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Privacy: bad for your health?

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TO THE EDITOR: In Australia, personal and health information that identifies an individual cannot be used or disclosed for research without specific requirements being met.¹ Even if these requirements are met, data custodians may still refuse access if their views are discordant with those of the relevant human research ethics committee (HREC). It is now evident that there are adverse consequences of this well-meaning legislation.

Our research group conducts community-based vaccine trials. Recently, we attempted to use school enrolment lists to mail information to parents about a study. Despite approval from the Royal Children's Hospital HREC, one major governing body of Victorian public schools rejected our proposal on privacy grounds, as did several independent schools. Only a small number of schools raised no privacy concerns at all. The main concern expressed was that the use of these registers for health research was not related to the primary purpose of collection, and families had not consented to this use. The net result was substantially reduced access to the population eligible for recruitment.

We now have a situation in which the legislation may actually do more harm than good. This is an emerging issue here in Australia and overseas.^{2,3} Even more worrying are the findings of an Australian survey in which 61% of adults believed that even their de-identified health information should not be used for research purposes without their consent.⁴ Health research is dependent on access to population datasets to recruit participants, monitor health indicators, identify risk factors and inform interventions. Non-representative access threatens a study's validity, resulting in poorly informed interventions, policy and funding decisions. The situation may now have progressed beyond reasonable trade-offs between the public good and individual privacy to the point

where important research cannot be done at all, and the opportunity for advances in health are lost.

Despite statutory guidelines,^{1,5} there are widespread differences in interpretation of the legislation, particularly regarding the terms "practicable" and "public good". Amendment of the legislation in this respect is therefore urgently required, together with clauses which facilitate a researcher's ability to inform the public of a particular project and enable individuals, not organisations, to decide whether they wish to participate. There needs to be greater effort in gaining public understanding of the legislation and its intent with respect to research. In addition, upfront declarations and "opt-out" clauses about the use of personal information for health research must also be included in the privacy statements that organisations are now legally required to provide to individuals at the point of data collection.

1. National Health and Medical Research Council. Guidelines approved under Section 95a of the Privacy Act 1988. Canberra: NHMRC, 2001. Available at: www.health.gov.au/nhmrc/publications/pdf/e43.pdf (accessed Feb 2004).
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IN REPLY: We are familiar with concerns such as those expressed by O'Grady and Nolan, and we are grateful for this opportunity to respond, so that readers can consider the views side by side.

Privacy is not new. Ethical obligations of confidentiality in medical settings date back to Hippocrates. New privacy legislation — *Health Records Act 2001* (Vic); *Information Privacy Act 2000* (Vic); *Privacy Act 1988* (Cwlth) — clarifies these obligations and also sets a higher standard of accountability. (Other states and territories also have

legislation or are contemplating it.) The new laws cover all sorts of personal information, but health information is especially delicate. Wrongly handled, it can lead to discrimination — not just embarrassment or loss of dignity. In Victoria, this was recognised by Parliament when it passed the Health Records Act as a separate piece of legislation to deal specifically with health information.

The policy behind the privacy laws is aimed at promoting trust between health service providers and the public by reassuring them that their personal information will be respected, particularly in an electronic age in which information can be speedily transmitted far and wide. If surveys show the public to be wary about the use of their health information for research, it would seem to be in the best interests of the research community to embrace new standards rather than to seek to unravel or avoid them.

Privacy legislation was drafted after extensive consultation, taking into account competing factors and the need to balance respect for privacy with other public interests, including research. Research is very important, and privacy is a cherished and longstanding value. Reputable research can coexist with the recent statutory expressions of privacy, just as reputable research has always coexisted with respect for privacy.

Many data custodians perhaps do not yet realise that privacy laws rarely require an existing legitimate practice to cease completely, but rather may require the practice to be adapted to meet new standards. For example, for researchers seeking to recruit subjects for a study, the data custodian may disseminate the researchers' initial letter rather than hand over lists of names and addresses to researchers. Once recipients opt in, direct consensual dealings with the researchers proceed as usual. Researchers can always use properly de-identified information, or they may use information with the consent of the subject.

As with all new laws, the privacy laws will become better understood with time and experience. Some data custodians are understandably overcautious, while others have blamed privacy laws for preventing them from providing

information in situations in which disclosure is permitted. Many adapt with ingenuity and effectiveness. Privacy Commissioners and the Health Services Commissioner are available to explain the laws.

