

## Privacy legislation and research

Jonathan R Carapetis,\*  
Jonathon W Passmore,† Kerry Ann O'Grady‡

\*Senior Lecturer and Research Fellow, Department of Paediatrics and Murdoch Children's Research Institute, Royal Children's Hospital, Parkville, VIC 3052; †Victorian Public Health Training Scheme Registrar, ‡Epidemiologist, Victorian Department of Human Services, Melbourne, VIC.  
carapetj@cryptic.rch.unimelb.edu.au

**TO THE EDITOR:** The Victorian *Health Records Act 2001* became operational on 1 July 2002. This legislation provides important protection for the individual against misuse of health information through the establishment of Health Privacy Principles. We support the spirit of this legislation, but would like to draw attention to its potential effects on multicentre research and disease surveillance.

We recently began a study to estimate the burden of invasive group A streptococcal disease in Victoria. The study involves identification of patients through laboratory notifications, followed by collection of clinical data — a strategy similar to surveillance of notifiable diseases. The study is funded by the National Health and Medical Research Council. We have sought institutional ethics committee approval, and are obtaining individual informed consent from patients.

Despite approval from the Human Research Ethics Committee of the Victorian Department of Human Services, concerns arising from the new privacy legislation led most Victorian healthcare institutions to also require approval by their own ethics committees. We have now applied to over 30 separate committees, and the process is not yet complete. This has been an enormous drain on resources, has necessitated our establishing complex administrative procedures, and delayed commencement of the project. Moreover, many committees have required that we pay an application fee of several hundred dollars. Some have been uncertain about the implications of the new legislation for

our project, and have requested clarification from the Victorian Health Services Commissioner. Despite these processes, some clinicians we have contacted are unwilling to allow their patients to be approached for fear of breaching privacy legislation.

Our protocol is not controversial, and no substantive issues have been raised by any of the ethics committees. While ethical clearance is crucial to the success of the project, we were unprepared for the amount of work, confusion and expense involved. It is possible that these difficulties could discourage other researchers from conducting similar studies in Victoria. Similar concerns have been raised in the United Kingdom since the introduction of new privacy laws.<sup>1</sup>

The Victorian legislation allows for research and surveillance activities using identifying data if they are in the public interest, or if it is impracticable to seek individual consent. However, the legislation does not provide guidelines on what constitutes public interest or when consent is impracticable. The extent to which this legislation affects multicentre research or surveillance projects needs to be clarified, and a more simplified ethical approval process for surveillance activities identified.

1. Verity C, Nicoll A. Consent, confidentiality and the threat to public health surveillance. *BMJ* 2002; 324: 1210-1213. □

Kerry J Breen,\* Sandra M Hacker†

\*Chair, †Chair, Privacy Working Party of the Australian Health Ethics Committee, Australian Health Ethics Committee, National Health and Medical Research Council, GPO Box 9848, Canberra, ACT 2601.  
kbreen@access.net.au

**COMMENT:** It is unfortunate that a valuable research project has apparently been made more difficult or delayed by the combination of complex new privacy law and longer-standing inefficiencies in the ethical review of multicentre research proposals. Both are issues with which the Australian Health Ethics Committee (AHEC) is grappling at present.

Multicentre research was identified as a significant issue in the review that led to the revised 1999 National Statement on Ethical Conduct in Research Involving Humans.<sup>1</sup> The Statement makes it clear that researchers have a role in negotiating with human research ethics committees and institutions to seek agreement that the ethical and scientific assessment of one committee or institution will be accepted by other sites. The National Statement equally empowers ethics committees to minimise unnecessary duplication.

Ethics committees have been very slow to grasp the opportunities offered by the 1999 National Statement for reasons that may include the past practice of insisting that each committee make its own assessment. Initiatives are now in train in New South Wales, Victoria, Western Australia and Queensland to develop different forms of centralised assessment, but the benefits may take time to be realised. AHEC, through its bulletins and workshops for ethics committee members, has repeatedly reminded committees how to simplify multicentre review, but traditional practices appear to have obstructed this message. This letter is yet another opportunity to remind ethics committees and institutions that the National Statement permits and encourages them to exercise initiative, judgement and common sense in facilitating effective and timely review of multicentre research.

