British Heart Foundation

Clear and present data: how access to our medical records can help life-saving science

June 2012

Foreword

The NHS, by holding medical records for all of us from cradle to grave, has routinely collected data that has a vital role to play in the future health of the nation. Our medical records save lives. From aiding in the recruitment of patients for clinical trials, to large observational studies, our NHS records are a unique source of information.

Large cohort-based studies following specific patients across the decades helped researchers to establish the links between diet, lifestyle and heart disease. Had Sir Richard Doll been able to access a wide range of patient records he would have very quickly noticed that those who developed lung cancer and heart attacks were predominantly smokers and the dangers of smoking would have been recognised years earlier.

Such a resource of medical records as provided by the NHS is not available anywhere else in the world. We are therefore ideally placed in the UK to use the information in our records to make breakthroughs, not only for cardiovascular disease, but for all diseases both common and rare.

The UK needs to be doing much more to unlock the potential offered by patient data. Future discoveries will only be possible by providing an environment that safeguards the interests of patients while enabling suitable access to data for researchers.

From new discoveries about how the heart develops in the womb, to developing the treatments that could mend broken hearts in the future, the BHF is the single biggest independent funder of cardiovascular research in the UK – funding around £100 million each year. We asked some of the researchers we fund who rely on access to patient data for their experiences.[1] The results, including their thoughts on the processes involved in securing access to patient data, are presented in this report.

Our researchers highlight an overly complex system of regulation and governance relating to use of patient data that is restricting developments in medical research. The legal framework remains unclear, confounded by approval processes that see researchers seeking the same approval from numerous bodies – causing delays to major projects that can last years. This not only adds to the financial costs of grants, but there is also a resultant social cost, as the fruits of this research are being held back from enabling life-saving changes to patient care.

The UK Government has a number of opportunities to improve the situation. The single health research regulator launched last year, the Health Research Authority, provides a starting point to help speed up the process. Moves to amend relevant European legislation and the NHS Constitution also offer further vehicles to improve access to patient data. We recommend in this report that the UK Government:

- ensures the new European legislation on data protection enables greater clarity for patient data use in research and is proportionate to patient risk
- eliminates the duplication of approvals for patient data use, helping to streamline the current governance
- provides a clear legal framework for accessing patient data for research
- amends the NHS Constitution to introduce an opt out system for the use of anonymised patient data in research
- replaces the system of Caldicott Guardians with one of centralised approval, and
- brings the system of NHS Research and Development permissions within the Health Research Authority.

These changes would have an enormous impact on medical research – reducing many of the burdens on researchers, and enabling faster discoveries. This would not only support economic growth, but bring significant benefits to the 5 million people in the UK living with cardiovascular disease. The research community has for many years called for access to patient data to be improved – there is no better opportunity than now to ensure a safe environment with the interests of patients and researchers at the core.

Peter Weissberg
Medical Director

1 Online survey conducted by the British Heart Foundation in May 2012, responded to by 72 researchers that receive BHF funding.

Introduction

Medical research is an essential function of the NHS, necessary for the development of new treatments and to better understand how to prevent disease. It is a relationship that enriches the work of both researchers and the NHS – the medical research community benefits from the resources available through the NHS, which in turn benefits by being able to provide more effective care, and therefore better results for patients.

Every time someone uses the NHS, for example by visiting a local GP or if treated in hospital, a record of that interaction is created. The recording of health data starts at birth, and continues throughout a patient's lifetime, creating a medical history for each individual. Technological advances in the NHS are helping to make these records accessible to healthcare professionals electronically.

These records provide useful data that researchers can use in a variety of different ways, from evaluating current healthcare interventions to looking at links between disease and someone's lifestyle. Without data from a large pool of people it can be difficult for findings of this nature to emerge. The NHS holds the medical records for the largest single patient pool in the world and therefore potentially provides researchers in the UK with an invaluable resource for research.

Medical records held by the NHS do, however, contain personal information – some of which may be sensitive for some individuals. Confidentiality of these data is therefore of paramount importance to ensure the public is confident that their data will not be misused, and safeguards are in place to prevent disclosure of confidential information.

For more than fifty years, donations from our supporters have enabled scientists to study heart and circulatory diseases. This research has contributed to life-saving medical advances that benefit those people today living with cardiovascular disease. The public is supportive of charities funding medical research, with public polling showing overwhelming support for the NHS supporting medical research into new treatments.[2]

This report:

- explains the different types of patient data used in research
- outlines some of the breakthroughs in cardiovascular research that patient data have made possible
- details the legal framework for use of patient data
- describes the barriers to access faced by BHF-funded researchers
- makes recommendations for ensuring researchers can better access patient data.

Patient data in cardiovascular research

Each person that uses the NHS in the UK will have a medical record that contains basic personal information (such as name, date of birth, age), alongside their medical history. This information will potentially be held by different parts of the NHS at any given time, depending on which services they have used.

Medical researchers can use the patient data held within these records in a number of different ways to ultimately benefit patients.

