

## **Pilot 2 – Working paper**

### **The Use of Patient Records in Health Research – An Evaluation of the Potential Benefits and the Ethical, Logistical and Pragmatic Issues**

**Authors:**

Sandra MacRury, *Department of Diabetes and Cardiovascular Science, UHI Millennium Institute*  
Frances Hines, *Research and Development, NHS Highland*

**Suggested citation:**

MacRury, S. and Hines, F. (2010) *The Use of Patient Records in Health Research – An Evaluation of the Potential Benefits and the Ethical, Logistical and Pragmatic Issues*. Report for the Outdoors and Health Network, ESRC grant no. RES-355-25-0040

## **Contents**

|   |  |   |
|---|--|---|
| 1 | Introduction.....  | 1 |
| 2 | Patient records and the NHS .....  | 2 |
| 3 | Potential Benefits and Challenges of Using NHS Patient Records in Research ..... | 4 |
| 4 | Barriers for the Use of NHS Patient Records for Research.....                    | 5 |
| 5 | Using Patient Records – Reflections on the Required Processes .....              | 5 |
| 6 | Conclusions and recommendations .....  | 6 |
|   | References.....  | 7 |

## **1 Introduction**

This paper aims to provide a brief background to the use of NHS patient records in health research, and specifically in research that focuses on health and the use of the outdoors in the UK. It starts by identifying what kinds of patient records exist, and what type of information they are likely to contain. It considers the potential benefits and challenges of using patient records for research, and suggests some potential options for future research where the links can be made between such records and different types of research into the outdoors. The paper then goes on to discuss the process related issues that would face a researcher seeking to use patient records in this way, specifically discussing issues relating to ethics, access, analysis and interpretation and so on. It provides references and pointers to the relevant guidance and legislation where this applies. The paper concludes by summarising the potential benefits of and barriers to progressing with the use of patient records for researching projects within the health and outdoors framework, and provides some recommendations for potential ways forward.

It is generally acknowledged that research in the NHS is a vital part of ensuring better patient treatment and care (Department of Health, 2009). Research is needed to improve understanding of disease, and to find and assess the best clinical and non-clinical interventions to improving peoples' health. Most health related

research currently undertaken that involves patients will aim to access patient records in one form or another, whether directly in hospital where treatment may be directed by participation in a clinical trial, or indirectly through screening of records by a GP, for example, to identify potential suitable patients for participation in clinical trials or qualitative research at the request of a researcher, and to send out research packs to those patients. These points of access are largely made by clinical or medical or healthcare staff and therefore all the NHS processes of consent, confidentiality and data protection are in place and aim to protect the patient and their personal data to the highest level.

Currently, research activities that use patient records include audit, surveillance and monitoring e.g. of infectious diseases, drug safety and efficacy, vaccines and devices, epidemiological research and clinical trials or other research activities for the evaluation of drugs, treatments and interventions (Wellcome Trust, 2009:6). All of these research activities, with the general exception of audit (and service evaluation) will require NHS ethical approval through the research ethics committee process, and most will require NHS R&D management approval for each Health Board the research takes place in. Some studies will also require a range of different regulatory approvals. In summary, NHS related research activity is in itself quite a challenging activity, and the potential benefits have to be outweighed against the time and effort required to get the research approved and in place.

Accessing patient records for research activities that are instigated outside the NHS is quite common, and many Universities will take part in clinical research, for example, but the academic partners may be jointly sponsoring such research, may have joint or honorary contracts with the NHS, be funding the research through multi-centre trials, or be legally supported partner organisations. Even here, all such patient access is likely to be through patient consent and a lengthy ethical process. For academics not involved in any of these activities to find a way to access patient records is likely to be more problematic and challenging, as there is not a tradition of such activity, and the processes do not exist to support projects that are not medical or clinical but which still seek to access these records.

## **2 Patient records and the NHS**

The NHS is a huge organisation serving most of the population of the UK in some form or other, and as a result has the potential to generate patient records on approximately 60 million people. The situation is complicated by the fact that different types of patient records, and the mobility of the population which can generate new sets of records in some health related facilities. What this means is that the situation regarding patient records is complex, not transparent and not straightforward. In addition, there are differences between England, Scotland, Wales and Northern Ireland, and each Health Board, while ostensibly using the same or similar systems, can actually have local processes that further complicate the ways in which records are developed, used, stored, moved and accessed.

There are generally accepted definitions of what a health record is. The Department of Health, for example, using the Data Protection Act 1998 definitions, says that, a health record consists of “information about the physical or mental health or condition of an identifiable individual made by or on behalf of a health professional in connection with the care that individual receives”. ( ).

