Records management guidance and its implications for research

The UK Department of Health’s code of practice for managing records has important implications for nurse researchers. Naomi Reay and Jill Firth consider the steps researchers need to take to comply with the code.

Introduction

This paper discusses the Records Management: NHS Code of Practice (Department of Health (DH) 2006) and describes how it affects the management of data in research. It focuses on the pragmatic implications of this latest guidance for the creation, storage, maintenance, disclosure and disposal of records in healthcare research.

The value of patient records

Accessing patient records for research is not new. Researchers frequently use data sources such as paper health records of patients, electronic records, diagnostic test results and electronic databases to assist with their research. These records may serve as primary data sources or as a way of identifying potential research participants to be approached for recruitment.

While healthcare researchers focus on obtaining relevant approvals (DH 2005), they may be unprepared for the data management questions raised during these applications. They may also be unaware of the spe-
pecific data protection requirements of the NHS organisation in which their research is based.

This is unsurprising as many acts of legislation govern patient records. This legislation, together with examples of best practice, have been drawn together into the Records Management: NHS Code of Practice (DH 2006), a comprehensive document covering data held in any media and all NHS staff.

Published in April 2006, the code of practice draws upon over 40 acts of legislation as well as 'best practice'. Its intent is to establish a framework governing the creation, use, storage, management and disposal of all types of NHS record.

The stated aims of the code of practice are:

- to clarify the legal obligations that apply to NHS records
- to explain the actions required by chief executives and other managers to fulfil these obligations
- to explain the requirement to select records for permanent preservation
- to set out recommended minimum periods for retention of all types of NHS records, regardless of the media on which they are held
- to indicate where further information on records management may be found.

The document offers guidance for all those who work in or under contract to NHS organisations in England and covers all NHS records, even those of the deceased and patients treated in the private sector on behalf of the NHS.

**Types of records covered**
The code of practice covers all NHS records held in whatever media. This means that we have to expand our thinking beyond paper records or electronic databases to more modern media. Examples of these include:

- patient health records (electronic or paper-based, including those of all specialties and GP records)
- records of private patients seen on NHS premises
- accident and emergency, birth and all other registers
managing research

- theatre registers and minor operations (and other related) registers
- administration records (including, for example, personnel, estates, financial and accounting records, and notes associated with complaint-handling)
- X-ray and imaging reports, output and images
- photographs, slides and other images
- microform (for example, microfiche/microfilm)
- audio and video tapes, cassettes, CD-ROM and so on
- emails
- computerised records
- scanned records
- text messages (outgoing from the NHS and incoming responses from patients).

With work and research increasingly crossing the traditional boundaries of health and social care, the implications of the code of practice for social care records are also important. Although social care records lie outside the scope of the document, social care organisations are encouraged to consider adoption of this or similar standards of practice.

Creation, maintenance and transfer of records

In considering the implications for practice of the code, it is important to note that all NHS employees are responsible for any records that they create or use in the course of their work. All records created should be included in a record-keeping system to help users find them more easily, and each organisation is encouraged to audit what records are held, where and by whom. It is also part of the guidance that each record-keeping system should have a written set of rules for referencing, titling and indexing records. The guidance also stresses the importance of an audit trail of record movement and location.

Storage accommodation should be clean and tidy to prevent damage to the records. Digital records should be backed up and migrations planned to ensure safe storage and transfer. All media should be held in storage that is safe and secure from unauthorised access, and which meets health and safety and fire regulations.
Importantly for researchers, the transfer of information between organisations is mentioned in the code; this may be a key issue when designing multi-centre research.

The underpinning theme here is that the mechanism for data transfer should be matched to the sensitivity of the data and the media in which it is stored. This should be addressed in research submissions and can include measures such as ‘anonymising’ data prior to transfer. Guidance can be found in the information governance toolkit in part two of the code of practice.

**Storage, disclosure and disposal of records**

Disclosure of records is covered in Annex C of the code or the information governance toolkit, where the range of statutory provisions governing disclosure is listed. Each organisation has a Caldicott guardian or data protection staff; if there is any doubt, they should be consulted prior to accessing or disclosing information. This differs from formal requests by patients to access their records: such requests should be referred to data protection staff or the patient advisory service of the organisation immediately as there is a short timescale in which to consider them.

The general principle for storage and disposal of records is to adopt the policy of the organisation in which the records are held. There is a slight anomaly here. The code of practice does mention the fifth principle of data protection, which is that the data should not be retained for longer than necessary. However, as part two of the code illustrates, the guidance on length of storage varies according to the purpose of the record. Clinical trial records relating to investigational medicinal products have a specific recommendation for retention times. It is also noted that some records may be appropriate for storage as part of a national archive and it is recommended that the advice of an archivist is sought if the data to be disposed of could be of this type (Annex D).

The situation in primary care differs slightly in that data disclosure from GP surgeries remains the decision of the GP. However, it is recommended that data protection officers be consulted regarding disclosure of records. Further information regarding the transfer of electronic patient records
between GP practices is available from the Department of Health website (DH 2005b).

**Implications for data management in healthcare research**

The implications of this guidance for NHS and nursing research are far-reaching. Records specific to research such as research databases or documentation created solely for research are not singled out for exemption. Indeed, the use of records to support improvements in clinical effectiveness through research is mentioned as one of the possible uses of data covered by this guidance. Therefore, unlike the Data Protection Act (HMSO 1998), where there are specific exemptions for some data recorded and stored for research purposes, this guidance appears to make no such distinction.

The scope of the code of practice is clearly broad and there are many practical implications for researchers to consider. These need to be considered when designing research and will influence the entire process, from identifying and sampling potential participants through to storing data after the project is complete. The guidelines that surround records management need to be acknowledged and addressed by healthcare researchers and included in the relevant research governance submissions for projects involving the use of NHS staff or records.

**Conclusion**

The *Records Management: NHS Code of Practice* gives clear and comprehensive guidance that applies to all NHS staff and health records. The code of practice affects the creation, storage and disposal of records, as well as the access to and disclosure and transfer of information. The potential impact of the code on the management of research records is considerable and needs to be disseminated in the healthcare research community.

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