- **Epidemiological research** – observational studies that identify links between types of disease and characteristics of the patient group (for example, levels of cholesterol). This type of research normally needs data from a large number of patients in order to establish any causal links, with longitudinal studies looking at data across a number of years.
- **Healthcare audit** – routine assessments of data in order to check standards and quality of care.
- **Pharmacovigilance** – monitoring the safety and efficacy of drugs or devices used in healthcare.
- **Clinical trials** – assessments of new drugs or treatments that require the participation of patient volunteers.

The degree of patient participation will differ depending on the type of research being carried out. An audit of healthcare, whereby data in existing patient records are analysed, would not normally require patients to be directly involved. An observational study may need to involve the patient directly depending on the type of data used. A clinical trial will require direct patient participation.

2 Ipsos MORI poll commissioned by the Association of Medical Research Charities, Breast Cancer Campaign and the British Heart Foundation; 2011. Available at: http://www.amrc.org.uk/news_2011_uk-public-want-nhs-to-support-research

Types of patient data used in research

- *Anonymised data – the information contained cannot identify the original patient record that the data come from. All identifiable information has been removed.*
- *Key-coded data – identifiable information is encrypted, and is in essence anonymised for the research team involved. A key to the code is held by a custodian, who can reconnect the data to the patient via the decoding key.*
- *Identifiable data – information such as a patient's name, address and NHS number are included.*

Where possible, all data used in research are anonymised data. However, in some instances there is a need for researchers to be able to link data back to the original patient record.

Removing all identifiable information may be impractical for certain types of research. For example, researchers conducting clinical trials testing how effective a new treatment is for a particular condition need to identify potential participants to invite to take part. In other instances, it may be potentially possible to identify patients if health information is combined with non-identifying information (such as age or a diagnosis date), particularly if they suffer a rare disease.

Key-coded data maintains the anonymity of the patient while allowing the custodian of the data to update it with new information or to correct errors. They can also withdraw the data if asked to do so by the patient – which would not be possible if the data were fully anonymised. In addition, this system allows different datasets to be linked, which would not be possible using anonymised data alone. This can add valuable information to the existing data, and remove any duplicated information that could show up in records from separate sources.

Why access to patient data matters

The use of patient data has led to significant advances in many aspects of healthcare. In the 1950s, research conducted by a doctor, Sir Richard Doll, and a statistician, Austin Bradford Hill, helped establish the link between smoking and lung cancer.[3] This followed an analysis of data collected from hospitalised patients in London and the surrounding communities over a four-year period (1948-1952). Hospital personnel at more than 20 hospitals were asked to contact Doll's team whenever a new patient was diagnosed with lung cancer – ensuring these patients were then interviewed about their smoking habits. In the 1950s, data within patient records were recorded by punching holes into cards that could be rapidly sorted by tabulating machines. Such a machine enabled Doll and Hill to analyse their data, and as a result demonstrate that smoking was the biggest factor linked to lung cancer.

This initial study helped Doll and Hill to explore links to cancer and other diseases through further epidemiological research.[4] The British Doctors Study saw around 35,000 male physicians in the UK recruited in 1951 into a longitudinal cohort study that ran for fifty years, with reports published every ten years that looked at the links between the health data collected (such as general physical health and smoking habits) and disease. Through the data collected, links between smoking and coronary heart disease were established.[5]

Patient data also helped to identify some of the other key risk factors for cardiovascular disease. The Framingham Heart Study started in 1948, at a time when little was known about the general causes of heart disease and stroke. Researchers collected data from around 5,200 healthy adults in Framingham, Massachusetts through a combination of lifestyle interviews and physical examinations, followed up every two years.[6] This built up a pool of data containing each participant's medical history, their history of cigarette smoking, alcohol use, physical activity, dietary intake, and levels of cholesterol and blood pressure.[7] By studying the data, the Framingham Heart Study established that levels of cholesterol and blood pressure affect the risk of heart disease. The study also identified many of the risk factors for cardiovascular disease that help inform healthcare today. A second generation made up of children and spouses of the original participants was added in 1971, and the project continues today.

3 Doll R, Hill AB. Smoking and carcinoma of the lung. Br Med J. 1950;2:739–748. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2038856/

4 Doll R, Hill AB. The mortality of doctors in relation to their smoking habits. Br Med J. 1954;1:1451–1455. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2085438/

5 Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. BMJ 2004;328:1519. Available at: http://www.bmj.com/content/328/7455/1519.full

6 www.framinghamheartstudy.org

7 Aschengrau A, Seage GR. *Essentials of Epidemiology in Public Health. Sudbury*, Massachusetts: Jones & Bartlett Publishers; 2008.

The work by Doll and Hill and the Framingham Heart Study investigators has shown the large healthcare benefits that can be delivered from analysis of patient data. But the investigators had to actively seek out information from patients directly over long periods of time to collate these results. Today the NHS routinely collects much of this type of information within its patient records – these records span many years and provide large amounts of data. With many of these records becoming electronic, there is considerable potential to conduct this type of epidemiological research at a quicker pace, and to analyse data from a larger number of patients. This may help to identify additional factors associated with cardiovascular disease that may not be easily identifiable from smaller studies, bringing benefits to patients sooner. This highlights the need for researchers to be able to access data held in health records so that they can conduct this type of study in a timely manner.

