Full Study Title: University of Cambridge NHS/HSC Health Data Consent Survey

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Sponsor:	Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) and the University of Cambridge

AMENDMENT HISTORY

Amendment No.	**Protocol Version No.**	**Date issued**	**Author(s) of changes**	**Details of Changes made**

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date: ....../....../...

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Name (please print):

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Position:

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Chief Investigator:

Signature: Date: ....../....../...

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Funder(s)	MRC Mental Health Data Pathfinder Award (MC_PC_17213)

LIST OF CONTENTS

SYNOPSIS

It may be useful to include a synopsis of the study for quick reference. Delete or alter as appropriate/required.

Study Title	University of Cambridge NHS/HSC Health Data Consent Survey
Internal ref. no.	R&D:
Study Design	Anonymous online questionnaire
Study Participants	Consenting UK residents over 16 (or under 16 with parent/guardian permission)
Planned Sample Size (if applicable)	20,000
Follow-up duration (if applicable)	Not applicable
Planned Study Period	December 2019 – May 2020
Primary Objective	To establish patient and public views on the sharing of identified NHS/HSC health data (for clinical purposes) and de-identified health data (for research) within the UK.
Secondary Objectives	a) To establish if opinions on sharing mental versus physical health data are affected by the framing of risk versus benefit. b) To propose a design of a national consent form governing NHS data sharing and seek views on it. c) To seek public views on a national web portal to sign up for mental health research. d) To examine views on “trusted third party” linkage followed by de-identification for research, between health data and a range of other UK state-held information sources.

1. BACKGROUND AND RATIONALE

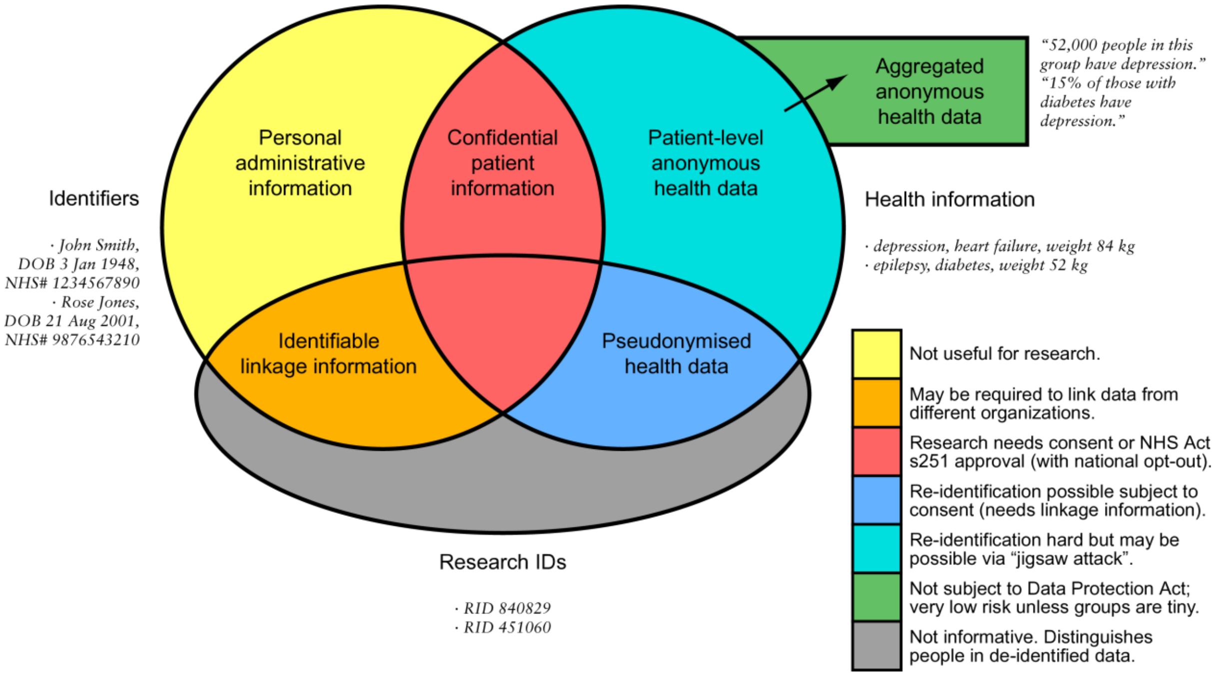
In summary, this study is an online anonymous survey of public opinion on the ways in which national health service data should be shared between health providers or restricted: (a) identifiably, for direct clinical care of patients; and (b) in de-identified fashion, for research. We seek also to learn whether the public holds different views about the sharing of mental versus physical health data, and, in the context of research, about structured versus "free text" (narrative) de-identified data. We aim to seek views on a generic tiered consent form that could be used widely across UK national health service providers and other partners. Finally, views will be sought on data linkage for research, and on a national web portal to sign up to be contacted about health research.

In this section we describe forms of health data, set out the current situation pertaining to data sharing in the UK, summarize previous work on public opinion, and set out the rationale for our proposed study.

1.1 NHS health data and its uses

NHS health information is recorded by the many professionals who look after a person's health within the National Health Service (NHS; England, Scotland, Wales) or Health and Social Care (HSC) in Northern Ireland. These data can take the form of a simple diagnosis or record of current medication, or more complex data such as narrative text, imaging (scan) results, blood tests, or genetic information. When combined with personal information such as names, date of birth, and addresses, the health data is identifiable and represents "confidential patient information" [1]; other versions of the data may be used in a de-identified or anonymised form for research (**Figure 1**).

Figure 1. Types of health data.



Such health data has two broad categories of use: direct health care, and research. Direct health care requires detailed identifiable information about an individual. In addition, health data from many people, collected as part of their routine care, is invaluable for research. Rich clinical data sets may permit research leading to better diagnosis, treatment, and prevention of disorders. The use of de-identified or anonymised data for research is strongly advocated by the NHS, via its Constitution pledge "to anonymise the information collected during the course of a patient's treatment and use it to support research and improve care for others" [2]. Under some (much more limited) circumstances, identifiable data may also be used for research [1,3].

1.2 Data sharing for clinical purposes (direct health care): current situation

Identifiable data is given by patients to healthcare staff, and generated by healthcare staff, under standard principles of consent and information governance [3–5]. It is *de facto* "owned" and managed by local parts of the NHS/HSC (henceforth "NHS" for brevity). The body responsible for a given piece of information is termed the Data Controller [3]. For example, if information is recorded by a general practitioner (GP), that GP surgery is typically the Data

Controller, and if recorded by a hospital, that hospital NHS Trust is typically the Data Controller. Regardless of technical subcontracting arrangements, Data Controllers are responsible for the security of data they hold and the way in which it is processed [3].

Health care is often delivered by multiple coordinating parts of the NHS. For example, a GP surgery, a community services Trust, an ambulance Trust, an acute hospital Trust, and a mental health Trust might all provide aspects of a patient's care. Information may be shared between these parts of the NHS in different ways [4–6]. (1) One part of the NHS might ask a patient for explicit permission to share information. For example, a GP might ask their patient for permission to refer them to a hospital specialist; a liaison psychiatrist might ask a hospitalized patient for permission to see their GP records. (2) Sometimes information is shared with implicit (implied) consent. For example, the patient is likely to attend their hospital appointment, following GP referral, with the expectation that the specialist subsequently sends a letter to the patient and their GP setting out the specialist's advice. When a blood test is sent to a laboratory, there is implicit consent for the laboratory to see relevant parts of the patient's identifiable health data. Similarly, staff from many professions and subspecialties may become involved in the care of hospitalized patients, usually on the basis of implicit consent, and would be expected to have access to the patient's hospital records. (3) Sometimes, information is shared without consent but in the patient's best interests, for example in an emergency if the patient is unconscious [7]. (4) Sometimes information must be shared for other legal reasons [4], not discussed further.