With regard to the difficulties associated with the new privacy regimes being put in place by a combination of federal and State laws, AHEC anticipated some introductory problems in relation to human research. It is understandable that ethics committees and researchers will take time to adjust some of their established practices to comply with the law and associated guidelines. During the period of adjustment, some flexibility needs to be exercised by all parties. AHEC conducted a series of workshops in all capital cities earlier this year to assist researchers and ethics committees in this phase. An explanatory guide to the use of privacy law and the associated guidelines from the National Health and Medical Research Council was used at these workshops and will be made more widely available shortly.

Finally, the federal legislation will be the subject of a systematic review after two years. Unintended consequences of the law should be addressed at that time. AHEC understands that, in Victoria, the Health Services Commissioner, whose office has responsibility for supervising the application of the health privacy law, is in the process of producing a practical guide for Victorian healthcare researchers.

### Correspondents

We prefer to receive letters by email (editorial@ampco.com.au). Letters must be no longer than 400 words and must include a word count. All letters are subject to editing. Proofs will not normally be supplied. There should be no more than 4 authors per letter. Each author should provide current qualifications and position and full details of postal address, telephone and facsimile numbers.

There should be no more than 5 references. The reference list should not include anything that has not been published or accepted for publication. Reference details must be complete, including: names and initials for up to 4 authors, or 3 authors et al if there are more than 4 (see [mja.com.au/public/information/uniform.html#refs](http://mja.com.au/public/information/uniform.html#refs) for how to cite references other than journal articles).

1. National statement on ethical conduct in research involving humans. Canberra: National Health and Medical Research Council, 1999. <http://www.nhmrc.gov.au/publications/pdf/e35.pdf>. □

### Loane L C Skene

Professor, Faculty of Law, University of Melbourne, Parkville, VIC 3052. [l.skene@law.unimelb.edu.au](mailto:l.skene@law.unimelb.edu.au)

**COMMENT:** As I understand Carapetis et al's study, the researchers determine who has a group A streptococcal infection from the laboratory that performs the test (as this infection is not a notifiable disease,<sup>1</sup> there is no central source of information). The laboratory may be independent or in a public or private hospital, and may be situated anywhere in Victoria. The laboratory tells them who requested the test and the patient's name and infection status. The researchers then seek assistance from the hospital or doctor requesting the test in obtaining "individual informed consent" from the patient to release clinical information to the researchers. Each institution has required that its own human research ethics committee approve the project, as well as the Department of Human Services (DHS) Ethics Committee, before the laboratory releases information. This accords with the law, but the additional bureaucracy and costs involved will deter much important public health research.

**The law:** In Victoria, public and private hospitals and their employees have a statutory duty of confidentiality under section 141 of the *Health Services Act 1988* (Vic). There is an exception when the patient consents (s 141(3)(a)), but, in Carapetis et al's study, patients cannot be approached until the laboratory gives identifying information. Information may be divulged for medical research without patient consent if an ethics committee "established under the by-laws of the agency" has approved "the use to which the information will be put and the research methodology" (s 141(3)(g)). The giving of information must also accord with Health Privacy Principle (HPP) 2.2(g) in the *Health Records Act 2001* (Vic): it must be necessary and "in the public interest"; it is impracticable to seek consent; identifying information is needed; identifying information will not be published; and it must conform with the Guidelines of the Health Services Commissioner.<sup>2</sup> The federal *Privacy Act 1988* (Cwlth) contains similar provisions.<sup>3</sup>

**Options for change:** The Health Services Commissioner has power to issue guidelines varying the subparagraphs of HPP 2, and even to lessen the level of privacy protection, if it is in the public interest to do so.<sup>4</sup>

However, guidelines cannot override the requirement in the Health Services Act that projects must be approved by the ethics committee "established under the by-laws of [each] agency". There are four options for change:

- The Health Services Act could be amended so that approval of *one* human research ethics committee is sufficient.

- The Secretary of the DHS could prescribe more diseases as notifiable,<sup>1</sup> so that information is available centrally, and access could be authorised by the DHS Ethics Committee.

- The Secretary could request information from pathology laboratories for public health research and supply that to the researchers (laboratories would be protected under section 137 of the *Health Act 1958* [Vic]).

