Workshop report

Data confidentiality and data handling in research: a workshop report

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ABSTRACT

Background Medical records are not only a vital tool for the delivery of health care to individual patients but also hold information with significant potential for research. However, patient records contain personal information, and some medical details may be particularly sensitive. The Wellcome Trust produced a draft consensus statement for the use of patient data in research as a result of discussions with GPs, researchers and patient groups. The purpose of this document, produced in May 2008, was to provide guidelines for best practice when general practice records are used for research.

Method The recommendations made in the consensus statement were discussed by academic primary care researchers, National Health Service (NHS) research and development (R and D) department staff, and UK primary care research network managers at a workshop held at the Society for Academic Primary Care (SAPC) Annual Conference 2008 in Galway.

Outputs Workshop delegates were largely supportive of the recommendations made in the draft consensus document. Key recommendations included: a campaign at a national and local level highlighting the need to use personal patient records to inform research; standard operating procedures to ensure clearly defined processes are being followed; and the requirement for all patient data to be treated as confidential.

Keywords: computerised medical record systems, family practice, patient data privacy

Background

General practice is the primary route through which the NHS provides comprehensive health care to the UK population, from ‘the cradle to the grave’. Nearly all people in the UK are registered with a general practice, and there are high levels of contact, continuity and trust between patients and general practitioners (GPs). Patient records in general practice, particularly the electronic variety, are therefore a unique and valuable resource.1

In addition to being a vital tool for the delivery of health care to individual patients, information in patient records holds significant potential for research. Research evidence is needed to inform decisions in general practice and primary care, improve understanding of disease and evaluate new interventions.2 Because data held throughout the NHS are representative of the whole population, research findings can be relevant to a wide number of people.3 Alternatively, it is possible to use NHS records to identify sub-populations with specific conditions.

However, patient records contain personal information, and some medical details may be particularly sensitive. The general public and patient groups must have confidence that the security of confidential information is protected and that appropriate procedures are in place to safeguard data. The SAPC Annual Conference for 2008, in Galway, held a workshop to discuss a recent consensus statement prepared by the Wellcome Trust.4

Draft consensus statement

As a result of discussions with GPs, researchers and patient groups, hosted at the Wellcome Trust in May...
2008, a draft consensus statement *Towards a Consensus on Best Practice: use of patient records for research in general practice* was produced. The purpose of this document is to provide guidelines for best practice when general practice records are used for research. Research governance arrangements vary throughout the UK and this is reflected in the workshop discussions and the daily experience of researchers.

The document begins by providing background information about the different ways in which patient records may be used in research and the type of information that might be used. It then highlights a number of overarching principles that were agreed during the meeting:

- the need to ensure transparency, and to improve public awareness and understanding about the use of patient records in research
- the overriding importance of safeguarding patient confidentiality, and the need to clearly define the processes and procedures for the use of data, and
- the primary role of the GP as the patient’s advocate.

The main focus of the document is to provide guidance for best practice, including discussion of several specific issues which were identified as problematic and therefore needing particular clarification:

### Research using patient records as the starting point for participatory research

- Using patient records to identify potential participants
- Inviting patients to take part in a study
- Seeking informed consent

### Research using existing patient records alone

- Using anonymised data
- Using pseudonymised data
- Using identifiable data

### Maintaining confidentiality of patient records and data security

- Procedural controls
- Physical security
- Electronic security

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**Box 1 Draft consensus document recommendations**

1. A campaign to raise awareness of the importance of research and the need to use personal records to inform that research should be undertaken at:
   - national and
   - practice level.

2. Electronic measures to ensure data security should be deployed:
   - treat all data as sensitive
   - use privacy enhancing technologies
   - honest brokers, trusted third parties and safe havens.

3. Standard operating procedures (SOPs) should be in place:
   - contract between researcher and practice

4. Primary care team support and training in data confidentiality and data handling should be a priority in continuing professional development.

5. Anonymous records should be used where possible, e.g. anonymised datasets such as QResearch, GPRD.

6. Pseudonymisation should be applied:
   - when record linkage is required
   - multiple keys
   - honest brokers.

7. Consent for consent:
   - it is often necessary to review medical records to determine whether patients meet the eligibility criteria for a study
   - who should initially screen the records? In some cases, it may need to be a member of the research team if practices do not have adequate staff resource for this additional task – even if funded.
   - GP must retain ultimate responsibility for the process.
Aim of the workshop
To discuss current issues affecting researcher access to primary care data and approaches to addressing any problems.

Attendees
The workshop was chaired by Professor Frank Sullivan, Director of the Scottish School of Primary Care, and was attended by academic primary care researchers, NHS R and D department staff and UK primary care research network managers (28 in total).

Methods
Textual analysis of contemporaneous notes was undertaken after the workshop and the record was shared with all workshop participants prior to preparation of this report to ensure accuracy.

