

# Using patient records for medical research

The recent UK Academy of Medical Sciences report *Personal data for public good: using health information for medical research*<sup>1</sup> addressed several issues concerning uses of patient data for medical research, which are important for general practice.<sup>2</sup>

## STUDIES OF MEDICAL CARE

The primary concern of GPs, with respect to uses of patient records, is to do nothing that jeopardises the trust of patients, which is partly based on assurances of confidentiality concerning the content of consultations. The Academy report quotes one submission in response to its call for evidence:

*'When people go to their doctor or health professional, they are seeking treatment because they are unwell, and not to become subjects of research.'*<sup>1</sup>

Nevertheless, research is an important part of health care. To provide effective and equitable care for 100% of the population, the NHS needs research and intelligence based on 100% of the population, which is generally only available from studies of patient records. Many important research questions can only be addressed by combining data from large numbers of practices.

Increasingly, such data are becoming available, and will need to be used imaginatively and effectively if primary care is to be recognised and supported in its capacity as a major force for health improvement.

The general principle to be followed is that where records cannot be fully anonymised, the patient's informed consent must be sought. As the Academy's report illustrates, however, complete anonymisation is sometimes impossible (for example, for some types of record linkage), and may be counterproductive, in terms of the research questions being asked.

Obtaining informed consent is desirable but can be prohibitively expensive, and involve predictable effects in terms of responders and non-responders, introducing serious bias to the research, and reducing the generalisability of the findings.

Research ethics and governance committees have tended to take a strict line on these issues, putting protection of the individual above the public interest in high quality research. The Academy's report argues that ethics committees have been over-cautious, providing the public with a level of protection that patients may not want and that may be disproportionate to the risks involved in using patient records for epidemiological research. Research is needed on what people actually think. The limited research which exists suggests that while most people have never given any thought to such matters, they are generally understanding and supportive of the need for research based on medical records.

A key consideration is that there should be 'no surprises'. If we have learned anything from such episodes as the Alder Hey affair it is the danger of relying on professional assumptions about what is acceptable. The public needs to be 'on board' in understanding and supporting the types of uses to which medical records may be put.

## RECORDS AS THE STARTING POINT FOR RESEARCH

The report also recognises a series of issues concerned with the use of primary care records as the starting point for research studies involving either the general population or patients with particular conditions. It calls for good practice guidance on the procedures by which health records may be accessed at the start of the research process, and the mechanisms for contacting potential study recruits and for registering agreement or refusal to participate.

Particular issues concern the definition of 'sensitive' and 'non-sensitive' conditions, the extent of prior screening of records before patients are approached, who should have access to records, and the use of 'opting in' and 'opting out' as methods of recruitment. For example, while opting in is the approach of choice for protecting patient autonomy, the effects on case-mix and social selection have been shown to reduce the generalisability and, thus, the usefulness of research findings.

Responsibility for the development of guidelines on good research practice has been given to the UK Clinical Research Collaboration (UKCRC), which has primary care involvement and representation, but mainly involves secondary care interests.

There is an important potential role, therefore, for the RCGP and the Society for Academic Primary Care, in contributing to the development, discussion and promulgation of guidelines on good research practice, both for research studies analysing primary care data and for studies using primary care data as a sampling frame. The RCGP could also give guidance on the role of service GPs, in the various intermediary roles they may play, between patients and researchers.

## CONNECTING FOR HEALTH

The Academy report looks forward to potential uses of the NHS Care Record for research purposes, assuming that practical issues, concerning the establishment of the record and the associated information system, can be resolved. The RCGP, on the other hand, in its recent decision to recommend the inclusion of patient data on an 'opt in' basis, has focused on the practicalities and uncertainties of the new system, and has taken a 'safety first' approach.

In a sense, the Academy argues that public understanding and support needs to be gained, in order to allow research uses of personal data for public good,

# Flora medica

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while the RCGP argues that a prior task is to win public confidence in the new information system, as a secure and appropriate way of managing personal health information.

These positions focus on different stages of a process, and are not irreconcilable.

### CONCLUSION

The Academy report highlights many issues, many of which lie at the heart of current discussions and debates concerning the rights and responsibilities of patients in the NHS — consumers or citizens?

The report argues that in order to protect and promote uses of patient records for medical research, the general public and its representatives need to be convinced, not only of the value of research based on patient records, but also of the validity of assurances of good research practice.