However, the boundaries between explicit and implicit consent are not rigid, and it is an open question as to how well current practice reflects patients' expectations and wishes. When information crosses a boundary between providing organizations (e.g. between a GP and a secondary care provider, or between two NHS Trusts), explicit consent is more likely to be sought. When information moves within a single organization, implicit consent is more likely. However, the divisions of the NHS into its constituent organizations are to some degree arbitrary and fluid (they merge and divide for a range of reasons). The clinical dangers of unduly restrictive information sharing (for fear of breaking information governance law) have been emphasized by the Caldicott Review [5]. In our experience, patients are sometimes very surprised by explicit requests to access other parts of the NHS record, having presumed that would be automatic in a "national" health service, and this experience is widespread [8]. There are ongoing regional developments to improve NHS information sharing [8,9], in part on the basis of implicit (opt-out) consent for direct healthcare purposes [9,10].

Thus, currently there is limited sharing of health data for clinical purposes via implicit consent across the NHS. This has led to a situation where each time a patient attends any NHS/HSC appointment or visit, new consent may be sought, or patients asked for information time and time again, in order for the health care professional delivering care to access all of their relevant health data [9].

1.3 Data sharing for research: current situation

The situation for research is perhaps more complex, with several routes through which health data may be used for research (**Figure 1**). (1) The simplest situation, in information governance terms, is the use of identifiable health data for research with a patient's explicit consent. (2) A legal route to the use of identifiable data without consent in England is approval under section s251 of the NHS Act [1] ("s251 approval"), ultimately by the Secretary of State and in practice by the NHS Health Research Authority (HRA) Confidentiality Advisory Group (CAG) [11]. (3) Data that is fully anonymised, with no possibility of re-identification, is not subject to the Data Protection Act [3] and may be published freely and used for research. Much "bulk" data, summarizing information from large numbers of patients, is of this form. However, for "anonymised" data relating to individual patients, surprisingly small amounts of information may render data susceptible to re-identification via a so-called "jigsaw attack", in which other information sources (e.g. from newspapers) can give additional clues that can sometimes permit identification [12]; thus, patient-level data needs to be treated with considerable respect and care even after notional anonymisation. (4) Finally, many NHS organizations have systems for de-identification of data for research, under NHS ethics approvals and careful information governance controls [13,14]. The hosting clinical organization (but not, without explicit consent, researchers) may be permitted to re-identify such records, for example to support recruitment to research studies in furtherance of the NHS Constitution's pledge to "to inform patients of research studies in which they may be eligible to participate" [2]. These systems are advancing but are not universal or standardized.

One “grey zone” surrounds the way in which data may be linked between multiple organizations for research. For example, GPs hold synopses of nearly all aspects of a patient’s NHS care; mental health NHS Trusts have additional rich information on mental disorders; acute hospital Trusts have information on physical disorders; all secondary care NHS Trusts send identifiable summary information to NHS Digital (NHSD) to create the national Hospital Episode Statistics data set [15]; causes of death (from death certificates) are managed by the UK Office for National Statistics (ONS) [16] via NHSD. Thus, answering a question such as “what are the common causes of early death in schizophrenia?” might require linking data from a mental health Trust to data from the ONS/NHSD. Typically, such linkage is performed via NHS numbers, which are nationally unique. After linkage, the linked data (containing e.g. patient ages, psychiatric diagnoses, physical diagnoses, and causes of death) can be de-identified and used for research. Even though the researchers never see identifiable data, permission might need to be sought under s251 for the linkage process (in which identifiers, namely NHS numbers, are handled by the NHS Trust or NHSD). In this example, s251 approval might need to be sought for research linkage even though the participating organizations collectively manage this data (or large subsets of it) on an identifiable basis as part of their routine healthcare work (NHS Trusts) or are statutorily enabled to process identifiable data (NHSD). For linkage to information from non-NHS bodies (e.g. the UK Department for Education), the process may be yet more complex. Furthermore, s251 approval may be restricted to very specific research projects, leading to a need to re-apply when the same organizations link data for other research projects (this being a costly and time-consuming process). It is unclear to what degree the public would wish this to be more streamlined. We hypothesise also that the degree of public sensitivity about linkage of health data to other sources will vary with that source type (e.g. education versus criminal justice) but there is little prior research in this area [17].

1.4 Pertinent prior work on data sharing

The 2013 Caldicott Information Governance Review set out principles for the safe sharing of confidential patient information, noting the principle that “[t]he duty to share information can be as important as the duty to protect patient confidentiality” [5]. A further review of this topic in 2016 was led by Caldicott as the National Data Guardian [10]. This report noted the lack of progress in this regard despite recent legislation [18] creating a duty upon health and social care providers to share information with another such person where sharing is likely to facilitate the individual's health or social care, disclosure is in their best interests, and they do not or are not likely to object (that is, in essence an opt-out system). This conflicts with some prior studies of public opinion on this topic [19]. The Caldicott 2016 review noted that "[t]here continues to be a low level of public awareness and understanding of how health and social care information is used, but an expectation that information is shared for direct care" [10].

In relation to research and other non-clinical activities, the Caldicott 2016 Review also proposed a model in which people should be able to opt out from personal confidential data being used beyond their own direct care [10]. This has led to the National Data Opt-Out (rolling out 2018–2020), relating specifically to the use of *confidential patient information* (i.e. identifiable information) for purposes such as research [20]. The Review also emphasized that "the case for data sharing still needs to be made to the public", and that the lack of an opt-out does not imply consent (p30) so that there needs to be a specific legal basis for sharing identifiable information. The opt-out does not apply to direct clinical care, or to de-identified information. It is unclear whether this is widely known about or understood.

Despite this prior work, the current situation is that information is often not shared without explicit consent – likely for fear of inappropriate disclosure [10]; sometimes because relevant medical records software can be told not to permit this [21,22]. Similarly, s251 approval is still required for linkage studies in which researchers never see identifiable information, likely in part as a consequence of there being no standardized "trusted third party" system for centralized linkage of identifiable information.

It is therefore currently in practice impossible for:

- all NHS staff providing health care to an individual to access all their clinically identifiable NHS data without multiple consents;
- all NHS-approved researchers conducting healthcare research to see all relevant de-identified NHS data without multiple approvals;
- all NHS-approved researchers conducting healthcare research to see all relevant NHS health data from consenting patients and write to individuals about studies in which they may wish to participate.

There is also a lack of information on public attitudes to data sharing in relation to mental health specifically. In late 2018 the Wellcome Trust and Understanding Patient Data conducted a thorough literature review of public attitudes to patient health data use for research [17]. They noted that there were few studies relating to acceptability of sharing patient health data for groups with specific health conditions, but that sharing some types of sensitive data (on mental health, sexual health, sexuality, religion, etc.) held greater concern than for other types of data. It is also the case that mental illness is subject to significant stigma [23]. Nonetheless, many psychiatric disorders convey massive loss of life expectancy via physical illness [24], making the need for optimal physical healthcare in mental disorders critical and emphasizing the need for research in this area. Our project will therefore include questions about sharing mental and physical health data, for both clinical and research settings.

1.5 Study outline

This study therefore aims to seek current patient and public views on sharing NHS/HSC identifiable health data across the UK by means of a national survey (Appendices 1-3). Views will be sought on patient and public current understanding of health data sharing, how they would like to see their identifiable health data shared (or not), with whom they would want their data shared (identifiably for clinical purposes, or in de-identified fashion for research purposes), whether they would be willing to share their mental and physical health data equally, and whether different thresholds should apply to “free text” (narrative) versus structured data. Ideas on designing a single consent form will be sought, so that identifiable health data may be shared across the UK, as well as how sign up to this might be achieved. Finally, views will be sought on data linkage for research, and on a national web portal to sign up to be contacted about health research.

