THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

CONTENTS

Viewpoints

100 Years Ago in the NZMJ

Proceedings

Medical Image

Methuselah

Letters

Obituaries

Notice

Book Review

Better than well: American medicine meets the American dream (Carl Elliott)
Roger Mulder

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

This Issue in the Journal

New Zealand general practitioners' characteristics and workload: The National Primary Medical Care Survey
A Raymont, R Lay-Yee, J Pearson, P Davis

Based on a national survey undertaken in 2001, the workload of general practitioners (GPs) is described and related to their age, gender, and practice circumstances. Increasing numbers of GPs are women and more work part time. The average GP works 4 days (and undertakes 102 consultations) in a week; about 8% of visits occur after hours. Workload is higher in rural areas, which suggests recruitment difficulties there. If workload increases under the Primary Health Care Strategy, then the distribution of GPs may become an issue.

Advertising of medicines on New Zealand television
P Norris, L Nelson, K-L Ling, L Skellett, J Hoo, C Va'ai, A Gates

This paper describes the advertising of medicines on New Zealand television. During the 35 days sampled, there was (on average) 1 advertisement for medicine every 102 minutes; 37% of advertisements were for medicines available for general sale, 24% for dietary supplements, 21% for pharmacy- or pharmacist-only medicines, and 18% for prescription-only medicines. Advertisements for medicines were found in a wide range of programmes, including children's programmes. People who watch particular programmes, or who watch television at certain times of days, may be exposed to considerably more than 1 medicine advertisement per 102 minutes. While this study does not examine the effect of medicine advertisements on people's choices about medicines, previous research suggests this may be a significant factor.

New Zealand general practitioners' views on direct-to-consumer advertising (DTCA) of prescription medicines: a qualitative analysis
N Maubach, J Hoek

The debate over against direct-to-consumer advertising (DTCA) of prescription medicines has received detailed attention. The opinions of different interest groups are well represented, although the views of general practitioners (GPs) have received less comprehensive attention. Using a qualitative methodology, this research explored how a small sample of GPs' viewed DTCA and their perceptions of its effects on their practice. Informants held ambivalent views of DTCA, but outlined concerns that should be urgently addressed if this advertising is to continue.

Does the Priority Scoring System for Joint Replacement really identify those in most need?

B Coleman, S McChesney, B Twaddle

The joint replacement scoring system has been utilised to determine the priority for total hip and knee surgery within the public health system since its introduction in 1998. This study tested the scoring system compared to two internationally validated scoring systems for disability due to musculoskeletal illness. It demonstrated that the current scoring system (utilised to determine priority) is not a reliable assessor of disability (due to osteoarthritis of the hip or knee), thus indicating that the most disabled patients may not be receiving priority for surgery.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Patients' rights and access to unconventional treatment

Grant Gillett

Right 6 of the Health and Disability Commissioner (HDC) Code of Rights affirms the fact that the patient has a right to receive information about his or her condition and clause B specifies that information about his or her options within the range of treatments available for that condition should be included.

Several questions of clarification arise. What options should be covered in this information? There are treatments that are widely used so as to be considered standard (whatever the state of evidence for their efficacy), others that are more marginal, and some that are at the extremes of reasonable practice or even experimental in nature. There are also treatments not easily accessible to New Zealand patient. Which of these options should be mentioned?

Patients and their options

A recent (hotly contested) decision of the Health and Disability Commissioner (02HDC18414) clarifies some of these issues. The case concerned a patient with a brain tumour. The not-offered treatment was surgery to try and remove as much of the tumour as possible. This surgery was available elsewhere in New Zealand and Australia but this was not mentioned by the surgeon concerned or the radiotherapist involved in the case.

The patient complained that he was not offered the option of more extensive surgery than the limited biopsy resection he had been given, despite the fact that some surgeons, both in New Zealand and overseas, do offer more radical and aggressive surgery for malignant brain tumours than many surgeons in New Zealand would normally perform.

Although the more radical surgery lacks firm evidential support, it is an option that has attracted notice in the press and elsewhere, particularly in cases where the initial consultations offer the patient little hope. The HDC decided that patients should be told of the range of treatments on offer for a condition—even where some of those do not fall within the scope of practice of the particular provider whom the patient is consulting or the local healthcare setting. What, then, are the limits on the options that are required to be discussed?

As a first pass, one might think that any treatment option discussed should be one for which there is adequate evidence of efficacy. This standard is in accordance with the right of the consumer of services to be told about the results of research, but cannot be interpreted so that normal clinical advice should include only information adequately supported by research (as to efficacy for the patient's problem), because this would exclude much current practice.

Most current clinical practice falls within the less stringent constraint of being treatment in accordance with a reasonable body of medical opinion, a great deal of which has never been adequately tested in properly conducted prospective randomised

controlled trials of treatment . It seems reasonable that this fact should be conveyed where appropriate.

If a strict criterion of evidence-based treatment is, by and large, unworkable as a limit on options (even though perhaps that fact ought to be mentioned), what other constraint could be imposed? The default position seems to be treatment that 'is in accord with a responsible body of medical people skilled in that particular art' where this is defined as an opinion held by a significant number of competent practitioners in the area in question (even if contrary views exist). Therefore, although the treatment concerned may not be the majority opinion, neither can information be limited to just the range of options that would be offered by those surgeons with whom the particular provider agrees. To clarify this issue, we need to examine the recent case in somewhat more detail.

Information about unconventional options

The HDC opinion in the case under discussion pivoted on the following point:

At a time when New Zealand patients are not infrequently referred overseas for medical care (even in the publicly funded system), this includes information about treatment options available (albeit in private) overseas.

It implied that the consumer was entitled to make an informed choice about treatment options even if those were (to some extent) unorthodox; as the patient's wife said, the decision was 'our call, not his'.

The opinion held that it was not reasonable to expect the surgeon who disapproved of that mode of treatment to offer to perform it himself. Indeed, we can go further and argue (absent evidence for its efficacy) that such treatment should not be publicly funded where the expense involved is greater than that usually available for the diagnostic group concerned. The opinion also suggested that at least the feasibility of the treatment should have been opened for discussion. I would add that a provider giving advice ought to position his or her own perspective and practice on the spectrum of medical opinion that is out there without necessarily having to go into any detail on those not part of his or her own recommendations.

One could object, arguing that the claims made for this surgery are overblown and misleading, for the patients concerned—and therefore create false expectations. But some patients do better than expected as a result of aggressive therapy and it is hard to argue with a desperate patient and an enthusiastic surgeon. The ethical constraint that ought to hold here is that the surgeon should not falsify the prognosis and likely success of his or her technique (so as to create serious misconceptions in patients).

The judgment about falsification is, however, itself problematic (especially in such a case). The optimistic view is that there are a small group of patients who 'beat the odds' and that aggressive surgery stacks the odds slightly more in favour of the patient than would otherwise be the case (at an increased risk of morbidity).

If one is open about those odds but enthusiastic about the treatment, this is not misleading although it may create more hope in a patient than many would say is warranted. However, brutal honesty to the point of making sure that the patient takes a dim view of his or her prognosis (and abandons all hope) only commends itself to

melancholics or masochists, and arguably this should not be the only approved way of dealing with a patient who has a life-threatening or terminal condition.

It is in accord with normal practices of informed consent that the risks of an aggressive and unconventional treatment ought not be minimised, but these may differ depending on the surgeon concerned and that fact, where it holds, can be signalled.

Given that the range of treatment options must be adequately portrayed to the patient, avoiding as far as possible misrepresentations based on personal bias, there is an onus on doctors to mention and offer some guidance on what the patient is likely to find if, as they increasingly do, they access the Internet about their condition and read about different (and often new and unproven) options there. Faced with this fact, we ought to be realistic in our advice and relatively open where 'the jury is still out' on some new treatment that patients may read about.

The doctor cannot be expected to cover all this in any detail and may recommend the conventional mode of therapy, but the patient may still opt for an unconventional treatment. The question then becomes whether the state-funded health system is bound to honour the patient's autonomy by providing it.

State-funded care

A state-funded healthcare system only has a duty to provide treatments of proven or widely accepted efficacy so that treatments used by providers working at the margins of reasonable medical opinion or considered innovative (even experimental) should not attract state funding until they become established options.

There is, however, a fuzzy boundary at the edges of current therapy where we find relatively innovative treatments used by a progressive minority of responsible doctors. Treatments of this type are usually subject to ongoing evaluation, even though in the area of surgical advances there are problems with the standard prospective randomised controlled trial format.[1]

But this raises problems because it seems unethical to demand that a patient enter a research trial in order to access a given treatment. That demand can be justified when the state is funding the treatment, but it is hard to justify state interference in a therapeutic agreement made within ethical guidelines about the doctor-patient relationship and, in particular, informed consent.

It is obviously in the interest of all patients to do some kind of evaluation of such treatments. Therefore it would be justified to encourage the providers concerned to use a protocol in accordance with relevant guidelines. Thus some of these treatments may be deemed safe to proceed with only in the context of a clinical trial and if so the ethical requirements on the trial must be observed. (The reasons for the relevant decisions would, of course, have to be made clear to all concerned and defended where contested.)

It seems that if the treatment looked sufficiently promising in terms of benefit to the patient, then the public system could support its provision on the condition that availability be made contingent upon there being a proper study of a kind appropriate to the state of knowledge in the area. One would expect such a study to be conducted in an academically equipped centre where lessons can be learnt rather than uncertainty perpetuated.

Given that patients can sometimes successfully apply to have innovative treatment funded by the state (even where that involves the patient accessing the treatment offshore), one might even encourage the provision of such treatments within the state-funded system—but careful thinking needs to be done here about the opportunity costs in terms of core services. A patient who does not need to rely on state funding for access to care is in a different position.

The HDC Code (particularly in the light of the recent ruling) implies that we cannot paternalistically limit the patient's options with regard to treatment provided only that the providers of the treatment are careful about information and consent and adequately represent the options discussed. The provision of such treatments within the ambit of healthcare available in any society is in accordance with the principle of autonomy. That principle requires informed consent as part of the provision of any treatment, and we can (in the circumstances envisaged) require that the information is 'relativised' to conventional medical wisdom (a reasonable body of medical opinion), and also (ideally) to the personal audit-based experience of the treatment provider.

We need to protect people from doctors who are practising treatments that carry a great risk of harm (or who mislead their patients), but we should not be so restrictive that doctors pioneering a new and promising treatment are prevented from doing the work needed to develop those treatments. An important part of such development is the bringing of hope to patients who would otherwise have very bleak prospects.

Therefore, subject to the condition that the information given to the patient should be a fair representation of the state of knowledge in the field concerned, and the further condition that granting access will not deflect resources that would otherwise be used to provide proven (or well established) treatments, a patient who is able to mobilise the resources needed without encroaching on the provision of state funded orthodox medical care, should be able to opt for a treatment that might be considered fringe by some sectors of the profession.

If under those constraints the patient and provider agree on a treatment option, then it seems that the state funded system should not impede the patient's access. In fact the situation is not quite as neutral as that cautious conclusion makes it seem.

Any system has some (perhaps minimal) ongoing responsibility for patients whether or not those patients access treatment by means other than the public purse. What is more the state may be required to 'pick up the tab' if things go badly wrong and the patient needs ongoing services. Given that a patient wants to access a treatment, perhaps overseas, and perhaps using private funds, the state system has no right to block that but it is arguable that it owes the patient, and those like him or her, a setting in which the maximum gain for others in the society can be derived from providing the innovative treatment.

When we add to this the thought that we do not want to be landed with the cost of patient care resulting from unsupervised and possibly harmful treatment we might encourage patients to restrict themselves to treatments that can be accessed within a suitable New Zealand context of quality service and ongoing research. This is unlikely, however, if the treatment is forced outside the boundaries of a responsible teaching and service provision centre linked to the healthcare system normally treating the patient.

Therefore we may tentatively conclude that if:

- capacity to provide an innovative treatment exists in the system, the
- patient could access it using that capacity rather than use additional resources in going offshore for that treatment, and the
- state does not incur an extra burden which prejudices the opportunities of existing service users,

then a patient should have access to the contested treatment within the New Zealand health sector.

Furthermore, if the patient receives the innovative treatment in a setting where the experience gained and the research and development spin-offs will plausibly become available to others like them, then the patient should be encouraged to access the treatment in their native setting (i.e. for a New Zealander in the context of New Zealand health care) rather than an exotic location.

We could call this the principle of reasonable therapeutic access. Notice that it is a principle which goes some way to ensuring that data from the patient's therapeutic (good or bad) experience is not lost to other individuals suffering from the same condition and stands a chance of advancing the treatment of that condition for the benefit of all in their own community.

Note also that this is not an entitlement under the state-funded system which could entail a diversion of resources from patients needing access to established treatment modalities; it must therefore be cost neutral in terms of the state services provided..

Note finally, that the principle of access embeds a patient's right to take a risky option if he or she is cognisant of the risks involved and has made adequate provision for any harms that they suffer not to be a further drain on the state-funded health system.

Spinal cord repair: a case in point

These conclusions are directly applicable to the case of spinal repair using olfactory epithelium.

The spinal repair initiative has been forced ahead by patient activism despite the therapeutic nihilism of established or conventional medicine. In the process of moving towards what spinal cord patients call 'Cure not Care', a range of discoveries have been made about the plasticity of the human CNS and spinal function. The Egaz Moniz Hospital; in Lisbon, Portugal, is now providing this treatment at a cost in excess of US$100,000 for patients who wish to access it and has recently received funding from a US health insurer to operate on some paraplegic patients. Their retrospective series now includes patients who have made major gains in terms of spinal function:

> 'Day by day, I rediscover my capacities' (Luis, T4-5 injury, 2002)
>
> 'I have recovered some functional improvement through Dr Lima's procedure, such as the ability to hold my bladder and at times even void on my own. Sensation has been restored, though it is not completely normal…most important on my way to recovery is that I can now walk with the aid of braces' (Susan, thoracic injury, 2001)
>
> After the surgery…an MRI was taken and it revealed my spinal cord had begun to heal…Improvements in my sensory feelings have continued until the present time…one of the most evident improvements has been my ability to stand and remain standing, using a walker, and

> with minimal assistance…I am able, with assistance and the use of braces, to walk a distance of over 1400 feet (Laura, C6 injury, 2001)

These patients are typical of those desperate for a cure for their spinal injury, and their enthusiastic reactions to treatment may indicate some very powerful placebo effects but their testimony should not be discounted out of hand on such speculative reasons (which themselves lack evidential support).

The operation is relatively simple:

- The spinal lesion is explored and any gliotic and fibrous material resected.
- A piece of olfactory epithelium is harvested from the patient's nasal septum.
- The olfactory tissue is fragmented and inserted into the spinal injury cavity.
- The wound is closed in layers.

The downside of the Lisbon treatment does not seem to be very weighty: one patient has had mixed results with immediate post-operative loss of sensation in the right lower limb followed by some recovery of motor function in both lower limbs. The damage occurred after a myelotomy at the wrong level which was followed by subsequent repair at the correct level. The Lisbon Study is, however, not amenable to statistical analyses of efficacy or safety.

Therefore we are facing the following situation:

- First, an experimental treatment for spinal injury is now available in Portugal and increasingly being accessed by patients from the US and the European.community.
- Second, the only documented harms of this treatment to the patients that have received it is due to an operative mistake and has not been repeated .
- Third, some of the patients appear to have made significant gains subjectively and objectively.
- Fourth, patients with severe spinal cord injury that is neurologically stable want to access the treatment here or overseas.
- Fifth, such patients can access it at a high cost and a great distance.
- Sixth, the wherewithal to do the treatment exists in New Zealand without demands being made on state funding.
- Seventh, patients want to access spinal repair here on a fee for service basis.

Given the ethical and legal situation we find ourselves in, it does not seem that the rights of patients to access this treatment can reasonably be overridden. We might, however, require that an ethics committee review the proposed protocol for such patients so that it proceeds only with the necessary approvals (although it is hard to see what role they should have for individual cases).

Such a committee should probably try and ensure that the safety of the procedure be established first in a group where further damage is impossible because the lesion is complete—and that the recommendations of the International Workshop on Clinical trials for Spinal Injury be followed insofar as they are applicable to the development of an experimental therapy to a point of possible efficacy.

These recommendations are:

- That the procedure be initially evaluated in a pilot study looking at its safety in volunteers who have complete injuries and who understand the risks and uncertainties of the procedure (p597);
- That 'accurate and independent blind validation of neurological function of experimentally treated patients' be undertaken (p593).

The lack of statistical validation for a repair study is perhaps inevitable, given that every lesion is unique (creating large variance in a relatively small group of patients) and that early versions of the intervention are unlikely to be the most effective. This conclusion entails that we have no right to impede patients who want to access this treatment in New Zealand as long as they understand the nature of what they are trying to access.

Indeed we could go further and argue that those patients should be enabled to access the treatment they want at reasonable cost (provided that cost is met outside of the state-funded system and does not use resources devoted to proven interventions) and in a way which is most likely not only to benefit other New Zealand patients like them but also to contribute to the international effort to develop effective treatment for their problem.

Author information: Grant R Gillett, Bioethics Centre, Dunedin School of Medicine, University of Otago, Dunedin

Correspondence: Professor Grant Gillett, Bioethics Centre, Dunedin School of Medicine, University of Otago, PO Box 913, Dunedin. Fax: (03) 474 7601; email: grant.gillett@stonebow.otago.ac.nz

References:

1. Gillett GR. Unnecessary holes in the head. IRB. 2001;23:1–6.
2. Collins D. Medical Law in New Zealand. Wellington: Brooker and Friend; 1992, p49.
3. Lima C et al. Olfactory mucosa autografts in human spinal cord injury. European Congress of Neurosurgery (Lisbon, Portugal); 2003.
4. Lu J, Feron F, Mackay-Sim A, Waite PM. Olfactory ensheathing cells promote locomotor recovery after delayed transplantation into transacted spinal cord Brain. 2002 125:14–21.
5. Steeves, J, Fawcett J, Tuzsynski M. Report of the International Clinical trials Workshop on Spinal Cord Injury, 20-21 February 2004 (Vancouver, Canada). Spinal Cord. 2004;42:591-7.
6. Johnston L, Sa S. In: Paraplegia News; March 2003. Available online. URL: http://www.pvamagazines.com/pnnews/magazine/toc.php?iss=19 Accessed May 2005.
7. Testimonies of SR Fajt and L Dominguez before Senate committee on Science, Technology and Space, July 14 2004.
8. Personal Communication, Dr C Lima, ((year??))
9. Primitive neural tumours associated with the transplant of fetal cells have been documented where this has been done in Russia and elsewhere for spinal and cerebral lesions.
10. See n5.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Resistance to antiplatelet therapy: fact or fiction?

Shen Wong, David Lewis

Published evidence regarding aspirin resistance or aspirin non-response has been reviewed twice in the last year[1,2] but consensus on a definition of this 'condition' remains elusive.

Clinical aspirin resistance is the failure of aspirin to protect patients from ischaemic vascular events, but this practical definition is non-specific and encompasses a wide variety of processes whereby a patient may suffer an ischaemic event while taking aspirin.

