



BRIEFING

# TOWARDS CONSENSUS FOR BEST PRACTICE

Use of patient records from  
general practice for research

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### Introduction

Research is a core part of the NHS. It is central to advancing the understanding of disease, evaluating new treatments and interventions, predicting disease outbreaks, planning public health activities and generally improving patient care and treatment outcomes.

The foundation for much of this research is information contained in patient records. Patient records in general practice surgeries, which cover almost the entire population of the UK, are therefore a unique resource. Moreover, the increasing use of electronic records provides exciting new possibilities for analysing large volumes of data and answering new research questions.

Patient information, however, is both sensitive and private. If patient information is to be used for research, the general public, patients and healthcare professionals must all have confidence that the security of personal information is safeguarded.

Although some GP surgeries already participate in research activities, there is a lack of consistency as to how records can be accessed and used. The process whereby researchers can access and use patient information must be robust, and must have the confidence of all involved, allowing GPs to act in the patient's interest.

This briefing document summarises the agreement reached during a consensus meeting held in 2008 with GPs, researchers and patient groups on developing guidance for best practice in use of patient records for research purposes. Endorsed by the Royal College of General Practitioners (RCGP) and the British Medical Association (BMA), the guidance provided is a first step to ensuring confidence in the processes used to access information. It should apply to all research using patient data, whether undertaken by the public or private sectors, and should enable everyone to benefit from the huge research potential of medical records.

### Using patient information for research

Data from patient records can help with many areas of research. For example, the data can be used to:

- **observe trends** in infectious diseases
- **monitor** the **safety and efficacy** of prescribed drugs
- **assess** occupational, environmental or other **risks** to public health
- **evaluate new treatments and interventions** through clinical trials
- **carry out audits** that will help to inform healthcare management.

Much research can be conducted with anonymised information held in patient records. But in other cases, researchers need access to information from which a patient may be directly or indirectly identified.

Patient records may also be used to identify potential participants for a future research study such as a clinical trial.

As different levels of anonymity offer different risks and benefits, there is a need to distinguish between them. The terms used in this document for the different levels of identifiability are described in 'Identifiability of information' (p. 5).

It is important to note that:

- although researchers may need to have data at 'person level', they usually do not want to know the actual identity of the individual
- very few data are truly 'anonymous'
- all clinical data may be considered sensitive by patients.

# Overarching principles

Three overarching principles emerged from the 2008 consensus meeting, and were the basis on which the guidance given here was drawn together:

## 1. Patient confidentiality and privacy must be safeguarded

Personal information held within patient records may be both sensitive and private, so security and confidentiality must be safeguarded at all times.

Patient confidentiality could be controlled at two levels:

- at a **technical** level, by:
  - using the best available **electronic technologies** to ensure security and confidentiality
  - introducing **safe havens** and **honest brokers** (see 'Maintaining confidentiality of data', p. 5)
- at the **researcher** level, by:
  - ensuring that only **accredited, approved** researchers have access to identifiable patient information
  - placing researchers under the same **duty of confidentiality** as health professionals
  - applying appropriate and **substantive sanctions**, possibly criminal, for breaches of confidence.

The guidance is consistent with the Data Sharing Review published in 2008 and the government response to that report, which accepted the notion of an 'approved researcher'.

## 2. GPs and healthcare professionals should play the role of patient's advocate

The first priority of GPs must always be to deliver high-quality healthcare but the GP must also protect patients if patient records are to be used in research. GPs and their practices must retain ultimate responsibility for ensuring data are accessed appropriately.

GPs may need to provide advice to patients:

- about **taking part** in research (not least because it is recognised that patient trust in a study is often increased if the study is endorsed by the patient's GP)
- if any **feedback** is provided after research.

Additional **training, support and resources** may be needed to ensure that GPs are able to fulfil the role of 'patient's advocate' and to ensure that the practice can support research.

## 3. Public awareness and understanding of the use of records in research should be improved

Research has shown that the public are generally supportive of research. Two-thirds of people are likely or certain to allow 'personal health information' to be allowed for research – however, there is little public understanding of what this actually means in practice. As such, it is imperative to improve engagement and awareness among the general public:

- there should be a national **awareness-raising programme** highlighting the importance of using patient records for research, describing the difference between identifiable and non-identifiable data, and explaining the safeguards that will be put in place to protect privacy
- information should also be **provided locally through general practices**, for example as patients register at a practice, and through posters and leaflets.

**Transparency** is essential, and it should be clear that patients can **opt out** of the use of their identifiable information in research if they wish.

# Best practice guidance

## Use of anonymised data from patient records

- GPs and the practice need to be confident that the anonymisation process conforms to high standards.
- The anonymisation process should be as automated as possible and make use of best available technologies, including *safe havens*.
- Individual consent is not necessary for use of anonymised, non-identifiable records, but the public should be made aware that records may be used in this way.

## Use of coded data from patient records

- Encryption should be used with multiple keys needed to link coded and identifying data (e.g. one key at practice level, one at the level of research repository). The process should be handled by *honest brokers* in a *safe haven* where available.
- Safeguards should be proportionate to risks, and new technologies used wherever possible to minimise risk of identification.
- Individual consent should not be necessary for records to be used in a coded manner, provided that patients have been made aware that their records may be used in research and given an opportunity to opt out.

## Use of identifiable data from patient records

- Individual informed consent is normally required before identifiable records can be used.
- Special permission may be obtained where it is not possible or practicable to seek consent. The Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care considers applications in England (see 'The legal framework', p. 5).