For part of the survey, we will superimpose a randomised intervention, namely a framing statement, prior to seeking views relating to the sharing of mental versus physical health data. The framing statement will be one of three true statements: a “security” framing emphasising previous work reporting greater concerns about sharing mental health data versus other kinds of health data; a “neutral” statement; and a “holistic” framing emphasising the interrelationship between mental and physical illness.

This study is funded by the UK Medical Research Council (MRC) via a Mental Health Data Pathfinder (MHDP) Award (MC_PC_17213) and our CLIMB project team (Clinical Informatics for Mind and Brain Health; https://www.climbproject.org.uk/) is working together with other UK MDHP sites. This work is within the patient/public engagement workstream of that grant.

1. OBJECTIVES

2.1 Primary Objective

To establish patient and public views on the sharing of identified health data (for clinical purposes) and de-identified health data (for research) within the UK.

2.2 Secondary Objectives

a) To establish if opinions on sharing mental versus physical health data are affected by the "framing" of risk versus benefit, testing the hypothesis that a "security"-focused framing statement will increase reluctance to share mental (versus physical) health data regardless of purpose and a "holistic" framing statement will have the opposite effect.

b) To propose a design of a national consent form governing NHS data sharing and seek views on it.

c) To seek public views on a national web portal to sign up for mental health research.

d) To examine views on "trusted third party" linkage followed by de-identification for research, between health data and a range of other UK state-held information sources.

2.3 Outcome

The principal outcome will be a description and analysis of views on how health data may be shared across the UK, how these are related to demographic variables, and how opinions on sharing mental versus physical health data are affected by the framing of risk versus benefit. Other outcomes will include views on the design of a national consent form and on whether there should be a separate national web portal for mental health research as well as views on data linkage. We will seek to publish the findings in a peer-reviewed journal and report them to national funding and governance bodies.

The study team will share the results of the survey with a team at Edinburgh University, another MRC Mental Health Data Pathfinder site. The Edinburgh team are running a related but non-overlapping survey on NHS use and health data, and it is hoped that both survey results can be combined to produce recommendations about sharing health data across the UK.

2. STUDY DESIGN AND METHODS

The study will collect data from a national survey. The online survey will be available on the CLIMB project team website at https://www.climbproject.org.uk/

The team will advertise the study through several means. Advertising posters and leaflets have been designed. They also hope to use the NHS National Institute for Health Research (NIHR) Clinical Research Network (CRN) to reach out across the UK. The team will engage with other MRC MHDP-funded university sites and UK charities to promote the survey. Local media (radio, TV, and written) will be approached with the hope that it may gain some national coverage. The study team also have contacts in other hospitals and universities across the UK. ‘Pop-ups’ in towns and cities may be used, as well as stands at local and national events.

Data capture will be by REDCap[30]. REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support online or offline data capture for research studies and operations.

Views about data sharing will be the main objective of the study, particularly with regards to views on sharing identifiable NHS/HSC health data more freely across the UK. Views are also being sought on sharing identified and de-identified data for research purposes as well as scoping views on the format a national consent form may look like, linkage of data and a national sign up for research.

The study team will collect data on people's preferences regarding data sharing using Likert-style scales, yielding interval/ordinal data on preferences (e.g. "very unlikely to share"/"strongly disagree" through to "very likely to share").

For part of the survey, the study team will superimpose a randomized intervention, namely a framing statement, prior to seeking views relating to the sharing of mental versus physical health data. (See section 6.3 for further details).

Once the survey has closed any e-mail addresses (optionally given so that results of the survey may be sent directly to participants) will be removed and stored on password-protected files on University of Cambridge Computers. Any postcodes given (this being optional) will be converted to an ONS Lower Layer Super Output Area (LSOA) code so that individuals may not be inadvertently identified. (The LSOA is a "blurry" geographical indicator covering a population of approximately 1,500 [25].) The postcodes will then be deleted. (See section 7.1, *Data Protection and Patient Confidentiality,* for full details of how the study team will carry this out).

The team will examine the distribution of response data and anticipate using general linear modelling when its assumptions are satisfied (e.g. normally distributed residuals) but non-parametric alternatives (e.g. Kruskal-Wallis H test) where they are not. They will use R [26] for statistical analysis. Predictors to be examined include age (range), gender, ethnicity, self-reported educational level, geographical/socio-economic indicators (NHS region of respondent, index of multiple deprivation, National Statistics Socio-economic Classification) personal experience of relevant NHS services/disorders, and experimental manipulation (framing). (See section 6.3 for details regarding analysis of endpoints.)

Once the analysis has been finished, the fully de-identified data will be available to the public as per the Concordat on open research data [27]. This is made clear to participants in the information sheet at the start of the consent survey.

2.1 **Study Participants**

Study participants will be members of the public from the UK who wish to take part in the online survey

3.2 Inclusion Criteria

The following inclusion criteria will apply:

- Participant is willing and able to give informed consent for participation in the study.

- Participant currently resides in the UK

3.3 Exclusion Criteria

The participant may not enter the study if the following apply:

- Under 16 years of age without parent or guardian permission

4. STUDY PROCEDURES AND INTERVENTIONS

4.1 Recruitment

The University of Cambridge NHS/HSC health data consent survey is an online survey, and will be available on the following website:

CLIMB Project (www.climbproject.org.uk)

Participants living in the UK will be invited to take part in the survey through advertising leaflets and posters. The team will engage with other MRC-funded university sites (as part of its Mental Health Data Pathfinder funding stream) and UK charities to promote the survey. Local media (radio, TV, and written) will be approached with the hope that it may gain some national coverage. 'Pop-ups' in towns and cities may be used, as well as stands at local and national events.

The following have been designed specifically for the survey:

- Posters and leaflets
- Web pages containing the survey

Clinical research networks – Secondary care

The study team have approached the NHS National Institute for Health Research (NIHR) Clinical Research Network (CRN) to reach out across the UK. The CRN staff will use varied approaches to reach out to potential participants:

a) Displaying the studies advertising literature (posters, leaflets etc.) in the secondary care setting for potential participants to read/take home. This may be in paper format or on display screens.

b) Handing leaflets directly to potential participants attending their hospitals/clinics.

c) One method of recruitment will be via the Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) Research Database (ethics ref. 17/EE/0442), which contains linked anonymous information derived from CPFT clinical records. The database will be queried to find patients that are likely to meet the study's eligibility criteria, yielding a list of research identification numbers. This list will be submitted to the CPFT Research Database Manager, who will enter them into an automated system that can identify the patients. For patients that consent (either having previously consented, or having given specific consent after being approached by their primary clinical team), and only those patients, the Research Database Manager will provide the patient's details to the research team, and authorize them to view the patient's CPFT clinical records and to contact the patient to discuss participation in the study. Study participation itself, or provision of any additional information, would require the patient's further consent. (The ethics-approved consent process for this system includes consent for researchers to see medical information, but for the present study, no medical details would be accessed.)

d) Similar approaches to enhance participation may be used in other participating NHS sites, where Trust approved 'Research contact' lists or methods to contact potential research participants have been established e.g. newsletters websites, social media

e) Approaching staff through approved Trust communications e.g. newsletters, websites social media, etc to offer participation.

Primary care/community care

a) Displaying the studies advertising literature (posters, leaflets etc.) in the primary/community care setting for potential participants to read/take home

b) Handing leaflets directly to potential participants using their services.

c) Search of GP records by those members of the direct care team with permission to do so

d) Using established service approved 'research contact' lists or methods to find potential research participants e.g. by newsletters, websites, social media

e) Approaching staff through approved communications e.g. newsletters, websites, social media etc to offer participation.