Although the concept of clinical aspirin resistance is appealing in its simplicity, it does little to help identify and treat the cause of recurrent vascular events. Biochemical[3] or laboratory definitions of aspirin resistance are based on the failure of aspirin to produce an expected effect on a laboratory-based test of platelet function. Platelets are notoriously difficult to study which is reflected in the myriad of platelet function tests that have evolved and the lack of concordance when these tests have been compared in prospective randomised trials.[4]

Assessment of failure of inhibition of platelets, and prospectively linking this treatment failure to clinical vascular events, has so far remained under reported. Two groups have published data on this subject, but the methods used to study platelet response in these studies are open to criticism and arguably outdated.[5,6]. Furthermore the dose of aspirin was not mentioned in one study[5]—and a dose higher than that prescribed in New Zealand, Australian, and UK practice was used in the other study.[6]

The possible causes of aspirin resistance have been succinctly described previously[7] and include; wrong diagnosis (i.e. non-atherothrombotic causes of an ischaemic event), poor compliance, higher dose of aspirin needed to achieve an antiplatelet effect, alternative (i.e. non COX 1) pathway of platelet activation, drug interactions, and predisposing states (e.g. platelet glycoprotein polymorphisms or increased platelet turnover).

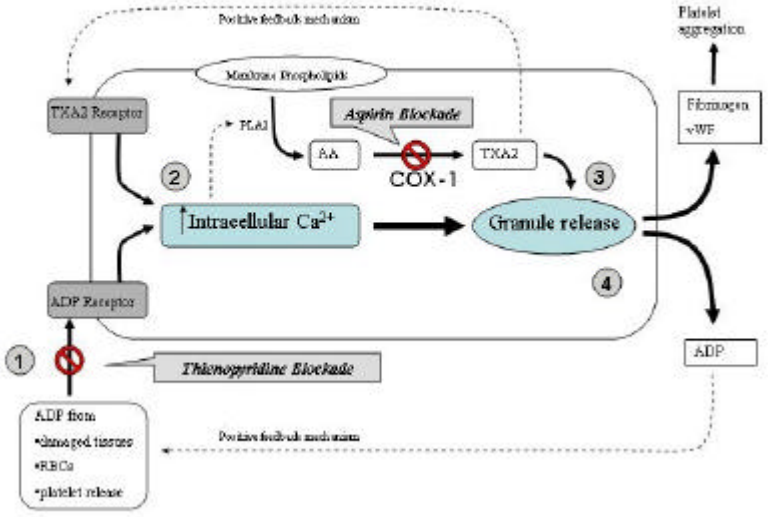
To overcome aspirin resistance, it is necessary to first identify with certainty which of the causes listed above is responsible for the clinical or laboratory observations.

As well as identifying a cause of aspirin resistance, clinicians must understand the treatment options available to achieve platelet inhibition in this (potentially vulnerable) group of patients. The mechanisms of action of the commonly used antiplatelet drugs are shown in Figures 1 and Figure 2.

Increasing the dose of aspirin is one possible solution but meta-analysis suggests that a dose in excess of 325 mg per day carries no therapeutic advantage but does have an increased risk of side-effects.[8] Prospective randomised trials have shown a small but significant reduction in recurrent ischaemic events with the use of clopidogrel[9] or clopidogrel in combination with aspirin[10]. These trials were not designed to identify subsets of patients with possible aspirin resistance and, as yet, no evidence has been

published to suggest any alternative to aspirin carries a clinical benefit in such patients. The effect of dipyridamole on patients with aspirin resistance is unknown.

Figure 1. Mechanism of action of aspirin and clopidogrel (a thienopyridine) on platelet activation



Thienopyridine blockade of ADP receptor (1) inhibits both exogenous ADP dependent platelet activation and granule release from raised intracellular Ca^{2+} (2 and 4) and the feedback effect of ADP released from platelet granules. COX1 inhibition inhibits formation of TXA2 induced granule release (3), but does not inhibit feedback from TXA2 already generated.

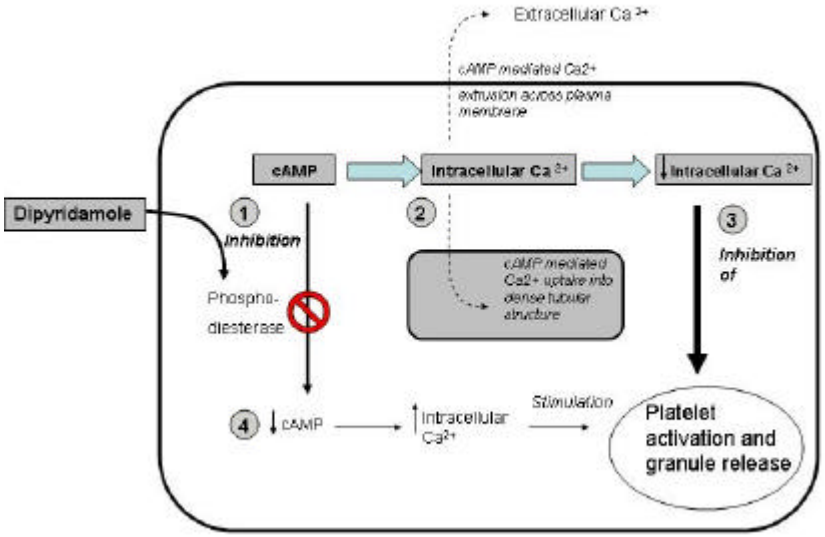
AA – Arachidonic Acid; ADP – Adenosine Diphosphate' Ca^{2+} – Calcium; COX1 – Cyclooxygenase 1; PLA_2 – Phospholipase A_2; RBC – Red blood cell; TXA_2 – Thromboxane A_2; vWF – von Willebrand's.

Non compliance with aspirin is probably an underestimated cause of 'failure' to prevent platelet activation. Compliance is recognised as being difficult to measure and it is not surprising that no robust data linking aspirin compliance and aspirin resistance exists. Pill-counting or patient-interview merely pay lip service to the notion of non compliance, while measurement of plasma salicylate levels only gives a snapshot of compliance unless performed on a daily basis.

As with most pharmacological interventions, the antiplatelet effect of a standard dose of aspirin has a range of response that is normally distributed. It remains unknown at what point on this Gaussian curve that a decreased antiplatelet effect of aspirin puts an individual at significantly increased risk of stroke, myocardial infarction, or other vascular event.

A similar range of response has also been reported with newer antiplatelet agents in a cohort of patients suffering acute myocardial infarction and the term 'clopidogrel resistance' has subsequently appeared in the literaturee.[11] The evidence surrounding clopidogrel resistance is even less clear cut than that surrounding aspirin resistance and the clinical implications are unknown.

Figure 2. Mechanism of action of dipyridamole on platelet activation



1. Inhibition of phosphodiesterase by dipyridamole elevates platelet cAMP levels by inhibiting its breakdown
2. High cAMP levels lead to a reduction in intracellular Ca^{2+} by increasing its uptake into the dense tubular system and its extracellular excretion
3. Low Ca^{2+} levels inhibit events leading to platelet activation and granule excretion.
4. Without dipyridamole, low cAMP levels would elevate intracellular Ca^{2+} levels and stimulate the events leading to platelet activation and granule release.

As clinicians, we would like a test of platelet function that has a high positive predictive value for future ischaemic events caused by failure of aspirin therapy. Furthermore, we need to know whether innate biochemical flaws are to blame for such events or whether 'failure' is a matter of simple non-compliance. Finally we need to know whether further medical manipulation of platelet activation will improve prognosis and which manipulation is most cost effective.

We are unlikely to see answers to any of these questions until there is consensus on a definition of aspirin resistance that centres around readily available and easily interpretable tests of platelet function. Until then, doctors managing patients with atherosclerotic disease must rely on the current evidence of best medical practice available to minimise the risk of atherothrombotic events in these patients.[8,12]

Author information: Shen Wong, Registrar, Department of Vascular Surgery, Sydney University, Royal North Shore Hospital, St Leonard's, Sydney, Australia; David Lewis; Consultant Vascular Surgeon, Department of Surgery, Christchurch Hospital, Christchurch

Correspondence: Mr David Lewis, Department of Surgery, Christchurch Hospital, Private Bag 4710, Christchurch 8001. Fax: (03) 364 0352; email: david.lewis@cdhb.govt.nz

References:

1. Wong S, Appleberg M, Ward CM, Lewis DR. Aspirin resistance in cardiovascular disease: a review. Eur J Vasc Endovasc Surg. 2004;27:456–65.
2. Sanderson S, Emery J, Baglin T, Kinmonth AL. Narrative review: aspirin resistance and its clinical implications. Ann Intern Med. 2005;142:370–80.
3. Patrono C. Aspirin resistance: definition, mechanisms and clinical read-outs. J Thromb Haemost. 2003;1:1710–3.
4. Wong S, Ward CM, Chen W, et al. Point of care versus laboratory testing of antiplatelet therapy. Br J Surg. 2004;91:106.
5. Eikelboom JW, Hirsh J, Weitz JI, et al. Aspirin-resistant thromboxane biosynthesis and the risk of myocardial infarction, stroke, or cardiovascular death in patients at high risk for cardiovascular events. Circulation. 2002;105:1650–5.
6. Gum PA, Kottke-Marchant K, Welsh P, et al. A prospective, blinded determination of the natural history of aspirin resistance among stable patients with cardiovascular disease. J Am CollCardiol. 2003;41:961–5.
7. Eikelboom JW, Hankey GJ. Aspirin resistance: a new independent predictor of vascular events? J Am Coll Cardiol. 2003;41:966–8.
8. Antiplatelet Trialists' Collaboration. Collaborative overview of randomised trials of antiplatelet therapy—I: Prevention of death, myocardial infarction, and stroke by prolonged antiplatelet therapy in various categories of patients. BMJ. 1994;308:81–106.
9. Bhatt DL, Hirsch AT, Ringleb PA, et al. Reduction in the need for hospitalization for recurrent ischemic events and bleeding with clopidogrel instead of aspirin. CAPRIE investigators. Am Heart J. 2000;140:67–73.
10. Mehta SR, Yusuf S; Clopidogrel in Unstable angina to prevent Recurrent Events (CURE) Study Investigators. The Clopidogrel in Unstable angina to prevent Recurrent Events (CURE) trial programme; rationale, design and baseline characteristics including a meta-analysis of the effects of thienopyridines in vascular disease. Eur Heart J. 2000;21:2033–41.
11. Matetzky S, Shenkman B, Guetta V, et al. Clopidogrel resistance is associated with increased risk of recurrent atherothrombotic events in patients with acute myocardial infarction. Circulation. 2004;109:3171–5.
12. Heart Protection Study Collaborative Group. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet. 2002;360:7–22.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Back to the future of healthcare: aetiology-centred medicine

Stephen Genuis

When Hippocrates, the 'Father of Medicine', was born on the Greek island of Kos in 460 BC, it was conventional medical wisdom that searching for disease aetiology in patients was futile. As illness was assumed to be the outworking of pernicious evil spirits and vengeful gods, the cure for health afflictions rested in treatment with magical concoctions.

When one observes the way medicine is often practiced today, interesting parallels can be drawn. With the widespread attribution of disease causation primarily to genetics, aetiology of illness with individual patients is frequently not explored while a plethora of pharmaceutical potions seem to be the ubiquitous answer to health difficulties.

An epic figure, Hippocrates earned deep respect from such notable philosophers as Aristotle and Plato for his challenges to the existing standard-of-care in both ethical and biological dimensions of healthcare provision. At a time when the tonics of bribed medical practitioners were frequently used to poison rivals, Hippocrates crafted the revered oath that bears his name; as a template for ethical practice in medicine, he wrote 'I will use treatment to help the sick according to my ability and judgment, but never with the view to injury and doing wrong.'

Although the medical literature contains countless papers that deliberate on the Hippocratic oath, his contribution to the physiological understanding of illness and disease is often overlooked, perhaps because modern medicine continues to deviate from his instruction. Challenging the notion that dark spiritual forces were the source of physical illness and that pain was caused by arrows from the Greek god Apollo, Hippocrates pioneered the hypothesis that 'every disease has a natural cause' and surmised that perhaps if you 'find the cause…then you can cure the disease.'

Amid the wonders of the modern world, the medical profession is currently challenged by individuals (young and old, rich and poor, and of every race and creed) that are crushed by the burden of debilitating health problems. Despite cutting-edge technology and awe-inspiring medical prowess, the incidence of chronic disease is rising, and many people (including young children) are compromised by ailments that appreciably diminish wellbeing. For example, recent American census figures reveal that an unprecedented one out of every dozen children and teenagers has a physical or mental disability, while exploding rates of crippling mood disorders in adults have led to annual hospitalisations for depression increasing by thirty times in the last 55 years.

As the management of patients with chronic mental and physical afflictions increasingly dominates medical practice, perpetually soaring healthcare costs are taxing the economic viability of individuals, families, and national governments. Yet, when addressing disease and suffering for individual patients as well as population groups, the perplexing response from much of the medical community is an exclusive search for management therapies rather than a concerted effort to understand what is happening.

Frequently, the unfolding algorithm in the medical office is the assignment of a ‘diagnosis’ followed by the initiation of effective therapies to mitigate signs and symptoms, without an adequate exploration of the underlying causes of the diagnosis. Many practitioners forget that a ‘diagnosis’ is simply a useful label given to a particular group of signs and symptoms; it does not necessarily identify the cause of the ailment nor why the disease process persists.

Consider, for example, the plethora of diagnoses using the suffix ‘itis’ such as iritis, vulvitis, pharyngitis, and so on; these helpful names are simply descriptive labels linking the Latin or Greek term for the site of the body to the Greek term for inflammation. Furthermore, in academic institutions, research into the origins of acute and chronic illness has increasingly taken a back seat to research and dissemination of information about lucrative therapies that relieve symptoms—an inevitable consequence of the progressively intimate relationship between medicine and industry.

A few principles are worth considering in addressing this dilemma. A primary goal of the physician must be to confront the origin of the problem when possible, rather than focusing on a temporary chemical or technological fix. Although obvious symptoms are not always present, illness commences only because a cause exists; illness continues and potentially worsens as long as the cause remains; and illness can only end when the cause is removed.

Suppressing symptoms with medication or surgery, while a reasonable course of action in many cases, does not address underlying aetiology. The tendency to put patients into preconceived diagnostic boxes with predetermined treatment regimes must be examined with critical thought and reasoned analysis.

Contemporary medical education often encourages trainees to studiously learn rather than to critically think and to abide by the status quo rather than to continuously evaluate current practices. Critical thinking and reasoned thought must be fostered at all levels and physicians need to be encouraged to believe what they see, rather than simply seeing what they have come to believe or been taught to accept.

The paramount importance of a renewed focus on aetiology-centred medicine and critical analysis is highlighted by a recent example from the medical literature. An article published in the *Journal of Epidemiology and Community Health* entitled ‘Childhood cancer and atmospheric carcinogens’ confirms previous suspicions that most childhood malignancies are likely the direct result of *in utero* exposure to certain environmental toxins.

The implications of such etiological research are colossal—the emotional, financial and social burden associated with caring for each child with cancer is profound; many, if not most of these cancers could be avoided altogether if physicians simply warned patients about toxic exposure during pregnancy.

However, with the spotlight of most cancer research and education focused on regimens of surgery, chemotherapy, and radiation, most practitioners are woefully unacquainted with the plethora of evidence correlating toxic exposure with disease, and few medical schools have yet to establish basic courses on environmental toxicity.

My erudite professor of epidemiology projected the same soporific slide at the start of most lectures. It read, ‘Disease is a function of determinants.’ This dogma is the modern vernacular for the same message Hippocrates delivered 2500 years ago—a message that is sorely needed today.

Author information: Stephen J Genuis, Associate Professor, University of Alberta, Edmonton, Alberta, Canada

Correspondence: Dr. Stephen Genuis, 2935-66 Street, Edmonton, Alberta, Canada T6K 4C1. Fax +1 780 4901803; email: sgenuis@ualberta.ca

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

New Zealand general practitioners' characteristics and workload: The National Primary Medical Care Survey

Antony Raymont, Roy Lay-Yee, Janet Pearson, Peter Davis

Abstract

Aims To describe the characteristics and workload of New Zealand general medical practitioners (GPs).

Methods Data were collected from a stratified random sample of GPs as part of the *The National Primary Medical Care Survey* carried out in 2001.

Results Data were submitted by 244 practitioners; a 62% response rate. Women made up 63% of the GP workforce aged under 40 years, but only 19% of those aged over 50 years. New Zealand graduates made up 69% of GPs; graduates from other areas occupied particular niches in the GP workforce. Each week, GPs worked (on average) 4 days and saw 102 patients. Eighty percent undertook after-hours work, and the average on-call roster was 1-in-8. At least 8% of visits to GPs occurred after-hours. Parameters of workload were lower for women and for those working in community-owned clinics, and higher for those working outside cities.

Conclusions An increasing proportion of GPs are women, and more GPs are working part time. In addition, if the changes in primary healthcare add to GPs' responsibilities, then more doctors will be needed. At present, GPs' workload is high in rural areas, which suggests inadequate recruitment; the distribution of GPs is a more important workforce issue than absolute numbers.

The New Zealand Government launched the *Primary Health Care Strategy* in 2002, proposing significant organisational change in the sector.[1] There has been concern that recruitment and retention of doctors (as well as of nurses) in primary care was insufficient, and that the system was unsustainable.[2] Such concerns have increased with the implementation of the *Strategy* that sets out to reduce barriers to care and to expand the role of the primary health care team. In particular, two 'pressure points' have been identified: recruiting practitioners to work in rural areas;[3] and provision of after-hours care.[4]

This paper presents New Zealand data on the characteristics of GPs and their workload. It was gathered in 2001, immediately prior to the initiation of the *Strategy*, and provides a baseline measurement of workload against which changing demands can be assessed.

The National Primary Medical Care *(NatMedCa)* Survey asked participating practitioners to provide information on patients seen during each of two data collection weeks. They were also asked to provide data on some personal and professional characteristics, and their workload.

Methods

The *NatMedCa* survey was carried out during 2001/2002 using a nationally representative, multi-stage probability sample of GPs, stratified by geographical location and practice type. A sampling frame of all active GPs was generated from telephone (Telecom) White Pages listings, and arrangements were made to include additional practitioners identified during the recruitment process and to replace those who were no longer in practice. Details of the methodology have been provided in detail elsewhere.[5]

Four types of practices were defined in 2001: independent practitioners; practitioners who were members of Independent Practitioners Associations (IPA); practitioners who were members of Independent Practitioners Associations and whose funding had been capitated (Cap't); and practitioners working for community-owned primary care organisations (Comm.). It has been established that the characteristics of practitioners and of workload vary across these types.[5–7] Data are given by practice type; data for all New Zealand were estimated as a weighted average to compensate for the over-representation, in the stratified sample, of capitated and community-owned practices.

