspect of this case study was that it would involve creation of an algorithm using AI, to help doctors assess patients with suspected heart attacks. As noted earlier, while there was general support for AI being used to help advance improvements in health care, and participants did not raise concerns about how AI might interact with health data in research. There were some reservations, however, about the AI tool replacing the role of human health care professionals and their personal judgement – and it was suggested that this might mean some patients "slip through the net" and be misdiagnosed. To help manage that risk, it was felt that there should be careful review and scrutiny of the accuracy of the tool.

2 The NHS Lothian innovation team analysing health data to create a tool that can help health care staff manage diabetes in their patients.

There was broad support for this type of research access request. This was partly due to the association with the NHS, which led participants to feel that it was trustworthy and motivated by a desire to improve health care provision – a factor that they closely associated with public benefit.

Support was also partly due to an understanding of the potential benefits for diabetes treatment specifically. Participants shared their own experiences of diabetes, or that of their friends and family, and recognised the potential for improvements to the way the condition is managed. The introduction of insulation pumps connected to mobile apps was cited as an example of an improvement that had already been made, and there was a desire to support further similar developments.

> The benefits appear to outweigh the risks. If accessing the data can enable this tool to be developed and to reach a greater pool of people, then let's do it.
>
> (Session two, Group six)

The main risk associated with this example was one that was highlighted in the case study itself – the risk of over-reliance on the tool by inexperienced doctors. This caused participants to again make the point about AI and other tools not replacing the knowledge and professional judgment of clinicians.

3 University of Edinburgh using synthetic health data to help students learn real about real-life health and social care data and practice their skills.

The overall purpose of this research was generally viewed positively, as it would help with learning and development of skills for health care professionals. There was no apparent suggestion in this example that the data would be used for profit or financial gain, which made it appealing.

A key aspect of this case study, that distinguished it from the others, was that it referred to using synthetic data, which mimics the properties of real data. This was mainly seen as a strength, as it could reduce the risk of individuals being identified and alleviate concerns over data security breaches.

> Anything to do with learning and teaching is good, where the main aim is to teach…they're using historical information, it is already anonymised and synthetic, so I don't see a problem or risk.
>
> (Session two, Group one)

However, participants acknowledged the risk (as noted in the case study) that synthetic data may not provide accurate enough information to base decisions on. They added that, as the data is not the same as real data, it may not be able to tell researchers everything they need to know and should therefore be treated with some caution. Overall, however, this was considered a relatively minor risk and was outweighed by the benefits in this example.

4 A housing society combining health data with data they collect on vulnerable tenants' routines, so that they can intervene with support sooner.

Participants were generally against this use of health data, some strongly so. It was felt that health data should sit beyond the remit of a housing association, and that monitoring the health of tenants should be the responsibility of health care professionals and not the association. As the use of the data in this example was to help understand patterns of behaviours, some felt that this to would feel like an intrusion on privacy – a sense of "Big Brother is watching you", as one participant put it. Even when participants were reminded that the data would be accessed via the TRE and that it would unlikely that it would be identifiable, there was still a sense of mistrust on the housing association's motives.

It was suggested that, unlike traditional researchers such as universities, housing associations may not be governed by codes of practice for research. This raised questions about their trustworthiness, and emphasised the importance of scrutiny of research access requests.

> I'm less comfortable with [data] going to a housing association. When it's a Uni they have been vetted and have a code of conduct. With a housing association, they might not have that background of conducting research…it comes back to vetting and having a good panel that makes sure companies don't jump through hoops to get access.
>
> (Session two, Group two)

It was also felt that the request for health data lacked credibility because it was potentially a distraction from the core purposes of a housing association and that they should, instead, concentrate on improving contact with residents on the ground.

5 A new mental health app accessing data that will help them improve the app's ability to screen for mental health issues and provide support.

There were some concerns expressed about the credibility of this request. Though there were perceived benefits to accessing support without having to wait for face-to-face treatment, these were outweighed by risks. It was felt that use of an app to provide support for those with mental health conditions, without the involvement of a clinician, posed the risk of mental health conditions being misdiagnosed or the wrong type of support provided.