Today, patient data continue to be used to help make key discoveries that aid our understanding of cardiovascular disease. The examples below involve data from patients that had previously consented for their information to be used in the studies mentioned, but are illustrative of the types of research discovery that could be made more quickly were data made more available for medical research.

The Framingham Heart Study – key early milestones

1960: *Cigarette smoking confirmed as increasing the risk of heart disease.*
1961: *Cholesterol level, blood pressure, and electrocardiogram abnormalities found to increase the risk of heart disease.*
1967: *Physical activity shown to reduce the risk of heart disease and obesity to increase the risk of heart disease.*
1970: *High blood pressure found to increase the risk of stroke.*
1976: *Menopause found to increase the risk of heart disease.*
1978: *Psychosocial factors found to affect heart disease.*
1988: *High levels of HDL cholesterol found to reduce risk of death.*

Individual patient data meta-analyses of trials of statin therapy

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Cholesterol-lowering drugs known as statins are a widely used treatment for patients who already have - or are at high risk of - heart and circulatory disease. An estimated seven million people in the UK take statins to reduce their risk of a heart attack or stroke.

The BHF has played a leading role in proving the safety and effectiveness of statins. Our support for the Clinical Trial Service Unit (CTSU) at the University of Oxford led to crucial breakthroughs proving that statins greatly reduce heart attack and stroke risk in a wide range of people.

By including individual patient data from all the previous large trials of statin therapy, the Cholesterol Treatment Trialists' (CTT) research group at the CTSU can reliably measure the effects of statins in different types of patients. By performing 'meta-analyses', statistical combinations of the results from the individual studies, they produce more statistically reliable results than are possible from individual studies.

Results from the CTT published in May 2012 examined the effects of lowering cholesterol with statins in people at low risk of cardiovascular disease. By performing a meta-analysis of individual data from around 175,000 individuals in 27 trials, they were able to demonstrate that the benefits of statins in preventing heart attacks and strokes among low risk people greatly exceeds any known hazards, raising the question of whether current treatment guidelines should be revised to extend statin treatment to lower risk patients.

Alongside other recent BHF-funded findings from the CTT – for example, that higher doses of statins further reduce cardiovascular risk compared with standard doses – the CTSU's work is an example of the power of patient data in making vital discoveries for patients.

Whitehall II study: how access to medical records can improve understanding of health inequalities

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The BHF provided ongoing funding to the massive Whitehall Study, originally set up in 1967, which enrolled 20,000 men in the Civil Service and followed them over the decades. The study looked in great detail at the men's lives – from their jobs, to what they ate – to find links between health, behaviour, and disease risk. The first Whitehall study made a number of important discoveries, for example that men in the lowest employment grades were much more likely to die prematurely than men in the highest grades.

The Whitehall II study, a separate long-term study of British civil servants, was set up in 1985 with the aim of finding more reasons for the social gradient in health and disease in men and extending the research to include women. It followed around 10,000 civil servants who had been working in the London office s of 20 Whitehall departments in 1985–88, aged between 35 and 55.

The whole group is invited to the research clinic at five-year intervals, and a postal questionnaire is sent to participants between clinic phases. Participants report back to Whitehall researchers to let them know about non-fatal events such as heart attacks and strokes, but self-reported information is not always accurate and can be incomplete. Validation of information through medical records is absolutely key to the study's success. Access to accurate information when a participant dies is also crucial.

By collecting detailed data and cross-referencing with NHS patient records over a period of 25 years, the Whitehall II study has made frequent breakthroughs that have highlighted the link between socioeconomic factors – from employment and education, to mental health and weight at birth – and disease, including coronary heart disease and diabetes. In doing so the study has not only made important breakthroughs in our understanding of disease – it has consistently underscored the need for government to tackle health inequality, helping to inform policy that aims to reduce the gap in health outcomes between the rich and the poor.

Regulation and governance

In order to unlock the potential of using patient data in health research, researchers need to be able to access the information that will help them to bring benefits to treatment and care in the future. This requires appropriate safeguards to ensure confidentiality of patient data, while providing an environment that does not place undue burdens on the researchers. As technology has developed and the aim of linking large datasets has been prioritised, the development of an effective framework to improve access to patient data has become particularly important.

Within the UK, there are a number of requirements researchers must fulfil to be able to access the patient data they need.

The current legal framework

Within the UK, the use of data is regulated through a complex combination of common law and written law, including some legislation originating from the European Union.

Under **common law** (based on previous court cases decided by judges) within the NHS health information is collected from patients in confidence and attracts the legal duty of confidence until it has been anonymised (data already anonymised are exempt). This means that all patient information, whether held on paper, computer, visually or audio recorded, or held in the memory of the professional, must not normally be disclosed without the consent of the patient – giving individuals control over who sees their patient data in confidence.[8] This can only be overridden if the law requires disclosure of this information or if disclosure is considered to be in the public interest.