We need to put our own house in order, therefore, by agreeing and following the highest standards of research practice. A bigger task is to win public understanding and support for the various research uses of patient records. Only if both of these objectives are achieved will everyone benefit from the huge research potential of medical records.

Graham Watt

### REFERENCES

1. Academy of Medical Sciences. *Personal data for public good: using health information in medical research*. <http://www.acmedsci.ac.uk/index.php?pid=99&puid=62> (accessed 4 Jul 2006).
2. Editorial. Striking the right balance between privacy and public good. *Lancet* 2006; **367**: 275.

#### *New Eng J Med* Vol 354/355

**2552** Wouldn't it be nice to have a marker to tell us which patients were at highest risk of developing type 2 diabetes, and how successful we were at preventing it? Serum retinol-binding protein 4 may be just the thing we need to guide our treatment.

**2645** As you'd expect, men who wear condoms spread less human papilloma virus.

**2764** Higher levels of homocysteine (HCy) are a risk factor for dementia, so successfully lowering HCy using three B vitamins over 5 years should have prevented dementia. But it didn't.

**2794** Learn to recognise early Lyme disease: as time ticks by, you may see a case.

**21** Sooty lungs in children work less well than clean lungs: a study of lung function in relation to carbon in sputum macrophages.

**31** Influenza is also bad for little lungs, and most of it could be prevented by universal childhood vaccination.

#### *Lancet* Vol 367/368

**1990** Aberdonian laboratory doctors decided that instead of moaning about the way that GPs used tests, they would give them feedback. It worked, though I don't agree with some of their advice.

**2061** Good old fashioned ECG changes can still have a prognostic role in acute myocardial infarction: Q waves on arrival in hospital predict a bad outcome.

**29** A rather crude trawl through a big Canadian database shows that if 'diabetes' appears on your medical record before old age, expect 15 fewer years of life.

**83** David Grimes speculates that statins might be analogues of vitamin D, bringing a bit of sunshine into people's lives.

**119** Newly released prisoners are at high risk of suicide. Am I alone in thinking that society is getting crueller and less interested in rehabilitating offenders?

**139** A study from London clinics shows that there are gay strains of gonorrhoea and straight strains, and rarely the twain do meet.

#### *JAMA* Vol 295/296

**2605** Anorexia nervosa continues to elude our efforts to understand and treat it. Merely giving fluoxetine does not prevent relapse.

**2752** Statins continue to star: perhaps they prevent cataracts?

**2851** Cognitive behavioural therapy (CBT) is a much better treatment than zopiclone for insomnia in Norway. British insomniacs

can simply lie awake thinking about CBT, or take zopiclone and dream about it.

**47** The pleasure of smoking is mimicked by a new nicotine receptor partial agonist, varenicline, which in a double-blind trial seems twice as effective for smoking cessation as bupropion.

**87** Puzzled by some mildly abnormal liver function tests? Ask about paracetamol, which can elevate aminotransferases even at normal therapeutic doses.

#### *Arch Intern Med* Vol 166

**1190** Coffee prevents alcoholic cirrhosis. This big cohort study provides as much prospective evidence we're ever likely to get, and it shows a marked dose-related benefit. And there's more evidence that coffee prevents type 2 diabetes too on page 1311.

**1196** Sssh! Here's a study that seems to show that there is a group of people for whom smoking confers no cardiovascular risk — black American men.

**1301** A British study shows no association between routine vaccinations and Guillain-Barré syndrome.

#### *Ann Intern Med* Vol 144/145

**877** Strange indeed are the ways of atopy. In Israeli army recruits, pre-existing asthma seems to lower the risk of inflammatory bowel disease and rheumatoid arthritis, especially in women.

**1** The Mediterranean diet is a good thing. Even in the first 3 months, it cuts your cardiovascular risk factors, rather like transcendental meditation (see *Arch Intern Med* page 1218).

**12** We need more sham acupuncturists. In every trial, sticking the needles in at random is as good as acupuncture, and both are better than physio for knee arthritis.

#### Guest Journal of the Month: *Br J Gen Pract* Vol 56

All GPs should seek the pleasure of interacting with their national journal. At least write a letter; maybe an editorial; a nice opinion piece for the Back Pages; or do some research. There were good examples of all these in the July issue. My favourite was the paper showing that nurse practitioners are poorer value than salaried GPs for most purposes (page 530).

#### Plant of the Month: *Fagus sylvatica* var *heterophylla* 'Aspleniifolia'

August is a month to seek shade. Posterity will bless you for planting the most beautiful of shade trees, the cut-leaved beech.