- Institutions could amend their by-laws — or ethics committees could adopt a policy — that the institution will follow the approval of the DHS Ethics Committee in public health research.<sup>5</sup>

The last seems the simplest option, but historically this approach has not been favoured in multicentre trials in Australia.

1. Health (Infectious Diseases) Regulations 2001 (Vic) reg 6, scheds 3, 6.
2. *Health Records Act 2001* (Vic) s 141(3)(g)(iii). Sched 1, Health Privacy Principle (HPP) 2.2(g).
3. National Health and Medical Research Council. Guidelines approved under Section 95A of the *Privacy Act 1988*. Canberra: NHMRC, 2001. Available at <<http://www.nhmrc.gov.au/publications/synopses/e43syn.htm>>
4. *Health Records Act 2001* (Vic) s 22(1)(a)(5).
5. Tully J, Ninis N, Booy R, Viner R. The new system of review by multicentre research ethics committees: prospective study. *BMJ* 2000; 320: 1179-1182. □

### Opportunistic screening for type 2 diabetes mellitus in public hospitals

Anthony T Zimmermann,\* Stephen N Stranks,† Sally L Gall,‡ Geoffrey S Hebbard§

\*Physician Trainee, Division of Medicine; †Director of Endocrinology; ‡Gastroenterology Nurse, Repatriation General Hospital, Daws Road, Daw Park, SA 5041. §Director of Gastroenterology, The Royal Melbourne Hospital, Parkville, VIC. [atzimm@ausdoctors.net](mailto:atzimm@ausdoctors.net)

**TO THE EDITOR:** Diabetes is a leading cause of morbidity and mortality in Australia, with 50% of cases remaining undiagnosed.<sup>1</sup> Consequently, the Australian National Diabetes Strategy has early detection of diabetes as a key priority.<sup>2</sup> We undertook a study to determine the prevalence of abnormal glucose metabolism (impaired fasting glycaemia [IFG] and diabetes) in patients presenting in the fasted state for endoscopy or colonoscopy at a metropolitan teaching hospital. We used the

### Results of fasting plasma glucose tests in 224 patients presenting for gastroenterological procedures

#### Fasting plasma glucose level

Normal (<6.1 mmol/L)	172 (77%)
Impaired fasting glycaemia (≥6.1 mmol/L, <7.0 mmol/L)	22 (10%)*
Diabetes (≥7.0 mmol/L)	6 (3%) <sup>†</sup>
Not tested (known diabetes)	24 (11%)

\*Diabetes was confirmed on subsequent oral glucose tolerance test (OGTT) in nine of these patients (four refused further testing).

<sup>†</sup>Diabetes was confirmed on subsequent OGTT in all six patients.

definitions of abnormal glucose metabolism outlined by the World Health Organization in 1999<sup>3</sup> and published in a position statement in the *Journal* in April 1999.<sup>4</sup>

Two hundred and twenty-four patients gave informed consent and participated in the study, comprising 126 men and 98 women. Mean age (SD) was 75.1 years (6.9) for men and 60.9 years (17.6) for women. Twenty-four participants (11%) had known diabetes. The remaining 200 patients had fasting venous plasma glucose levels determined (Box). Patients with abnormal glucose metabolism (fasting plasma glucose level >6.1 mmol/L) were offered further testing with a 2-hour oral glucose tolerance test (OGTT) after a 75 g glucose load. Nine patients initially classified with IFG had diabetes based on OGTT results. No patient classified with diabetes on initial testing was subsequently classified as not having diabetes by the OGTT. The overall prevalence of undiagnosed diabetes was 7% (15 patients).

We demonstrated a high prevalence of abnormal glucose metabolism in a group of predominantly elderly patients presenting for gastroenterological procedures. Furthermore, subsequent investigation of these patients revealed that a substantial proportion who were classified with IFG on initial screening were classified with diabetes based on 2-hour OGTT results, highlighting the importance of this test in diagnosing diabetes.

It is likely that we underestimated the prevalence of abnormal glucose metabolism, as OGTT was not performed in all patients. This is supported by results of the AusDiab study that revealed a high prevalence of abnormal glucose metabolism in older patients — 37% of those aged 55–64 years, 47% of those 65–74 years, and 53% of those 75 years and over.<sup>1</sup> National Health and Medical Research Council guidelines suggest that all patients with a fasting plasma glucose level of 5.5–6.9 mmol/L be