The **Data Protection Act** 1998 (DPA) provides a UK framework for ensuring identifiable data are only processed for appropriately authorised purposes, held in a secure environment, and not stored for longer than necessary. This was brought in to implement the Data Protection Directive passed by the EU in 1995, with the aim of providing people with a number of rights regarding their personal data. The DPA currently places several requirements with regards to health research, including placing those handling identifiable data under a duty of confidentiality to the patient – already the case for healthcare professionals. This law does not apply to anonymised data.

8 Department for Health. *NHS Information Governance: Guidance on Legal and Professional Obligations; 2007*. Available at: http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/codes/lglobligat.pdf

The **Human Rights Act 1998** (enforcing the European Convention on Human Rights) imposes a test on any intrusion into the private and family life of an individual, requiring that it must be in accordance with the law, proportionate and necessary.[9] This, together with the DPA and common law, places significant protections on data use with respect to individuals.

While there are protections listed above requiring clear consent for use of identifiable data by the individuals involved, Section 60 of the **Health and Social Care Act 2001** allows the Secretary of State for Health in England to allow use of this within England and Wales without individual consent in the interest of patients or the wider public good.[10] This is for use where there is no reasonably practicable alternative to obtain individual consent. If a research project requires identifiable data to be transferred from the NHS to the research team without consent, an application for support under Section 60 would normally be required – for example, in the event the patient has died or can no longer be traced.

Section 251 of the **National Health Service Act 2006** re-enacted Section 60 by providing the power to ensure that patient-identifiable information needed to support essential NHS activity can be used without the consent of patients, enabling the common law duty of confidentiality to be set aside. This can only be used to support medical purposes that are in the interests of patients or the wider public (such as research), where consent is not a practicable alternative and where anonymised data will not suffice. This was originally intended to be a transitional measure while consent or anonymisation procedures were developed. As a result each use of the power is reviewed annually, though it has since been acknowledged that there will continue to be a need for Section 251 powers, for some uses, on a more long-term basis.[11]

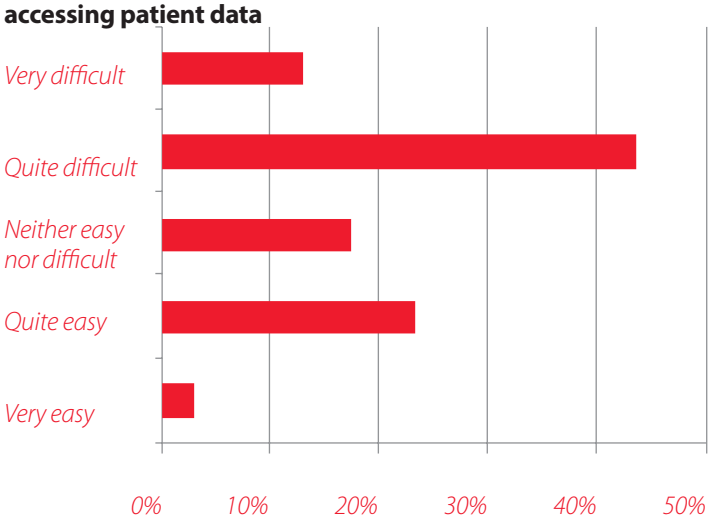
Within England and Wales, applications via Section 251 are considered by the National Information Governance Board (NIGB) through its **Ethics and Confidentiality Committee** (ECC), which can also advise researchers in general to either use anonymised data or obtain consent. In Scotland, it is the role of the NHS National Services Scotland Privacy Advisory Committee to advise on the use of identifiable patient data in research.

The incremental nature of the development of this framework has led to a complicated set of laws and lack of clarity for researchers. This, added to by an emphasis on privacy, has led to a conservative culture of research governance.[12]

Barriers to access

We asked our researchers how they find navigating the current framework for patient data. More than half (57 per cent) expressed some or considerable difficulty in accessing patient data for research. Each respondent was asked to give their views on a selection of common barriers. Most researchers were clearly frustrated by a combination of the complexity of many of the approval processes, the impracticality of many of the processes required for access to patient data, the lack of consistency between the different organisations involved for approval, and an environment in the NHS that was not conducive to supporting the type of research requiring access to data.

Cardiovascular researchers' experience of accessing patient data



9 http://www.hrcr.org/docs/Eur_Convention/euroconv.html (Article 8)

10 Department of Health. Guidance notes: *Section 60 of the Health and Social Care Act 2001*; 2002. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108953

11 http://www.nigb.nhs.uk/s251/abouts251

12 Academy of Medical Sciences. Personal data for public good: using health information in *medical research*; 2006. Available at: http://www.acmedsci.ac.uk/p99puid62.html

As highlighted in the Academy of Medical Science's 2011 report on the regulation and governance of health research, it is important for regulation and governance in health research to be proportionate to enable life-saving research to take place, while at the same time safeguarding the interests of patients.[13] In the context of patient data, this should mean providing a balance between protecting personal data and making data available for health research. One consultant cardiologist, expressing a sentiment echoed by most respondents, commented:

> "there is quite a lot of red tape to access data, designed originally for legitimate reasons, that acts as a significant bar in the way it is being implemented – routinely delaying the start-up of projects after funding has been secured."

