Protecting patient information

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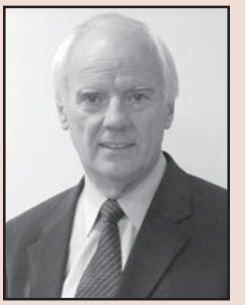
A general practitioner recently contacted me expressing concern that a researcher had advised him that he wished to approach one of his patients to recruit her to a study on the possible relationship between her disease and her occupation. The patient was distressed that, without her permission, the researcher had obtained her name and diagnosis from the Cancer Registry. Her doctor was also concerned that he had not been consulted about the release of her diagnosis and wondered how widespread this practice was becoming and whether doctors should be alarmed on behalf of those in their care. This was the second case of the sort reported to me in one week.

Hence my invitation to author this paper. I am grateful for the opportunity for, as a chairman of a Regional Ethics Committee, this matter has been a cause for concern to me and my colleagues for a few years. It is important that the views of doctors on the matter are canvassed and, as we shall see, that their cooperation in facilitating worthwhile research is encouraged. The latter cannot occur whilst there is concern about the confidentiality of patient information which doctors are obliged to respect.

Stored personal information is carefully protected by the Privacy Act. Health information is particularly sensitive and there are specific rules laid down in the Health Information Privacy Code for the limits on its use (Rule 10) and on its disclosure (Rule 11). Each of these rules has a bearing on the problem at issue.



Don Evans has been engaged in ethical review of research on human participants for almost twenty years in various parts of the world. He has conducted research into ethical review for the UK Department of Health, The European Commission, The World Health Organisation and the Council for International Organisations of Medical Sciences and consulted on the same in numerous countries including Russia, the United States, Zambia, the Philippines and Thailand. He has co-authored a book on the subject with Martyn Evans entitled A Decent Proposal: Ethical Review of Clinical Research *(John Wiley and Sons; 1996). He was appointed Professor and Director of the Bioethics Centre at the Dunedin School of Medicine in 1997.*

Rule 10 covers the responsibilities of agencies holding health information to restrict its use for the purpose for which it was gathered. There are exceptions to this restriction and these include cases where:

- the consent of patients or their representatives is given;
- the use is related to lessen a serious and imminent threat to public health or the health of the patient or another individual;
- the information is used in a form in which the individual is not identified;
- the information is used to avoid prejudice to law and order.

The section which specifically relates to the use of information for research purposes reads as follows:

'The information...is used for research purposes (for which approval by an ethics committee, if required, has been given)...10(1)(e)(iii)'

The role which the ethics committee plays in required cases is expanded in the commentary on the provisions of Rule 11 on the Disclosure of Health Information 11(2)(c)(iii) which reads:

'When an agency is approached by a researcher seeking the disclosure of health information, it will need to be satisfied (in addition to any other practical or ethical matters) that ethical approval has been obtained (if required)...The agency will also want to be satisfied as to the security safeguards and the manner of approach to the individual (if any). These issues should be anticipated by the researcher and addressed expressly within the protocol, with the ethics committee and in the approach to the agency.'

Given that the approach to potential research participants is a matter which ethics committees need to be informed about, it follows that those committees might be expected to make a range of judgements about it. Sometimes particular protocols are not approved because of an unsatisfactory proposed approach to patients. Others are given conditional

approval where suggestions for improving the approach are made by the committee and others are approved without reservation.

What are the concerns which exercise committees in this area of ethical review? Has any policy been developed to deal with the difficulties which arise?

The concerns of committees centre around the welfare of the research participant whose protection is their raison d'être. This has been expressed well by a legal observer concerned about privacy issues.[1]

'...the privacy of health information is special, in that a feeling of autonomy is part of what we see as a healthy person – part of the goal of health care. And Privacy is inextricably bound up with individual autonomy and feelings of self-worth. So to breach a patient's privacy is to prejudice their overall health.'

Some commentators have suggested that personal privacy has been overemphasised since the Cartwright Report and that such concerns are impeding important health evaluations and research.[2] It is certainly not the wish of ethics committees to impede research, but it is their responsibility to protect the welfare of research participants and this is a duty they cannot shirk even though it might make them unpopular. Why have we reached this impasse between the process of ethical review on the one hand and some groups of researchers on the other? There are two possible explanations which I shall canvass.

It is the business of ethics committees to view any piece of research dispassionately through the lens of the participants' interests

First, there is the possibility that ethics committees and these researchers do not share the same view of harm. There are more kinds of harm possible than physical harm. Devotion to the research enterprise is to be admired in researchers. This often manifests itself in their estimation of the importance of the kind of research they undertake, many researchers believing that their area of concern trumps those of others and calls for greater compromises of participant welfare to be made. For such researchers their estimation of the harms done to participants might be informed by their respective devotions to their activity. It is the business of ethics committees to view any piece of research dispassionately through the lens of the participants' interests. Such orientation will certainly link the question of privacy to the health interests of the recruit.