First approach may be by members of the research team. As this project is an online survey, the study team feel it is justified that members of the research team may approach patients directly and offer them the leaflet about the study, as most participants will complete this in their own time and will ultimately make the decision to take part or not away from the hospital/practice. Consent is 'self-completed' online and requires no input from clinical or research staff. Research staff will not be aware of who has taken part and will not be able to identify any participants. There is no follow up or other direct contact by research staff. We emphasize that because the eligibility criteria are so broad, recruitment does not require that the research team know the identity of the patient (even with face-to-face contact, e.g. at a stand or stall) and in no circumstances is knowledge of confidential patient information (e.g. medical details) required or desired by the research team.

Should participants wish, staff may offer participants use of local Trust/service approved devices to complete the survey, and staff may be on hand to deal with any queries the participants may have in this scenario.

Potential participants receiving the link to the survey can decide whether to access the survey or not. Participant information, giving more details about the survey and what is expected from the participants, is available once the participant has logged into the survey itself, in the form of an information sheet (See Appendix 1).

4.2 Informed Consent

Once logged onto the survey and having read the participant information sheet, informed consent will be obtained by a series of self-ticked boxes (See Appendix 2). These include confirmation/understanding on:

- Age
- How participants may withdraw at any time and what happens to any data given if they do

- That data given will be used for analysis and publication
- That participants will not be identified from the answers given
- That not everyone will see the same questions or definitions
- Whom to contact for questions or problems
- That they consent to take part in the survey

Only after all boxes have been ticked will the participant be able to commence the study (See Appendix 3).

It will not be possible for the study team to identify those taking part and therefore assess capacity for consent (nor monitor any fluctuations in capacity). However, as the study only involves filling in an online survey, no harm will be done to any of the participants who lack capacity, or who have fluctuations in capacity.

4.3 Study Assessments/Interventions

This is a single 20-25 minute survey. No interventions or treatments are scheduled

4.4 Definition of End of Study

The survey will close on the 31st May 2020 which will be defined as the end of the study. The survey will not be accessible after this date.

5. SAFETY REPORTING (IF APPLICABLE)

Not applicable.

6. STATISTICS

6.1 The Number of Participants

The study team aim for a power of 0.9 to detect three-group differences in quantitative variables with f = 0.1 (Cohen's "small" effect size), and therefore a total response rate of at least n = 1,269. Based on sites who have expressed interest, our total estimated sample size is 20,000.

6.2 Sampling

Study participants will be members of the public from the UK who wish to take part in the online survey. REDCap will be used to ensure balanced randomisation to the framing statements.

6.3 Analysis of Endpoints

The study team will collect data on people's preferences regarding data sharing using Likert-style scales, yielding interval/ordinal data on preferences (e.g. "very unlikely to share"/"strongly disagree" through to "very likely to share"). For part of the survey, the team will superimpose a randomised intervention, namely a framing statement, prior to seeking views relating to the sharing of mental versus physical health data. The framing statement will be one of three: a "security" framing emphasising previous work reporting others' greater concerns about sharing mental health data versus other kinds of health data; a "neutral" statement; and a "holistic" framing emphasising the interrelationship between mental and physical illness.

The team will examine the distribution of response data and anticipate using general linear modelling when its assumptions are satisfied (e.g. normally distributed residuals) [28] but non-parametric alternatives (e.g. Kruskall-Wallis H test) where they are not. They will use R [26] for statistical analysis. Predictors to be examined include age range, gender, ethnicity, self-reported educational level, geographical indicators (NHS region of respondent, index of multiple deprivation), personal experience of relevant NHS services/disorders, and experimental manipulation (framing).

Primary measures will be the self-reported overall degree of support for: (a) sharing physical health data for NHS clinical care without explicit consent each time, and how far such sharing should extend; (b) likewise for mental health data; (c) sharing de-identified structured physical health data for research without explicit consent, and how far such sharing should extend (e.g. NHS, academic, charities, industry, publicly); (d) likewise for mental health data; (e) as for (c) but with de-identified free text data; (f) as for (d) but with de-identified free text data.

Secondary measures will include (g) the effect of the framing interventions; (h) the degree of support for a single national sign-up mechanism for sharing one's health data for clinical care and/or research; (i) views on a prototype national NHS data sharing consent form; (j) views on trusted-third-party linkage between health data and a range of other UK state-held data sources (e.g. education, criminal justice).

7. ETHICAL AND REGULATORY COMPLIANCE

7.1 Data Protection and Patient Confidentiality

No mandatory personal data is being collected in the survey. However, participants have the option to leave an e-mail address (in order to receive the results of the study) and a further option to leave their postcode. The survey makes clear to participants this will not be used to identify them, but so that results can be analysed by geographic indicators, such as urban versus rural areas and the Index of Multiple Deprivation (IMD) or equivalent outside England.

Participants who choose to leave e-mail addresses will have these removed from the survey data once the survey is closed (but before analysis) and stored on password-protected computers at the University of Cambridge. Access to these e-mail addresses will be by the study team only and will only be used to send out results of the study. Once the initial results have been sent out, the participant will be asked if they would like further updates on the study (publications, abstracts, posters etc) or for their e-mail address to be deleted. Participants will be given 4 weeks to reply with their preference, including 1 reminder email, and if no further correspondence is received the e-mail address will be deleted. Once the likelihood of further results being available is minimal, those participants whose email addresses are still being held will be sent a final email informing them there will be no further results and that their e-mail address will be deleted.

At the same time (once the survey is closed but before analysis) any postcodes given will be converted to a Lower Layer Super Output Area (LSOA) code and the postcode will then be deleted, thus deidentifying all of the data. LSOAs are a geographic division designed to improve the reporting of small area statistics and have been automatically generated from Census data to be as consistent in population size as possible [25]. The minimum population is 1000 and the mean is 1500. Postcodes from Scotland and Northern Ireland will be converted to similar geographical areas (Data Zone in Scotland, Super Output Area in Northern Ireland)

and adjusted for IMD [29]. If the team are unable to identify an appropriate de-identifiable geographical area, the team will just delete the postcode.

All survey data (now deidentified) will be analysed on University of Cambridge password-protected computers. Once the analysis has been finished the fully de-identified data will be available to the public as per the Concordat on Open Research Data [27].

All investigators and study personnel will comply with the requirements of the Data Protection Act [3] with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The Chief Investigator of the study will act as custodian of the data.

7.2 Indemnity

The trial is jointly sponsored by the Cambridge and Peterborough NHS Foundation Trust (CPFT) and the University of Cambridge.

CPFT will accept full financial liability for harm caused to participants in the clinical trial caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the trial, where no-one has acted negligently.

The University of Cambridge is providing insurance for the study. The University Insurance Manager has advised that insurance for negligent and non-negligent harm under the University's Clinical Trials policy has been arranged. The University's insurers are xxxxx, the insurance policy reference is xxxxx and the Limit of Indemnity under the policy is xxx

8 DISSEMINATION POLICY

The data generated from the survey will be owned by the Chief Investigator for the study. On completion of the study the data will be analysed, and a final study report will be prepared. The study report (and associated documents) will be accessible on the CLIMB project teams website (www.climbproject.org.uk) and the University of Cambridge, Department of

Psychiatry web pages (https://www.psychiatry.cam.ac.uk/) . Findings will also be published in journals and at meetings and conferences.

The study team will share the results of the survey with a team at Edinburgh University, who were also successful in being awarded MRC Mental Health Data Pathfinder funding. The Edinburgh team are planning a related but non-overlapping survey on NHS use and health data, and it is hoped that both survey results can be combined to produce some recommendations about sharing health data across the UK.