Difficulties obtaining consent

The type of consent approval required often depends on the type of research being carried out, the data being used, and the type of body involved in the process. The issue of when and how patient consent is obtained was raised throughout the survey responses. One research training fellow provided the following example highlighting the issue of re-consent for patients that had already agreed for their data to be used in a study:

> "There exists a huge focus around the consent process and this acts as a barrier to set up an ongoing study participation in those who have consented. A good example is if I make a change to the patient information sheet I have to re-consent all existing participants to the new sheet even if it does not materially affect their risk or ongoing participation. Many study participants want the paperwork kept to a minimum and really do not appreciate being asked to re-consent to a study five or six times."

A common problem identified in the area of consent is the requirement for some researchers to go back to gain further consent for further research that does not require patient participation. Even in examples where expressed consent was originally provided, problems in gaining access can arise, as indicated by one professor, who was intending to use patient data of participants in a drug trial to examine the long-term safety and efficacy of the drug:

> "The NHS Information Centre initially refused to provide Hospital Episode Statistics data for long-term follow-up of consented patients. The rationale was that the current name of the HES data system had not been used specifically in the original consent materials about 10 years earlier (when the organisation did not exist so its name was unknown!). It took about one year to get this decision reversed and approval to access these data provided, to the detriment of the research (increasing costs) and to patient safety."

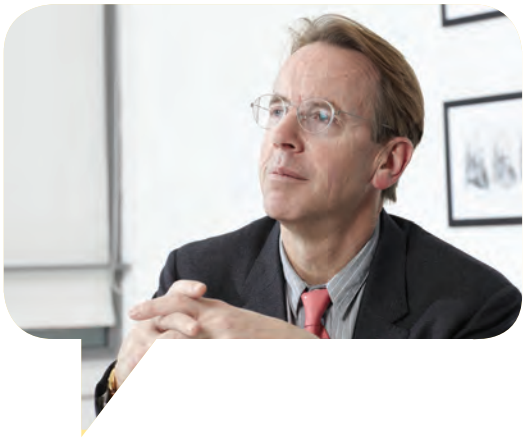
Gaining informed consent from the patient is also a key requirement in instances where identifiable data are required, but this can be complicated. For example, in order to invite a patient to participate in a particular clinical trial, they must first be contacted by the person that holds those data (such as a GP or nurse) to ask permission for their personal data to be passed to a research team – who must then re-contact the patient to inform them of their research, how their data would be used, and gain consent for their data to be used. This is known as **'consent for consent'**. The 2008 data sharing review by the Information Commissioner and Sir Mark Walport recommended that the NHS develop a system to enable approved researchers to access data in order to facilitate this type of data use for clinical studies, in addition to the creation of safe havens that would provide researchers with safe and secure environments for their research.[14]

The issue of 'consent for consent' was highlighted by a number of researchers surveyed, with 59 per cent identifying it as being a particular barrier to being able to access patient data for their work. As part of the research commitment within the NHS Constitution, the NHS is expected to do all it can to ensure that patients are made aware of research that is of particular relevance to them.[15] However, the 'consent for consent' issue is often considered a barrier to achieving this aim, hindering researchers from identifying patients to invite to take part in clinical studies and often leading to significant delays to research – particularly for studies involving a large number of people.

13 Academy of Medical Sciences. *A new pathway for the regulation and governance of health research*; 2011. Available at: http://www.acmedsci.ac.uk/p47prid88.html

14 Thomas R and Walport M. Data sharing review report; 2008.

15 http://www.nihr.ac.uk/awareness/Pages/awareness_constitution.aspx



Professor Sir Rory Collins

BHF Professor of Medicine and Epidemiology
University of Oxford

Oxford's Clinical Trial Service Unit established the use of very large, randomised 'megatrials' to reliably assess the effects on survival of widely practicable treatments Professor Collins's work has helped save the lives of tens of thousands of people.

In the Heart Protection Study, backed by the BHF and Medical Research Council, Professor Collins's team recruited 20,000 people into a trial that looked at the effects of reducing LDL cholesterol on mortality. The results showed the importance of statins in lowering risk of heart attack in this population, and that these benefits can extend to people whose cholesterol levels might previously have been considered normal or even low.

Since 2005 Professor Collins has been the Principal Investigator and Chief Executive of the UK Biobank prospective study of 500,000 British men and women aged 40-69, part-funded by the BHF.

Being able to identify potential study participants for these studies that involve large numbers of people is crucial to their success:

> *"Recruitment into the Heart Protection Study required access to contact details for people with specific medical conditions, for example those that had suffered a heart attack. This was necessary in order to recruit sufficiently large numbers of patients cost-effectively and provide clear evidence about the benefit of cholesterol-lowering treatments for a much wider range of patients than had previously been thought to benefit.*
>
> *"For UK Biobank, access to names and addresses (no medical information) of people within a particular age range and location for invitation into the study took over one year to get approval, putting the project at substantial risk."*
>
> *"We need to ensure that the approval systems for accessing identifiable patient data are streamlined – this would be hugely beneficial for recruitment to clinical trials and for follow-up of past studies."*