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Such was the case in the celebrated case which figured in the Gisborne hearings. The issue which caused ethics committees to require an amendment to the protocol was the manner of approach to the women who were to be recruited to a study in which they would be interviewed by people unconnected with their treatment. Whereas in other cases committees had reluctantly approved such approaches, it was not thought that the release of identifiable information in those cases was as threatening as in the case of women who had been at the heart of the cervical screening programme failure. Numbers of those women had complained that they had been disempowered by what had occurred in their treatment, or lack of treatment, and that things had always progressed beyond their control. The committees believed that for these persons to receive a letter from independent researchers who had been informed of their diagnosis would reinforce this sense of disempowerment. The suggestion was therefore made that the Cancer Registry send the letter of invitation on behalf of the research team. This proved to be impossible and, on reflection, undesirable for a number of reasons. However, contact through some agency which was entitled to access the information, such as the GP or the consultant responsible for their care, would have circumvented the problem.

The fear was expressed that this would so reduce the response rate that the research would be undermined. However when the study was redesigned to accommodate such an approach, the response rate was reported to be consistently high and consent rates in excess of 80% were achieved. Indeed, most of the women requested a face-to-face interview. Ethics committees have followed this precedent in subsequent cases. For this approach, which both protects individual participant interests and facilitates worthy research, to succeed the prompt cooperation of consultants and GPs is crucial. It is to be hoped that this collaboration will come to be seen as an integral part of good clinical practice in the interests of current and future patients. The case of the leukaemic patient cited above turned out well in that, after consultation with her practitioner, the patient was happy to enter the study. How much better it would have been had those discussions been prompted by the GP's approach to the patient proposing her recruitment to the study. And how much more likely it would be that patients would generally be prepared to cooperate in research enterprises if they were not at first distressed by the apparent disregard of the confidentiality of their medical records.

The second reason that estimation of patients' welfare might be differently perceived by researchers and ethics committees arises from the dif-

ferences in focus which might occur between the two. This dissonance is most obvious in the case of epidemiological studies where the researcher is not interested in particular cases but rather in populations or groups of patients. The notion of the public good is most highly profiled in this kind of research. Ethics committees, on the other hand, have a responsibility to protect individual research participants and make decisions which accord with a basic principle of the Helsinki Declaration I(5) which reads:

'Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.'

Thus there is a potential tension set up between the duties of ethics committees on the one hand and epidemiological research on the other.

The task of balancing risks to research participants and benefits to others is not straightforward, but ethics committees are obliged, in certain circumstances, to engage in such calculations. However in situations where both the protection of the interests of participants and the facilitation of research can be achieved together such balancing acts would not be required. Where no compromises on the part of the participants or the research enterprise can be achieved this is clearly the best route for committees to take.

The above suggestion for designing approaches to participants is one means of achieving this. Another is to encourage the use of non-identified health information. Much epidemiological work does not entail making contact with participants. Neither is the identity of individual patients significant in the research. Thus the encryption of health records in registers and databases together with the linking of registers offers a much more efficient and unobjectionable means of accessing relevant information than trawling through the medical records of known patients. This was a proposal made at the time of the Gisborne hearings but, according to recent reports, little progress seems to have been made in this direction. There are excellent precedents for it in registers such as the ANZDATA Registry concerned with tracking all records of renal patients in Australia and New Zealand, and the RNZCGP Research Unit Primary Care Database. Each of these databases protects the identity of both the patients and the hospital department or general practice from which the patient record is generated. Each provides a superb facility both for research and audit to which ready access is available. The latter uses an encrypted NHI number which is applied before the data reaches the register and this enables the data to be linked to the National Minimum Data Set for Secondary Care, belonging to the NZHIS, which is similarly encrypted.

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Thus there are both national and international precedents for the adoption of this means of facilitating good research and respecting the privacy of research participants. The latter Register has been developed in close consultation with the Otago Regional Ethics Committee and succeeds on the basis of the commitment of general practitioners to contribute to the research environment whilst honouring their obligation to respect the confidentiality of their patients.

I respect the concerns of both the GP who reported the leukaemia case to me and his patient. I support wholeheartedly the pursuit of health research in all its forms. I uphold the responsibilities of ethics committees to protect the safety and interests of research participants. Finally, I believe that there is no necessary clash between the commitments of caring practitioners, researchers and ethics committees. But carelessness about the protection of patient information in the research setting will produce tensions which will militate against the interests of both current and future patients.

References

1. Stevens R. 'Collation of medical records' presented at the Privacy Forum, Wellington, 28 March 2003; p1.
2. For example Ailsa Duffy, 'Effective quality assurance of health professionals', Privacy Forum, Wellington, 28 March 2003; p3–6.