There is a difference between a health record held by a GP, and that held by a hospital. GP records include information about all points of contact with a patient, all issues raised by a patient at point of visit and comments by GP, details of all illnesses, details of all treatments and prescriptions, details of referrals and subsequent actions by secondary healthcare, results of scans, lab tests and other such activities, and other such details. GP notes can therefore be highly intimate and contain details that are not available to anyone other than the GP, and to some extent the patient. Even a patient’s family is unlikely to be given access to records, even after the patient is deceased, although this can be applied for. GP records are generally computerised and highly coded for illness and for treatment, and this data is gathered and returned to give national, regional and local pictures of disease and condition occurrence.

Hospital records generally hold a relatively wide range of details about a patient including:

- Basic details about the patient, such as address and next of kin
- Contacts the hospital has had with the patient, such as clinic visits
- Notes and reports about the patient's health, treatment and care
- Details and records about the patient's treatment and care
- Results of investigations, such as X-rays and laboratory tests
- Relevant information from other health professionals
- Relatives or people who care for the patient

A hospital health record is unlikely to be a neat and tidy collection of notes, or an e-record. It can be computerised, and there will probably be some handwritten notes, letters, lab reports, radiology reports including X-rays, scans, photographs, notes from telephone conversations and a mixture of other things.

Hospital patient records tend to be unwieldy and not easily interpreted except by a clinician.

The Department of Health has published a Code of Practice for Records Management (REF). This sets out the minimum periods for the times different sorts of health records must be kept. These are shown in Box 1 below.

**GP records** - until 10 years after the patient's death or after the patient has permanently left the country, unless the patient remains within the European Union. (Exceptions are patients serving in the armed forces or serving a prison sentence, when the records must not be destroyed.)

**GP records relating to children and young people** (including paediatric and vaccination records) - until the patient's 25th birthday, or 26th birthday if an entry was made when the young person was 17; or 10 years after the patient's death, if sooner.

**Dental records** - 11 years for adults. For children, 11 years or until the patient is 25 years old, whichever is the longer.

**Ophthalmic (eye) records** - 11 years for adults. For children, 11 years or until the patient is 25 years old, whichever is the longer.

**Children and young people** (all types of records relating to children and young people) - retain until the patient's 25th birthday, or 26th if the young person was 17 at conclusion of treatment; or eight years after death if sooner.

**Immunisation and vaccination records** - for children and young people, retain until the patient's 25th birthday, or 26th if the young person was 17 at conclusion of treatment. For adults, retain until 10 years after conclusion of treatment.

**Maternity records** - 25 years after last birth.

**Records relating to persons receiving treatment for a mental disorder within the meaning of the Mental Health Act 1983** - 20 years after the date of last contact between the patient and any healthcare provider, or eight years after the patient's death if sooner.

Box 1: Minimum Periods for Retaining Health Records (<http://www.nhs.uk/chq/Pages/1889.aspx>)

Following the expiry of the minimum periods for different health records, there are three possible actions that can be taken. First, the health organisation can decide in needs to keep the records for longer for some reason, but it has to be sure that it doesn't contravene the Data Protection Act (1998) in doing so. Second, it can transfer the records to an archive, and this is partly because of the potential for research i.e. "The Data Protection Act allows for personal data identified as being of historical or statistical research value to be kept

as archives” (<http://www.nhs.uk/chq/Pages/1889.aspx>). Finally, the health organisation can choose to destroy the records if it sees no value in keeping them.

### **3 Potential Benefits and Challenges of Using NHS Patient Records in Research**

Patient records hold a wealth of detail. The GP held record tracks the history of a patient from the point of birth to the point of death (and beyond to an extent), although the age of the patient at the beginning of the 21st century will determine the quality and accessibility of such records. It is also likely when patients move from one GP to another, as some patients do numerous times across their life, that records may become disorganised, missing some documents and lack comprehensibility. This is especially likely if the patient is not born in the UK, as countries of origin have varying qualities of healthcare systems and may not generate or provide records for such patients. Having identified these issues, however, if it is possible to access the GP held record, via consent and then agreement from the GP, the detail provided would clearly provide an opportunity to undertake longitudinal research activities. For example, matching health events to life experiences or to identifiable activities such as periods of sporting or outdoors based activity through substantial interviews with patients, and collection of other documentary evidence (sporting certificates, photographs, diaries etc), would be relatively simple and could provide a rich source of data, that has, because of the challenges of accessing patient records, been an area undeveloped from the health service or academic perspective.