Doctors are bound by a strict duty of confidentiality, as set out by the General Medical Council. Several respondents to the survey suggested that these requirements are themselves a safeguard that should help to facilitate access to patient data. One respondent pointed out that this is further strengthened by the annual appraisals (and soon, accreditation) that help to ensure all individuals maintain patient confidentiality. Another, a clinical research fellow, detailed this point further with regards to identifying potential trial participants:

"There is a requirement that only members of the direct healthcare team may access such data, but there is a failure among regulatory bodies to understand how modern healthcare is delivered in large teams. Large numbers of administrative staff have access to identifiable patient information, but medically qualified specialists, who are required by regulatory bodies to maintain confidentiality, and for whom there are robust misconduct procedures in place, are not permitted to look at the notes of patients within their own departments, because they are under the care of another consultant. If it were an audit (no regulation whatsoever) we'd just look. Try to inform others of the results, and it's research and then you can't look. It is research exceptionalism."

Duplication and inconsistency of approvals

The overall regulatory framework for health research has been highlighted as overly complex, with numerous bodies involved in the approval of a project.[12] With the incremental development of law and guidance around access to patient data, a number of bodies are now involved in the approval process. This can significantly delay a project from starting, which can be costly not only to the funders of that research but also to patients, who will benefit less quickly from the outcomes of that research. Where patient data are required from a large number of people, or from a number of different sites, these problems can be magnified – creating further delays to projects.

Researchers seeking to use patient data in research are also required to gain ethical approval for their projects. Any health-related research project which involves humans, their tissue and/or data must be reviewed by a Research Ethics Committee before it can begin, and potentially additional ethics committees depending on the type of research.

Within NHS organisations, researchers also need to receive approval for a project from each individual Research and Development (R&D) department in each site where the research is taking place. NHS R&D permissions were a key barrier highlighted in the Academy's review, in particular for multi-site clinical studies.[12] Our survey reflected this, with duplication in guidance and procedures from different NHS bodies considered significantly restrictive by around 65 per cent of respondents. One professor provided an example of the difficulty in being able to identify hypertensive patients from GP databases, with duplication of a number of approvals at health trust level:

> "Each GP surgery we approach to view databases to identify whether there may be eligible patients, you need to have relevant trust approval despite already having ethics permission. This means not only one duplication but duplication for each trust, which is an unbelievable waste of time when ethics permission already exists."

Inconsistencies in what NHS R&D departments require create a further obstacle for access to patient data. A research fellow provided an account of the difficulties experienced in obtaining data for a follow-up study of a population-based cohort 20 years after the baseline:

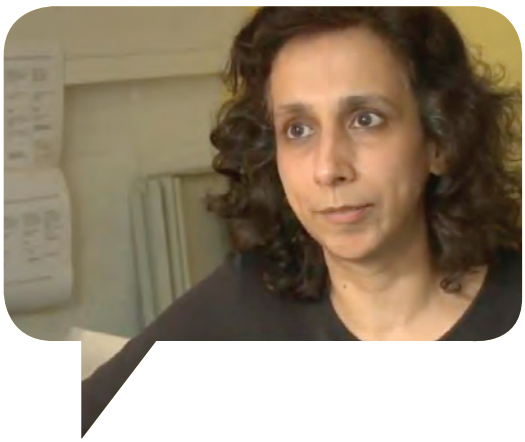
> "We needed access to primary care medical records for living participants (with consent) and for deceased participants (via Section 251), and also applied for access to HES data for the entire cohort. Access to medical records of deceased participants was particularly awkward and involved a multitude of trusts and comprehensive local research networks as many participants had moved away on retirement. Most trusts seemed to require different forms of documentation regarding the entire study of living and dead participants – many trees were felled and email accounts overloaded. We frequently felt as if we were trying to gain consent for some form of criminal activity!"

In addition, many NHS organisations will also carry out local assessments through **Caldicott Guardians** – senior roles in NHS Trusts that are intended to protect patient confidentiality and enable suitable information-sharing. Approval can be complicated by the different standards Caldicott Guardians tend to work to, particularly for research that involves several different NHS Trusts – requiring approval from each Guardian.

Over a quarter of respondents considered the local assessments carried out by Caldicott Guardians before access to data is granted to be barriers to access, though roughly the same proportion appeared to have had problem-free experiences, demonstrating the variability in how Caldicott Guardians operate. A clinical research fellow from Scotland indicated in the survey that the application process is simple, but the process is very slow and the information required poorly defined. One professor went further, indicating that the system as a whole was flawed:

> "It requires isolated individuals to make decisions around issues of data access when the regulatory framework is complex and lacks clarity and when that individual has nothing to gain and everything to lose in allowing access. As a consequence, their decisions tend to be risk-averse as well as inconsistent between different individuals."

There was a similar divide on the extent to which Research Ethics Committees provide a restrictive barrier to accessing data. Around 41 per cent of respondents highlighted ethics committees as being a particular barrier compared to around 35 per cent that felt they were far less of a problem compared to other factors.



