Policy statement

Patient data in medical research

Introduction

The British Heart Foundation (BHF) is the largest funder of non-commercial cardiovascular research in the UK, spending over £100 million each year. We fund more than half of all university-based heart research in the UK, with BHF-funded researchers and projects at centres in over 30 cities across the UK.

Patient data are essential to improve our knowledge of disease, develop new interventions, and plan services. The NHS treats the largest single pool of patients in the world – opening up access to these data for medical research while retaining patient confidentiality is essential to ensure the potential benefits are realised.

Policy statement

NHS patient records are a unique resource of life-saving information, which is not found anywhere else in the world. By making these patient data more widely available to medical researchers, the BHF believes that the UK could lead the world in discovering the causes of disease and adopting new treatments for conditions such as cardiovascular disease.

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

- improve the legal framework for accessing patient data to help reduce the complexity for researchers, and to provide clarity on identifying potential clinical trial participants
- through the Health Research Authority eliminate the duplication of approvals for the use of patient data and streamline the existing governance
- ensure that any upcoming changes to European law on data protection provide greater clarity and proportionality on the use of patient data in medical research, and
- help to improve public understanding of the use of patient data within medical research.

Background

When a patient uses the NHS, information is routinely collected by healthcare professionals on that person's health, lifestyle and the medical treatment that they have received. The data help to build a medical history for each patient that can help influence future care, and can be held in a variety of forms, from paper or electronic records at GP surgeries to disease registers.

Routine collection of patient data helps us to know the number of people that suffer with cardiovascular disease in the UK, in addition to the specific disease type. The data are already used to help underpin aspects of NHS service delivery, and are therefore regularly shared with clinical care teams. These data are also fundamental for certain types of research into cardiovascular disease.

The UK is uniquely placed globally, having collected patient data since the NHS was established in the 1940s. Today, the NHS treats the largest pool of patients within a single healthcare system anywhere in the world. From birth to death, the NHS keeps detailed records on its patients.

Use of patient data in medical research

Medical research is recognised as a core part of the NHS across the UK. The patient data held by the NHS are essential for particular aspects of medical research:

- epidemiological research, and
- clinical trials.

Epidemiological research identifies causes of disease through observational studies that analyse a large patient population. This requires access to large amounts of patient data. In the past, this type of research has helped to identify the link between smoking and heart disease.

Clinical trials that assess the efficacy of new drugs or other type of treatment rely on the participation of patient volunteers. Patient data are important to help identify patients that are eligible to participate in a trial, particularly for those trials for rarer conditions.

The development of electronic patient records within the NHS opens up the possibility to maximise the use of patient data for both applications to benefit medical research.

Types and sources of patient data

Patient data can be used in medical research in a number of different forms. Broadly, these are defined as:

- **Identifiable data**, whereby information such as a patient's name, address, and NHS number are included
- **Anonymised data**, where the information contained cannot be linked back to the original patient record it came from, and
- **Pseudonymised data**, where the normal identifiers of a patient are replaced with a code to protect the identity of the patient. These can be reconnected to the patient via a key that re-links the data.

Researchers generally use anonymised data wherever possible, but there are instances where this is not possible. Bringing together the existing sources of data is important for medical research, but also presents challenges to ensure that patient confidentiality is securely held while being accessible to researchers.

Improving access to patient data

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 while retaining patient confidentiality has become particularly important.

Current problems hindering access include:

- the overall complexity of the current legal framework on access, which includes UK statutory legislation, common law decisions, and EU law
- a variety of guidance from numerous bodies that has led to inconsistent advice
- a lack of clarity on the mechanisms enabling researcher to search records to identify patients to invite to participate in research ('consent for consent'), and
- a lack of consistent public information on the use of patient data.

Several attempts have been made to address these problems. In 2006, the Academy of Medical Sciences recommended that identifiable data could be used for medical research, without consent, provided that such use is necessary and proportionate in relation to privacy and public interest benefits, and that relevant bodies involved in approving access should use this interpretation to combat the conservative culture currently in place.[1]

In 2007, the then UK Government asked Information Commissioner Richard Thomas and Sir Mark Walport to review all aspects of data sharing. Their report recommended the creation of 'safe havens' as an environment for population-based research and statistical analysis in which the risk of identifying individuals is minimised.[2] These safe havens would require a suitable system to allow the data to be accessed only by those researchers that had been approved or accredited. In addition, they recommended that the NHS develop a system to enable approved researchers to access data to identify patients to approach for clinical studies.

While many of the reports' recommendations were taken forward by the previous Government, many of the problems are yet to be addressed. The National Information Governance Board created an Ethics and Confidentiality Committee (ECC) in 2009, which has advisory powers over the use of identifiable patient data without consent within England and Wales. However, numerous forms of guidance still exist from a range of organisations on accessing this type of data.