We, along with everyone with an interest in collecting and using the sensitive information of others, must recognise and consider the subtleties inherent in balanced privacy protection. □

Achieving equity in the Australian healthcare system

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TO THE EDITOR: In response to Leeder,¹ there is no community in this world that can provide free, at the point of contact, healthcare for all its citizens to the current limits of modern medical technology. This problem will in fact become greater as the technology increases and becomes more expensive.

Within the available healthcare resources, there is some medical treatment that is essential and there is some that is quality-of-life treatment; where the two merge depends on one's point of view.

If you choose to play sport and injure your knee, the question of who should pay for the treatment arises. If you smoke or have any other lifestyle risk factors, how much should be funded by you, and how much by others? And, within a healthcare system where there is patient contribution, does this contribution empower and encourage individuals to adopt a healthy lifestyle?

In essence, I believe the debate in healthcare should be about accessibility of limited resources. Who draws the line, how is the line drawn, and at what level is it drawn?

Pouring money into the public health sector may well parallel the analogy of adding another lane to the motorway. We must be careful to share the responsibility of healthcare between the individual and the healthcare providers in an inclusive and not exclusive manner. □

1. Leeder SR. Achieving equity in the Australian healthcare system. *Med J Aust* 2003; 179: 475-478.

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TO THE EDITOR: Leeder rightly points out that increased funding of the healthcare system does not necessarily result in improved equity within the health system or better health outcomes for the population.¹ This challenges us to develop ways of systematically examining how current healthcare practices either increase or decrease equity. The following two Australian initiatives illustrate how we might work to achieve equity in health — that is, provide opportunities for all Australians to achieve their full health potential.²

Clinical practice guidelines (CPGs) are one mechanism frequently used to facilitate improvements in the quality of clinical practice and healthcare. However, the evidence on which CPGs are based often excludes, or does not consider, the needs of relatively disadvantaged populations.³⁻⁵ Recognising this gap, the Health Advisory Committee of Australia's National Health and Medical Research Council published a handbook for developers of guidelines about ways to access, review and collate evidence of the effect of socioeconomic position on health, and apply that evidence when developing CPGs.^{5,6}

At the policy level, Health Impact Assessment (HIA) is gaining increasing recognition as a tool for assessing the potential effects of a policy or program on health. Health Impact Assessment that systematically addresses equity may also offer a way of incorporating equity concerns into the decision-making process. However, HIA is a comparatively new field, and decision makers are not usually trained in assessing the impact of policy decisions on equity. Through the Public Health Education and Research Program, the Australian Government has commissioned the development of an HIA framework to assist decision makers in systematically identifying potential health equity impacts of policies. This equity-focused HIA framework is currently being tested

(through case studies in Australia and New Zealand) to assess whether and where it adds value to the decision-making processes.

These two examples illustrate practical ways in which decisions by practitioners and policy makers can routinely incorporate equity issues in the Australian healthcare system. Ongoing investment and commitment is required to evaluate whether such initiatives make a real difference in achieving equity in health.

Acknowledgements: We were contracted by the National Health and Medical Research Council to draft the handbook *Using socioeconomic evidence in clinical practice guidelines*, and by the Australian Government Department of Health and Ageing to develop the Equity Focused Health Impact Assessment framework.

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A prospective before-and-after trial of a medical emergency team

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TO THE EDITOR: The introduction of a medical emergency team (MET) at the Austin Hospital significantly reduced cardiac arrest and deaths, and reduced time spent by survivors of cardiac arrest in the intensive care unit (ICU) and in hospital.¹

We note that the evaluation of the MET was preceded by a 12-month period of education and a 2-month "run-in" period before the effects of the MET were analysed. We would be interested to know the incidence of death and cardiac arrest, and the duration of ICU and hospital admission in survi-

vors of cardiac arrest during these two periods.

Another MET service also claimed substantial benefits in patient outcomes,² but was criticised on the basis that the results may have been due to better education of ward staff in recognising the antecedent signs of cardiac arrest and/or the creation of more "do-not-resuscitate" orders.³ While the latter criticism cannot be levelled at the study by Bellomo et al, no attempt is made to separate out the effects of the lengthy education period and the operation of the MET. This is a pity, because it would have been a relatively simple matter to do so without detracting from the obvious benefit of the service.

Why was a 2-month "run-in" period between education and operation of the MET allowed before analysis of results? Was this a post-hoc decision or were there foreseeable difficulties during the introduction of the MET?

Did patient outcomes change during these two periods compared with the period before the MET?