Practice 'site' was classified as: metropolitan (Auckland): city (>100,000 population); town (30,000–100,000 population); and rural (<30,000). Place-of-graduation was classified as: New Zealand (NZ); United Kingdom (UK); Other English speaking countries (Other English); Asia; and Other non-English speaking.

The practitioner questionnaire asked the doctors to indicate the average number of patients they saw, and the number of half-days they worked, in a week. It also asked whether the GPs took call outside office hours and, if so, how often they worked.

It proved difficult to gather data on after-hours work performed by GPs. Such services were often provided away from the GP's surgery so that data collection routines were disrupted or they were provided by individuals or organisations not participating in the survey. Summary data were therefore sought from GP after-hours services in order to quantify the after-hours workload in primary medical care.

The *NatMedCa* study, from which these data come, was approved by the relevant district Ethics Committees, a process coordinated by the Auckland Ethics Committee.

Results

Recruitment—2779 GPs were identified; 25% of them were classified as independent, 58% as IPA members, 15% as Capitated IPA members, and 2% as working for community organisations. Table 1 gives these data as well as the sample sizes and the response rates.

Table 1. Characteristics of New Zealand GPs in 2001 (response rates by practice type)

Variable	Total	Independent	IPA	Cap'd	Comm
Number of GPs in New Zealand	2779	708	1598	411	62
Distribution by practice type	100%	25%	58%	15%	2%
Sample	396	76	134	124	62
Number of GPs responding	244	37	88	74	45
Response rate	62%	49%	66%	60%	73%

IPA=Practitioners who were members of Independent Practitioners Associations; Cap'd=Practitioners who were members of Independent Practitioners Associations and whose funding had been capitated; Comm=Practitioners working for community-owned primary care organisations.

Overall the response rate was 62%. A third of those GPs unwilling to participate did provide some data on themselves and their practices. On average, these practitioners worked longer hours and saw more patients than respondents.

Nineteen GP after-hours services were identified which provided coverage for a defined number of GPs. Eight of these after-hours services were excluded from the study because they did not provide an overnight service and two were unwilling to provide data. Three of the remainder have been treated as a single service since they served adjacent populations and only one remains open overnight covering the whole area. Data from seven services are presented. Tables 2 and 3 show the GPs' gender, age, and place-of-graduation.

Table 2. Characteristics of New Zealand GPs in 2001 (by practice type)

Variable	National estimate	Independent	IPA	Cap'd	Comm
N	2779	37	88	74	45
Gender (% female)	37.2	35.1	37.5	35.1	68.9
Mean age (years)	45.6	50.0	45.0	38.3	40.9
Mean years in Practice	16.2	18.5	15.6	15.5	10.2
Place of graduation					
- in NZ (%)	68.6	67.9	71.6	59.5	62.2
- in UK (%)	11.2	8.1	11.4	16.2	8.9
- in Other English* (%)	13.5	16.2	12.5	13.5	6.7
- in Asia (%)	8.1	8.1	2.3	10.8	17.8
- in Other non-English† (%)	1.4	0.0	2.3	0.0	4.4

*Other English-speaking country (e.g. Australia); †Other non-English-speaking country/region; IPA=Practitioners who were members of Independent Practitioners Associations; Cap'd=Practitioners who were members of Independent Practitioners Associations and whose funding had been capitated; Comm=Practitioners working for community-owned primary care organisations; NZ=New Zealand; UK=United Kingdom.

Table 3. Characteristics of New Zealand GPs in 2001 (by location)

Variable	Metro	Cities	Towns	Rural	North Is	South Is
N	55	88	23	78	201	43
Gender (% female)	43.6	47.7	52.2	32.1	42.3	41.9
Mean age	44.8	43.6	44.0	46.6	44.8	45.3
Mean years in Practice	15.4	13.5	13.5	16.9	14.7	16.2
Place of graduation						
- in NZ (%)	65.5	73.9	65.2	56.4	63.7	74.4
- in UK (%)	9.1	6.8	13.0	19.2	11.9	11.6
- in Other English* (%)	9.1	6.8	17.4	19.2	11.9	14.0
- in Asia (%)	16.4	8.0	4.3	5.1	10.4	0.0
- in Other non-English† (%)	0.0	4.5	0.0	0.0	2.0	0.0

*Other English-speaking country (e.g. Australia); †Other non-English-speaking country/region; Metro=Auckland; Is=Island; NZ=New Zealand; UK=United Kingdom.

Gender—37% of practitioners were female, and this percentage was considerably higher (69%) for community-based practices. Women favoured 'towns' but made up only 32% of rural practitioners. Studies undertaken a decade ago found that 17% of GPs were female[8]—the recent increase in female GPs was reflected in the gender percentages by age group; past 50 years of age, 19% of practitioners were women; at ages 40–49, the figure was 44%; and below 40, the figure was 63%.

Age—The mean age of all GPs was 45.6 years. Males and females averaged 47.2 and 41.7 years respectively. Women reported correspondingly shorter times in practice.

Independent practitioners tended to be older while practitioners in capitated and community-based practices were younger.

Place of graduation—Of all practitioners, 69% graduated in New Zealand. The figure was lower for those in capitated and community-based practices, as well as those in rural areas. UK graduates made up 11% of surveyed practitioners and made up a larger proportion of capitated and rural practices. Asian graduates made up 8%, and favour metropolitan and community-based practices; they were also less likely to be members of (non-capitated) IPA practices. Tables 4, 5, and 6 show the GPs' workload.

Table 4. Workload of New Zealand GPs in 2001 (by practice type)

Variable	Total	Independent	IPA	Cap'd	Comm
N	244	37	88	74	45
Mean days per week	3.9	4.0	4.0	4.0	3.5
Mean patients per week	102.5	101.4	103.9	118.1	74.8
Patients per day	26.4	25.3	26.2	29.8	21.3
AH work (%)	78.7	78.4	81.8	86.5	60.0
Mean eve. on call (%)	13	15	15	12	7
Mean WE on call (%)	12	16	14	11	6

AH=After hours; eve.=Evenings; WE=Weekends; IPA=Practitioners who were members of Independent Practitioners Associations; Cap'd=Practitioners who were members of Independent Practitioners Associations and whose funding had been capitated; Comm=Practitioners working for community-owned primary care organisations.

Days worked and patients seen—On average, GPs worked 3.9 days, and saw 102.5 patients per week (or 26.4 patients per day). Just under 80% of them undertook after-hours work, and these GPs worked about 1 evening or weekend in 8.

Table 5. Workload of New Zealand GPs in 2001 (by location)

Variable	Metro	Cities	Towns	Rural	North Is	South Is
N	55	88	23	78	201	43
Mean days per week	3.6	3.9	3.9	4.0	3.9	3.9
Mean patients per week	94.5	93.3	104.3	118.1	102.1	104.2
Patients per day	26.1	23.8	26.7	29.3	26.4	26.4
AH work (%)	40.0	84.1	87.0	97.4	75.6	93.0
Roster number	6	12	10	18	11	19
Mean WE on call (%)	7	11	10	18	11	17

AH=After hours; WE=Weekends.

Practice type and site – The average number of days worked per week (mean 3.9) were less for community-based practices (3.5 days) and those in Auckland (3.6 days). The average number of patients seen per week (mean 102.5) was higher for capitated and rural practices (both 118.1) and lower for community-based (74.8), Auckland (94.5), and City (93.3) practices. Salaried practitioners saw fewer patients per week (88.2 vs 106.5), reflecting the association with community-based practice; the number of patients seen per day was also somewhat less (24.3 vs 26.9).

Table 6. Workload of GPs (by practitioner characteristics)

Variable	Males				Females			
Age group (years)	**<40**	**40–49**	**50–59**	**60+**	**<40**	**40–49**	**50–59**	**60+**
N	23	65	38	13	39	52	9	2
Mean days per week	3.9	4.3	4.5	4.7	2.8	3.3	4.3	4.5
Mean patients per week	121.1	126.4	124.1	100.1	60.3	82.3	100.9	85.0
Patients seen per day	31.0	29.1	27.4	21.2	21.4	24.8	23.6	18.9
AH work (%)	87.0	86.2	81.6	69.2	64.1	78.8	77.8	50.0
Mean eve on call (%)	16	15	17	3	7	12	10	36
Mean WE on call (%)	17	15	14	20	7	9	4	16

AH=After hours; eve=Evenings; WE=Weekends.

Gender—Relative to males, female practitioners worked less (mean 3.2 vs 4.3) days per week, saw fewer patients (mean 74.8 vs 120.7) per week, and had a lower work rate (23.1 vs 27.8 patients) per day.

Age—For male practitioners, the number of days worked per week increased with age with those under 40 working an average of 3.9 days. The number of patients seen per day was stable (at around 30) but decreased to an average of 21.2 for the 13 doctors aged over 60 years. For female practitioners, the number of days worked per week increased with age, with those under 40 working an average of 2.8 days. Those under 40 or over 60 saw relatively few patients per day. For the three major age groups (<40, 40–49, 50–59), women worked 28%, 25%, and 4% less time than men, and saw 50%, 35% and 17% fewer patients per week.

After-hours work—Overall, 81% of practitioners reported that they undertook after-hours call. The percentage was much lower in Auckland (40%) than in the cities (84%), towns (87%), or rural areas (97%)—and the average for the South Island was high (93%). Only 60% of practitioners in community-based practices undertook after-hours call. The mean rate for men was 82% and for women was 72%. Women less than 40 years old took call less often (64%) but women were close to the average above the age of 40.

For those GPs who took call, most worked 12% of the time, which corresponds to a roster of 1-in-8. Metropolitan and women practitioners, and those working at community-owned practices were on call for about 6% of the time, which corresponds to a roster of 1-in-16.

Data concerning the volume of after-hours work (obtained from the 7 GP after-hours services covering 400 GPs) showed that the annual number of after-hours visit per GP averaged 375 but varied from 223 to 710. About 44% of cases were children, and 26.5% were subsidised by ACC. About 60% of the after-hours work occurred on weekends or on holidays, the remainder being weekday evenings and nights.

Comparison with 1992 data—Table 7 compares the data presented above with data gathered in three related studies carried out during 1992.[8] It should be noted that these studies were conducted in Auckland, Waikato, and Taranaki only and were not nationally representative. Therefore, comparisons should be regarded with caution.

The percentage of female practitioners has doubled from 17% to 37%. It would appear that workload has decreased: hours-worked-per-week has diminished by 19% (from 38.4 to 31.1 hours); and patients-seen-per-week has decreased by 21% (from 129.3 to 102.5).

Table 7. Comparison with 1991/2 data

Variable	2001 NatMedCa	1992 Wt'd Mean	1992 Auckland	1992 Urban Waikato	1992 Rural Waikato	1992 Tarnki
N	244	–	167	80	105	79
Female (%)	37.2	17.3	20	20	14	13
Hours per week	31.1	38.4	41.9	36.8	35.9	35.9
Patients per week	102.5	129.3	133	126	141	109

NatMedCa=National Primary Medical Care Survey; Wt'd=Weighted; Tarnki=Taranaki.

Discussion

Over the last 10 years there has been a dramatic increase in the proportion of GPs who are female. Females now make up 37% of the total GP workforce and 63% of those GPs under 40 years of age. The situation is similar in Australia, Canada, England, and the United States where nearly 50% of medical students (and 20–30% of practising doctors) are female.[9]

The increase in the proportion of female GPs has workforce implications since women (especially younger women) work fewer days and see fewer patients than their male counterparts. Overseas studies have similarly reported that females work between 7 and 11 hours less than males.[9,10]

Furthermore, female practitioners in New Zealand are somewhat less likely to practice in rural areas. Similar findings have been reported from the Canadian province of Quebec,[11] and in the Netherlands.[12]

Workload (expressed as patients seen per week) averaged 102.5, and was lower in metropolitan and city practices (approximately 94) and higher in rural practices (118). The number of patients seen per week is also lower in community-based practices (75) and higher in capitated ones (118). The New Zealand figures are within the international range; an average of 87 patients per week was been reported from the Canadian city of Winnipeg[13] and an analysis of four studies from the UK suggested an average rate of 150 patients per week with 26 additional home visits.[14] It is possible that these numbers reflect, to some extent, the funding context: capitated in the UK; fee-for-service in Canada; and mixed in New Zealand.

Between 1992 and 2001, the data suggest a reduction of 21% (129.3 to 102.5 patients) in the mean number of patients seen per week per medical practitioner. The main cause of this drop is the increase in the number of part-time practitioners. However, given differences in data collection and response rates between the studies, it would be unwarranted to say that the number of patients seen per week has diminished for all categories of practitioner.

Workload expressed as responsibility for after-hours care, is highest (97%) for rural areas. In metropolitan areas, after-hours responsibility is born by a much smaller

percentage of practitioners (40%). Frequency of call was 1:3 in rural areas and 1:10 in towns and cities.

It appears that the average GP's practice generates about 375 after-hours visits per year. Assuming 4 weeks of annual leave, the average GP can be expected to undertake about 4,800 daytime consultations per year, so about 8% of primary-care patient contacts are after hours.

The variability in the number of after-hours visits per GP probably reflects local factors such as the socioeconomic status of the population, the distance to hospital-based emergency services, and the availability of evening surgeries in general practice. It is also likely, given the established tendency for healthcare services to vary by area, that local practice styles may develop.

Relatively few centres were able to provide after-hours data related to a specified group of GPs; this reflects multiple options for the provision of cover. In Auckland, and over the North of the North Island, for example, there are many Accident and Medical clinics providing services from 8am to 10pm and some are open 24 hours per day. GPs may refer their patients to these clinics officially or unofficially, and the clinics may not be able to relate their clientele to a specific 'denominator' population. In smaller towns, local GPs have a roster, with the GP on-call often using his or her own surgery. Often no distinguishable records are kept of after-hours work.

The effect of the implementation of the Strategy on workload remains uncertain.[15] Reduced co-payments can be expected to increase the number of visits per patient and an expansion of the responsibilities of primary care may further increase the workload. British GPs felt that the move to a primary-care-led health service was increasing their workload.[16] This may be offset (to some degree) by a wider use of nurses and, possibly, other professionals. However, there is evidence[4] that recruitment of nurses into primary care may also be problematic.

This study describes the workload of GPs in 2001, and relates it to the characteristics of the practitioner and to the practice context. *NatMedCa* asked practitioners to indicate how many half days they worked in their surgery; it did not quantify the number of hours worked or distinguish administrative from patient-contact work. It is recommended that future assessment of workload should consider these issues.

In assessing the adequacy of the GP workforce under the *Strategy*, workload should also be related to the population served and the distribution of work across members of the primary healthcare team. Particular attention should be given to new functions required. Such an assessment might move some way to assessing the number (in full-time-equivalents [FTEs]) of primary medical care practitioners required for an efficient health system, and to clarify the issue of recruitment levels.

The higher workload in small towns and rural areas (both in terms of patients-per-week and in frequency of after-hours call) suggests that maintaining adequate services in these areas may become increasingly problematic. It should be noted that the same problems may occur in less desirable areas of the cities. Lower workloads in Auckland and the cities may indicate spare capacity; they may also indicate a preference for a lower workload.

To summarise, there is no clear case for more GPs according to these data; of greater importance is their distribution, the delineation of work roles in the primary health care team, and new demands of the *Primary Health Care Strategy*.

Author information: Antony Raymont, Senior Research Fellow, Health Services Research Centre, School of Government, Victoria University of Wellington, Wellington; Roy Lay-Yee, Research Fellow, Department of Sociology; Janet Pearson, Analyst, Department of Sociology; Peter Davis, Professor, Department of Sociology, Faculty of Arts, University of Auckland, Auckland

Acknowledgements: This research was funded by the Health Research Council of New Zealand. We thank the general practitioners who contributed their time to this study.

Correspondence: Dr Antony Raymont, Health Services Research Centre, School of Government, Victoria University of Wellington, PO Box 600, Wellington. Fax: (09) 463 6568; email: antony.raymont@vuw.ac.nz

References:

1. King A. The Primary Health Care Strategy. Wellington: Minister of Health; 2001. Available online. URL: http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/7bafad2531e04d92cc2569e600013d04?OpenDocument Accessed May 2005.
2. Austin C. Primary Care in New Zealand – Viable but Vulnerable? Wellington: The Royal New Zealand College of General Practitioners; 2003:15.
3. Janes R, Dowell A, Cormack D. New Zealand rural general practitioners 1999 survey – part 1: an overview of the rural doctor workforce and their concerns. N Z Med J. 2001;114:492–5.
4. Cumming J, Raymont A, Gribben B, et al. Evaluation of the implementation and intermediate outcomes of the primary health care strategy. Wellington: Ministry of Health.
5. Raymont A, Lay-Yee R, Davis P, Scott A. Family Doctors: methodology and description of the activities of private GPs. Wellington: Ministry of Health; 2004:101. Available online. URL: http://www.moh.govt.nz/moh.nsf/wpg_Index/Publications-Family+Doctors+NatMedCa+Report+One Accessed May 2005.
6. Crampton P, Davis P, Lay-Yee R, et al. Comparison of private for-profit with private community-governed not-for-profit primary care services in New Zealand. Journal of J Health Serv Res Policy. 2004;9(Suppl. 2):17–22.
7. Crampton P, Davis P, Lay-Yee R, et al. Does community-governed non-profit primary care improve access to services? Cross-sectional survey of practice characteristics. International Journal of Health Services. 2005 (in press).
8. Gribben B, Bonita R, Broad J, et al. Geographical variations in the organisation of general practice. N Z Med J 1995;108:361–3.
9. McMurray J, Cohen M, Angus G, et al. Women in medicine: a four-nation comparison. J Am Med Womens Association. 2002;57:185–90.
10. Slade S, Busing N. Weekly work hours and clinical activities of Canadian family physicians: results of the 1997/98 National Family Physician Survey of the College of Family Physicians of Canada. CMAJ. 2002;166:1407–11.
11. Maheux B, Dufort F, Lambert J, Berthiaume M. Do female general practitioners have a distinctive type of medical practice? CMAJ. 1988;139:737–40.
12. Boerma WG, van den Brink-Muinen A. Gender-related differences in the organization and provision of services among general practitioners in Europe: a signal to health care planners. Med Care. 2000;38:993–1002.

13. Watson D, Katz A, Reid R, et al. Family physician workloads and access to care in Winnipeg in 2001. CMAJ. 2004;171:339–42.

14. Thomas K, Birch S, Milner P, et al. Estimates of general practitioner workload: a review. J R Coll Gen Pract. 1989;39:509–13.

15. Crampton P, Davis P, Lay-Yee R. Primary care teams: New Zealand's experience with community-governed non-profit primary care. Health Policy. 2005;72(2);233-43.

16. Scott A, Wordsworth S. The effects of shifts in the balance of care on general practice workload. Fam Pract. 1999;16:12–17.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Advertising of medicines on New Zealand television

Pauline Norris, Lucy Nelson, Koal Lin Ling, Lucy Skellett, Joyce Hoo, Cecilia Va'ai, Amber Gates

Abstract:

Aims To measure the frequency of advertising of medicines on New Zealand television and to describe the distribution of advertising.