Participants felt that mental health was a complex and sensitive issue and that people could easily misinterpret the information conveyed over an app, which may be detrimental to patients and ultimately make them feel worse. The apparent absence of human interaction and communication were therefore one of the key drawbacks of this case study.

> There's more need for face-to-face treatment for mental health, it's not tangible like other diseases. There's nothing better than speaking to someone in person…a one-stop shop app isn't enough.
>
> (Session one, Group one)

The risk of digital exclusion was also raised, meaning that those without access to the app or a suitable device could miss out, which was considered unfair.

Further, the fact this was a new organisation, a start-up, raised further concerns about their trustworthiness. One group said they would feel more reassured if the organisation was partnering with the NHS or with a university, and therefore subject to their relevant codes of practice.

6 A cancer research centre making it easier for cancer pharmaceutical companies to access NHS data (in the NHS environment) to help provide evidence that their medicine is worth buying.

There was recognition of the benefits of this access to health data, if it ultimately helped to improve the drugs available to cancer patients and improved treatment. For one group, the aim of improving cancer treatment was seen as a more justifiable reason for accessing health data than the case put forward by the housing association which seemed less directly related to health benefits (this group discussed these two examples in detail). There was a desire for reassurance that the cancer centre was completely objective, and not linked to one of the drug manufacturers. Participants also emphasised the need for checks on the suitability of the organisation and researcher to make sure they were credible and trustworthy, specifically to check that they did not have any conflicts of interest (such as being aligned with a pharmaceutical company) and that they could provide a clear justification for the research.

The main concern related to one of the researcher's goals, which was to help provide evidence that their medicine was worth buying. This raised the possibility that the research may be motivated by financial considerations, with the aim of helping drug manufacturers make more profit. While there was no overarching objection to data being accessed to ensure that medicines are safe and effective, if the motivation is more of a financial one, participants were less comfortable. Some participants suggested that this example could have public health benefits and also lead to the pharmaceutical company generating profit as a result – but if making profit was the sole motivation, they felt uncomfortable with this type of access request. Echoing findings from the first session, the concerns about commercial motivations caused some to raise the idea of the organisation being asked to "give back" some of its profits to the NHS.

> Anything that helps with cancer is obviously brilliant but, at the same time, there is a risk of commercial exploitation. But if it can somehow benefit the NHS, then there is no problem. [The question] is how we can safeguard against those companies being able to exploit the [data] for financial gain that doesn't support the NHS.
>
> (Session two, Group six)

Conclusion

Having learned about and deliberated on the range of different type of potential research request, participants acknowledged the potential benefits of non-traditional researchers accessing health data. The main benefit was that research could ultimately help to improve the diagnoses and treatment of health conditions, which in some cases could mean saving lives. The access to knowledge, expertise and financial resources within these organisations was seen as offering a means of potentially helping to advance medical research. A related benefit was that advancements in research into health conditions could alleviate pressure on the NHS, if it reduced the need for people to seek treatment from clinicians.

However, this did not mean there was blanket acceptance of non-traditional researchers accessing health data. Some examples, particularly those involving organisations operating outside of the health care field and those that operate for profit, raised particular concern – and these are noted under the examples above.

In terms of how participants judged organisations, their perception of trustworthiness and credibility centred around the following areas:

- **Motivations of the organisation seeking access to the data**. Where the research was clearly motivated by a desire to improve health care treatment, or advance learning and understanding of health conditions, then it was typically considered trustworthy or credible. Where the motivation was solely for profit or commercial gain, this was considered a less acceptable use of health data. However, there was some recognition that access to health data by commercial organisations may lead to health benefits (such as treatment of cancer) and also ultimately make profit for an organisation (such as increasing sales for a pharmaceutical company). Where this was the case, it was suggested that the organisation should contribute some of those profits to the NHS.

- **Whether or not the organisation was in the field of health care or academia.** Related to the point above, researchers working within the health care field or in academia were seen as having a more credible and understandable reason for accessing health data. Those working in other areas, such as housing or technology, were not seen as having an obvious need for health data.