Participants who choose to leave an e-mail address will be sent a copy of the final report as discussed in the information sheet for the study. Full details of how the study team will do this are in section 7.1 of this protocol. Participants also have the option to receive a copy of any further papers etc. after the results have been published. It is made clear in the information sheet where results can be found for those who do not wish to leave an e-mail address.

The study team will acknowledge the following in their publications: MRC (funders of the mental health data pathfinder award), NIHR. The study team are affiliated to the University of Cambridge and to CPFT.

Once the analysis has been finished the fully de-identified data will be available to the public as per the Concordat on Open Research Data [27] through the University of Cambridge Research Data Repository (https://www.data.cam.ac.uk/repository). This is made clear to participants in the information sheet at the start of the consent survey.

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10 Appendices

Appendix 1

Invitation letter at start of survey

What am I being invited to do?

You are being invited to take part in an online survey about the UK’s views on sharing National Health Service (NHS) (or Health and Social Care in Northern Ireland) health data, for both clinical and research purposes. This survey is open to anyone living in the UK over 16 years of age (or under 16 with parental permission).

What will taking part involve?

If you agree to take part, after filling in a consent form, you will be asked a series of questions about your views on sharing your NHS/HSC health data for both clinical and research purposes. By ‘health data’ we mean any information collected about a person’s health including things like medical notes, blood test results, prescription information etc. collected by an appropriate health care professional. As well as asking about sharing health data, we will also ask you some questions about your physical and mental health and any health services you may have used, as well as some questions about you, for example your age and gender. The survey does not ask for any identifiable personal information, and at any time you may click the prefer not to answer box if you wish.

The survey has been tested and will take approximately 18-25 minutes to complete. The survey does not need to be completed at one sitting.

Your answers won't affect the way your own health information is managed.

What are the benefits or disadvantages of taking part in the survey?

There are no direct benefits or disadvantages to taking part in this survey nor are there any payments. However, the study team hopes the results of this survey can be used to inform and improve the way the NHS/HSC manage data for clinical and research purposes.

Do I have to take part?

No, taking part in this survey is entirely up to you. The consent form at the start of the survey asks for your permission to use your data, even if you decide not to complete all of the survey. Unfortunately, once data has been submitted it will not be possible for the study team to find and delete your answers as we are not asking for any personal details, making it impossible for us to retrieve and delete your individual answers.

How will the information I give be kept confidential?

No information that can identify you is being collected in this study. There is an option to leave an email address, should you wish to personally receive the results of the survey. Email addresses will be removed from the survey responses and stored on password protected computers at the University of Cambridge. Access to these email addresses will be by the study team only and will only be used to send you the final results of the survey. Once you have received the results you will be asked if you would like any further updates, for example any publications or posters that arise from the results of the study. If you decide you do not want any further information, we will delete your email address. If you would like further updates, we will keep your email address securely until we have sent you the final publications from the study, at which time point your email address will then be deleted from our records.

There is also an option to leave your postcode (or not) in the survey. The study team would like to look at whether there are any effects of geographical area on answers to the survey. Once the survey has closed the study team will convert all postcodes to a nationally available ‘code’ of the area you live in, and then delete your postcode. By doing this it will never be possible to identify you or the road that you live in, as one code is given to multiple postcodes in the same area. Whether or not you agree to give us your post code is entirely up to you.

Once the study team have finished using the anonymised data, they will make it freely available for public use via the University of Cambridge Research Data Repository (https://www.data.cam.ac.uk/repository). Please be assured, as in the information above that any email addresses or postcodes given will have been deleted before this happens. There will be no way that anyone will be able to identify you from the data, but we hope that others may use the data to further understand the sharing of health data with the aim to improve mental and physical health.

Who is conducting this survey?

This survey is being conducted by the CLIMB project study team based at the University of Cambridge in conjunction with a patient and public research advisory group. Funding for the study team is from the Medical Research Councils (MRC) mental health data Pathfinder awards.

Who has reviewed this study?

This study has been reviewed and given a favourable opinion by members of the xxx Research Ethics Committee

Where can I find the results of this survey?

Once the study has concluded and the results have been analysed, a report will be made available. If you have chosen to leave an email address this report will be sent directly to you. Results will also be published on the following websites: https://www.climbproject.org.uk/ and www.psychiatry.cam.ac.uk/ . You may like to note these down now before you move on or, alternatively, they will be displayed again at the end of the survey.

What if I have any concerns about this study?

The study team can be contacted in the following ways:

Mrs Linda Jones

Email: laj28@cam.ac.uk

Telephone (01223) 764670

Further contact details are available at: https://www.climbproject.org.uk/

Appendix 2

Copy of consent at start of survey.

(Note: Participants will not be able to access the survey unless all statements are ticked.)

Thank you very much for reading the information sheet about the survey. If you would now like to take part in the survey, please read the following statements and tick the boxes to show that you agree.

- I confirm I am aged 16 or over, or I am under 16 years of age but have the consent of my parent/guardian.
- I confirm that I am a resident of the UK.
- I understand I may quit the survey at any time but any data I have provided may still be used.
- I understand that the answers I give will be used for analysis and publication.
- I understand my data will be recorded such that I cannot be identified from the answers I give.
- I understand that not everyone will see the same questions or definitions.
- If I have any problems or questions with the survey, I understand I can contact Linda Jones, e-mail: laj28@cam.ac.uk, telephone: 01223 764670
- I consent to take part in this survey.

Appendix 3

Survey

The live survey can be found at:

https://www.redcap-ide-cam.org.uk/surveys/?s=NKTYE8JHCT

or accessed through the project team's website: https://www.climbproject.org.uk/

Actual Survey

Before starting we would like to know where you heard about our study. This is particularly important if you were given information by a GP practice, Hospital or other member of staff. You may prefer not to say if you wish.

- Prefer not to say
- GP (via a poster, leaflet, or from a staff member) [If ticked an option to include GP surgery name will appear]
- Hospital (via a poster, leaflet, or from a staff member) [If ticked an option to include a hospital trust will appear]
- Another health care professional
- Group to which I belong
- Charity website/email/newsletter etc.
- Social media
- Poster (other than at your GP or hospital)
- Browsing the internet
- Friend
- Not sure
- Other (Please specify)

Please read the following definitions:

- **By "NHS" we mean all parts of the national health service in the UK: NHS England, NHS Scotland, NHS Wales, and Health and Social Care in Northern Ireland (HSC) and referred to as NHS in this survey**
- **Health data means any information about a person's health such as might be collected by a nurse, doctor or other appropriate member of NHS staff. Health data includes things like your medical notes, blood test results, prescription information, scans etc.**
- **Identifiable health data means any health data (as described above) that can also identify a person e.g. any health data that also contains names, addresses, NHS numbers etc.**

- **Clinical care means providing health care directly to people, for example, diagnosing illnesses or treating ill health**

Q1.

We would like to know/gauge your understanding of how NHS clinical care providers currently share your identifiable health data for your clinical care, without asking you each time. If you are not sure, please have a 'best guess' as to what you think might happen.

My understanding is that (please tick only one):

- My identifiable health data is currently shared freely between all NHS sites across the UK-- i.e. all acute hospital Trusts, my GP, all mental health Trusts, ambulance service etc. in the whole UK
- My identifiable health data is currently shared between all NHS sites but only in the home nation that I live in -- i.e. shared only in England, or Scotland, or Northern Ireland, or Wales, but not between them
- My identifiable health data is currently only shared between all NHS sites in my region (cluster of hospitals nearest to your local hospital)
- My identifiable health data is currently only shared between my GP, acute local hospital, local mental health Trust and other local services
- My identifiable health data is currently not shared between any NHS sites

Q2.