Prof Nish Chaturvedi

Chair in Clinical Epidemiology
Imperial College London

Since 1990 Professor Chaturvedi has performed the Brent study – one of the largest cross sectional studies of cardiovascular disease and diabetes in the UK ethnic minority community. She was the first to report ethnic differences in diabetes related mortality using population based cohorts of South Asians and African Caribbeans. This success led to additional funding from the BHF and Wellcome Trust to follow up a large tri-ethnic (European, South Asian and African Caribbean) cohort in the UK. This is the SABRE study (Southall And Brent REvisited), which is looking at how the risk factors related to heart and circulatory disease and diabetes differ between ethnic groups and with increasing age.

Access to data in the medical records of those in the cohort is essential to the study:

> *"For our study, where we needed data from clinic records and primary care, we needed to fill in different sets of forms, have different sets of approvals, granted by different sets of committee – which are not the same in different parts of the country. For hospital data in particular there is a much more complex set of forms and approvals. For relatively non-sensitive information of the type used in our study – where people have given consent for the data to be accessed and where ethical approval has been given – the burden seems to be disproportionately large."*

> *"The process could be significantly improved by having a one-stop-shop – one point of access, one set of forms, one committee, with a clearly identified pathway through the process so that you know exactly who to approach to obtain access to data."*

Complexity and inconsistency of the legal framework

As highlighted both above and within the Academy's review, the breadth of legislation that impacts on access to patient data has led to a legal framework that is complicated and unclear. The Data Protection Act, for example, was highlighted in the review as not providing enough clarification on access to data – resulting in a risk-averse culture, with misinterpretation resulting in delays to important research.

Around 65 per cent of researchers we surveyed indicated the complexity of the legal framework presented a significant barrier to data access, with over 60 per cent concerned by the lack of clarity around the data protection laws.

One professor commented that guidance on being able to approach patients to take part in research had added to the problems:

> "The legal framework isn't clear. For example, increasingly people want to approach patients to ask them whether they would be happy to take part in research and the guidance says that you can only do that if you are part of the healthcare team. But usually those people are too busy to approach those patients and dedicated research staff should be allowed to approach them but are blocked from doing so because they aren't part of the care team. In some areas of the country this is interpreted differently and some can ask the patients; in others it is interpreted very strictly and they cannot."

Recent developments on access to patient data

Since the Academy's wide-ranging review of regulation and governance in health research, there have been several developments that present opportunities for some of the problems around researchers gaining access to patient data to be reconciled.

One of the key recommendations of the review was to establish a single health research regulator to help streamline the complex system of regulation and governance in the UK. The UK Government accepted this recommendation and the **Health Research Authority** (HRA) launched in December 2011. The HRA is set to take on further powers, including approving access to identifiable data under Section 251 by 2013. The UK Government also intends to establish the HRA as a non-departmental public body within the current Parliament, providing opportunities for its role to be strengthened further as its functions develop.

In addition, a new resource has been established to link anonymised data previously held within the General Practice Research Databank with hospital records – the **Clinical Practice Research Datalink** (CPRD), which launched in March 2012, and is hosted by the Medicines and Healthcare Products Regulatory Agency. In the survey, we asked our researchers the extent to which they anticipated using this resource in the future to access patient data. In the next year, 13 per cent of respondents intend to apply to access to data from the CPRD for their work, with a quarter at some point in the future – 27 per cent do not intend to use this resource in the immediate future. Some respondents were particularly concerned that more needs to be done to enable the linkage of primary care records and clinical outcome data, particularly with regards to improvements in infrastructure to better facilitate this linkage.

The UK Government announced within its Life Sciences Strategy in autumn 2011 that it would consider changes to the NHS Constitution to help facilitate use of anonymised patient data for research. This would make it easier for patients to be involved in research, with access to patient data set as the default, but protecting the individual's right to opt out. In our survey, the idea of an **opt-out system for use of anonymised patient data** in research received overwhelming support from researchers, with 82 per cent believing it would have a very positive impact (16 per cent saying some impact). A professor of epidemiology commented that this 'would be transformational for certain types of biomedical research in England.' There are a number of examples that highlight the support in practice of patient involvement in research following contact by researchers – from the UK Biobank's pilot phase only one person from every 1,000 invitations indicated they did not want to participate over concerns that the NHS had provided UK Biobank with their contact details.[16]

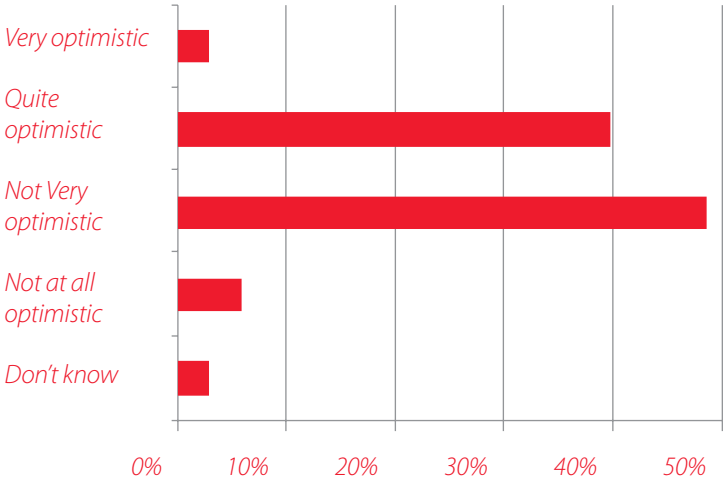
The Department of Health in England announced in February 2012 that Dame Fiona Caldicott would lead an independent review of the balance between protecting patient information and sharing data, in order to improve patient care. This will be led by a working group of clinical, social care, research and other professionals, as well as patients and service users, and could consider the issues around **Caldicott Guardians** raised by researchers.

