Confidentiality, clinical governance and research in the community

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If the police and data protection registrars can be unclear and contradictory about laws regarding information about individuals, as they seem to be in the United Kingdom (UK), how does this affect those who want to access data in primary care computer systems for non-clinical purposes?1 The UK Data Protection Act of 1998 has presented challenges for those engaged in epidemiological research using patient data.2,3 But the precise meaning of this Act, and others that flow from European human rights legislation, is still very much open to interpretation. In this climate of uncertainty, custodians of health information might feel that the only way to protect themselves from future allegations of impropriety with data is to take the most conservative option when considering requests from researchers. Perhaps unsurprisingly, Caldicott Guardians and other controllers of individually identifiable patient data have often been reluctant to give permission to access data for fear of acting unlawfully.4

Debate as to what research activities may legally be undertaken has occurred in research ethics committees, scientific grant-awarding bodies, the General Medical Council, the British Medical Association and the Royal Colleges, but a unified opinion has not yet emerged.5,6 Such conflicts between individual data subjects’ rights and the benefits to patients and society are not unique to the UK. Legislation in the United States (US), New Zealand and Australia poses similar challenges to health professionals and academics.7

The conservatism of this uncertain environment creates problems for those who seek to carry out research with routinely collected health information. Where databases have been maintained for a long period of time, the current climate threatens their continuity, potentially destroying some of the most unique and valuable aspects of long-term structures in the health system.8

At worst, conservatism over data protection can impede clinical governance and research activities even when there is a clear and relatively uncontroversial need for them. In 2001, a New Zealand ministerial inquiry reported upon an investigation of serious faults in the national cervical screening programme, which resulted in undetected cancers and subsequent deaths. The inquiry found that there were substantial impediments to the collection of information for the effective monitoring and evaluation of the cervical screening programme; it was recommended that legislative changes be implemented in order to facilitate the necessary information collection, and that the role of ethics committees be clarified so they would not delay audit, monitoring and evaluation activities.9 In the atmosphere of concern about data protection, those recommendations have taken three years to implement, rather than the six months originally proposed.10 In the absence of definitive arbitration from the courts about approaches to working within the legislation, a means of clarification that investigators are unlikely to pursue by choice, the process of bringing greater certainty to the conduct of research based upon individual-level information will have to proceed through a renewed effort to achieve consensus.11,12 This has greater urgency for some researchers than for others. In primary care, with its inherently distributed and fragmented infrastructure, the ability to link data at the individual level is key to many research projects. This can be contrasted with institutional healthcare settings where the information for a piece of research might well be collected routinely under the aegis of a single organisation, making further data linkage less critical.

The Nuffield Trust has identified three alternative approaches to the problem of using individual information for research purposes. Briefly, these are:13

- use personal data with consent or other assent from the data subjects
• anonymise the data, and then use them
• use personal data without explicit consent, under a public-interest mandate.

The second of these proposals has been explored in Scotland, with the concept of ‘acceptable anonymisation’ proposed by a Committee on Confidentiality and Security. This approach allows data from primary care to be extracted into regional repositories of data where, with appropriate ethical committee and Caldicott Guardian approvals, it may be linked to other data sources for the purposes of research and clinical governance. To date this system appears to be serving the needs of the various stakeholders, and has the support of researchers and information guardians.

The cost of this approach is in the additional layer of management required to conduct the anonymisation process independently from researchers. This involves providing staff and facilities for the linking and anonymising task, which can be substantial. It also involves allowing time for researchers and anonymisation staff to work together to develop a mutual understanding of the dataset and the research imperatives, so they can accurately specify the dataset for any one research project. These costs can be significant, but they are crucial to the success of a programme which meets the needs of ethical data management as well as effective research. However, it is envisaged that as experience with the system develops, and as new technology is implemented, access to data will become more direct within the ethical constraints that are embedded in the system.

The use of routinely collected individual patient data for research purposes is a relatively recent phenomenon. The necessary technology to collect data in a timely fashion from many sources, to collate them in a consistent way and to render the results in a form that is useful to researchers has only become widely available in recent years. Most readers of this journal will not need to be convinced that these techniques bring considerable new powers to investigate and improve health systems, but it is important always to be conscious that the ability to conduct this type of research is dependent upon having effective safeguards against the misuse of research resources. While the atmosphere of uncertainty about data protection presents, in some respects, a threat to informatics research in primary care, it should also serve as an extra motivation to the research community to develop effective ethical processes for managing information that justify the trust of the community. Uncertainty is a challenge, but a positive response to that challenge will bring us a stronger system for managing individual data in health research.

REFERENCES
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