Methods A stratified random sample of 35 days (577.5 hours) of television was video-recorded, including five free to air channels for each day of the week. Videotapes were watched, then advertisements were recorded on a pre-designed form.

Results 340 advertisements for medicines were identified, an average of 1 per 102 minutes; 37% of advertisements were for medicines available for general sale, 24% for dietary supplements, 21% for pharmacy- or pharmacist-only medicines, and 18% for prescription-only medicines. Four channels had similar amounts of advertising. Channels varied in the kind of medicines they had advertisements for. There were more advertisements per hour in the afternoon than in the morning or evening. Advertisements for medicines were found in a wide range of programmes, including children's programmes.

Conclusions People who watch particular programmes, or who watch television at some times of days may be exposed to considerably more than one medicine's advertisement per 102 minutes. While this study does not examine the effect of medicines advertisements on consumer behaviour, previous research suggests this may be significant.

Consumers have a wide range of medicines available to them in supermarkets, health food and other stores, and over the counter in pharmacies. Many of these medicines are advertised widely in print and broadcast media.

In New Zealand, prescription-only medicines are also advertised to the public. These advertisements attempt to influence consumers' choices about medicines. This can have significant consequences for individual and public health, as medicines can potentially either harm or improve health.[1,2]

An advertised medicine may be inappropriate for a particular person for several reasons, including:

- Incorrect self-diagnosis,
- Contraindication in their condition,
- Possible interaction with other currently taken medication,
- Risks that may outweigh any possible benefit,
- Availability of a more suitable non-drug treatment alternative, and the
- Significant economic burden the medicine imposes on them.

If advertising leads consumers to use inappropriate medicines, to use them inappropriately, or to misdiagnose health problems (and therefore delay treatment for serious problems), this can lead to significant health problems. An additional concern is *medicalisation*—the tendency to regard medicines as solutions for everyday problems associated with normal life processes.[3,4]

Considerable research has been done on the advertising and promotion of medicines, and its impact on prescribers.[5] Concerns have been raised about the quality of information contained in medicines advertisements, and the impact of these on prescribing practice. Less research has been done on the impact of advertising of medicines to the public, and there is little data available on the extent of consumers' exposure to medicines advertising.

The advertising of prescription medicines to the public has caused considerable debate in New Zealand.[6,7,8] New Zealand and the United States (US) are the only two developed countries that allow such advertising of prescription-only medicines. There is evidence that the US public is less becoming sympathetic to direct to consumer advertising.[9]

Descriptive studies overseas have looked at the educational value of direct to consumer advertisements for prescription products or the appeals made in these advertisements.[10–14] These studies are heavily focused on print advertisements. Research has also been done on consumers' reports of their exposure to and recall of advertisements, and their views about direct to consumer advertising.[15–18] There is a small body of evidence of the impact of these advertisements, although this is a difficult topic to research.[19–22]

As well as advertisements for prescription-only medicines, New Zealand consumers are exposed to a great deal of advertising of non-prescription medicines, and (to our knowledge) there is no published research on the impact of this. There have been no other published studies on the extent of advertising of both prescription and non-prescription drugs to consumers. The one exception we could find is Hardon's study which included the extent of radio advertising of medicines in the Phillipines.[23]

In this study, we measured the frequency and distribution of advertisements for medicines on New Zealand television over a 1-year period.

Methods

A stratified random sample of 577.5 hours (35 days) of television was video-recorded during the period 15 November 2001 to 11 December 2002. Seven days (6:30am to 11pm) of each free-to-air national TV channel (TV1, TV2, TV3, TV4, Prime) were recorded.

Taping started on a randomly selected date in November 2001 (Thursday 15 November), and one day of each channel was recorded in turn. This sequence was repeated every 64 days, ensuring that each time a different day of the week was recorded for each channel. If any taping was missed because of technological problems or human error, the same channel was recorded at the same time the following week. There were very few such problems, but the final day of TV1 programming (Wednesday 4 December) was missed, so it was replaced with TV1 Wednesday 11 December programming.

We defined medicines more broadly than the legal definition of registered medicines. We included prescription medicines, pharmacy medicines, herbal medicines, homeopathic medicines, and dietary supplements. We considered medicines to be 'products intended for humans, that claimed to treat health problems'.

We distinguished medicines from food and drinks on the basis that a medicine's primary purpose is therapeutic whereas the primary purpose of a food or drink was to satisfy hunger or thirst. Thus we

classified *Lemsip* (a lemon drink containing paracetamol and phenylephrine) and *Fastburner* (a meal replacement drink) as medicines since their primary purpose is to treat colds or to reduce weight respectively, while we did not classify *V* (an energy drink including Caffeine and Guarana) and mineral waters (with additives such as vitamins) as medicines.

We distinguished medicines from cosmetics by defining medicines as products advertised for:

- Diseases (e.g. acne, eczema, athlete's foot),
- Sensitive teeth and plaque (apart from ordinary toothpaste);
- Smoking addiction (e.g. patches, gum); and
- Internal use for wrinkles, cellulite, and changing the appearance of skin.

On the other hand, we defined moisturisers, under-arm deodorants, foot deodorants, and other topical products for dry or sensitive skin as cosmetics—and hence excluded them from the study.

A standard form for reporting medicines advertisements was developed. Apart from PN, all tapes were watched the authors and those listed in the Acknowledgements, and the forms were completed whenever an advertisement for a medicine was identified.

The date, time, channel, wording, and a description of the visual aspects of the advertisement were recorded. Products were classified according the *New Ethicals Catalogue*,[24] the *MedSafe* website (www.medsafe.govt.nz) and by discussion amongst group members (for alternative medicines and dietary supplements). Where it was unclear what products were, *Google* searches (www.google.com) were done to find manufacturers' or sellers' websites which might give active ingredients.

To assess the reliability of the recording process, two hours of each person's viewing were randomly selected and reviewed independently by PN. Significant under-reporting was identified in one person's recording, while no problems were identified in any other. All of this person's viewing (49.5 hours) was then repeated by PN.

The extent and distribution of advertisements were analysed using Microsoft Excel software.

Results

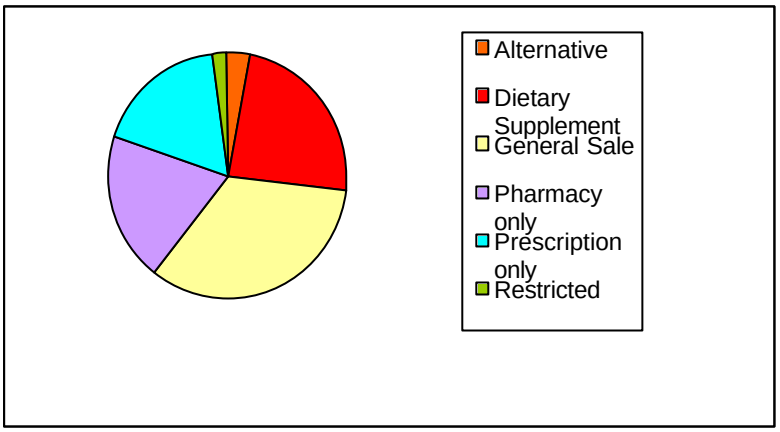
During the 35 days of television, we found 340 advertisements for medicines. On average, this was 0.59 advertisements per hour, or 1 advertisement per 102 minutes. Sixty-four different medicines were advertised (this includes 3 formulations each, of *Nurofen* and *Panadol*).

Of the 64 products advertised, 12 were prescription-only medicines, 2 were pharmacist-only medicines, and 17 were pharmacy-only medicines; the remainder were 33 products available for general sale. Of these, we classified 6 as dietary supplements (mostly vitamins) and 4 as alternative medicines (such as herbal or homeopathic products).

The prescription-only products advertised during the study period were: *Viagra* (sildenafil, for erectile dysfunction), *Flixotide* (flucticasone, for asthma), *Propecia* (finasteride, for baldness), *Xenical* (orlistat, for obesity), *Zyban* (bupropion, for smoking cessation), *Vioxx* (rofecoxib, an anti-inflammatory), *Losec* (omeprazole, a proton pump inhibitor for gastric problems such as reflux), *Reductil* (subutramine, for obesity), *Twinrix* (vaccine for Hepatitis A and B), *Detrusitol* (tolterodine, for over-active bladder), *Somac* (pantoprazole, a proton pump inhibitor for gastric problems such as reflux), and *Symbicort* (budesonide and eformoterol, for asthma).

Most advertisements were for products that were available outside of pharmacies (Figure 1). Advertisements for prescription-only products made up 17.9% of advertisements.

Figure 1: Number of advertisements by drug type



The most commonly advertised products were: *Comprehensive Formula* (a vitamin and mineral supplement sold in combination with fitness equipment 'Abslide') *Nature Bee Pollen* (a dietary supplement containing 'potentiated' bee pollen), *Fastburner* (a meal replacement formula for weight loss), *Nicobrevin* (a nicotine-free anti-smoking aid), *Panadol* (paracetamol), *Propecia* (finasteride), *Sensodyne* (a toothpaste to treat sensitive teeth), and *Buccaline Berna* (prophylaxis for common cold). Each of these products was advertised between 10 and 35 times during our viewing period.

The Prime TV channel showed a significantly lower number of advertisements than the other channels (Poisson, $p<0.001$). Prime had 19 medicines advertisements over the period (almost all of which were on Wednesday), while the other four channels showed between 70 and 90 (average 80.25).

More medicine advertisements were shown on Mondays (62), Wednesdays (61), and Sundays (56) than on other days of the week (36–45), but there appears to be no clear pattern between channels.

The channels varied in the kind of advertisements they screened (comparing all 'general sale products, pharmacy, and pharmacist-only products' with 'prescription only products' (chi-squared=87.7, df=8, $p<0.001$). On each of the channels more than a quarter of advertisements were for general-sale medicines (Table 1). Apart from that category, the most common categories in each channel were: prescription-only products on TV1, pharmacy-only products and dietary supplements on TV2, prescription-only products on TV3, dietary supplements on TV4, and pharmacy-only products on Prime TV.

Advertisements were concentrated in different times of day. Twenty-one percent of advertisements were in the morning (6:30am–12noon). Almost half of all advertisements (46%) were in the afternoon (12noon–6pm), while 33% were in the evening (6pm–11pm). Thus, in the peak advertising time, afternoons, there were 0.74 medicines advertisements per hour, or 1 advertisement per 81 minutes.

Few advertisements for prescription medicines were shown in the morning (3%); more were shown in the afternoon (51%) and evening (46%). There were more advertisements for prescription-only medicines per hour in the evening (0.16 per hour, or 1 advertisement per 375 minutes) that at other times of the day.

Table 1. Number and (percentage) of advertisements for types of product on each TV channel

	Medicine type						Total
	Pres-only	P'cist-only	Pharm-only	Gen sale	Altern	Diet suppl	
TV1	25 (27.8)	3 (3.3)	16 (17.8)	31 (34.4)	4 (4.4)	11 (12.2)	**90**
TV2	7 (8.0)	4 (4.6)	26 (29.9)	22 (25.3)	6 (6.9)	22 (25.3)	**87**
TV3	26 (35.1)	0 (0)	11 (14.9)	31 (41.9)	0 (0)	6 (8.1)	**74**
TV4	0 (0)	0 (0)	2 (2.9)	25 (35.7)	0 (0)	43 (61.4)	**70**
Prime	3 (15.8)	0 (0)	11 (57.9)	5 (26.3)	0 (0)	0 (0)	**19**
Total	**61**	**7**	**66**	**114**	**10**	**82**	**340**

Pres=Prescription; P'cist= Pharmacist; Pharm=Pharmacy; Gen=General; Altern=Alternative; Diet suppl=Dietary supplement.

Advertisements for medicines were found in a very wide range of programmes. Fewer advertisements were found amongst children's programmes. Ten advertisements (for *Robitusson* [a cough mixture], *Panadol* [paracetamol], *Nature Bee Pollen*, *Claramax* [an antihistamine for hayfever], and a children's vitamin formulation were found in programmes that seemed to be directly targeted at children.

We found more than six advertisements in the following programmes (it should be noted that some of these have daily episodes and so do not necessarily have a high hourly rate of advertising): Athletics coverage (from the Commonwealth games), Home and Away (Australian soap opera), Infomercials, News, Oprah (talk show), Shortland Street (New Zealand soap opera), The Young and the Restless (US soap opera).

Advertisements for prescription medicines were also found in a wide range of programmes. Twenty-nine programmes (news broadcasts, soap operas, movies, comedies, documentaries, a fishing programme, and a cooking programme) included one advertisement for a prescription medicine. Those which included more than one prescription medicine advertisement included reality TV shows, dramas, soap operas, comedies, and documentaries. Eleven advertisements for prescription drugs were found during sports coverage.

Discussion

Although we attempted to standardise reporting and ensure inter-rater reliability, some problems may still exist. Special events occurring during the study period may also potentially influence the results. The study included such a large sample of television, which allowed us to detect the significant variation between the extent of medicines advertising between channels and between days of the week. Any future attempts to monitor the extent of medicines advertising must take this variation into account. There also appeared to be seasonal variation in types of products advertised, but we were able to minimise this by studying a whole year's television.

We identified a large number of medicines advertisements. While viewers on average would be exposed to less than one medicine's advertisement per hour, those who watch particular channels at peak-viewing time may be exposed to considerably more

advertisements. In addition, there are medicines advertisements on radio and in print media, which increase the level of consumers' exposure to advertising.

We found a variety of different forms of medicines advertising. Programmes were sometimes sponsored by medicines' manufacturers (eg *Propecia* sponsored a rally driving event during our study period). Advertisements for these programmes then also contain the product name. A pharmacy marketing group also produces a 'Family Health Diary', which, while ostensibly educating consumers about common health problems, usually advertises several medicines.

Advertisements were frequently repeated. For example, in one 8-hour period on TV4 there were eight advertisements for *Nicobrevin* and four advertisements for *Berocca*. Some products had two or three different advertisements that they repeated in sequence. Studies that assess the impact of advertising on consumers must take account of this repetition: viewers may often be exposed to several advertisements for one product during one viewing session. People who watch particular types of programmes may also be exposed to higher levels of medicine advertising. For instance, there appears to be a high level of advertising of prescription medicines during sports coverage. Indeed, this is likely to be part of a targeting strategy by manufacturers and advertisers.

This study cannot determine the impact of medicines advertisements on consumer behaviour. Previous studies on advertisements for prescription medicines have strongly suggested that advertisements have a powerful effect on consumers. Most research has focused on prescription-only medicines. Everett found that, when faced with a hypothetical situation, about one-third of his respondents said they would ask their doctor for a medicine they saw advertised.[19]

In Bell, Wilkes, and Kravitz's study, 15% of people said they would consider terminating their relationship with their doctor if they refused their request for an advertised drug.[20] And, in another study, 32% of consumers who had seen a DTC advertisement had talked to their doctor about an advertised medicine. Twenty-six percent had asked for a prescription for the advertised medicine; and of these, 71% received the prescription.[16]

Mintzies et al, in study of patient visits to primary care physicians, found that doctors were ambivalent about the choice of treatment they gave in 40% of cases, and about 50% of cases where the patient had requested an advertised drug.[22] Using a quasi-experimental, interrupted time-series research design, Basara found a significant increase in the number of new prescriptions for a product during and after it was advertised direct to consumers.[25] In a New Zealand survey, around 10% of consumers reported that an advertisement had prompted them to ask for a prescription-only medicine. Most of these had received the medicine they asked for.[8]

There are fewer studies looking at the effect of advertising on non-prescription medicines on consumers. In New Zealand, pharmacists have reported that consumers request pharmacist-only medicines after seeing advertisements for them.[26]

In summary, further research should be undertaken on the whole range of medicines advertisements directed at consumers, their impact on consumer behaviour, and their public health consequences. This should include examining the health-related claims

made in advertisements, whether those advertisements meet regulatory requirements and guidelines, and how the advertisements are evaluated by consumers.

Of special mention, while our study focused on medicines, we also noticed that health claims were made for a range of non-medicine products: such as magnetic underlays for beds. We suggest that these health claims should be subject to similar regulations as those made in medicines advertisements.

Author information: Pauline Norris, Senior Lecturer and Leader: Clinical/Pharmacy Practice Research; Lucy Nelson, Exchange student; Koal Lin Ling, 4th year student; Lucy Skellett, 4th year student; Joyce Hoo, 4th year student; Cecilia Va'ai, 4th year student; Amber Gates, 4th year student, School of Pharmacy, University of Otago, Dunedin

Acknowledgements: Karen Morris, Emily Toner, and Nicola Schumacher also watched some of the television coverage. University of Otago funded the project. The University of Nottingham School of Pharmacy (UK) arranged the exchange programme through which Nicola Schumacher and Lucy Nelson became involved in the project.

Correspondence: Pauline Norris, School of Pharmacy, University of Otago, PO Box 913, Dunedin. Fax: (03) 479 7034; email: pauline.norris@stonebow.otago.ac.nz

References:

1. National Medicines Policy 2000. Canberra, Australia: Commonwealth Department of Health and Aged Care; 1999.
2. A Policy on the Quality Use of Medicines. Canberra, Australia: Commonwealth Department of Health, Housing and Community Services and The Pharmaceutical Health and the Rational Use of Medicines (PHARM) Committee; 1992.
3. Moynihan R, Heath I, Henry D. Selling sickness: the pharmaceutical industry and disease mongering. BMJ. 2002;324:886–91.
4. Moynihan, R., The making of a disease: female sexual dysfunction. BMJ. 2003;326:45–7.
5. Norris P. Drug Promotion Database: what's known and what is missing. WHO and HAI Europe; 2003.
6. Ministry of Health. Direct-to-consumer advertising of prescription medicines in New Zealand: a discussion paper. Wellington: Ministry of Health; 2000, p41.
7. Ministry of Health. Summary of submissions on the Direct-to-Consumer Advertising of Prescription Medicines in New Zealand discussion paper. Wellington: Ministry of Health; 2001 p.10.
8. Toop L, Richards D, Dowell T, et al., Direct to consumer advertising of prescription drugs in New Zealand: For health or for profit: Report to the Minister of Health supporting the case for a ban on DTCA. Christchurch: University of Otago; 2003, p61. Available online. URL: http://www.chmeds.ac.nz/report.pdf Accessed May 2005.
9. Aikin K, Swasy JL, Braman AC. Patient and physician attitudes and behaviors associated with DTC promotion of Prescription Drugs – Summary of FDA Survey Research Results. Final Report. Washington, DC: US Dept of Health and Human Services; 2004.
10. Bell RA, Wilkes MS, Kravitz RL. The educational value of consumer-targeted prescription drug print advertising. J Fam Pract. 2000; 49:1092–8.
11. Woloshin S, Schwartz LM, Tremmel J, Welch HG. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? Lancet. 2001;358:1141–6.

12. Bell RA., Kravitz RL, Wilkes MS. Direct-to-consumer prescription drug advertising, 1989-1998: a content analysis of conditions, targets, inducements, and appeals. J Fam Pract. 2000;49:329–35.