Access to GP records for the purposes of research is the subject of much debate currently in the UK, with a number of documents identifying the need to manage this issue with rigour and clear compliance with existing regulations. Chief amongst this guidance is the Wellcome Trust “Towards Consensus for Best Practice – Use of Patient Records from General Practice for Research” published in June 2009. The guidance is based on three key principles, which provide both a challenge as well as a potential benefit for researchers. First, is the “overriding importance of safeguarding patient confidentiality and privacy” (Wellcome Trust, 2009:2) with clear reference to the need to determine what the data is to be used for. Second, is that “GPs and healthcare professionals should play the role of patient’s advocate” (op.cit) and must make sure that the protection for patients is the ultimate focus for any research activity. Lastly, there is “the need to improve public awareness and understanding”(op.cit) and it is suggested in the guidance that this should be through both national and local routes and that patients should be able to opt out of their records being used if they wish, and that such processes should be fully transparent.

The whole issue of managing patient records centrally and allowing patients to opt out of the system is currently a matter of high debate. In March 2010, the Summary Care Records system being developed in England and Wales, which aims to link 30000 GPs and 300 hospitals through a centralised computer system, has been under significant pressure and criticism from the BMA amongst other organisations, because of increased concerns about security and the lack of interest in the technology by GPs (<http://news.bbc.co.uk/1/hi/health/8559045.stm>). This is despite the rapid pace at which this programme is occurring, and it obviously has implications for access to such records for research, as well as treatment, purposes.

Hospital records present other challenges. They are not held for long periods in comparison to GP records, and may therefore, be intermittent throughout a patients life, unless that patient has a continuing history of accessing the secondary healthcare system. They do relate to higher level health activity on the whole i.e. to more serious health issues or events (these will be identified in the GP records, and some of the activity of the secondary care system will also be in these records, but not to the detail found in the hospital record). As indicated above, the hospital record is also likely to be difficult to interpret consisting as it does largely of a variety of formats including scans, photographs, handwritten (and often illegible) notes and so on. It will take a clinician to interpret and analyse such data, and that clinician would have to have clear structures and analytical frameworks to direct an efficient search profile.

There is already a system in place whereby researchers, and others, can access patient records without consent. The Caldicott Guardian process allows access to such records where it is not feasible for a researcher to gain consent, either, for example, because of the scale of the number of records that are wanted or because it is not feasible to seek consent for one reason or another. However, it does entail the researcher developing a lengthy application to the Caldicott Guardian of each Health Board and there is no guarantee that this application will be approved. In addition, the records accessed to not grant access to the patient in any way so it would not then be possible to contact a patient from a review of their records and then ask them for an interview or for further details. This kind of activity would have to have been consented to by a patient from the initial point of the research.

#### **4 Barriers for the Use of NHS Patient Records for Research**

Patient records are personal and private. GP records are even more protected than hospital records. As the GP Guidance states, “The general public, patient groups and individuals must have confidence that the security and confidentiality of personal information are protected, and that appropriate procedures are in place to safeguard data” (Wellcome Trust, 2009:2).

However, it is not just the immediate advocate of the patient who provides defence of access to patient records. There is substantial legislation governing such activities. While the Freedom of Information Act 2000 provides access to such public records in principle, health records are exempted under Section 21 as such information is available by alternative means (i.e. the Data Protection Act 1998). The Data Protection Act 1998 is a key piece of legislation which operates to ensure that access to health records is carried out only by those individuals and organisations given permission to do so, either by their professional and employment status, or through systems of access such as consent and ethical approval<sup>1</sup>. Access to the medical records of deceased people is equally controlled<sup>2</sup>. There are also a range of supplementary pieces of legislation, for example, the Access to Medical Reports Act 1988<sup>3</sup>, which is specifically focussed on access for employment or other such purposes.

One of the main problems in accessing GP patient records would be from the perspective of individual confidentiality. As the GP record is the only record of health and related events and issues for each person in the UK from point of birth to point of death, it is entirely comprehensive.

Further barriers to access may be from the patient themselves. There is not a very positive attitude amongst the patient population, or general public, about the use of patient records for research purposes.

#### **5 Using Patient Records – Reflections on the Required Processes**

If it is thought that despite the barriers and challenges identified above, that it would be useful to pursue the use of patient records there is a process and certain procedures that would need to be followed. The following brief account is based on the context that patient records from primary care (and secondary care where hospital contacts are involved) may be used in a project that attempts to parallel the use of the outdoors where information is gathered from an individual through life histories, and events are matched with health events.