MOST hospital Trusts, GPs, mental health Trusts are separate and currently DO NOT share identifiable health data without asking you, though they correspond and communicate with each other with your permission.

In view of the statement above, we would now like to ask you your views on sharing your own identifiable health data for YOUR CLINICAL CARE, without having to be asked each time (please tick only one):

- I would like my identifiable health data to be shared for clinical purposes with any part of the NHS in the UK, without asking me first
- I would like my identifiable health data to be shared for clinical purposes with any part of the NHS in my home nation only (i.e. only in England, or only in Northern Ireland, or only in Scotland, or only in Wales) without asking me first
- I would like my identifiable health data to be shared for clinical purposes with any part of my region (cluster of hospitals nearest to your local hospital), without asking me first
- I would like my identifiable health data to be shared for clinical purposes only with my GP, local hospital, and local mental health services, without asking me first
- No one in the NHS should share my identifiable health data without asking me first
- Not sure

We would now like to ask you some questions about your own PHYSICAL and MENTAL health. You can 'prefer not to say' if you wish.

Q3

We would like to ask if you have had a mental health condition either recently or at some point in your life. By mental health conditions we include things like delirium, self-harm, substance abuse, dementia, mania, schizophrenia, depression, anxiety disorders, psychosis, eating disorders, OCD, personality disorders, etc.

- I prefer not to say [Will take you straight to Q4]
- Yes, I have had a mental health condition either recently or at some point in my lifetime
- No, I have never had a mental health condition [Will take you straight to Q4)

Q3a

We would like to know if you would be willing to share what mental health condition you have had. You may tick as many boxes as you wish.

If you prefer not to say, please use the "next page" button below to move on.

Condition	Recently (in the last 5 years)	More than 5 years ago
Delirium		
Alcohol or substance abuse		
Schizophrenia, schizoaffective disorder, or delusional disorder		
Dementia		
Mania or bipolar affective disorder		
Depression		
Anxiety disorder (e.g. phobia, panic, generalized anxiety disorder, post-traumatic stress disorder)		
Psychosis of any cause		
Eating disorder (e.g. anorexia nervosa, bulimia)		
Obsessive-compulsive disorder		
Personality disorder		
Self harm		
Other (Please specify)		

Q3b

And also, in relation to mental health. We would also like to know if you have accessed any mental health services for your own mental health condition. These might include your GP, online services, mental health forums, psychological therapy services, crisis care, home treatments or visits, outpatient or inpatient care, services from the private sector, support from a mental health charity, etc.

- I prefer not to say [Will take you straight to Q4]
- I have used mental health services
- I have not used any mental health services (not even my GP or surgery) for my mental health condition [Will take you straight to Q4]

Q3c

We would like to know if you would be willing to share what mental health services you have used for your own mental health condition. You may tick as many boxes as you wish.

Please use the 'next page' button if you prefer not to answer.

Services used	Recently (in the last 5 years)	More than 5 years ago
Mental health support from your GP or surgery		
An NHS psychological therapy service, e.g. IAPT or other therapy service (INDIVIDUAL session)		
An NHS psychological therapy service, e.g. IAPT or other therapy service (GROUP session)		
An NHS psychological therapy service, e.g. IAPT or other therapy service (ONLINE)		
NHS outpatient or community mental health services, or key worker		
NHS crisis care/Home Treatment teams		
NHS inpatient mental health services in a mental health hospital		
NHS inpatient mental health services in a general hospital (liaison psychiatry)		
Private services		
Services in the workplace e.g. Occupational Health		
Charity providing mental health support		
Online forum		
Other (Please specify)		

Q4

We are also interested to know if you have accessed any services regarding your own physical health. This could be services like your GP, outpatient hospital appointments, inpatient services, online support, Accident and Emergency, 111 service, private services, charities providing physical health support, etc.

Have you ever used any of the following services for your own physical health?

- I prefer not to say [Will take you straight to Q5]
- I have used physical health services (this includes using your GP)
- I have not used any physical health services [Will take you straight to Q5]

Q4a

And finally, in this section, we would like to know if you would be willing to share what physical health services you have used for your own physical health. You may tick as many boxes as you wish.

Please use the 'next page' button if you prefer not to answer.

Services used	Recently (in the last 5 years)	More than 5 years ago
Physical health support from your GP or surgery		
NHS hospital outpatient services (outpatient clinics etc.)		
NHS Urgent Care Centre (not A&E) or NHS 111 helpline		
NHS Accident and Emergency services (A&E)		
NHS inpatient services (procedures not completed in 1 day)		
NHS Day Surgery/day care in a hospital		
Private services		
Services in the workplace e.g. Occupational Health		

Charity providing mental health support		
Online forum		
Other (Please specify)		

Moving on…

The table below shows what NHS identifiable health data may look like. This sort of data is used for health care by NHS staff. (Please note the examples shown are not real).

NHS number	Title	Forename	Surname	Date of birth	Address	Diagnoses	Notes
9876543210	Mr	John	Smith	20 Jan 1950	1 The Street, Maidstone	pneumonia high blood pressure	1 Apr 2019. Seen in clinic. Mr Smith has a fever and a cough. His chest sounds crackly. I think he has pneumonia. Sent to hospital.
8765432109	Miss	Alice	Jones	16 Jun 1994	15 The Road, Dundee	depression carpal tunnel syndrome	2 Apr 2019. Alice's rates her mood as 1/10 on average, she is more tired, and she is not looking forward to anything. Her depression has worsened. She wishes to restart citalopram.
7654321098	Mrs	Chloe	Williams	4 May 1930	5 Tree Close, Cardiff	broken humerus anxiety	3 Apr 2019. Chloe fell after skidding on an oily patch while cycling and was hit by a car. Has an obvious fracture of her left upper arm. Needs X-ray.
6543210987	Mr	Pradeep	Agarwal	22 Sep 1973	27 The Mews, London	schizophrenia diabetes	4 Apr 2019. Pradeep still worries that other people can hear his thoughts, but this is getting less common. He is attending cognitive–behavioural therapy sessions.

[Participants will now randomised to see one of the following three framing questions]

Previous surveys have found that people have more concerns about the use of their identifiable health data relating to their mental health than other aspects of their physical health care.

or

We would like to find out your perspective on using information about your mental health and your physical health.

or

Mental and physical illnesses overlap, so holistic health care is important. Mental health problems have physical consequences, and physical illnesses have important consequences for mental health.

Q5

Regardless of whether you have a physical health condition or have used physical health services:

How likely are you to agree to share your identifiable PHYSICAL health data for your clinical care with the following, without being asked every time?

Sharing Physical Health Data	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Between my local NHS services -- i.e. between my local physical and mental health hospitals, my GP, etc.						
Any part of the NHS in my region (cluster of hospitals nearest to my local hospital)						
Any part of the NHS in my home nation only (i.e. only in England, or only in Northern Ireland, or only in Scotland, or only in Wales)						
Any part of the NHS in the UK						

Q6

Regardless of whether you have a mental health condition or have used mental health services:

How likely are you to agree to share your identifiable MENTAL health data for your clinical care with the following, without being asked every time?

Sharing Mental Health Data	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Between my local NHS services -- i.e. between my local physical and mental health hospitals, my GP, etc.						
Any part of the NHS in my region (cluster of hospitals nearest to my local hospital)						
Any part of the NHS in my home nation only (i.e. only in England, or only in Northern Ireland, or only in Scotland, or only in Wales)						
Any part of the NHS in the UK						

In the next two questions we would like to ask you about sharing your NHS data for research purposes. Research is used to improve overall healthcare for everyone.

Firstly, please look at some of the NHS health care data that you saw previously, which has now been de-identified.