1. Bellomo R, Goldsmith D, Uchino S, et al. A prospective before-and-after trial of a medical emergency team. *Med J Aust* 2003; 179: 283-287.
2. Buist MD, Moore GE, Bernard SA, et al. Effects of a medical emergency team on reduction of incidence of and mortality from unexpected cardiac arrests in hospital: preliminary study. *BMJ* 2002; 324: 1-5.
3. Smith GB, Nolan J. Medical emergency teams and cardiac arrests in hospital [letter]. *BMJ* 2002; 324: 1215. □

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IN REPLY: Tibballs and Kinney raise important questions about our trial of a medical emergency team (MET).¹ My colleagues and I are, in fact, currently studying these issues.

Preliminary (not fully double-checked) data show that during the education period there were 69 cardiac arrests — an average of 23 cardiac arrests per 4-month block. This is a clear reduction from the 63 recorded during the 4-month control period and similar to the 22 cardiac arrests reported during the 4-month MET period.

These 69 cardiac arrests led to a total of 227 intensive care unit bed-days or a 75 bed-day average for each 4-month

block, about 50% of the number recorded during the control period, but more than twice as many as during the MET period. These patients remained in hospital for a total of 986 hospital bed-days or 328 days per 4-month block, close to an 80% reduction compared with our control period, and twice as many as the number achieved during the MET period. Unfortunately, although we are pursuing mortality data, we won't be able to provide them for another 6 months because of a changeover in the computer system at our hospital. Tibballs and Kinney are invited to contact me directly by mid-2004.

The 2-month run-in period was chosen prospectively, as we expected that the uptake of the MET (a major change of culture) might be slow and require time and encouragement. We were wrong: the MET was taken up with zest and enthusiasm. The histogram (Box 4) in our article¹ shows no cardiac arrests during the run-in period, not because they were not recorded, but because there were literally none for 2 months in a row! Obviously, there were also no post-cardiac-arrest bed-days. Again, mortality figures for this period should be available by mid-2004.

As we stated in the Discussion of our article, the educational program associated with the MET may indeed have been partly responsible for the findings. We were careful at all times to say that introducing the MET was effective, not the MET *per se* (see Conclusion).¹

We are not aware of any prospective studies testing the effectiveness of introducing a hospital-wide education program aimed at increasing awareness of the significance of physiological instability. Our findings support a powerfully beneficial role of education, but only represent a post-hoc analysis and require validation in other settings and institutions. The role of education was prospectively and separately investigated in the recently completed multi-centre cluster-randomisation MERIT study (Medical Early Response Intervention and Therapy). Its results should be available in the second half of this year.

1. Bellomo R, Goldsmith D, Uchino S, et al. A prospective before-and-after trial of a medical emergency team. *Med J Aust* 2003; 179: 283-287. □

Lessons from early large-scale adoption of celecoxib and rofecoxib by Australian general practitioners

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TO THE EDITOR: In their article on adoption of celecoxib and rofecoxib by Australian general practitioners, Kerr et al noted that "the increase in COX-2 [cyclooxygenase-2] prescribing coincided with a period of energetic marketing to the medical profession, which promoted the message that the new C2SNs [COX-2-selective non-steroidal anti-inflammatory drugs] were 'safer' than traditional NSAIDs [non-steroidal anti-inflammatory drugs]."¹ The implication is that the decision of Australian GPs to prescribe these new drugs may have been less than independent or rationally informed.

The reason for prescribing C2SNs is that, like traditional NSAIDs, they relieve arthritic pain and so promote mobility, although, unlike traditional NSAIDs, they do not inhibit cyclooxygenase-1. While the power of advertising is undeniable, the simple message about C2SNs is that there is an approximate 50% reduction in clinically significant gastrointestinal (GI) complications compared with traditional NSAIDs.² There are over a dozen articles to support the better GI side-effect profile of C2SNs. Most data support a non-cumulative, reversible, but constant, risk of peptic and other, more distal GI bleeds, or perforation, with the coefficient of risk being significantly greater for NSAIDs.³ Although the data from the CLASS study did suggest that the higher GI morbidity of NSAIDs seemed to diminish with time,⁴ that of celecoxib remained at a constantly lower rate.⁵ This is clinically important for all our patients, and especially for our ageing population with their comorbid conditions and polypharmacy. I suggest that it is for this single reason that many doctors have been quick to take up C2SNs for their patients. The better GI safety franchised patients who previously could not take NSAIDs safely, and could

explain why the overall anti-inflammatory market increased by 20%.¹

However, no one suggests that the C2SNs are free of non-GI side-effects. To the best of my knowledge, COX-2-specific NSAIDs have not been promoted as being free of non-GI side-effects or better than COX-1-specific NSAIDs in this regard.