13. Parker BJ, Delene LM. Direct-to-consumer prescription drug advertising: content analysis and public policy implications. Journal of Pharmaceutical Marketing & Management. 1998;12:27–42.

14. Roth MS. Patterns in direct-to-consumer prescription drug print advertising and their public policy implications. Journal of Public Policy & Marketing. 1996;15:63–75.

15. Bell RA, Kravitz RL, Wilkes MS, Direct-to-consumer prescription drug advertising and the public. J Gen Int Med. 1999;14:651–7.

16. Slaughter E, Schumacher M. Prevention's International Survey on Wellness and Consumer reaction to DTC Advertising of Rx Drugs: US Report with International Perspectives. Prevention Magazine. 2000/2001, p72.

17. Maddox LM, Katsanis LP, Direct-to-consumer advertising of prescription drugs in Canada: its potential effect on patient-physician interaction. Journal of Pharmaceutical Marketing & Management. 1997;12:1–21.

18. Alperstein NM, Peyrot M. Consumer awareness of prescription drug advertising. Journal of Advertising Research. 1993;33:50–6.

19. Everett SE. Lay audience response to prescription drug advertising. Journal of Advertising Research. 1991;31:43–9.

20. Bell RA, Wilkes MS, Kravitz RL, Advertisement-induced prescription drug requests: patients' anticipated reactions to a physician who refuses. J Fam Pract. 1999;48:446–52.

21. Perri M, Dickson WM. Direct to consumer prescription drug advertising: consumer attitudes and physician reaction. Journal of Pharmaceutical Marketing & Management. 1987;2:3–25.

22. Mintzes B, Barer ML, Kravitz RL, et al. Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: two site cross sectional survey. BMJ. 2002;324:278–9.

23. Hardon A. Towards rational drug-use in urban primary health care. Drug Monitor 3. 1988;3:111–9.

24. New Ethicals Catalogue (Vol 38). Auckland: Adis International; 2001.

25. Basara LR. The impact of a direct-to-consumer prescription medication advertising campaign on new prescription volume. Drug Inform J. 1996;30:715–29.

26. Norris P. New Zealand pharmacists' views about pharmacist-only medicines. J Pharm Pract Res. 2004; 34:282-285.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

New Zealand general practitioners' views on direct-to-consumer advertising (DTCA) of prescription medicines: a qualitative analysis

Ninya Maubach, Janet Hoek

Abstract

Aim To explore the range of opinions held by a sample of New Zealand general practitioners (GPs) toward direct-to-consumer advertising (DTCA) of prescription medicines.

Method Depth interviews were conducted with 20 GPs. The interview protocol examined several aspects of the debate over DTCA, including its appropriateness, informativeness, and effect on doctors' relationships with their patients. The interview included five sets of forced choice statements that summarised key strands of the debate; these were used as preliminary stimuli to elicit doctors' views.

Results The results reveal a low incidence of DTCA-related queries and a wide range of views on the appropriateness of DTCA. Respondents favourably viewed DTCA's ability to increase awareness of some health conditions, although they had serious concerns about the adequacy of the risk and contraindication information provided as well as the general absence of specific cost details. While some doctors resented having to deal with questions arising from DTCA, few considered that this advertising undermined the relationship they have with their patients.

Conclusions Overall, while the majority of respondents did not support a ban on DTCA, most of them thought that stricter regulation was necessary. These findings clarify the conclusions drawn from quantitative studies, and suggest doctors' views of DTCA may be more complex than previously reported.

The arguments for and against direct-to-consumer advertising of prescription medicines (DTCA) have been well rehearsed. Initially, these focussed on the ethics of advertising products to lay people who may not fully understand the potentially harmful effects arising from contraindications, interactions and side effects.[1] More recently, the empirical literature has examined stakeholders' views of DTCA; and the results of several recently published consumer surveys suggest that consumers appreciate DTCA as an information source and do not experience more negative health effects than patients taking non-advertised medicines.[2,3]

Researchers have also surveyed doctors to explore the effects of DTCA on them and their patients, and a disparate range of opinion has been uncovered.[4,5] However, the debate in New Zealand (NZ) has been dominated by interest groups that advocate a particular position, and by research that has not always been disinterested. In addition, the typical self-completion surveys used to study GPs' views offer only superficial insights into the complex and sometimes contradictory issues involved.

Therefore, to provide a richer perspective on doctors' opinions on DTCA, we used a qualitative methodology to probe GPs' experiences of DTCA and their views on its future.

Research context—Although pharmaceutical industry representatives argue that DTCA helps 'meet the growing demand for medical information, empowering consumers by educating them about health conditions and possible treatments,'[6] doctors have been less sanguine about its benefits. Hollon, for example, argued that DTCA had, at best, a negligible public health value and several undesirable consequences.[7]

Toop et al provided a comprehensive review of studies opposed to DTCA and argued that doctors had at least four serious concerns about this advertising,[4] including: deterioration in doctor-patient relationships; increasing medicalisation of well populations; a lack of balance in the information provided; and confusion created by omission of risk, side effect and cost details.[8]

Concern that DTCA leads patients to demand medicines from their doctors has led health lobbyists to argue that this advertising erodes the trust on which a healthy doctor-patient relationship depends.[9] Instead of viewing doctors as dispassionate and expert advisors, Bell, Wilkes, and Kravitz found that a sizeable proportion of their respondents would not necessarily accept their doctor's advice if it conflicted with their requests.[10] They reported that, if denied a prescription they had sought, 25% of respondents would seek to change their doctor's mind; the same proportion would seek the prescription elsewhere, and 15% would consider ending their relationship with that doctor.

These findings led researchers to conclude that doctors might avoid conflict by acceding to patients' requests, even if they do not fully agree with these.[11] As a result, patients may adopt pharmaceutical solutions to health problems instead of implementing lifestyle changes, such as losing weight.[12] This, in turn, may place pressure on the health budget if prescribing rates of subsidised drugs increase, or if drug companies used evidence of consumer demand to support applications for product subsidies.[13]

Some doctors have also argued that the lack of balance in DTC advertisements creates misleading impressions, which they must dispel before they can discuss a patient's condition.[14] Ensuring patients understand a drug's risk profile and its compatibility with other medications can take several minutes and thus creates time pressures as doctors struggle to maintain their appointment schedule. More importantly, time spent in this way reduces the time available to discuss the patient's health and the optimal way of maintaining this.

Yet, despite the forcefulness with which critics of DTCA have presented these arguments, there is surprisingly little empirical evidence of doctors' views. A United States (US) Food and Drug Administration (FDA) survey of 500 physicians found that 68% of respondents believed DTCA had either a positive effect or no effect on their patient relationships.[15]

In NZ, Toop et al's research presents a sharply contrasting perspective.[4] The results from selected statements tested in these two studies are contrasted in Table 1 and highlight the different views that exist.

Table 1. Comparison of selected FDA[15] and Toop et al[4] findings of GP responses to questions about DTC advertising

FDA[15] (United States)		Toop et al[4] (New Zealand)	
Statement or question	**Percent agreeing***	**Statement or question**	**Percent agreeing***
DTC advertising causes your patients to seek treatment for potentially serious conditions.	44%	Generally, DTC ads have helped my patients to get necessary medical care at an earlier stage.	16%
To what extent did you feel pressured to prescribe a drug for the patient (who had asked for a specific drug to be prescribed)?	28%†	I have felt under pressure to prescribe advertised medications	69%
Did the fact that this patient saw an advertisement create any problems for your interaction with this patient?	18%‡	In my experience consultations in which patients seek advertised medications can lead to difficulties in the Dr-Patient relationship	50%

FDA=Food and Drug Administration; GP=general practitioner; DTC=direct-to-consumer;
*Respondents to the FDA Physician survey were asked whether they agreed a 'great deal' or 'somewhat' with the statements. The percentages reported aggregate these two categories except where noted. Respondents to the Toop survey used a five-point Likert Scale to indicate their level of agreement with the statements; the percentages reported aggregate the 'strongly agree' and 'slightly agree' categories; †The percentage aggregates those respondents who indicated they felt 'somewhat pressured' or "very pressured" to prescribe. ‡Respondents were asked to respond 'yes' or 'no'. The percentage reported is the proportion who answered 'yes' to the question.

The different perceptions shown in Table 1 may reflect differences in the two countries' regulatory environments, where quite different systems are used to control DTCA. Other explanations may include the disparate nature of the health systems, the types of treatment promoted, and patients' differing expectations of doctors. However, US and NZ consumers' responses are generally similar, despite differences in the questions used, the rules governing DTCA, and the structure of the health care system.[16] Methodological differences, such as variations in the question wording, and the tone and content of the covering letter used by Toop et al[4], may also have contributed to the differences noted.

Methods

A sample of New Zealand GPs was purposively selected from the 'Registered Medical Practitioners & Medical Centres' section of three (Telecom) telephone directories in the lower central North Island. Invitations to participate in the study were sent to one GP in each medical centre listed, and to every GP in solo practice. Women GPs were first approached to increase the proportion of female respondents; and when one GP declined, another from the practice was randomly selected. This sampling procedure complemented the research objective, which was to examine the spectrum of opinion that existed among GPs.

The cover letter stated the research objective was 'to assess and document GPs' views on DTCA'. The letter was neutrally framed and did not express any opinion about the merits of DTCA; it included an endorsement by the local representative of the RNZCGP. In total, 67 letters were sent out, 11 of which were returned as 'gone no address' or by retired doctors.

Twenty-two doctors agreed to participate (a response rate of 39%), resulting in 20 eligible interviews (one respondent was no longer in general practice, and a high workload prevented another from participating). Sixteen interviewees were male, and 16 had also practised as a GP for more than 10 years.

Interviews were conducted in GPs' consulting rooms during clinic hours in January and February 2003, and a payment of NZ$80 was offered during recruitment in recognition of the consultation time forgone. Each interview lasted between 30 and 45 minutes, and was recorded using a dictaphone for subsequent transcription by the interviewer. The interview protocol examined several issues, and included five sets of forced choice statements that were used as preliminary stimuli to elicit doctors' views on aspects of DTCA, which form the basis of the discussion reported here.

The interview transcripts were independently coded by two researchers: one interviewer and an independent researcher. The separate analyses were compared and there was a high degree of overlap between constructs identified, which suggests the themes extracted accurately represented the respondents' views.

The Ministry of Health (MOH) review of DTCA highlighted three areas of concern that we explored with GPs.[17] These were whether DTCA improved access to health information, damaged the relationship doctors have with their patients, and led to an increasingly 'medicalised' population.

Table 2 contains details of the forced choice statements used as preliminary stimuli, which were chosen to reflect the concerns raised by submissions to the MOH discussion paper.

Table 2. Forced choice statements used as preliminary stimuli to elicit doctors' views

Quality of Information				
1	Most people probably feel confused by the information in advertisements for prescription medicines (9)	OR	Most people probably understand the information in advertisements for prescription medicines (9)	
2	In general, prescription medicine advertisements overemphasise the benefits of the medicine and don't explain the risks enough (16)	OR	In general, prescription medicine advertisements provide balanced information about the risks and benefits of taking the medicine (1)	
Demand Effects of DTCA				
3	Advertising for prescription medicines leads people to demand from their doctor medicines that may not be suitable for them (8)	OR	Advertising for prescription medicines leads people to have more informed discussions with their doctor about treatments that might suit them (4)	
4	Advertising for prescription medicines makes people rely more on medicines to treat their health conditions (9)	OR	Advertising for prescription medicines make people more aware of the different options available to treat their health problems (7)	
Future of DTCA				
5	Continuation of DTCA under industry self-regulation (2)	Continuation of DTCA but under government regulation (6)	Banning of DTCA (8)	Other regulatory solution (4)

Note: The number of respondents agreeing with each force-choice statement is presented inside parentheses ().

Results

Some respondents could not choose between the statements in each pair, either because they thought each was equally true or untrue, hence the rows do not always add to 20. Readers should note that these were initial responses, and that the level of agreement that each respondent exhibited towards the statements varied, as many qualified their responses when explaining their choices.

Quality of information— The first two sets of statements examined the quality of the information provided in DTC promotions and whether this promotes adequate consumer understanding.

Respondents were equally divided in their views on the first pair of statements. Those who believed patients would be confused by the information provided in DTC promotions cited lay consumers' lack of knowledge and subsequent inability to judge the appropriateness of the advertised treatments. One doctor noted, 'Advertisements present the material in a way that asks patients to request them [treatments] from their doctor, which may not always be the most appropriate for them.'

Some respondents felt that prompting patients to ask their doctors about new treatment options created confusion among those who were already being treated with another drug, particularly if this was not advertised, and thus led patients to question whether they were receiving the best treatment. Moreover, several doctors noted that the very fact drugs were advertised meant some patients viewed these as superior to non-advertised treatments: *they think it's this wonder new drug*.

Doctors also commented on the adequacy of the information provided; one commented: *I think the problem is more what they leave out, not what they put in*. Even doctors who thought consumers did understand DTCA were concerned that the promotions did not provide sufficient detail: *It's more that the message isn't full*. These respondents felt the simple messages presented may be understood, but noted that these failed to convey the complex factors doctors consider when deciding whether, and what, to prescribe: *[DTC advertisements are] not giving all the information for them to understand the complexity of the issues*.

Virtually all respondents believed that DTCA does not provide balanced information, although a minority commented that, as DTC advertisements aim to persuade rather than inform, it was unrealistic to expect them to provide fully balanced information: *It's not aimed at information at all, it's aimed at persuading*.

Another respondent noted that the purpose of advertising is to generate interest in a product, saying: *I don't feel it's the job of an advertisement to actually go into side effects and risks. They're just trying to get the product known … they do emphasise the benefits of the medicine and they don't explain risks, but I think that's probably appropriate.* While not widely held, these comments suggest at least some GPs accept that DTCA can convey only a limited amount of information, and do not necessarily see this as being problematic.

Many of those respondents who felt DTCA was unbalanced also noted that the risk and side effect information is not displayed in an accessible format: *[these details] are usually in very, very small print and it is unrealistic to think that people read it on a television screen*. For these doctors, the difficulty viewers have in accessing information compounds the problems created by inadequate provision of risk and side effect details, in particular. Changes to the format and content of DTC promotions and adoption of the US FDA regulations, which require the major risks to be conveyed both visually and aurally, may alleviate these concerns and improve the accessibility of the information currently provided.

Demand effects of DTCA— Two pairs of statements were designed to tap concerns over DTCA's effect on patients' demand for prescription medicines and the

implications of this for doctors' relationships with their patients.[10] These statements elicited diverse views as although some respondents reported requests for specific drugs, which they attributed to DTCA; they also found that DTCA had promoted more informed discussions. However, they balanced these apparently competing views by noting that DTCA prompted patients to request what they considered to be unsuitable medicines.

Respondents gave several reasons for describing medicines as unsuitable. For example, they felt that the prohibitive price of some advertised drugs, the contraindications that consumers are not aware of, and the adequacy of current treatment regimes, all constituted reasons why an advertised medicine may not be appropriate.

By contrast, other respondents considered that DTCA promoted better informed discussions and were less troubled by requests for specific medications. In one doctor's words, DTCA *more often leads to a discussion [about] the pros and cons, rather than demands*. Others indicated that discussions about an advertised drug *opens up the discussion forum to start talking about these issues*, thus suggesting that some patients might not recognise or discuss their symptoms if they had not been exposed to DTCA.

Respondents also held mixed views on the issue of whether DTCA promotes medicalisation, which paired-statement four addressed. Some felt medicalisation was not balanced by an increase in awareness, although others agreed that DTCA improved awareness of treatment options and did not foster a culture of pharmacological over-dependency.

Respondents located their views within a broader context of social change, commenting that human nature instinctively sought the easiest solution to problems and that *we have become a pill oriented society.* However, other respondents believed that DTCA fostered rather than simply tapped into this culture, and suggested it encouraged medicalisation of normal states. One doctor noted: *I think a lot of people are taking things because we medicalise things not normally being treated … now they feel like they've got to have a drug for everything*.

Nevertheless, respondents who considered that DTCA improved awareness of different options felt that the advertisements served a useful function by increasing patients' knowledge, even if they did not impart much information. Concern that DTCA depicts only one treatment option was common; however, respondents recognised their own role in promoting knowledge of alternative treatments: *advertising makes them come here, then I make them aware of other treatment options*.

Future of DTCA—Finally, respondents were asked if they would like to see DTCA either continue in its present form (under advertising industry regulation), continue under government regulation, or whether it should be banned.

Respondents who preferred continuation of DTCA in some form and those who wished to see it banned were evenly divided; four respondents preferred an alternative regulatory structure. Those who supported continuation of DTCA recognised that consumers actively sought out health information and felt regulated advertisements could guarantee the quality of information available. Those who favoured greater

government regulation believed that DTCA is valuable, but wanted Government to *make sure that it's correct information and safe information*.

However, other respondents had doubts over the Government's ability to create satisfactory regulations, and expressed concern about public money being spent to regulate DTCA. As an alternative, some respondents even suggested complete deregulation of DTCA, stating: *the free market…is more rapidly adjusting…to the pressures of all people, including doctors, and I think the drug company advertising will be quite sensitive to the pressure from doctors*.

These respondents noted that if DTC advertisements were dishonest or misleading, then doctors would deliberately choose to not prescribe the products, and the offending pharmaceutical company would suffer. However, this stance is unlikely to receive widespread endorsement from other GPs, given concern over the harm that may arise from irresponsible promotions.

By contrast, those who supported a ban referred to the increasing demands on them and their time that DTCA created. As one noted: *you have to spend more and more time discussing…why the medicines are not suitable for them*. Others expressed concern that pharmaceutical companies would use DTC to increase demand, and then lobby PHARMAC to subsidise their product: *it creates demands for things which the pharmaceutical company hopes will be funded later if there is sufficient demand*. Other reasons proposed in support of banning DTCA included the fact that it is not permissible internationally, and that *our patients did pretty well before*.

Discussion

Overall, although based on a small sample size, these results nevertheless suggest a high level of ambivalence about DTCA, and it is clear that doctors have a range of concerns about this advertising. While specific brand requests were made during consultations, respondents indicated a low level of DTCA driven enquiry and did not report feeling undue pressure to prescribe requested medications. Furthermore, many respondents appreciated patients taking a more active role in managing their health in response to DTCA.

Yet, while some respondents saw benefits arising from DTCA, it is clear that the current format and regulation of DTCA is not optimal. In particular, advertisements need to provide clear and balanced information about the risks, side effects, and costs of medicines. Currently, GPs reported spending time dispelling misunderstandings created by inadequate communications, and this caused frustration for respondents as it increases the pressure on their already tight schedule. Indeed, those who favoured a ban on DTCA cited the inefficient use of their time as a primary reason for their view, rather than a philosophical or ethical opposition to the advertising of prescription medicines.