The UK Government is attempting to develop safe havens through the National Institute for Health Research's Research Capability Programme, established in 2008. This has included piloting the Health Research Support Service to help provide access to anonymised datasets in England. In 2011, the UK Government announced that it would establish the Clinical Practice Research Datalink, which will bring together two existing patient datasets from GP and hospital care into a secure data service. This will be hosted by the Medicines and Healthcare Products Regulatory Agency and established by April 2012 with further functions added in future years.[3]

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[1] The Academy of Medical Sciences. *Personal data for public good: using health information in medical research*; 2006. Available at: http://www.acmedsci.ac.uk/download.php?file=/images/publication/Personal.pdf
[2] Thomas R and Walport M. *Data sharing review report*; 2008.
[3] Department of Health. *The Government plan for a secure data service*; 2011. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131242.pdf

Elsewhere in the UK, the Scottish Health Informatics Programme and the Health Information Research Unit of Wales both aim to create opportunities for medical researchers to access anonymised patient data to conduct high-quality research.[4,5]

Barriers hindering access to data

In the UK, the use of patient data is tightly controlled within a complex regulatory and governance framework. The contents of the UK's Data Protection Act have implemented the EU Data Protection Directive, passed in 1995. Many aspects of data use were not thoroughly defined in the Directive, leading to significant variation between member states in terms of the Directive's implementation, and inconsistencies in application.

The European Commission has proposed to replace the Directive with a new EU regulation, which would reduce the potential for inconsistent application across the EU.[6] This could provide an opportunity to resolve issues around the practicability of consent, anonymisation, and processing for further purposes.

In 2011, the Academy of Medical Sciences published a report that identified inconsistencies in guidelines and variability in advice on patient data use.[7] This has meant that researchers often face significant delays in obtaining access to data.

The Academy report highlighted the duplication that can exist in the current system. A Research Ethics Committee (REC) requires information on the use of patient data, and where appropriate this information is also a requirement for ECC approval. In addition, many NHS organisations will also carry out local assessments via Caldicott Guardians (senior roles in NHS Trusts that protect patient confidentiality and enable suitable information-sharing). This is further complicated by the different standards Caldicott Guardians tend to work to, particularly for research that involves several different NHS Trusts. A key recommendation of the report was to remove duplication of these approvals, already performed via RECs and the ECC.

To tackle some of the issues around identifying eligible trial participants, a Research Passport scheme was introduced by the NHS to streamline the issuing of honorary NHS contracts or letters of access to researchers that have no contractual arrangements with the NHS organisation hosting the research. However, the Academy report suggests that this has not proved to be effective, with delays of 6-12 months for some researchers in receiving their research passports.

The Health Research Authority (HRA), established in 2011 in response to the Academy's regulatory review, is aiming to streamline many of the processes of regulation of medical research. By 2013 the HRA will take on board the functions currently performed by the Secretary of State on the advice of the ECC, making decisions over the use of patient data for research.[8]

Public opinion on use of data

There are consistently high levels of public support for the use of patient data in research. In polling during 2011, 80 per cent of British people stated they would like to consider allowing a researcher confidential access to their medical records, while 72 per cent stated that in the

[4] http://www.scot-ship.ac.uk/
[5] http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=14733
[6] http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm
[7] 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
[8] http://www.publications.parliament.uk/pa/ld201011/ldhansrd/text/111207-0002.htm#11120770000070

event they had a health condition that affected their day-to-day life they would like to be contacted about potential opportunities to take part in clinical trials.[9]

In practice, objection from individuals to being contacted about possible participation in clinical trials has been reportedly extremely low. The UKCTOCS trial recruited 200,000 women following 1.2 million invitations being sent to people – only 32 complained that they had been contacted.[10] Similarly, 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.[11]

While patient confidentiality is key, the public support for the use of patient data in research suggests that a conservative approach towards data-sharing is inappropriate. The NHS Constitution undertakes to ensure that patients are notified of opportunities to join in relevant research. The UK Government has indicated that it will consider changes to the NHS Constitution that would allow anonymous patient data to be routinely used for research unless the patient has asked to opt out, with a goal of increasing the opportunities for patients to be involved in research.[12]

The use of patient data for medical research is at times considered alongside broader public and political debate about personal information and concerns about civil liberties. Past high profile losses of public data held by the Government can erode public confidence in how information will be handled. Highlighting the safeguards that are in place to protect patient confidentiality is therefore important to help to ensure that patients can trust that their information is not in going to be misused.

Public engagement is important to help to provide the public with greater information on the use of patient data in medical research. The UK Clinical Research Collaboration Subgroup on Clinical Awareness aims to raise awareness, change attitudes and encourage behaviour change through better information to the public about the use of, and benefits of using, patient data for research. The group is aiming to provide materials for the public, patients and healthcare professions, and in 2011 produced a leaflet for GP surgeries outlining ways that patient data are used in the NHS.[13]

For more information, contact policy@bhf.org.uk

[9] 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
[10] Menon U et al. Recruitment to multicentre trials – lessons from UKCTOCS: descriptive study. *BMJ* 2008; 337: a2079. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2583394/
[11] UK Biobank Coordinating Centre. *UK Biobank: report of the integrated pilot phase*; 2006. Available at: http://www.ukbiobank.ac.uk/docs/IntegratedPilotReport.pdf
[12] Office of Life Sciences. *Strategy for UK Life Sciences: Building a life sciences ecosystem*. London: HM Government; 2011. Available at: http://www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences
[13] http://www.ukcrc.org/patientsandpublic/awareness/patientdata/