Research ID	Age	Sex	Region	Diagnoses
5X62V	69	M	Kent	pneumonia high blood pressure
597PT	24	F	Dundee	depression carpal tunnel syndrome
8HG7S	89	F	Glamorganshire	broken humerus anxiety
BA6A9	45	M	London	schizophrenia diabetes

This type of data is often used for health research. The data still relates to individual people, but information that can identify a person has been removed. The data must still be kept securely, as it still contains details about an individual.

Q7

How likely would you be to share your de-identified PHYSICAL health data with the following, without giving consent every time:

Physical health	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Any part of the NHS doing research						
Academic institutions doing research (e.g. universities)						
A national charity doing research (e.g. MIND, Cancer Research UK, British Heart Foundation)						
A profit-making company doing research into treatments (e.g. a pharmaceutical company, health technology company)						
A profit-making company doing other research (e.g. an insurance company, broadband provider)						
Publicly						

Q8

How likely would you be to share your de-identified MENTAL health data with the following, without giving consent every time:

Mental Health	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Any part of the NHS doing research						
Academic institutions doing research (e.g. universities)						
A national charity doing research (e.g. MIND, Cancer Research UK, British Heart Foundation)						
A profit-making company doing research into treatments (e.g. a pharmaceutical company, health technology company)						
A profit-making company doing other research (e.g. an insurance company, broadband provider)						
Publicly						

The final question in this section relates to sharing de-identified "free text" data for research.

Here is the table of de-identified health care data you saw earlier, but this time a column labelled "Notes" has been added. This is known as "free text" data.

Research ID	Age	Sex	Region	Diagnoses	Notes
5X62V	69	M	Kent	pneumonia high blood pressure	1st April 2019. XXX has a fever and cough. His chest sounds crackly. I think he has pneumonia. Sent to hospital.
597PT	24	F	Dundee	depression carpal tunnel syndrome	2nd April 2019. XXX rates her mood as 1/10 on average, she is more tired, and she is not looking forward to anything. Her depression has worsened. She wishes to restart citalopram.
8HG7S	89	F	Glamorganshire	broken humerus anxiety	3rd April 2019. XXX fell after skidding on an oily patch while cycling and was hit by a car. She has an obvious fracture of her left upper arm. She needs an X-ray.
BA6A9	45	M	London	schizophrenia diabetes	4th April 2019. XXX still worries that other people can hear his thoughts, but this is getting less common. He is attending cognitive-behavioural therapy sessions.

Like the last example the data remains de-identified but gives the researchers more information. As there is more information there is a slightly increased risk of someone being identified from the data.

For example, in the table above, an "89-year-old cyclist skidding on oil and being hit by a car" may be reported in a local newspaper. Whilst the lady is not named in the data above, she would almost certainly be named in the newspaper and it may therefore be possible for researchers to work out who she is.

Q9

How likely would you be to share your FREE TEXT de-identified PHYSICAL health data with the following, without giving consent every time:

Physical Health	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Any part of the NHS doing research						
Academic institutions doing research (e.g. universities)						
A national charity doing research (e.g. MIND, Cancer Research UK, British Heart Foundation)						
A profit-making company doing research into treatments (e.g. a pharmaceutical company, health technology company)						
A profit-making company doing other research (e.g. an insurance company, broadband provider)						
Publicly						

Q10

How likely would you be to share your FREE TEXT de-identified MENTAL health data with the following, without giving consent every time:

Mental Health	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Any part of the NHS doing research						
Academic institutions doing research (e.g. universities)						
A national charity doing research (e.g. MIND, Cancer Research UK, British Heart Foundation)						
A profit-making company doing research into treatments (e.g. a pharmaceutical company, health technology company)						
A profit-making company doing other research (e.g. an insurance company, broadband provider)						
Publicly						

On a slightly different topic….

Imagine that there was a single place where you could securely sign up to choose how your NHS identifiable health data is used.

This would cover how your confidential patient information is managed across all UK NHS services, and how your NHS de-identified data could (or could not) be used for research.

It would be in the form of a standardised UK-wide CONSENT FORM that all NHS services could use.

Q11

How likely would you be to sign up if you were asked to sign:

	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Online (via a website)						
By downloading an app (e.g. the NHS App)						
On paper forms available from pharmacies, the Post Office, etc. (and sent by post)						
In person (e.g. when attending your GP, at a hospital clinic, etc.)						

Q12

Would you be likely to sign up if your consent form were then stored and managed securely by the following institutions?

	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Centrally by NHS England/NHS Scotland/NHS Wales/HSC Northern Ireland						
Your local NHS Trust						
Your GP						

Q13

If you wanted to change your preferences, how likely would you be to use the following methods?

	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Online (via a website)						
By downloading an app (e.g. the NHS App)						
On paper forms available from pharmacies, the Post Office, etc. (and sent by post)						
In person (e.g. when attending your GP, at a hospital clinic, etc.)						

Q14 Assume that you were able to sign up and change your choices in a way you preferred, and that the consent form was stored securely in a place where you felt comfortable.

How likely would you be to use this system to choose how your NHS health data is managed?

	Very Likely	Likely	Not Sure	Unlikely	Very Unlikely	Prefer not to say
Overall likelihood that you would sign up						

The last part of the survey (before we ask a few questions to ensure we have reached a broad section of the UK) examines what a consent form to share our health data could look like. By completing one consent form it would then be possible for all UK NHS professionals to access their patient's identifiable health data for their clinical care, saving time for both patients and health care professionals.

Please take a look at the consent form below:

National NHS/HSC data sharing consent form

Health and Social Care

Full name ______________________________
Date of birth _______________
NHS number ______________________________
Address ____
____
E-mail address ______________________________

I confirm I have read the information sheet 'Sharing My Health Data' version XXX dated XXX. I have had the opportunity to consider the information and ask questions. I understand that my participation is voluntary, and that I am free to change or withdraw my consent at any time, without giving a reason and without my medical care or rights being affected. Yes [ ]

1. Providing health care to you

Confidential patient information is information that can identify you and that says something about your health care or treatment. Information about you might be held by several NHS organizations (such as GP surgeries and hospitals). May they share your information with each other when providing health care to you?

I agree that all NHS care providers and professionals may share my confidential patient information with each other for the purpose of my treatment and care. Yes [ ] No [ ]

2. Using your de-identified data to help others

The NHS promises to **anonymise** the information collected during the course of your treatment and use it to support research and improve care for others. Research is conducted by the NHS and by NHS-approved researchers in organizations such as universities. Strict security controls apply to the use of NHS data, even after information that might identify you (such as names and addresses) has been removed. All research involving NHS data must be approved by the NHS.

Saying no doesn't prevent all uses of your confidential information for research. To do that, use the national data opt-out at https://www.nhs.uk/your-nhs-data-matters.

I agree that all NHS care providers may share my confidential patient information with each other and de-identify it for the purpose of research. Yes [ ] No [ ]

3. Taking part in research

Some research involves **direct participation.** This ranges from questionnaires to trials of new treatments. The NHS promises to inform you of research studies in which you may be eligible to participate. There is never a commitment to take part.

I agree that NHS-approved researchers may learn my identity and contact me directly about research studies for which I may be eligible. Yes [ ] No [ ]

Signature: ______________________________

Date: _______________

Q15

Having looked at the consent form, please agree or disagree with the following statements.

(If you would like to take another look at the consent form at any time while answering this question, you can use the 'previous' button at the bottom of this page to look back. This will not affect answers already given.)