Any project involving the NHS in any way will require NHS Research Ethics approval. To gain this, the research team would have to complete an ethics application and accompanying it with a very clearly

---

<sup>1</sup> *Data Protection Act 1998 governs access to the health records of living people. It became effective from 1st March 2000, and superseded the Data Protection Act 1984 and the Access to Health Records Act 1990, though the Access to Health Records Act 1990 still governs access to the health records of deceased people. The Data Protection Act 1998 gives every living person the right to apply for access to their health records.*

<sup>2</sup> *Health records relating to deceased people do not carry a common law duty of confidentiality. However, it is Department of Health and General Medical Council policy that records relating to deceased people should be treated with the same level of confidentiality as those relating to living people. Access to the health records of a deceased person is governed by the Access to Health Records Act 1990. Under this legislation when a patient has died, their personal representative or executor or administrator or anyone having a claim resulting from the death (this could be a relative or another person), has the right to apply for access to the deceased's health records.*

<sup>3</sup> *The Access to Medical Reports Act 1988 governs access to medical reports made by a patient's normal clinician for insurance or employment purposes. The Act only applies to a report prepared by the medical practitioner who usually looks after the clinical care of the person.*

developed protocol. The ethics committees expect to see evidence of available resources i.e. funding, insurance, scientific quality of the project, as well as peer reviews, evidence of researcher ability i.e. CVs, and a range of documents that are designed to explain the project to any patients, GPs, clinicians or others who will be requested to participate in some form. Ethical approval is a relatively long process, and from the point of submission of the application (without even taking into account all the preparation required to meet that point), it may take 3 months or longer to gain ethical approval. A project is also required to obtain NHS R&D management approval, and if the project is multi-centre it will have to be, in the UK at least, reviewed and processed by one of the central coordinating and review bodies. In Scotland, this is the NHS Research Scotland Permissions Coordinating Centre (NRSPCC). Once a project is approved centrally, it then has to go to each Health Board to be approved locally before it may proceed.

Even, when the governance aspects are satisfied and permissions given, it does not mean immediate access to patient records. Each patient that might be involved has to be identified (and this might be through screening by a GP), approached and invited to participate, provided with information about the project (using a Patient or Participant Information Sheet), and most importantly consented. Informed consent is the key component of the research governance process in health research, if a participant is not clearly informed about what they will be involved in, how and why, they are under no obligation to give their consent, and without written consent they cannot be included. While the patient may be happy to participate and the process of consenting is satisfactorily completed, this does not mean that the researcher will be able to gain access to records. GPs are legally responsible for the patient records they keep, and they are perfectly within their rights to refuse access to records, even when the patient has consented. This is because the records may contain information that they deem confidential or unsuitable for anybody other than practice staff to view. It is possible that a GP may agree to view the record on the researcher's behalf, and analyse the data contained to provide a summary, but this, of course, requires substantial resources and is expensive. If a project has sufficient funding to pay for GP involvement this might be one avenue to explore. Hospital records in some ways are more easily accessible as they do not have quite the same process of governance, as they exist for variable lengths of time, and are largely accessible to a potentially wide range of clinical and health staff. The problem with these records is in the interpretation of data, which will be in a variety of formats and may in such a way as to appear codified to non-specialist. Here, again, it is likely that access to such records, and the analysis of each record, would have to be undertaken by clinical staff who agree to take part in a project with the written consent procedure for patients supporting that decision.

Patient record analysis at GP level takes place continuously through data returns identifying disease and health trends, but there is less analysis of individuals over periods of time (other than for clinical review purposes). Thus, frameworks for analysis would have to be carefully developed for a project that wanted to track health events in the suggested way, with criteria for defining relevant events or markers perhaps being used to categorise the type and severity of health event. For hospital records, a clinician would have to be provided with a tightly focused framework for analysis that specified very clearly the categories and types of event, but perhaps using different values for categories as hospital care may generally be expected to involve health events of greater severity.

Parallel to these analytical challenges are those of interpretation. Without the use of categorisation in analysis of data the interpretation would be very subjective, and of relatively little value, even when matched with outdoor activity events. For example, a patient who identified a period of intensive walking activity and who felt this was related to a parallel timed cardiac event would not be in a position to know whether these activities had any correlation, and only careful scanning of the details of the cardiac event would allow a clinician to understand whether there was a relationship or not.

## **6 Conclusions and recommendations**

It is clear that there are a number of challenges facing researchers wishing to use patient records or details in any form of research. It is without doubt an area of concern to some patients and clinicians alike, and

while the UK Government seeks to have in place a comprehensive system or database of records predicated on an opt-out system, there is much current debate about the ethical issues surrounding this.

The challenges may seem to present a series of impossible hurdles that have to be overcome, with each one having the potential to derail the research process completely. If this wasn't the case, social science and health research of this type would be much more common. A weighing of the potential benefits and research outcomes from carrying out such projects would have to be carefully considered if such an approach was to be used.

It should not be an approach that is dismissed out of hand, however. Despite the challenges and difficulties faced, there are rich research and data opportunities available from using patient records for analysis that is not purely clinical in its focus, and the relating of health events to outdoor activity is one possible case that might be very fruitful to pursue.

## References

Department of Health. (2009). *The NHS Constitution for England*. Department of Health : London

Wellcome Trust. (2009). *Towards Consensus for Best Practice: Use of Patient Records from General Practice for Research*. Wellcome Trust: London