Scottish primary care research SOP for data handling and data confidentiality
Delegates first highlighted any issues in relation to data handling and data confidentiality. Workshop participants were invited to comment on the SOP dealing with this topic currently being used by the Scottish Primary Care Research Network.

There was general agreement that at this point in time the SOP could not be used in England and that patients were being disadvantaged by not being given the opportunity to participate in research. It was felt that whilst patients are largely enthusiastic about taking part in research, the difficulty lies with individuals in positions of responsibility taking a paternalistic attitude. There was discussion around which organisation would be responsible for policing any processes put in place and whether it would be the body that replaces the Patient Information Advisory Group (PIAG).

Discussion of draft consensus document recommendations
1 Improving public awareness and engagement
Participants agreed that a national campaign undertaken by the UK Clinical Research Network (UKCRN) to raise the importance of research could be part of a wider raising of awareness around security of patient data, possibly associated with the 60th anniversary of the NHS highlighting 'what we can achieve in the next 60 years'.

Information could be provided locally on an opt-out basis – the new NHS constitution will emphasise that research is part of the NHS and patients will have to opt out if they do not want their data to be used. There was some discussion as to whether practices as well as patients could opt out; it was felt that the gold standard would be that all practices should take part in research and that opting out would be seen as being out of step.

2 Safeguarding patient confidentiality
Delegates agreed that all clinical patient data should be treated as potentially sensitive.

3 Confidentiality agreement
It was agreed that a confidentiality agreement rather than a contract was required between researchers and practices and that there should be clear penalties for any researcher breaching the agreement. There was discussion around who should be responsible for monitoring adherence to the contract and whether the recently introduced research passport would be an acceptable permit to practice, with the possibility of additional information such as criminal records checks being provided if necessary. Any agreement should be clear and understandable to the practice and emphasise the safety of the patient.

Further information about research passports and honorary contracts can be obtained within the current National Institute for Health Research guidance. There is at present insufficient experience of implementation of this arrangement throughout the UK to be able to say whether it will address many of the problems currently experienced.

The Health Information Governance Toolkit is a series of requirements produced jointly by the Department of Health and NHS Connecting for Health and is a tool with which organisations can assess their compliance with current legislation and national guidance.

4 The role of the GP
Paragraphs 24 and 25 of the Draft Consensus document state that, in relation to research, the primary role of the GP should be to act as an advocate for the patient and he or she must retain ultimate responsibility for access to data and the associated processes. Delegates recommended that the word 'GP' should be replaced with 'responsible primary care professional' in this section of the document.
5 Preconditions for research studies in general practice

Delegates agreed that any research included in the UKCRN portfolio could be considered by GPs to have reached a certain benchmark in terms of quality, relevance and importance. Research which is not within that portfolio would require further consideration by practices on whether they should enable access to researchers. Several delegates considered that they were inadequately skilled or resourced for this task and would appreciate support from local primary care research network or other academic colleagues.

6 Using anonymous data

There was consensus that anonymised patient records should be used wherever possible for the purposes of research. There was discussion around who should be responsible for monitoring the process of anonymisation and it was suggested this needed to be a high level authority such as the successor to the PIAG.

7 Reviewing records to identify potential participants

Delegates agreed that whilst the GP or responsible custodian must retain ultimate responsibility for the process of accessing records, it should be viewed as best practice for the researcher to undertake this on behalf of practice. GP data extraction services such as Morbidity Information Query and Export Syntax (MIQUEST) in England (soon to be the GP Extraction Service – GPES) and Scottish Enhanced Functionality (SEF) already allow the numbers of potentially eligible patients to be estimated if practices consent to allow such access. The emphasis should be on a partnership between the practice, the patient and the researcher.

Key workshop recommendations

• A national campaign undertaken by UKCRN to raise importance of research could be part of wider raising of awareness around security of patient data. Information could be provided locally on an opt-out basis – the new NHS constitution will emphasise that research is part of the NHS and patients will have to opt out if they do not want their data to be used.
• SOPs should be in place to ensure clearly defined processes for uses of data, with appropriate procedural controls, including accreditation and sanctions for those who have access to data.
• All patient data is potentially sensitive and the privacy of such information must be protected.

The readers of Informatics in Primary Care represent a knowledgeable group whose views regarding the issues highlighted in this paper are welcomed. Please submit further information either to Frank Sullivan fm.sullivan@chs.dundee.ac.uk, who will pass any comments to the Wellcome Trust secretariat, or directly to Nicola Perrin n.perrin@wellcome.ac.uk. The journal would also welcome letters to the editor on this issue.

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REFERENCES

8 Scottish School of Primary Care. www.sspc.ac.uk/spcrn/
9 PIAG. www.advisorybodies.doh.gov.uk/piag/
CONFLICTS OF INTEREST
None.

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