## Use of patient records as the starting-point to identify participants for research

### Reviewing records to identify potential participants

- Patients should be made aware that records may be used to identify potential research participants, and that they can opt out if they wish.
- GPs must retain ultimate responsibility for the process of accessing records, making case-by-case judgements as to whether it is appropriate for a researcher to view records.
- Where possible, the best available privacy-enhancing technologies should be used to maximise security and minimise access to identifiable data.
- If researchers still need to view records, they should be accredited and should have a duty of confidentiality as a health professional.
- Where researchers have access to records, this access should be to the minimum amount of information needed to identify potential study participants, as defined by ethics/other committees and documented in the study proposal.

### Inviting participants to take part in a study

- Practices retain responsibility for the process of contacting and inviting potential research participants.
- GPs should screen the list of potential participants so as to exclude, for example, recently bereaved individuals.
- Best practice is for the invitation to participate in a study to come from GPs on practice headed paper.

- It is appropriate and acceptable for researchers to make resources available to practices to help with screening participants and inviting them to take part. Such resources can include clerical/administrative support.
- Patients should be assured that their quality of care and relationship with their GP will not be affected by whether or not they choose to participate in a study. They should not feel coerced or be given undue worry or embarrassment.

## Before research studies begin

1. Practices should check that any proposed research has been approved by a research ethics committee, an NHS or university R&D office, and the research funder.
2. GPs should assure themselves that the practice provides an appropriate setting and has the necessary resources (which may be provided by the researcher), and that any potential conflicts of interest have been addressed.

## Informed consent

Where patients are contacted to seek consent to take part in research, the process is well established:

- Potential research participants must be provided with information on the purpose and nature of the study, their role, what will happen to samples, plus other relevant information, including the right to withdraw from the study at any time and an assurance that this will not affect their relationship with their care team.
- Published guidance (e.g. General Medical Council guidelines) should be followed when obtaining consent from adults who lack capacity or for undertaking research with children.
- Consent/dissent should be logged in the patient records (unless they specify otherwise, in which case patients should be informed that they may be contacted again in future).

## Feedback of research findings

- Researchers are responsible for reporting overall findings to the practice GPs as agreed.
- Participants should be aware of the findings that they may receive; the level of such feedback, or the option to decline to receive such feedback, is agreed as part of the consent process.
- As the patient's advocate, GPs are responsible for discussing a patient's results with them where appropriate.
- Feedback should be sensitive to the needs of the participant and communities in which they live.

# Concepts and legislation

## Identifiability of information

### Anonymised

- **It is not possible to identify an individual:** although data are provided at an individual level, there is no way of establishing a link with the original, identifiable clinical record.
- Data **do not include identifiers** such as name, address, full postcode, full date of birth or NHS number. ('Strong identifiers' such as these have been defined by the Committee on Standards of Data Extraction.)

*[Other terms used: irreversibly de-identified; unlinked anonymised information; unidentifiable.]*

### Coded

- **It is not possible to directly identify an individual**, but a 'key' is available that enables the identity of the patient to be **re-linked** to the data by the person who holds the key. The coded identifier should be globally unique and the key held under strict conditions.
- Alternatively, the data may become identifiable when used together with other data sources. The likelihood of such identification is increased where data relate to individuals with rare illnesses or exposures, or to small or unusual populations.

*[Other terms used: pseudonymous, key-coded, reversibly de-identified, linked anonymised, masked, encrypted.]*

### Identifiable

- This type of information contains personal data that **directly identifies individuals**.

*[Other terms used: identified, personal, nominative.]*

## Maintaining confidentiality of data

Several mechanisms have been put forward to maintain patient privacy and confidentiality. These include:

### Honest broker

A trusted custodian of data, with the dual role of "ensuring patient data confidentiality and security and ensuring scientific integrity of data". Responsible for:

- ensuring that coding and anonymisation processes are correctly implemented
- carrying out data quality checks that, for reasons of confidentiality, are not possible for researchers to do themselves.

### Safe havens

A designated physical or electronic area that provides the most appropriate level of security for the use of data. Researchers working in safe havens should be "bound by a strict code, preventing disclosure of any personally identifying information".

The Research Capability Programme of Connecting for Health<sup>1</sup> is currently defining how these services might be delivered across England. The Government, in its response to the Data Sharing Review, accepted the recommendation for the development of safe havens to minimise the risk of identifying individuals, and committed to develop a system to ensure that only 'accredited researchers' work within safe havens.

## The legal framework

The use of patient information for research in England is governed by a number of laws: the Data Protection Act (1998), the Human Rights Act (1998), the common law of confidentiality, Section 60 of the Health and Social Care Act (2001) and Section 251 of the NHS Act (2006).

Section 251 of the NHS Act (2006) permits the common law duty of confidentiality "to be set aside in specific circumstances for medical purposes", where it is not possible to use anonymised information and where seeking individual consent is not practicable. The Ethics and Confidentiality Committee, part of the National Information Governance Board for Health and Social Care, is now responsible for assessing applications for the sharing of identifiable patient information in such circumstances. The situation differs in the devolved administrations, and there is still considerable confusion and inconsistencies in the decision-making process.

<sup>1</sup> NHS Connecting for Health is a Department of Health agency that provides new computer systems and services to the NHS.

# Further reading

## Full report

- Wellcome Trust. Towards Consensus for Best Practice: Use of patient records from general practice for research. London: Wellcome Trust; 2009. [www.wellcome.ac.uk/GPRecords](http://www.wellcome.ac.uk/GPRecords).

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## Guidance for GPs and researchers

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