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Prefer not to say
The consent form is easy to read.						
The consent form is clear and easy to understand.						
The statements (in blue) help me to understand what I am consenting to.						
The consent form is clear that my identifiable health data would only be used by appropriate NHS health care professionals.						
I understand the term 'NHS-approved researchers' and which individuals this may refer to.						
The consent form makes clear that it would be used for my preferences about sharing my IDENTIFIABLE health data within the NHS for my CLINICAL CARE.						
The consent form makes clear that it would also be used for my preferences about sharing my DE-IDENTIFIED health data for RESEARCH purposes.						
I would like the consent form to give specific options about how researchers can contact me (e.g. by post only, e-mail).						
I would like to see a statement added about the security of data sharing.						
I would like to see a statement added about where my consent preferences will be stored.						
Before seeing this consent form, I was aware of the NHS National Data Opt-Out.						
The consent form reassures me that my identifiable health data is safe in the NHS.						
If this consent form were put in front of me today, I would sign it.						

If you would like to make any comments about the consent form, please do so here:

There are currently many individual websites where people can sign up to take part in research. Examples include charity websites, the national "Join Dementia Research" register, and the National Institute for Health Research (NIHR) "be part of research" campaign.

Q16

An alternative might be a national sign-up portal, on a web site, where people could register their preferences about taking part in all NHS research.

Choose the statement you agree with most:

- Everything is fine as it is; leave it to individuals to sign up with the various organisations.
- Have two national NHS research websites, one where people can sign up for mental health research, and a second website where people can sign up for physical health research.
- Have a national NHS research website where people can sign up for all conditions.
- Not sure.

Q17

Finally, it can be very valuable for research to link health (NHS) data to other data sources.

For example, causes of death (from death certificates) are held by the UK Office of National Statistics (ONS), rather than the NHS -- so to find out more about the reasons people die, NHS and ONS data must be linked.

Usually, this is done as follows:

a) Research teams seek special permission for the process.

b) The relevant information from each organization, plus a small amount of identifiable information, is given to a "trusted third party" (e.g. an NHS Trust, the Office of National Statistics).

c) The trusted third party links the information, then removes any details that can identify anyone.

d) Researchers are then given access to the de-identified information only, under special controls.

We are interested to hear whether you would be happy for your health data to be linked, in this way, to:

	Yes	Not sure	No	Prefer not to say
Educational data (e.g. to study impact of illness on education)				
Police/Criminal Justice data (e.g. to study health in the victims of crime)				
Transport/DVLA data (e.g. to study health and pollution)				
Housing data (e.g. impact of social housing on health)				
Immigration data (e.g. health in immigrants)				
Social security/Work and Pensions (e.g. to study health and financial insecurity)				

Data held about you for research by universities (e.g. if you have volunteered for research studies)				
Data held about you by private companies				

Demographics

And finally, to ensure we have surveyed a wide range of the population (please note, all questions have a "prefer not to say" option and have been written to apply to all of the home nations):

Do you consider yourself to be:
- Prefer not to say
- Female
- Male
- Prefer to self-describe (please specify)

May we know which age range you fit in?
- Prefer not to say
- Under 12
- 12-17
- 18-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65-74
- 75-84
- 85+

What do you consider your ethnicity to be?
- Prefer not to say
- White
- Irish Traveller
- Mixed/Multiple ethnic groups
- Asian or Asian British
- Indian
- Pakistani
- Bangladeshi
- Chinese
- Black/African/Caribbean/Black British
- Arab
- Other ethnic group or prefer to self-describe (please specify)

What is the highest qualification you have achieved?
- Prefer not to say

- No formal qualifications
- Secondary school level qualifications e.g. CSE, GCSE, O-Levels, Nationals, or equivalent
- A-Levels, Highers, or equivalent
- Vocational qualification or equivalent
- Undergraduate degree or equivalent
- Postgraduate or professional qualification or equivalent

Do you consider yourself to be

- Prefer not to say
- Heterosexual (straight)
- Homosexual (gay or lesbian)
- Bisexual
- Other or prefer to self-describe (Please specify)

What is your religion if any?

- Prefer not to say
- No religion
- Christian
- Muslim
- Hindu
- Sikh
- Jewish
- Buddhist
- Other or prefer to self-describe (Please specify)

Thinking about your current (or last) main job or occupation. Do (did) you work as an employee or are (were) you self-employed?

- Prefer not to say [If ticked will automatically move to question about where you live]
- Never worked [If ticked will automatically move to question about where you live]
- Employee [If ticked will move to how many people work for your employer question]
- Self-employed with employees [If ticked will move to how many people you employ]
- Self-employed/freelance without employees [If ticked will move to question about description of work]

How many people work (worked) for your employer at the place where you work (worked)?

- Prefer not to say [If ticked will automatically move to question about where you live]
- 1-24 [If ticked will move to question about supervisory role]
- 25 or more [If ticked will move to question about supervisory role]

How many people do (did) you employ?

- Prefer not to say [If ticked will automatically move to question about where you live]
- 1-24
- 25 or more

Do (did) you supervise any other employees on a day to day basis?

- Prefer not to say [If ticked will automatically move to question about where you live]

- Yes
- No

And which best describes the work you do (did)?

- Prefer not to say
- Modern professional occupations such as: teacher - nurse - physiotherapist - social worker - welfare officer - artist - musician - police office (sergeant or above) - software designer
- Clerical and intermediate occupations such as: secretary - personal assistant - clerical worker - office clerk - call centre agent - nursing auxiliary - nursery nurse
- Senior managers or administrators (responsible for planning, organising, and co-coordinating work and for finance) such as: finance manager - chief executive
- Technical and craft occupations such as: motor mechanic - fitter - inspector - plumber - printer - tool maker - electrician - gardener - train driver
- Semi-routine manual and service occupations such as: postal worker - machine operative - security guard - caretaker - farm worker - catering assistant - receptionist - sales assistant
- Routine manual and service occupations such as: HGV driver - van driver - cleaner - porter - packer - sewing machinist - messenger - labourer - waiter/waitress - bar staff
- Middle or junior managers such as: office manager - retail manager - bank manager - restaurant manager - warehouse manager - publican
- Traditional professional occupations such as: accountant - solicitor - medical practitioner - scientist - civil/mechanical engineer

And where in the UK do you currently live?

- Prefer not to say
- England
- Northern Ireland
- Scotland
- Wales
- Channel Islands
- Isle of Man
- None of these

[If England ticked the following further options appear:
Prefer not to say, North East, North West, Yorkshire and Humber, West Midlands
East Midlands, East of England, London, South East, South West, Other (Please specify)]

[If Scotland ticked the following further options appear:
Prefer not to say, North Scotland, North East Scotland, East Scotland, West Scotland, South Scotland, Other (Please specify)]

We would like to know your postcode so that we can analyse our results by "geography", such as urban versus rural areas. You do not have to give this. However, if you do, we will never disclose it or identify you from it.

- I prefer not to give my postcode
- I am happy to give my postcode [If ticked box provided to type in postcode]

Before you submit your answers there is the option to leave an e-mail address should you wish to have the final report of the survey results personally e-mailed to you.

Please note: all e-mail addresses will be removed from the survey answers so that you cannot be identified and will be held securely on password-protected computers at the University of Cambridge until the results are available, as described in the information sheet at the start of the survey.

If you wish to leave an e-mail address, please do so in the box below and then submit your answers. Otherwise, please submit your answers now.

Optional
____

[Once submitted the following statement appears]

What happens next?

Once the survey has closed the results will be analysed by members of the CLIMB project team, colleagues at the University of Cambridge and their partners.

The study team hope the results of this survey can be used to inform and improve the way the NHS/HSC manage data for clinical and research purposes. Once a final report has been written it will be published on the research teams' websites at the following addresses:

https://www.climbproject.org.uk/ and https://www.psychiatry.cam.ac.uk/

You may wish to write these down. If you have left an email address the study team will email you with the results when they are available.

Thank you very much for taking part in this survey. We really appreciate your time.