- **Existence of internal codes of practice or conduct.** There was a perception that the NHS and universities would have to follow codes of conduct for any research using health data. Existence of these types of governance arrangements (for the research organisations themselves, aside from the governance of the TRE) would provide reassurance about their trustworthiness and credibility.
- **How established the organisation is.** Positive perceptions of universities were often linked to how long they had been established and their reputation as respected centres of research. In contrast, questions were raised about the trustworthiness of newer organisations if they were not yet able to demonstrate their track record in conducting research.

Overall, it was felt that the acceptability, or otherwise, relied on a sense of trust that there were systems in place to keep the TRE secure and that researchers accessing health data were doing so for a trustworthy reason that had benefits for the public. Participants' suggested principles for access to TREs by non-traditional researchers are outlined in the next chapter.

5 Suggested conditions on non-traditional researchers for access to health data

The deliberative discussions concluded with participants identifying their principles and “red lines”; with principles being the suggested conditions that would make it acceptable for health data to be accessed by non-traditional researchers, and “red lines” being lines that, if crossed, would make access to health data unacceptable.

Overarching themes

There was a general assumption (based on the information provided about TREs and data services) that minimum standards would be in place for all researchers, whether traditional or non-traditional. These were:

- that data within the TRE would be de-identified
- that researchers would have to submit an access request that was subject to scrutiny before being granted approval
- that researchers would need to enter into a formal agreement, or contract, covering their access to and use of the data, and
- that data would not be shared beyond the research study.

In addition to these factors, some clear themes cut across the principles and red lines. These were:

- **Commercial interests** – a clear message throughout the deliberations was a desire to avoid health data being used by private-sector companies purely for generating profit. While it was acknowledged that some research by private-sector companies may have public benefit, such as the development of medicines and improvements in treatment, there was concern about data being accessed by organisations where their sole motivation was to make profit. If profit was generated as a result of the research, there was a desire that some of this be put back into the NHS.
- **Transparency of purpose** – it was felt that every researcher should be required to provide a clear justification for why they need data, what data they need and how they will use it. Making the purpose of the research clear would help to provide reassurance that it would have public value and was motivated by a desire to support or improve health care.
- **Health-related impacts** – related to the principles above, there was a desire for non-traditional researchers to be able to demonstrate how their research would ultimately benefit the health care service or research on health conditions.
- **Ethics panel** – having an ethics panel to review research requests was seen as an effective way of providing scrutiny of research requests. It was suggested that the ethics panel should be made up of a combination of health care professionals, people with expertise in health data research, and members of the public.

- **Quality standard or code of conduct** – it was suggested that there should be a quality standard, code of conduct or agreed set of terms and conditions for use of health data, that non-traditional researchers should be expected to meet. Participants felt that all researchers, regardless of their organisation, should be held to the same standards and subject to the same level of scrutiny before they were granted access to health data.

- **Monitoring and review** – having a mechanism to review how researchers have used data, and checking whether that aligns with their original stated purposes, was seen as a way of providing reassurance about the ongoing level of scrutiny of the process.

Principles

Specific principles suggested by participants are shown below. These represent the principles that received support from more than one group, or which were considered the most important principles by

Principles: *'Access to health data by non-traditional researchers is acceptable if…'*
Data is kept safe and secure and is de-identified.
Researchers can only have access to the data that they request, and only for the purposes that they specify in their request for access.
They can demonstrate a clear public benefit for their use of the data, a positive intended outcome, and a clear reason why they need the data.
Research ultimately benefits the NHS (either through sharing of findings or outcomes from the research, or through financial contribution from any profit made).
Researchers agree the data is not going to be used solely for profit.
Pharmaceutical companies can agree the data will not be used to increase the price of the drugs they manufacture, and if they generate profit they contribute some back to the NHS.
Research requests are subject to review and scrutiny by an ethics panel.
Researchers can conform to meeting and adhering to a quality standard, code of conduct or an agreed set of terms and conditions.
Researchers are open to having their research and its outputs audited after being granted access to the data.
Breaches of terms and conditions are proportionately penalised, such as through fines or being prevented from accessing the data in future.
Traditional researchers from the NHS and universities continue to get free or at cost access to health data, and that any additional charges for access are targeted at private-sector / commercial organisations.