Some critics have argued that the heightened profile of prescription medicines (created by DTCA) increases medicalisation by depicting aspects of normal human ageing as disease states in need of remedy. Others challenge this view, however, and call for greater medicalisation of age-related conditions.[18]

Our respondents also reported divergent views on this topic. The medicalisation of lifestyle conditions did concern some respondents, as they felt it distracted attention away from more appropriate forms of treatment such as dietary modification and

exercise. However, many thought that DTCA could promote discussion of lifestyle conditions between patients and their doctors, particularly conditions such as obesity or joint pain, and the prevention of chronic disease.

Recent modifications to the Research Medicines Industry (RMI) Code of Practice may foster better quality DTC advertisements; however, current DTCA promotions suggest not all companies have adopted the Code's recommendations.[19] Indeed, the advertising and pharmaceutical industries have been disappointingly slow to adopt suggestions that would increase the informativeness of prescription medicine promotions.

Several respondents stated they would appreciate advertising that emphasised their role as prescribers. Changing the phrase—*ask your doctor if X is right for you* to *X is one option for the treatment of condition Y; only your doctor can determine the correct treatment for you*—may address concerns over patient confusion and derogation of doctors' role, and would also recognise the existence of other treatment options. However, our research did not explore doctors' views of this statement, and further work is required to assess whether it would ameliorate their concerns.

Although the concerns raised by doctors in this sample did not indicate trenchant opposition to DTCA, we detected strong disquiet with particular aspects of DTCA. While some doctors' responses suggest DTCA has the potential to provide information that fosters better dialogue between doctors and their patients, it is clear that this potential is far from being realised.

Indeed, continuing failure by the pharmaceutical industry and advertisers to address doctors' concerns in full will make a ban on DTCA inevitable.

Author information: Ninya Maubach, Tutor; Janet Hoek, Professor, Department of Marketing, Massey University, Palmerston North

Acknowledgements: This project was funded by a grant from the Academy of Business Research of the College of Business, Massey University. Professor Hoek has acted as an independent consultant to the Association of New Zealand Advertisers and has been an expert consultant to the Ministry of Health.

Correspondence: Ninya Maubach, Department of Marketing, Massey University, Private Bag 11 222, Palmerston North. Fax: (06) 350 2260; email: N.B.Maubach@massey.ac.nz

References

1. Lexchin J, Mintzes B. Direct-to-consumer advertising of prescription drugs: The evidence says no. J Public Policy Marketing. 2002;21:194–202.
2. Hoek J, Gendall P. Direct to consumer advertising of prescription medicines: A consumer survey. Palmerston North: Department of Marketing, Massey University; 2003.
3. Weissman JS, Blumenthal D, Silk AJ, et al. Physicians report on patient encounters involving direct-to-consumer advertising. Health Aff. 2004;23:W4.219–33.
4. Toop L, Richards D, Dowell T, et al. Direct to consumer advertising of prescription drugs in New Zealand: For health or for profit? Report to the Minister of Health supporting the case for a ban on DTCA. Dunedin: University of Otago; 2003. Available online. URL: http://www.chmeds.ac.nz/report.htmAccessed May 2005.
5. Weissman JS, Blumenthal D, Silk AJ, et al. Consumers' reports on the health effects of direct-to-consumer drug advertising. Health Aff. 2003;22:W82–W95.

6. Holmer A. Direct-to-consumer prescription drug advertising builds bridges between patients and physicians. JAMA. 1999;281:380–2.

7. Hollon M. Direct-to-consumer marketing of prescription drugs. JAMA. 1999;281:382–4.

8. Wilkes MS, Bell RA, Kravitz RL. Direct-to-consumer prescription drug advertising: Trends, impact and implications. Health Aff. 2000;19:110–28.

9. Cockburn J, Pit S. Prescribing behaviour in clinical practice: Patients' expectations and doctors' perceptions of patients' expectations. BMJ. 1997;315:520–3.

10. Bell RA, Wilkes MS, Kravitz RL. Advertisement-induced prescription drug requests: Patients' anticipated reactions to a physician who refuses. J Fam Pract. 1999;48:446–52.

11. Lipsky MS, Taylor CA. The opinions and experiences of family physicians regarding direct-to-consumer advertising. J Fam Pract. 1997;45:495–9.

12. Coney S. Direct to consumer advertising of prescription pharmaceuticals: A consumer perspective from New Zealand. J Public Policy Marketing. 2002;21:213–23.

13. Pharmac. Pharmac submission for Ministry of Health review of direct to consumer advertising. Wellington: Pharmac; 2000.

14. Davis J. Riskier than we think? The relationship between risk statement completeness and perceptions of direct to consumer advertised prescription drugs. J Health Comm. 2001;5:349–69.

15. Aitken KJ. Direct-to-consumer advertising of prescription drugs: Physician survey, preliminary results. Washington: FDA, 2003. Available online. URL: http://www.fda.gov/cder/ddmac/globalsummit2003 Accessed May 2005.

16. Hoek J, Gendall P, Calfee J. Direct-to-consumer-advertising of prescription medicine in the United States and New Zealand: An analysis of regulatory approaches and consumer responses. Int J Advertising. 2004;23:197–227.

17. Ministry of Health. Direct-to-consumer advertising of prescription medicines in New Zealand: A discussion paper. Wellington: Ministry of Health, 2000. Available online. URL: http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/60d7a3792a5eb5b7cc256a41000ad997?OpenDocument Accessed May 2005.

18. Ebrahim S. The medicalisation of old age: Should be encouraged. BMJ. 2002;324:861–3.

19. Researched Medicines Industry Association of New Zealand. RMI Code of Practice, Edition 13. Auckland: RMI, 2003. Available online. URL: http://www.rmianz.co.nz/html/publications/publications-3-3.asp Accessed May 2005.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Does the Priority Scoring System for Joint Replacement really identify those in most need?

Brendan Coleman, Stephen McChesney, Bruce Twaddle

Abstract

The *Priority Criteria for Major Joint Replacement Scoring System* was introduced to prioritise patients on the basis of clinical and social need for surgery. The purpose of this study was to assess its correlation with the Western Ontario and McMasters Universities Arthritis Index (WOMAC) and musculoskeletal functional assessment questionnaires. Fifty patients placed on the waiting list for total joint arthroplasty were surveyed comparing the physician derived priority score and the patient-derived WOMAC and musculoskeletal functional assessment questionnaires. Results demonstrate a poor correlation between the priority scoring system and the WOMAC and musculoskeletal functional assessment. In addition, the results indicates that the priority scoring system for major joint replacement does not differentiate between severity of impairment secondary to joint disease in patients placed on the surgical waiting list for joint replacement.

During the early 1990s, a radical reshaping of the health system in New Zealand took place establishing regional health authorities. As part of this process, the Government aimed to establish core services which 'everyone should have access, on affordable terms and without unreasonable waiting time.'[1]

In response to funding constraints and access to surgery, the clinical priority scoring system was developed and introduced as part of the national booking system in July 1998 where patients were prioritised on the basis of clinical and social need for surgery.[2] The inequality of healthcare resources in relation to demand for surgical services has led to long surgical waiting lists. It has been shown that these long waiting lists for elective surgery have led to inaccurate waiting lists with a proportion of patients undergoing reassessment not requiring or not wanting surgery.[3]

The clinical priority scoring system utilises five sections for assessment of the severity of a patient's condition—pain, functional limitation, movement, and deformity, multiple joint involvement, and social limitation. The generic priority scoring system has been shown to differentiate those patients in whom their musculoskeletal condition is impacting significantly of their quality of life enabling assessment of those patients who would benefit most from surgery[4] although the priority criteria for major joint replacement has not been validated.

The aim of this study was to compare the priority scoring system for joint replacement currently in use in New Zealand with two validated questionnaires of disability from musculoskeletal disease to assess if the current system is an accurate method of assessing priority for joint replacement surgery.

Method

Design—Between February 2003 and October 2004, 50 patients (who were placed on the waiting list for hip of knee arthroplasty at our institution) were recruited to participate in the study. Approval was gained from the Regional Ethics Board prior to commencement of this study.

The *Priority Criteria for Major Joint Replacement Scoring System* was utilised in this study (Table 1). This system assesses patient's need based on pain, functional activity, movement and deformity, multiple joint involvement, and ability to care for self and dependents. It has a maximum score of 100 points indicating urgent need for surgical intervention.

The Western Ontario and McMasters Universities Arthritis Index (WOMAC) questionnaire is a self-administered questionnaire assessing the three dimensions of pain, disability, and joint stiffness in hip and knee arthritis using 24 questions. Since its inception in 1982, WOMAC has proved to be a reliable and valid assessment of disability due to hip and knee arthritis which has been shown to be responsive to treatment outcomes and time-dependent disease progression.[5,6] The WOMAC index results in a score out of 100 points with an increasing score representing increasing disability.

The Musculoskeletal Function Assessment (MFA) was developed at the University of Washington in Seattle, USA in 1993. It is a self-administered questionnaire using 100 yes / no questions to assess the patient's movement, functional ability, and emotional response to disability from musculoskeletal disease. The MFA questionnaire has been validated as a reliable assessor of disability over time caused by musculoskeletal disease.[7,8] The MFA records scores out of 100 points with increasing scores representing increasing disability.

There were 29 females and 21 males recruited into this study with the average age of 67 years (range 56 to 83 years). All patients had a primary diagnosis of osteoarthritis of the knee or hip requiring total joint arthroplasty, and had failed a course of non-operative treatment. No patients had inflammatory arthritis, avascular necrosis, or fracture as the indication for surgery. There were 31 patients requiring total hip arthroplasty and 19 patients requiring total knee arthroplasty, with no difference in the demographics between the groups.

Patients were assessed by the consultant orthopaedic surgeon in the outpatient clinic and the decision was made to place the patient of the waiting list and a priority score was calculated by the consultant surgeon utilising the priority criteria for joint replacement scoring system. The WOMAC and MFA questionnaires were completed by the patient immediately following the completion of the clinical consultation under the supervision of a clinic nurse to ensure all questionnaires were completed satisfactorily.

Statistics—The priority scoring system for joint replacement and the WOMAC and MFA questionnaires were analysed using the Pearson correlation coefficient to establish the relationship between the validated WOMAC and MFA scores and the priority scoring system.

Results

The mean priority scoring system score was 76.8 points (range 55 to 100 points). The mean WOMAC score was 56.6 points (range 11 to 93 points) and the mean MFA score was 44.0 points (range 9 to 70 points). The Pearson correlation coefficient was 0.261 when comparing the priority scoring system with the WOMAC score, and 0.194 when comparing to the MFA indicating poor correlation of the scoring systems. When the WOMAC and MFA questionnaires were correlated, the Pearson coefficient was 0.742, thus indicating a good correlation between the validated scoring systems.

Table 1. Priority Scoring System for Major Joint Replacement

Pain (40%)

Degree	Points
None	0
Mild, slight or occasional pain patient has not altered patterns of activity or work	4
Mild-moderate or frequent pain patient has not altered patterns of activity or work	6
Moderate patient is active but has had to modify or give up some activities because of pain	9
Moderate-severe or fairly severe pain substantial limitation of activities	14
Severe major pain and serious limitation	20
Patient must be on maximum medical therapy at the time of rating	

Occurrence	Points
None or with first steps only	0
Only after long walks (30 mins)	4
With all walking, mostly day pain	10
Significant, regular night pain	20

Functional Activity (20%)

Time walked	Points
Unlimited	0
31-60 minutes (e.g. longer shopping trips to mall)	2
11-30 minutes (e.g. gardening, grocery shopping)	4
2-10 minutes (e.g. trip to letter box)	6
<2 minutes or indoors only (more or less house-bound)	10
Unable to walk	10

Other functional limitations*	Points
None	0
Mild	2
Moderate	4
Severe	10
**For example: putting on shoes, managing stairs, sitting to standing, sexual activity, recreation or hobbies, walking aids needed*	

Movement and Deformity (20%)

Pain on examination*	Points
None	0
Mild	4
Moderate	6
Severe	10
**Overall results of both active and passive range of motion*	

Other abnormal findings*	Points
None	0
Mild	4
Moderate	6
Severe	10
**Limited to orthopaedic problems e.g. reduced range of motion, deformity, limp, instability, progressive X-ray findings*	

Other Factors (20%)

Multiple joint involvement	Points
No, single joint	0
Yes, each affected joint mild-moderate severity	4
Yes, severe involvement (e.g. severe rheumatoid arthritis)	10

Ability to work, give care to dependents, or live independently*	Points
Not threatened or difficult	0
Not threatened but more difficult	4
Threatened but not more difficult	6
Immediately threatened	10
**Difficulty must be related to affected joint*	

Discussion

The requirement for prioritisation in the provision of elective surgical services in New Zealand led to the development of the priority scoring system for surgical procedures during the 1990s. The scoring system was introduced in 1998 to prioritise patients in order of clinical and social need for surgery, and was further refined to enable increased certainty for patients by booking them for surgery within 6 months of placement on the waiting list.

The WOMAC and MFA scoring systems are validated systems in the assessment of musculoskeletal disorders and their impact on quality of life and function.[5–8] These functional questionnaires have been demonstrated to be reliable assessors of impairment due to musculoskeletal disorders and reliable in terms of disease progression over time.

This study has shown that the clinical priority scoring system for joint replacement has a poor correlation with both the WOMAC and MFA scores in patients being placed on the waiting list. This suggests that the patients who have the greatest degree of impairment due to their musculoskeletal condition are not receiving the greatest priority on the waiting list for total joint arthroplasty. This study demonstrates that the sub-sections of the priority booking system have a poor correlation with the corresponding sub-sections of the WOMAC score in terms of pain, function and movement. This indicates that all sections of the priority scoring system are inaccurate in determining severity of impact due to musculoskeletal disease in patients placed on the waiting list for total joint arthroplasty.

The priority scoring system for major joint replacement currently utilised does not differentiate the severity of impact due to arthritis of the hip or knee in patients on the waiting list for total joint replacement. The inability of the priority scoring system to accurately determine those patients most in need of joint replacement suggests that the priority scoring system requires revision and validation. Alternatively, a validated scoring system for disability from musculoskeletal disease such as the WOMAC should be used to prioritise patients for surgery.

Author information: Brendan Coleman, Senior Orthopaedic Registrar; Stephen McChesney, Orthopaedic Registrar; Bruce Twaddle, Consultant Orthopaedic Surgeon, Auckland City Hospital, Auckland

Correspondence: Dr Brendan Coleman, Dept of Orthopaedic Surgery, Auckland City Hospital, Park Road, Auckland. Email: BColema1@middlemore.co.nz

References:

1. Upton S. Your health and the public health: a statement of government health policy. Wellington: Department of Health; 1991.
2. Gauld R, Derrett S. Solving the surgical waiting list problem? New Zealand's "booking system". Int J Health Plann Manage. 2000;15:259–72.
3. Tomlinson M, Cullen J. A clinical audit of patients on an orthopaedic waiting list for greater than 2 years. N Z Med J. 1992;105:226–68.
4. Theis J-C. Clinical priority criteria in orthopaedics: a validation study using the SF36 quality of life questionnaire. Health Serv Manage Res. 2004;17:59–61.

5. Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to anti-rheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol. 1988;15:1833–40.

6. Bellamy N, Goldsmith CH, Buchanan WW, et al. Prior score availability: observations using the WOMAC osteoarthritis index. Br J Rheumatol. 1991;30:150–1.

7. Martin DP, Engelberg R, Agel J, et al. Development of a musculoskeletal extremity health instrument: the musculoskeletal functional assessment instrument. J Orth Res.1996;14:173–81.

8. Martin DP, Engelberg R, Agel J, Swiontkowski MF. Comparison of the musculoskeletal function assessment questionnaire with the short form-36, the Western Ontario and McMaster osteoarthritis index, and the sickness impact profile health-status measures. J Bone Joint Surg Am. 1997;79:1323–35.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Medical practitioners and competition law in Australia and New Zealand

Warren Pengilley

Abstract

There is a lack of awareness among Australian and New Zealand medical practitioners about how competition law applies to them. In this article, basic legal issues relating to interaction between medical practitioners (which all medical practitioners should be aware of) are discussed. The New Zealand *Ophthalmologists Case* and some relevant Australian and United States cases are analysed. Three key areas of competition law (of relevance to medical practitioners) are identified as being important and relevant. In conclusion, medical practitioners must be able to distinguish between legal and illegal activities; and guidelines outlined in this paper provide some clarification.

Is there anything different about medical practitioners in relation to competition law which should excite the interest of national competition enforcers? Surely competition-law principles are the same for everyone?

The principles of competition law are the same for everyone. So, this makes the asking of the question *is there anything different about medicos?* appear somewhat illogical. And answering the question is even more illogical. Nevertheless there are areas in which medical practitioners have unique problems with competition law.

In general terms, competition law mandates individual decision-making about prices charged and parties dealt with. Problems occur in relation to joint activity engaged in by practitioners or their respective professional associations. Some of these problems (e.g. general activities relating to price-fixing) have no specific issues unique to medical practitioners.

However, it seems to me that there are three areas where medical practitioners do face specific problems (or where their exposure, actual or potential, is greater than that of other businesses or professions).

The three critical competition areas are conduct relating to:

- **Joint negotiations—**Medical fees, as a function of the society in which we live, frequently require Government policy input. Medical fees are often recovered from health funds and are reimbursed by compensation tribunals. Some type of joint negotiation (about the level of fees) is often necessary. Yet the essence of competition policy is that each market participant must ‘compete’ with his or her colleague and make individual decisions. Where are the respective boundaries?;
- **Exclusionary activities—**Law reports (particularly in the United States) are replete with cases of doctors trying to exclude other practitioners from their patch—either their hospital (access to which is essential to practice), their specialist accreditation college, or their geographic practising area; and

- **Breaches of professional ethics and the 'right' of 'self regulation' to enforce these ethics—**By necessity, society has to have professional standards. No-one believes that brain surgery should be performed on a park bench. But who sets the standards and how are they enforced? Obviously, a competitor judging the ethics and competence of their colleague is actual or potential competition dynamite. Unless there are appropriate safeguards, this process can become a method of excluding new entrant medicos from the turf of present practitioners. How does one ensure that proper ethical standards are observed without using standards of competency as an exclusionary device?

In Australasia (Australia and New Zealand), these issues are daily becoming of greater relevance. In Australia, individuals trading totally within State borders have enjoyed immunity from the Federal competition writ (for constitutional reasons). It was only with the enactment of supplementary State legislation in 1995 and 1996 that individuals were totally covered by the Australian Trade Practices Act. Although the Australian Act is now three decades old, for two of those three decades medical practitioners have enjoyed considerable immunity from the reach of the Federal Commissars.

New Zealand, thankfully, has no such constitutional difficulties but the whole issue of competition law and medical practitioners has recently leapt into prominence because of the *New Zealand Ophthalmologists Case*[1] decided in March 2004. As Justice Gendall remarked in his penalty decision of 30 June 2004,[2] the *New Zealand Ophthalmologists Case* was not a 'test case' but it was a 'first-time' case involving professional persons and their Society.

Applicable competition principles

Past experience of New Zealand, Australian, and United States law is taken as the basis of the discussion which follows. Each of the three critical competition areas identified above is discussed below.