While agreeing with the last sentence of Dowden's editorial that "new is not always better",³ the opposite — that "new is sometimes better" — is also true. Thus, we persuaded the accountants in our hospital, who rightly participate in the determination of which drugs are available on its formulary, to accept one of the COX-2 drugs because of its better GI complication profile. While this will not reduce its pharmacy budget, it is anticipated to reduce overall hospital costs in this area,⁵ which should allow a reapportionment of its budget to other areas of need. Of course, the hospital is watching carefully for any unforeseen "serious adverse effects which sometimes only emerge after marketing".³

Competing interests: The author is a co-investigator on several clinical trials, including a Pharmacia-sponsored randomised placebo-controlled trial of anti-paratuberculosis treatment for patients with active Crohn's disease.

1. Kerr S, Mant A, Horn F, et al. Lessons from early large-scale adoption of celecoxib and rofecoxib by Australian general practitioners. *Med J Aust* 2003; 179: 403-407.
2. MacDonald T, Morant S, Goldstein J, et al. Channelling bias and the incidence of gastrointestinal haemorrhage in users of meloxicam, coxibs, and older, non-specific non-steroidal anti-inflammatory drugs. *Gut* 2003; 52: 1265-1270.
3. Dowden J, Coax, COX and cola [editorial]. *Med J Aust* 2003; 179: 397-398.
4. Silverstein FE, Faich G, Goldstein JL, et al. Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis: the CLASS study. A randomized controlled trial. *Celecoxib Long-term Arthritis Safety Study*. *JAMA* 2000; 284: 1247-1255.
5. Solomon D, Glynn R, Bohr R, et al. The hidden cost of nonselective nonsteroidal antiinflammatory drugs in older patients. *J Rheumatol* 2003; 30: 792-798. □

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IN REPLY: The advantage of the COX-2-selective NSAIDs (C2SNs) is the reduction in clinically significant gastrointestinal complications compared with conventional NSAIDs, but, as

Florin agrees, other toxicities, including the risk of renal failure and heart failure, are similar for C2SNs and the older drugs.¹ We speculated that doctors may have been more aware of the differences between the new and the conventional anti-inflammatories rather than the similarities: between 4.7% and 7.9% of patients in our study cohorts were treated with a combination of drugs which placed the patient at risk of renal complications. Florin points out that there is an approximate 50% reduction in clinically significant gastrointestinal (GI) complications with C2SNs compared with conventional NSAIDs. If, in a population, the annual incidence of serious GI complications with NSAID use is around 1.4%,² then the absolute risk reduction is 0.7%. This means that about 140 patients would need to be treated with a C2SN for one year to prevent one serious GI complication. Messages conveyed in this way may be more pertinent to clinical decision making than a statement about relative risk reduction.

Florin also notes the problems with elderly patients who often take multiple medications, and are probably at increased risk of upper-GI events with NSAIDs. Our data demonstrated very high prescribing rates in patients who were not elderly. Over 20% of patients in our cohorts were aged less than 50 years, and over 50% were aged less than 65 years. Furthermore, between 34.5% and 61.3% had no pain medication prescribed in the 12 months before the first C2SN prescription, suggesting that C2SNs may have been used as a first-line pain medication in these patients. Quality use of medicines advocates prescribing which is safe, judicious, effective and cost-effective. Recent pharmacoeconomic studies suggest the cost-effectiveness may only be realised when prescribing of C2SNs is confined to patients who are at high risk of GI complications.^{3,4}

Competing interests: In 1997, Associate Professor Andrea Mant provided consultancy advice on Quality Use of Medicines to Merck Sharp & Dohme.

1. Considerations for the safe prescribing and use of COX-2-specific inhibitors. *Med J Aust* 2002; 176: 328-331.
2. Bombardier C, Laine L, Reicin A, et al. Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. VIGOR Study Group. *N Engl J Med* 2000; 343: 1520-1528.

3. Maetzel A, Krahn M, Naglie G. The cost effectiveness of rofecoxib and celecoxib in patients with osteoarthritis or rheumatoid arthritis. *Arthritis Rheum* 2003; 49: 283-292.
4. Spiegel BM, Targownik L, Dulai GS, Gralnek IM. The cost-effectiveness of cyclooxygenase-2 selective inhibitors in the management of chronic arthritis. *Ann Intern Med* 2003; 138: 795-806. □

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IN REPLY: The general practitioners' decision to prescribe COX-2 inhibitors was rational, but the information underpinning their decision was less than independent. A big reduction in short-term relative risk can be persuasive, even if the absolute benefit is small.