Circumstances that would make access to health data unacceptable

The ‘red lines’ that would make access to health data by non-traditional researchers are outlined below. Again, these are based on the common or strongest themes to emerge from the deliberations.

Red Lines: *‘Access to health data by non-traditional researchers becomes unacceptable if…’*
It is solely for commercial gain.
There is any use of the data beyond its stated purpose (for instance using the data to target people).
Researchers cannot agree to comply with the terms and conditions for access.
Researchers are unable to demonstrate that they, or the organisation they are part of, have the track record, skills and expertise to research with health data.
The organisation has a history of misuse of data or unethical practices.
Researchers cannot demonstrate the potential benefits to the NHS from the research.
The research doesn’t serve a health purpose (e.g. an insurance provider changing their cover).
Public sector agencies, such as housing providers, use health data to monitor individuals’ behaviours without their consent.

6 Conclusion

This concluding chapter revisits the research aims and research questions and reflects on the main findings with respect to each.

What is expected from non-traditional researchers and/or organisations to be considered trustworthy and credible?

Trustworthiness and credibility were often discussed together and were linked with a number of factors.

Firstly, the motivations of the organisation seeking access to the data. Where the research was clearly motivated by a desire to improve health care treatment, or advance learning and understanding of health conditions, then it was typically considered trustworthy or credible. Where the motivation was solely for profit or commercial gain, this was considered a less acceptable use of health data (though it was accepted that some organisations may make a profit, some of which participants felt should be paid back to benefit the NHS).

Secondly, whether or not the organisation was in the field of health care or academia. Linked to the point above, both the NHS and universities were described as “trustworthy” because they were seen to have legitimate reasons for wanting to access health data and were not motivated by profit. In contrast, there was a sense of mistrust about access to health data from organisations that did not work within the field of health care or academia, particularly insurance and technology companies. There was a perception that insurance companies would be solely motivated by commercial interests and would want to access health data to help them increase premiums, while it was suggested that technology companies may be able to link health data to other personal information they might have access to via smart devices, social media accounts and search engines. However, it was acknowledged that researchers outside of the health care setting could bring expertise that could advance and ultimately benefit health-related research.

Thirdly, there also a sense of trust in the NHS and universities because they were likely to have codes of conduct that governed their research. Existence of these types of governance arrangements for the organisation, and the researchers working within it, would provide reassurance about trustworthiness and credibility.

Finally, how established the organisation was, with universities being viewed positively due to their long established reputations as centres of research. In contrast, questions were raised about the trustworthiness of newer organisations if they were not yet able to demonstrate this through their track record in conducting research. This did not mean that newer organisations should not be granted access, but emphasised the need for scrutiny of the research access request and the acceptance of terms and conditions by the researcher.

In summary, for non-traditional researchers to be considered trustworthy and credible, the public expected: transparency of purpose and motivation, adherence to a code of conduct or quality standard for researchers, and agreement to a set of terms and conditions for access to health data.

What public concerns exist about non-traditional researchers accessing health and social care data in general, as well as through TREs?

As is clear throughout this report, the main concern raised about non-traditional researchers having access to health data, including through TREs, was that it would be used purely for profit and not for

public benefit. There was somewhat of a conflict between the idea that health data could provide public value (which participants saw as improving health care) and the potential for organisations to benefit financially from having access to health data.

However, there was some acceptance that commercial organisations could add public value and help to advance innovation in medical research due to their expertise, scale and the financial resources they have at their disposal. As deliberations progressed and specific examples of research were discussed, there was also recognition that public value and profit were not always mutually exclusive – for example, pharmaceutical companies may make profit from developing a drug that also helps improve the treatment of a serious health condition. As noted above, where the sole motivation and sole purpose of the research was for profit, this was a 'red line' for participants that meant health data should not be accessed. But if the research was motivated by public value, and the organisation also made a profit, this was considered acceptable if some of that profit was fed back to the NHS.