Joint negotiations—In relation to medical practitioners, the Australian Competition and Consumer Commission ('ACCC') gives the view of a competition enforcer. It has taken a very strong line against the employment of a negotiator to represent competitor parties. It takes the view that a negotiator in this event sets a background level around which the individual's fees will be established. Furthermore, it takes the view that there will, therefore, be an anticompetitive arrangement between competitors even if the parties represented by the negotiator decide individually whether or not to supply their services at the negotiated price.[3]

Obviously, the joint appointment of a negotiator may be a cloak for a price fixing arrangement. In particular, parties must expect problems when they give the negotiator the power to bind them to the negotiated result or where the parties, or any two of them, agree (pre or post the negotiation) to implement the results of it.

But what is the position when parties jointly agree to appoint a negotiator but:

- Expressly provide that the negotiator has no power to bind them but merely a power to probe alternatives, ascertain attitudes, seek a range of prices within which individuals may further negotiate, or even ascertain a particular price at which another party is prepared to stand in the market; and

- Expressly provide that the parties between themselves do not agree and will not agree to adopt the result of any negotiations, that each party reserves the right to make his or her own decision, and that no concerted action will be taken to implement the negotiated result.

In such an event, assuming it represents the actuality,[4] what is the 'arrangement' between competitors? The joint arrangement is only that the parties will appoint a negotiator. There is no arrangement that the parties will adopt or implement anything the negotiator reports back. This remains a matter for individual decision. If the parties individually decide to adopt the result of the negotiation, this may mean that the negotiation gives rise to economic consequences. But this does not prove that such consequences stem from the joint appointment of a negotiator or what has been negotiated by the appointee.

Economic consequences are not the same thing as anticompetitive effect. Economic consequences can follow from individual decisions to adopt (or not adopt) a negotiated position. Indeed, if decisions (whatever their consequences) are made individually, the requirement of mutuality, which is fundamental to illegality, is not present. The issue of whether a party would (as a result of communication) regard himself or herself as bound, at least in honour, to act in a certain way is crucial to identifying what the subject of an 'arrangement' is. Indeed, consensus and expectation are the key issues. If there is no consensus and no expectation by one party *vis a vis* another as to what each will do pursuant to the arrangement, there is no arrangement to do that thing.[5]

Obviously competition authorities will watch joint negotiation procedures carefully. However, the views expressed are (in my view) backed by the authority of the Western Australian Medical Association Case in Australia[6] and the Hawaiian Medical Association Case in the United States.[7]

I believe, therefore, that medical practitioners must be careful (perhaps more careful than most other professions) in their conduct of joint negotiations. But the nature of the profession virtually necessitates the joint appointment of negotiators when arrangements are being entered into with Government, with health funds or with hospitals. The competition law mandates individual decision-making but, in my view, does not outlaw the joint appointment of negotiators.

I believe that the approach of competition authorities may, to date, have deterred the joint appointment of negotiators when this can clearly benefit both the medical practitioners involved (in the saving of time and the acquisition of negotiating expertise) and also benefit the party with whom negotiations are conducted (in perhaps not having to negotiate with individual practitioners on many issues, saving time because of this limitation and being able to negotiate with a party of expertise on the other side). The benefits to each party are clearly shown when all parties want to deal with jointly appointed negotiators, do so willingly and regard the alternative of multiple individual negotiations as inefficient in the extreme.

The line between legality and illegality in the joint appointment of a negotiator is a fine one. For this reason, competent legal advice should always be sought if any such appointment is contemplated. But there is, in my view, no reason why such a joint appointment necessarily breaches competition law and, if specific steps are taken, it can be ensured that no breach will occur.

Exclusionary activity—Since 1880, when a group of Irish tenants organised and refused to work on the estate managed by Captain Charles Cunningham Boycott (who perhaps not so willingly loaned his name to the tactic), the concerted refusal to deal or the collective boycott, has been recognised as an effective way of achieving certain types of economic and political goals. To invoke Captain Boycott's name in the context of competition law is, however, generally a prelude to condemnation.

Both Australian and New Zealand law have specific provisions dealing with collective boycotts; although they are (in both pieces of legislation) more antiseptically described as exclusionary provisions. The philosophy behind the legislation dealing with exclusionary provisions is to make it clear that collective activity (whereby competitors agree not to deal with others) is to be regarded harshly under competition law. For example, the Australian Trade Practices Act prohibits all arrangements between competitors which have the purpose of 'preventing, restricting, or limiting' the supply of services to, or the acquisition of services from, particular persons or classes of persons.

In Australia, the ban is absolute.[8] It matters not who the 'target' of the arrangement is (provided the target is a particular person or class of persons), and there is no defence that 'the arrangement does not substantially lessen competition'.

New Zealand, having initially adopted the strong Australian *per se* ban in s.29 of the Commerce Act, has subsequently amended that section to provide that the 'targeted' entity must be a competitor (actual or potential) of the parties to the arrangement and that the defendant parties have a defence, on a reverse onus basis, if they can demonstrate that, even though they come presumptively within the ban, the arrangement does not substantially lessen competition.[9]

The New Zealand law is by far the more logical in my view and equates to the judicially decided United States position. The Australian law, on the other hand, is a mistranslation of the Sherman Act downunder because it encompasses neither of the above two important provisions incorporated into the New Zealand law.

Even though the New Zealand section is not as all embracing as the Australian provisions, the defences in s.29 of the Commerce Act will not, in my view, be (in the case of medical practitioners) as useful as first thought. Boycotts by doctors are usually (but not solely) aimed at other doctors and it is with these types of boycotts that the case law has primarily been concerned.

In these cases, the target of the conduct will be a competitor of those in the arrangement and this criterion of s.29 will be satisfied. Once a collective refusal to deal is found in this circumstance it is, in my view, unlikely that a competition defence will be successful in any but the unusual case. This is because the history of medical boycotts shows that they are, except rarely, aimed at excluding new entry doctors. New entry has been held to be the most important factor in competition and its inhibition or exclusion to be the major anticompetitive sin.[10] Thus it is important (under either Australian or New Zealand law) to address the issue of what can and cannot be done in the medical field without running foul of the applicable exclusionary provision legislation.

At first glance, it appears as if doctors can never exclude another doctor from hospital accreditation or admission to a learned medical college (even if the excluded doctor is

totally incompetent) without running into difficulties under the exclusionary provision laws. Clearly this is an arrangement between competitors to limit services (for example the services which go with hospital accreditation) and, when a specific doctor is excluded, he or she becomes a particular targeted person. On the face of it, all the factors necessary to bring the conduct within the exclusionary provision prohibition are complied with.

In Australia, it appeared that even unimpeachably proper standards of conduct and training had the real possibility of being illegal under the Australian ban on exclusionary provisions. This was especially so when objective standards for admission to the *National Rugby League (NRL)* competition were ruled invalid by the Full Federal Court.

The *NRL* is the result of an arrangement between competitors[11] who have combined their prior separate rugby league competitions but limited the numbers of participating clubs to 14. There was a total of 22 teams playing in the two separate competitions (media magnate Rupert Murdoch's *Super League* and the original *Australian Rugby League [ARL]*). Objective standards were set down and impartially administered to determine which clubs, if any, would miss out on admission to the new single *NRL* competition. Fifteen clubs applied for admission to the *NRL* but only 14 places were available. The *South Sydney Rabbitohs* were refused admission after application of the admission criteria. However, the Full Federal Court held that the *Rabbitohs* were within a relevant 'class of persons' as they had previously been a competition participating club[12] and that the *Rabbitohs* were, therefore, illegally excluded from the combined competition.

The High Court reversed[13] the decision (and the *Rabbitohs* were subsequently admitted to the *NRL*). The essence of the High Court decision, and particularly the strong views expressed by Chief Justice Gleeson and Justice Callinan, was that, as the criteria were objective and impartially applied, there was no identifiable club or any identifiable excluded class of clubs 'aimed at', and thus there was no exclusionary conduct involved. The time to evaluate the conduct is when it is engaged in i.e. at the time the criteria were put in place and, at that time, it could not be ascertained which club or clubs would be excluded. A particular class of excluded entities cannot be held to exist merely because the application of objective criteria results in non-supply or exclusion at a future time.

The High Court decision in the *South Sydney Case* is a victory for standards setting.

In setting criteria for medical accreditation, one cannot know who is being excluded and a class of persons cannot be defined by, or ascertained only by, the fact of a future exclusion itself. Hence genuinely set standards do not run the risk (by their application) of being illegal as an exclusionary provision. It must be stressed, however, that, in the *South Sydney Case*, the standards were, in fact, objective and impartially administered and no objection was taken to them on this basis. In my view, the same criteria must apply to any standards, which rely on this case as establishing that medical standards are not within the exclusionary provisions definition.

If medical standards are set which are aimed at particular practitioners or other particular identifiable groups, or if seemingly 'objective' standards are administered

arbitrarily or capriciously, the courts will assuredly have little difficulty in finding them to be a sham behind which exclusion is practised.

The line between the acceptable and the non-acceptable may be a thin one in the administration of medical accreditation for hospitals or admission to specialist medical colleges. But the line is a real one and conduct must be aimed at being on the correct side of it.

Probably the major danger area in relation to exclusionary activity in the medical field is in the peer-review process for hospital accreditation. There are some common sense precautions which can be taken to avoid allegations of exclusionary conduct in this area and these principles can be elsewhere applied—for example in relation to admission to learned medical colleges.

The principles are:

- Have no two clinicians on the accreditation committee from the same field of practice. This means that the decision to admit, or reject, an applicant will not be made by his or her competitors. If this does not prove possible in particular cases (because, say the hospital is a local one and all practitioners are GPs), practitioners outside the local area should be called in to serve on the peer review board or the application should be referred for competent external evaluation.
- Have decisions made by the hospital involved rather than an accreditation committee. An accreditation committee's view should be put only as a recommendation to the hospital itself. If the final decision on accreditation is made by the hospital as an independent decision maker, the ultimate credentialling decision is made unilaterally and unilateral decisions do not a conspiracy make.
- Ensure that rules of credentialling are objectively expressed and not based on anticompetitive or exclusionary grounds. The short position from the competition case law is that rules must be genuinely medically based and not capable of being interpreted in an arbitrary or capricious manner.

  However, this does not preclude genuine policy decisions—for example:

  - Making a decision to terminate a medical practitioner's accreditation because a hospital has decided to amalgamate certain services with those of another hospital and to reduce its own services in a particular medical area. As a result of this, a peer review board may be compelled to make certain decisions which may result in the denial of future accreditation to presently accredited practitioners; or
  - A hospital making a policy decision to grant hospital accreditation only to employed anaesthetists because of a genuine belief that this policy gives rise to less professional friction, better rosters and more efficient patient assignment. As a result of this, a peer review committee is compelled to recommend for accreditation only doctors prepared to accept the hospital's policy decision.

The High Court of Australia has saved accreditation from exclusionary provision condemnation. But it is really not a satisfactory situation that saving from such condemnation is determined by the somewhat ethereal[14] legal evaluation of whether or not a 'particular person or class of persons' is involved. There is much to be said

for the enactment downunder of legislation akin to the United States Health Care Quality Improvement Act of 1986.

This Act provides immunity from action in relation to peer review decisions if:

The peer review concludes that there was a reasonable belief that the action was in the furtherance of quality health care; and

- After a reasonable attempt has been made to obtain all the facts; and
- Fair notice has been given to parties affected and a fair hearing conducted; and
- The reasonable belief was held that the action was warranted by the facts known after a reasonable effort was made to obtain the facts, after the giving of fair notice and after the conduct of a fair procedural hearing.[15]

Legislation of this kind has the advantage of requiring the court to make a substantive evaluation of the issues involved rather than engaging in semantics in trying to work out whether the target is a particular person or class of persons. The case for such legislation is far stronger in Australia than in New Zealand because of the *per se* nature of the exclusionary provision ban in Australia and because of the inability to argue a defence in Australia, as can now be done in New Zealand, that the conduct involved does not substantially lessen competition.

The New Zealand *Ophthalmologists Case* shows up the importance which exclusionary conduct plays in competition assessments. In brief, this case involved concerted action initiated by the sole ophthalmologist in Invercargill to inhibit or prevent Southern Health from employing Australian ophthalmologists to perform cataract operations at a cheaper rate in order to clear a two-year public patient backlog in Southland Province.

The Invercargill opthalmologist involved various other ophthalmologists and sought and obtained the assistance of The Ophthalmology Society of New Zealand in his efforts. His actions prevented the relevant Australian ophthalmologists carrying out the operations and included:

- Concerted non-cooperation,
- Concerted pressure being placed on Southern Health to reverse its decision, and
- Attempts to have the relevant Australian ophthalmologists denied New Zealand medical registration.

Although the Commerce Commission succeeded in the case on the basis that the conduct involved was substantially anticompetitive, the case would appear to be one clearly within the exclusionary provisions law in s.29 of the Commerce Act.[16]

In New Zealand, the effect of bringing the case under s.29 would have been for the Commerce Commission to have obtained the advantage of a per se breach on proof of the relevant arrangement as the competition defence now available under s.29(1A) of the Commerce Act was enacted after the relevant conduct occurred. Thus, the present Australian position would have applied then (but not now) in New Zealand, and all that would have had to be demonstrated would have been the facts and *per se* illegality would have automatically followed. That ‘anticompetitive purpose’ was so easily demonstrated by the Commission makes one wonder whether any specific

legislation dealing with exclusionary activity is really necessary. My view is that such provisions are not necessary; that exclusionary activity can be evaluated under general principles of whether or not they substantially lessen competition; and that specific statutory provisions complicate, rather than effectuate, competition policy.[17]

The 'right' of self regulation

The third area of vulnerability of medical practitioners under competition law is that of ethics and the 'right' of 'self regulation' to enforce these.

Ethics looms high in the psyche of all professions, and deservedly so. It is basic to understand that no competition law anywhere in the world prevents the setting of proper ethical standards and the enforcement of these. The issue, however, is what constitutes 'ethics' and what is the rationale behind permitting their extra judicial enforcement by way of professional self regulation.

I believe that the basic rationale of ethics has perhaps been most articulately put by a Report some years ago by a Royal Commission into Civil Rights in Ontario. This Report said:

> The granting of self government is a delegation of legislative and judicial functions and can only be justified as a safeguard to the public interest. The power is not conferred to give or reinforce a professional or occupational status. The relevant question is not 'do the practitioners of this occupation desire the power of self government' but is 'is self government necessary for the protection of the public?' No right of self government should be claimed merely because the term 'profession' has been attached to the occupation.[18]

The question, therefore, is *what is necessary for the protection of the public?* The fact that a profession may, in its own self interest, want an exemption from competition law is not itself a matter of public protection. Neither is public protection served by 'ethical' restraints against giving fee reductions or in relation to advertising prohibitions provided that such advertising is both honest and appropriate.[19] But there is public protection in setting standards of competency and enforcing these by peer review—with the provision that such review must be on a fair 'due process' basis.

There have been several pronouncements made by competition authorities around the world as to the setting of ethical standards and the enforcement of these.[20] In essence, standards must serve a public protection purpose, be based on clear and non-discriminatory criteria (one of which is that suitably qualified overseas parties not be subject to discrimination on the basis of nationality or residence), and be enforced by independent and impartial evaluation. If this is done, then standards setting and enforcement will not run foul of competition law.

New Zealand's situation

The above sets out the relevant applicable competition principles. The result in New Zealand shows, however, the need for much more education of medical practitioners as to the application of competition law to them.

The recent *New Zealand Ophthalmologists Case* is notable because it so clearly illustrates the total misunderstanding by the medicos there involved of the role of professional ethics and competition law. In that case, the New Zealand ophthalmologists involved, and their professional association, sought to exclude qualified Australian ophthalmologists from operating in New Zealand. This was

effected by the invention of quite spurious “ethical” objections. So, they claimed that routine cataract operations required access to emergency post-operative care and that this was an important service, which could not be provided by itinerant surgeons. No doubt such access was important but it could be provided in other ways because cataract operations were standard ones with few complications. The ophthalmologists, however, took steps to seek to ensure that post-operative care would not be provided. The term “itinerant surgeon” was used in a derogatory manner in order to provide an ethical reason or justification for what the ophthalmologists did.

The court, however, held that this was:

> ‘A convenient label to which opposition could be expressed. But it was no more than an excuse’

The New Zealand ophthalmologists also attempted to have qualified Australian ophthalmologists not registered in New Zealand by not providing surgical ‘oversight’ required by New Zealand registration requirements. They alleged that the employment of an overseas ophthalmologist (rather than giving all such business to the sole Invercargill ophthalmologist) was ethically unacceptable because it would destroy:

> ‘A long-term relationship with the resident Invercargill ophthalmologist whose desire is to dedicate his professional life to the ophthalmic welfare of the Southland community’

But words are frequently a mask rarely expressing (and frequently hiding) their true meaning. So it was with the New Zealand ophthalmologists. The Court held that their ethical justifications had nothing to do with ethics. They simply demanded that additional surgery should be offered locally and that the sole Invercargill ophthalmologist, ethically, had a prior right to veto new entry or at least that there was an ethical requirement that no ophthalmic surgery be carried out unless he so agreed. This, of course, is the direct negation of a fundamental principle of competition policy, that is that competition should be preserved by preventing private blockades on new market entry.

The *New Zealand Ophthalmologists Case* shows that professionals cannot use ethics as subterfuge for anticompetitive activities. Case law clearly delineates the borders within which professional ethical conduct is to be confined. The Ophthalmologists Case was the first in New Zealand involving professionals and their professional association. A penalty of $NZ25,000 was imposed on the Invercargill instigator of the conduct and a penalty of $NZ100,000 imposed by the Ophthalmological Society of New Zealand. In assessing penalty, the Court specifically took into account the fact that the case was the first in New Zealand involving a professional association. Presumably the court is implying in this comment that future conduct of this kind will be regarded more seriously.

Discussion

There is nothing unique in the interaction of medical practice and competition law. The applicable principles are quite generally relevant to all professions and occupations. But, historically, throughout the world, there have been major conflicts between the views of competition-policy enforcers and what medical practitioners believe they should be entitled to do. All is not smooth in competition land as its territory expands over greater areas in the medical fiefdom. The *New Zealand Ophthalmologists Case* shows how basic the differing views can be. But there is

plenty of room for mutual harmonious accommodation and, hopefully, this article gives some indication of where this accommodation can occur.

We have to remember that it is the policy of both the Australian and New Zealand Governments, as set out in the Closer Economic Relations Treaty, that there be one market, not two, in Australasia. This necessarily involves freedom of entry by Australians into the New Zealand market, and vice versa.

There is no doubt that individual businesspersons or professionals can have their freedom of choice of what they will do, how they will do it, what prices they will charge, and the areas in which they will conduct their business taken away from them just as effectively by an anticompetitive private arrangement as by any government edict. Competition law is a sensible restraint which aims to preserve freedom of business decision making and freedom of market entry. It is these basic freedoms which were so endangered by the *Ophthalmologists Case*. This is why this case has importance, which far transcends its limited direct application to ophthalmology in Southland.