16 UK Biobank Coordinating Centre. *UK Biobank: report of the integrated pilot phase*; 2006. Available at: http://www.ukbiobank.ac.uk/docs/IntegratedPilotReport.pdf

The European Commission has published a draft of its revised data protection legislation, which is set to be considered by the European Parliament by the end of 2012 – with subsequent implementation within the UK. The draft **Data Protection Regulation** could potentially add clarity to a number of issues identified in the current Data Protection Act, with several provisions included in the Regulation to support the use of data in health research.

In terms of their outlook on access to patient data in the future, researchers in our survey were divided. Over half are not optimistic that there will be improvements on access, highlighting the need for further action to be taken to help ensure a more proportionate and facilitative system for researchers.

Cardiovascular researchers' outlook for accessing patient data in the future



Where next for patient data?

There is great potential for the use of patient data within medical research to lead to significant breakthroughs in the future that benefit patients, including people living with cardiovascular disease.

However, our researchers have told us that the considerable barriers in place resulting from the complexities of the legal framework, and multitude of bodies involved in the process of advising and approving use of patient data, are holding back that potential – delaying research and adding costs.

There are some positive developments designed to reduce these barriers. The UK Government should build on these to aid the streamlining of regulation and governance to a more proportionate level, and act as a strong representative for the research community within the EU on the use of patient data in health research.

Recommendations

Safeguards should be in place to fully respect the confidentiality of patients, while also ensuring that health researchers can gain access to patient data within a secure environment. To achieve this, we believe that the UK Government should:

1. Ensure that any upcoming changes to European law on data protection provide greater clarity and proportionality on the use of patient data in health research

The introduction of a new Data Protection Regulation could significantly address many of the problems associated with current data protection legislation and patient data. The UK Government should provide a strong voice on the passage of this legislation in order to ensure that it is conducive to improving access to patient data for health researchers.

In particular, we believe the UK Government should help to ensure the Regulation:

- balances the facilitation of research and its associated benefits, with the protection of the interests of patients
- is clear on the types of data usage that would be exempt, in order to reduce the possibility of misinterpretation within the UK, and
- is proportionate to protect the status of the use of key-coded data in health research.

This recommendation also extends to Members of the European Parliament, who are expected to vote on the proposal by the end of 2012.

2. Through the Health Research Authority eliminate the duplication of approvals for the use of patient data and help to streamline the existing governance

The newly-established HRA should take steps to help reduce the administrative burdens that researchers face through multiple approvals, which provide disincentives to data use and delay research.

In addition, as it grows to take on functions performed by the National Information Governance Board, we believe the HRA should ensure a streamlined and consistent approach to allowing access to identifiable data for health research.

3. Provide a clear legal framework for accessing patient data to help reduce the complexity for researchers

We believe that the incremental nature in this area to date has contributed to a system that is not fit for purpose and has led to inconsistencies in interpretation.

The UK Government should, following passage of the EU Data Protection Regulation, in collaboration with the Information Commissioner, the HRA, and other key stakeholders, provide a clear framework to aid both health researchers and those controlling access to patient data. This should also provide clarity on the issue of identifying potential clinical trial participants.

4. Introduce an opt out system for use of anonymised patient data within health research in England, making the necessary amendments to the NHS Constitution to achieve this

There is strong public support for health research, and practical examples that highlight support for use of their patient data where they cannot be identified.

We welcome the UK Government's commitment to consult on this issue, and strongly support this measure. This consultation is also an opportunity to raise public awareness of the importance of patient data to research.

5. Replace the system of Caldicott Guardians with one of centralised approval

The number of approvals in place for projects requiring access to patient data makes the role of Caldicott Guardians in approving use of identifiable data an additional hurdle that is already served by other bodies.

We agree with the Academy of Medical Sciences review that Caldicott Guardians should instead focus on facilitating the delivery of research studies that have gained approval for data use, rather than be involved in the approval process.

6. Bring NHS Research and Development permissions within the Health Research Authority

The UK Government has taken a number of encouraging steps to implement many of the recommendations of the Academy of Medical Sciences review, but there are several that have not been implemented that would further streamline regulation and governance.

We remain concerned that some of the roles recommended for the single health research regulator, specifically around incorporating NHS R&D permissions, have not been included within the remit of the new HRA. Researchers continue to raise this as a major barrier to cardiovascular research being conducted. As legislation is considered to establish the HRA as a non-departmental body we encourage the UK Government to implement the Academy's recommendations on the single regulator in full and bring NHS R&D permissions within control of the HRA.

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In producing this report the BHF has considered the contributions of the individuals listed above, but the report should not be taken as representing the views of any one individual or organisation mentioned.

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Phone lines open 9am to 5pm Monday to Friday
Similar cost to 01 or 02 numbers

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