The other underlying concern, at least in the early stages of deliberations, was about data security and the ability for individuals to be identified. Although it was explained that personally identifying information would be removed from the data before researchers had access via the TRE, participants nonetheless expressed concern that it would still be possible for individuals to be targeted through their health data. As more information was provided and deliberations progressed, participants were more reassured about this and generally placed their trust in the security of the TRE as it was described to them. However, in their principles around access to health data it was clear that they wanted systems in place (including terms and conditions for researchers) to ensure that data remained as safe as possible and that individuals would not be identified.

What user accreditation standards are required to provide reassurance about the public value of projects requiring data access through TREs?

The workshops provided clear principles, or conditions under which it would be acceptable for health data to be accessed by non-traditional researchers, along with the red lines that would make access unacceptable. These principles provide a foundation for developing standards that researchers could be asked to meet before they are granted access to data.

One of these principles referred to a quality standard, code of conduct, or terms and conditions for access to health data. Participants felt strongly that all researchers, regardless of their organisation, should be held to the same standards and subject to the same level of scrutiny before they were granted access to health data. Participants did not define the exact content of a quality standard or the terms of a code of conduct, but strongly felt that researchers should be asked to:

- provide a clear statement of the purpose of their research and their reasons for accessing the data,
- prove a clear public benefit for their use of the data and a positive intended outcome,
- agree that the data is not going to be used solely for profit, and
- show how the research will ultimately benefit the NHS.

In terms of the review process, it was suggested that an ethics panel was one way of reviewing requests for access to data (with representation from medical professionals, researchers and members of the public). Though participants did not provide further insights into the review and oversight process, they

were clear that all access requests should be subject to the same level of scrutiny and should, if required, be willing to be audited to check on their use of data and progress against research outcomes.

7 Appendix

Sample of participants

Participants were recruited in line with the quotas design to reflect the profile of the South-East Scotland population.

Characteristic	Quota category	Number of participants
Age	16-24	6
	25-34	8
	35-54	18
	55+	12
Gender	Men	21
	Women	25
Location	East Lothian	5
	Edinburgh	12
	Fife	12
	Midlothian	3
	Scottish Borders	3
	West Lothian	11
Ethnicity	Ethnic minorities	8
	White Scottish/British	38
Deprivation level (SIMD)	1 – most deprived	10
	2	8
	3	9
	4	8
	5 – least deprived	8

Our standards and accreditations

Ipsos' standards and accreditations provide our clients with the peace of mind that they can always depend on us to deliver reliable, sustainable findings. Our focus on quality and continuous improvement means we have embedded a "right first time" approach throughout our organisation.

Our standards and accreditations are shown overleaf.

ISO 20252

This is the international market research specific standard that supersedes BS 7911/MRQSA and incorporates IQCS (Interviewer Quality Control Scheme). It covers the five stages of a Market Research project. Ipsos was the first company in the world to gain this accreditation.

Market Research Society (MRS) Company Partnership

By being an MRS Company Partner, Ipsos endorses and supports the core MRS brand values of professionalism, research excellence and business effectiveness, and commits to comply with the MRS Code of Conduct throughout the organisation. We were the first company to sign up to the requirements and self-regulation of the MRS Code. More than 350 companies have followed our lead.

ISO 9001

This is the international general company standard with a focus on continual improvement through quality management systems. In 1994, we became one of the early adopters of the ISO 9001 business standard.

ISO 27001

This is the international standard for information security, designed to ensure the selection of adequate and proportionate security controls. Ipsos was the first research company in the UK to be awarded this in August 2008.

The UK General Data Protection Regulation (GDPR) and the UK Data Protection Act (DPA) 2018

Ipsos is required to comply with the UK GDPR and the UK DPA. It covers the processing of personal data and the protection of privacy.

HMG Cyber Essentials

This is a government-backed scheme and a key deliverable of the UK's National Cyber Security Programme. Ipsos was assessment-validated for Cyber Essentials certification in 2016. Cyber Essentials defines a set of controls which, when properly implemented, provide organisations with basic protection from the most prevalent forms of threat coming from the internet.

Fair Data

Ipsos is signed up as a "Fair Data" company, agreeing to adhere to 10 core principles. The principles support and complement other standards such as ISOs, and the requirements of Data Protection legislation.

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