General practitioners deal with whole patients, so they consider the overall risks of treatment, and not just one adverse effect. While COX-2 inhibitors may have gastrointestinal advantages, they may have cardiovascular disadvantages.

Treatments for chronic conditions should be based on long-term data. The observation that most of the ulcer complications in the second half of the CLASS study were in patients taking celecoxib is therefore important.¹

Undoubtedly, some patients who could not take non-selective non-steroidal anti-inflammatory drugs (NSAIDs) were able to tolerate COX-2 inhibitors. However, Kerr et al found that up to 61% of patients given a COX-2 inhibitor had not previously been prescribed any analgesia.² It seems unlikely that so many people suddenly required analgesia that only a COX-2 inhibitor could provide.

The Pfizer-funded study by MacDonald et al shows that UK general practitioners tended to prescribe COX-2 inhibitors for patients at risk of gastrointestinal haemorrhage.³ This follows the advice of the National Institute of Clinical Excellence (NICE). However, NICE also recommended against the routine use of COX-2 inhibitors.⁴ A review by the Canadian Co-ordinating Office for Health Technology Assessment has also concluded that COX-2 inhibitors may have no significant safety advantage over diclofenac.⁵

Solomon et al conclude that the cost of adverse effects of NSAIDs in low-risk elderly patients is modest.⁶ However,

there is no comparison with COX-2 inhibitors, so we do not know if they reduce this cost. Hospital accountants may be interested to know that researchers at the Mayo Clinic concluded that, in terms of averting gastrointestinal events, the most cost-effective analgesic is paracetamol.⁷

Competing interests: Australian Prescriber is published by the National Prescribing Service. John Dowden is an unpaid director of Therapeutic Guidelines Ltd, and a member of the Editorial Advisory Board of the *Australian Medicines Handbook*.

1. Juni P, Rutjes AW, Dieppe PA. Are selective COX-2 inhibitors superior to traditional non-steroidal anti-inflammatory drugs? *BMJ* 2002; 324: 1287-1288.
2. Kerr SJ, Mant A, Horn FE, et al. Lessons from early large-scale adoption of celecoxib and rofecoxib by Australian general practitioners. *Med J Aust* 2003; 179: 403-407.
3. MacDonald T, Morant S, Goldstein J, et al. Channelling bias and the incidence of gastrointestinal haemorrhage in users of meloxicam, coxibs, and older, non-specific non-steroidal anti-inflammatory drugs. *Gut* 2003; 52: 1265-1270.
4. National Institute for Clinical Excellence. Guidance on the use of cyclooxygenase (COX) II selective inhibitors, celecoxib, rofecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis. London: NICE, 2001.
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What drives the NHS?

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TO THE EDITOR: In their amusing *Post-card from the UK*, Jamrozik, Heller and Weller¹ paint a picture familiar to most of us in the National Health Service (NHS), but, as with most art, some licence has been permitted. Comparing the size of the UK NHS workforce with that of the Chinese army is unfair: there are, as they know, four different health services in the UK (England, Scotland, Wales and Northern Ireland), which function separately and distinctly.

The NHS Jamrozik et al describe is much more the English model. In Scotland, targets for cancer care have been set, although they will not be applied for over a year yet. In the meantime, NHS Scotland has awarded the three Scottish regional cancer networks an extra £25 million (A\$62.5 million) to improve and

enhance agreed cancer services to assist them achieve the agreed targets on waiting times, etc.

Another example of the difference between the Scottish and English NHS can be found in the detail of the new consultant contract. Scotland is offering its consultants a sabbatical and England does not. I am reliably informed by one of the negotiators that the seed of that idea was sown by me when I was recounting enthusiastically some of the better experiences of working in Australia's own, if complex, national health service.

Finally, those of us who laboured during the 1990s at the coal face of Victoria's health service will not be unfamiliar with targets. Infringement of targets set for the upper levels of the waiting list (no one in Category 3 could ever expect treatment, so no target was set), and for 12-hour waits in the emergency department, carried huge financial penalties for the institution. The good old NHS is far from unique in its fondness for targets.

1. Jamrozik K, Heller R, Weller D. What drives the NHS? *Med J Aust* 2003; 179: 575-576. □

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