Despite the attempt to exclude Australian ophthalmologists from New Zealand, a comparative price evaluation of cataract operations is illuminating. In Invercargill, cataract operations were being performed initially at NZ$1,100 and, after the threat of new entry, at NZ$675. The price of cataracts in Australia, according to one newspaper survey, is about AU$2,090. That survey also concludes that there are close to 12,000 people waiting for cataract operations in New South Wales alone.[21]

So perhaps I can offer the following pro-competitive advice to New Zealand Kiwi ophthalmologists:

> Do not despair. Get on a plane to Aussie and do some itinerant cataract surgery across the Tasman. You have seen how competition law can assist you in this regard. Try using it to your advantage to make some money. No doubt one can cynically say that ready money is ready medicine. But, so what? Aussie needs you to move its two year cataract queue. The Australian Trade Practices Act protects your ability to practise in the Australian market in the same way as the *Ophthalmologists Case* shows that the New Zealand Commerce Act protects the ability of Australian surgeons to practise in yours. New Zealand ophthalmologists will be a blessing to help clear the unforgivable backlog of cataract queues in Australia. So don't complain. Get competitive!

Author information: Warren Pengilley; Emeritus Professor, University of Newcastle, Newcastle (and Lawyer, Deacons, Sydney), NSW, Australia

Correspondence: Professor Warren Pengilley, 35 Skelton Street, Hamilton, NSW 2303, Australia. Fax: +61 (0)2 9330 8111; email: wpeng@bigpond.com

References:

1. Commerce Commission v The Ophthalmological Society of New Zealand & Ors (High Court of New Zealand: Wellington Registry CIV – 1997 – H85-34; CP 354/97: Decision of Gendall J: 1 March 2004).
2. n.1 above. Penalty decision of Gendall J on 30 June 2004.
3. ACCC: Guide to the Trade Practices Act for the Health Sector (Nov. 1995) p.13.
4. It being assumed throughout this discussion that this represents the factual situation as well as that which is expressed.
5. For the concept of what is "an arrangement" see Re British Basic Slag Agreements [1963] 2 All ER 807; Gilltrap v Commerce Commission & McKenzie CA 235/01; CA 40/02; CA

41/02; Judgment 5 November 2003. Specifically in relation to the difference between an "arrangement" and the making of a statement in the hope that another will follow (this not being an "arrangement" within the prohibitions of competition law), see TPC v Email (1980) ATPR 40-172.

6. ACCC v The Australian Medical Association (Western Australian Branch) Inc. (2003) 199 ALR 423.

7. International Healthcare Management v Hawaii Coalition for Health & Others (9th Cir. C.A.): Opinion June 6, 2003.

8. Trade Practices Act s.45 and definition in s.4D.

9. Commerce Act s.29.

10. See Australian Trade Practices Tribunal Determination in Queensland Cooperative Milling Association (1976) ATPR 40-012 (followed in New Zealand in Tru Tone Ltd v Festival Records Retail Marketing Ltd [1988] 2 NZLR 352 and Auckland Regional Authority v Mutual Rental Cars [1987] 2 NZLR 647).

11. The Australian Rugby League and News Limited, each of which had previously run competing rugby league competitions – the Australian Rugby League competition and the "Super League" competition respectively.

12. South Sydney District Rugby League Football Club v News Ltd (2001) 111 FCR 456; [2001] FCA 862. For the writer's commentary on this decision see W.J. Pengilley: "Fifteen into fourteen will go: The Full Federal Court defies the laws of mathematics in the South Sydney Case" (2001) 17(4) ANZ Trade Practices Law Bulletin 25.

13. South Sydney District Rugby League Football Club v News Ltd 2003 HCA 45; (2003) 200 ALR 157. For the writer's commentary on this decision see W.J. Pengilley: "Rabbitohs not illegally excluded from the NRL competition" (2003) 19(6) ANZ Trade Practices Law Bulletin 73.

14. In the sense of "extremely delicate" and not in the sense of ethereal beauty or heavenly.

15. United States decisions are also frequently affected by the U.S. Local Government Antitrust Act 1984 giving pecuniary immunity to actions taken against local government entities. Hospitals have frequently been held to be entitled to take advantage of this immunity. See, for example, Crosby v Hospital Authority of Valdosta 1996 2 Trade Cases 71563 (11 CCA).

16. The reason why the New Zealand Commerce Commission brought the case under s.27 of the Commerce Act requiring it to prove a substantial lessening of competition instead of arguing an exclusionary provision per se breach under s.29 is not known to the writer. There are two possible reasons which present themselves. The first is technical. The Commission proved a geographic market limited to the Southland. Many of the participants in the arrangements were outside this area. The Commission may have taken the view that s.29 was not applicable as the section applies only in relation to arrangements between "competitors" and those outside the Southland area were not competitors for s.29 purposes. If this is the rationale of the Commission's approach, one can understand it but the writer believes it is wrong (see commentary in Gault on Commercial Law (Brookers NZ) Para 29.07(3)). On the other hand, the Commission may simply have taken the view that the case, being the first taken against a professional organisation, was one in which it should have, as a matter of principle, accepted the onus of demonstrating a substantial lessening of competition.

17. As stated in the text, this issue may well now be considered somewhat historical. The per se condemnation of exclusionary provisions in New Zealand was the law at the time of the conduct involved. The present law provides a competition defence on a "reverse onus" basis. Whether future cases are brought under s.27 or s.29, the question of illegality will substantially be a competition issue, albeit on a different onus of proof requirement.

18. Royal Commission into Civil Rights (Ontario) 1968 p.1162. This view has been reiterated by the Law Reform Commission of NSW – see NSW Law Reform Commission – The Legal Profession, Discussion Paper No. 1 (1979) p.45.

19. As regards the view of the New Zealand Commerce Commission in relation to the enforcement of advertising constraints see Re Chemists Guild of New Zealand Inc. (1967) 1 NZBLC (Com) 104058.

20. See Trade Practices Commission Guideline No. 9 (26 May 1995) re "Codes of Ethics"; ACCC Report to Australian Senate on Health Fund Practices 1 July 2000 – 30 June 2001, p.54; ACCC Determination in relation to Royal Australasian College of Surgeons (30 June 2003); U.S. Federal Trade Commission Advisory Opinion re National Standards Institute 78 FTC at 128-30; U.S. Federal Trade Commission Guideline 83 FTC 1849; New Zealand Commerce Commission decision on Chemists Guild Case (n.19).

21. See Sydney Daily Telegraph "Vision of Hope" 28 May 2004.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Prenatal genetic testing: full information is needed

James Harraway

Fragile X is the most common single-gene cause of developmental delay/intellectual disability; molecular testing for the causative mutation in this disorder has become an important part of the investigation of intellectual disability.[1,2] The mutation responsible for Fragile X is an expansion of a CGG triplet repeat located upstream of the gene *FMR1*. Normal individuals carry between 5 and 44 copies of the CGG repeat, while affected males carry over 200 copies.[3]

Most laboratories use a combination of the polymerase chain reaction (PCR) and Southern Blotting to detect CGG expansions in Fragile X.[4] While the PCR is a rapid test, it is restricted in the size of expansion that it is able to detect and so is used to screen samples. If one normal-sized allele is seen in a male, or if two normal alleles are seen in a female, no further analysis is required. Otherwise, samples proceed to analysis by Southern Blotting.

For example, if one allele is seen in a female on PCR, this could be either due to homozygosity for a single size of repeat in a normal individual, or to the presence of one normal repeat and an expansion which cannot be detected by PCR. Southern blotting can detect large expansions, but is slower than PCR (taking approximately 1 to 2 weeks), and can be more difficult to interpret.[4]

Case Report

Canterbury Health Laboratories received an EDTA-blood sample from a referring laboratory for Fragile X testing on a 28-year-old woman, Patient X. Clinical details given on the request form were *"Family history of Fragile X"*. DNA was extracted and batched for PCR analysis, and one normal-sized allele was seen. Two weeks after the sample was received (when it was due to be batched for Southern Blot analysis), the referring laboratory enquired after the result of the test. At this stage they provided the additional information that the patient had two brothers with Fragile X, was now 17/40 pregnant, and that the test had been requested to determine the need for prenatal diagnosis. The Southern Blot was carried out urgently (taking 1 week), and no expanded alleles were seen.

Discussion

This case demonstrates two major principles. Firstly, clinical laboratories require full clinical information with any patient sample, particularly if testing is urgent.[5] There was no indication of urgency nor that the patient was pregnant on the initial request form, and accordingly it was batched as a routine test.

If Patient X had carried an expanded allele, prenatal testing would have taken at least another week to 10 days, placing the pregnancy at the limit of acceptability for termination. In contrast, if full clinical information had been given initially, the entire process would have been advanced by at least 2 weeks.

Secondly, prenatal testing for inherited disorders requires careful coordination between the laboratory and clinicians. Ideally, if a patient has a known family history of a monogenic disease, then the possibility of prenatal testing should be discussed (by their general practitioner and Clinical Genetics Services) when they decide to have children. During that discussion, the implications of such testing should be thoroughly explored.[6,7]

Many genetic disorders are caused by family-specific mutations, which can take several weeks to identify. Although Fragile X is almost exclusively caused by the CGG expansion, other mutations can occur, and ideally the presence of the expanded allele should have been confirmed in Patient X's brother(s) before proceeding with testing Patient X. In addition, the work-up for prenatal genetic testing requires samples from both parents regardless of the mode of inheritance, to rule out maternal contamination of the foetal sample.[8]

In consultation with the testing laboratory, the clinician coordinating prenatal testing (usually an obstetrician or clinical geneticist) should determine the amount of time needed for this work-up, and which of the family members need to be tested. Following this work-up, if the couple wish to go ahead with prenatal diagnosis, then informed consent should be obtained, and the type and date of sampling discussed with the laboratory.

Overall, a coordinated process should allow prenatal testing to be carried out in a timely manner, and avoid the situation illustrated in this case report.[7]

Author information: James Harraway, Genetic Pathology Registrar, Molecular Pathology Laboratory, Canterbury District Health Laboratories, Christchurch

Correspondence: Dr James Harraway, Molecular Pathology Laboratory, Canterbury District Health Laboratories, PO Box 151, Christchurch. Fax: (03) 364 0545; email: james.harraway@cdhb.govt.nz

References:

1. Curry CJ, Stevenson RE, Aughton, D, et al. Evaluation of mental retardation: recommendations of a consensus conference. Am J Med Genet. 1997;72:468–77.
2. Hartley L, Salt A, Dorling J, Gringras J. Investigation of children with "developmental delay". West J Med. 2002;176:29–33.
3. Oostra BA, Willemsen R. A fragile balance: FMR1 expression levels. Hum Mol Genet. 2003;12(R2):R249–R257.
4. Maddalena A, Richards C, McGinniss M, et al. American College of Medical Genetics: Technical Standards and Guidelines for Fragile X. Genet Med. 2001;3:200–5.
5. Requests and Collection Section. RCPA Manual. Royal College of Pathologists of Australasia [Online Manual]; 2004. Available online: URL: http://www.rcpamanual.edu.au/sections/singlearticle.asp?s=45 Accessed May 2005.
6. Trent RJA, Williamson R, Sutherland GR. The "new genetics" and clinical practice. Med J Aust. 2003;178:406–9.
7. Joint HGSA/RANZCOG Prenatal Diagnosis Policy. Human Genetics Society of Australasia Policy; 2004. Available online. URL: http://www.hgsa.com.au/PDF/Prenatal%20diagnosis%20policy%20C-Obs%205%20Mar2004.pdf Accessed May 2005.

8. American College of Medical Genetics: Standards and Guidelines for Clinical Genetics Laboratories; Section G19, Prenatal Testing; 2003; Available online. URL: http://www.acmg.net/Pages/ACMG_Activities/stds-2002/g.htm Accessed May 2005.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Sustained supraventricular tachycardia in Ebstein's anomaly

Paul Grant

Abstract

A case is reported of a middle-aged female with congenital heart disease who presented with treatment-resistant supraventricular tachycardia. Supraventricular tachycardias (SVTs) in congenital heart disease (and their management) are discussed. The authors are not aware of any similar reports in the literature.

Supraventricular tachycardias (SVTs) are a common complication of congenital heart disease in adults. Their management can be difficult, especially when the patient becomes compromised and the arrhythmia is resistant to treatment. We describe one such life-threatening case which presented us with significant diagnostic and management difficulty.

Case report

A 46-year-old Caucasian lady was brought into Timaru Hospital's Emergency Department after being found unconscious. Paramedics reported the patient was having difficulty breathing prior to collapse. The patient had regained consciousness on arrival and was alert, complaining of palpitations, chest pain, shortness of breath, and dizziness.

Her past medical history included a diagnosis of Ebstein's anomaly (a form of congenital heart disease). She had had two previous admissions for fast atrial fibrillation in the past 10 years. Her regular medication included aspirin and digoxin.

On examination, her breathing was rapid and shallow; pulse >200 beats per minute (bpm); blood pressure 126/60 mmHg; and there was a diastolic murmur. Oxygen saturation was initially 89% on air. Chest X-ray revealed an enlarged heart with bilateral pleural effusions. An electrocardiogram (ECG) showed an SVT at a rate of 300 bpm (ventricular rate).

Initial treatment for her arrhythmia comprised of vagal manoeuvres and three bolus injections of adenosine, which had no effect. The on-call physician repeated the adenosine and then a digoxin infusion, both to no avail. The patient's systolic BP dropped to 100 mmHg and her heart rate was 310 bpm. The patient was transferred to the Coronary Care Unit at Timaru Hospital.

An echocardiograph was performed which showed a grossly enlarged right atrium and ventricle; also the tricuspid valve appeared to have become displaced downwards into the right ventricle.

Electrical (DC) cardioversion was then attempted (six times) both in the standard and anteroposterior positions, with higher initial energy monophasic shocks of 360 joules. The arrhythmia was not terminated at any point. The patient was still compromised.

A central line was then inserted, and amiodarone administered. This reduced her rate to a relatively stable 150 bpm. She was feeling dizzy and very nauseous.

After discussion with a tertiary centre it was agreed that she should be transferred via helicopter to undergo urgent review and radiofrequency ablation via a catheter procedure at Timaru Hospital.

Two weeks later, she attended the Cardiology Clinic for follow-up. She was much improved and her ECG showed a rate of 80 bpm and right axis deviation. The sustained SVT was found to be secondary to a proliferation of accessory conduction pathways caused by a distorted right atrium. This in itself a sequelae of her congenital heart disease. However the reasons for its resistance to emergency management were incompletely understood.

Discussion

Ebstein's anomaly has four main features: downward displacement of the tricuspid valve into the right ventricle with variable distortion of the valve and resultant regurgitation of blood into the right atrium; enlarged right heart chambers; atrial-septal defect (in 50% of patients); and irregular heart rhythms, particularly AF. Ebstein's anomaly is the most common congenital heart disease associated with atrial arrhythmias and can cause significant morbidity and mortality, as well as sudden death.

Approximately 25% of patients with Ebstein's anomaly have an accessory pathway in the heart's conduction system which can bypass the normal impulse circuit causing arrhythmias.[1] These can reduce the heart's performance particularly when the tricuspid valve is leaking severely.

In our patient, heart failure exacerbated the arrhythmia and treatment of this condition with digoxin, diuretics and vasodilators can suppress some of the arrhythmias that accompany cardiac decompensation.

With treatment of a tachyarrhythmia, slowing the ventricular rate is the initial and often most important therapeutic manoeuvre. Cardioversion appears to terminate most effectively those tachycardias presumed to be due to nodal re-entry, such as atrial flutter and fibrillation—however it is not always successful because of technical factors or factors within the heart. As the patient was still symptomatically unwell, centrally administered Amiodarone was utilised. Success rates vary widely depending on patient population, arrhythmia, underlying heart disease, and other factors. In general, amiodarone's efficacy equals or exceeds that of all other antiarrhythmic agents.[2,3]

The patients rate was brought down to 150 bpm and her condition stabilised sufficiently to enable her transfer to a tertiary medical centre for life-saving treatment in the form of catheter ablation therapy. The purpose of which is to destroy myocardial tissue integrally related to the arrhythmia.

Why was this patient's SVT resistant to medical treatment? The reasons for this are multifactorial. The underlying reason being her congenital heart disease. Electrophysiological studies showed that there was a proliferation of abnormal electrical conducting tissue, with more than one accessory pathway to perpetuate the re-entrant arrhythmia.[4] Also we suspect that the pro-arrhythmic effects of repeated

doses of several antiarrhythmic medications compounded the problem. On top of this, worsening heart failure meant that the malpositioned tricuspid valve had become severely regurgitant and was adding to her compromised state.[5]

In patients with pre-excitation syndrome (that is producing life-threatening rhythm disturbances), the accessory conduction pathway should be divided.[6] This summarises the outcome for our patient who underwent ablation therapy acutely and is now awaiting cardiac surgical review for valve repair.

The case illustrates the problems of arrhythmia management in the acute setting, especially as the added complications of rare congenital heart diseases may hinder the response to treatment. It is very important to clarify the underlying pathophysiology and stabilise the patient's condition. Advances in electrophysiological catheterisation techniques have allowed the diagnosis, localisation and successful treatment of these arrhythmias.

Acknowledgement: I thank C Ilsley for proofreading the manuscript draft.

Correspondence: Dr PS Grant, Emergency Department, Timaru Hospital, Private Bag, Timaru, South Canterbury. Email: drpaul.grant@orange.net

References:

1. Greason KL, Dearani JA, Theodoro DA, et al. Surgical management of atrial tachyarrhythmia's associated with congenital cardiac anomalies: Mayo Clinic experience. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2003;6:59–71.
2. McNamara RL, Tamariz LJ, Segal JB, Bass EB. Management of atrial fibrillation: review of the evidence for the role of pharmacologic therapy, electrical cardioversion, and echocardiography. Ann Intern Med. 2003;139:1018–33 (Review).
3. Siddoway LA. Amiodarone: guidelines for use and monitoring. Am Fam Physician. 2003;68:2189–96.
4. Lindsay BD. Smith JM. Electrophysiological aspects of human atrial fibrillation. Cardiol Clin. 1996;14:483–505.
5. Guiliani ER. Fuster V. Ebstein's anomaly. he clinical features and natural history of Ebstein's anomaly of the Tricsuspid valve. Mayo Clin Proc. 1979;54:163.
6. Carpentier A. Chavaud S. Mace L, et al. A new reconstructive operation for Ebstein's anomaly of the tricuspid valve. Surgery 1988;96:92.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Horner's syndrome after central venous catheterisation

John Jarvis, Angus Watson, Greg Robertson

Case report

A 19-year-old female patient presented for surgery with indeterminate colitis refractory to medical therapy. She had severe diarrhoea despite being on maximal medical therapy. Colonoscopic examination of the lower bowel demonstrated a confluent colitis with granular mucosa and a mucopurulent exudate throughout the colon.

The patient underwent a subtotal colectomy with preservation of the rectum and formation of end ileostomy. The patient initially had an uncomplicated recovery and was discharged home. However she became unwell and was readmitted acutely with peritonitis the following day. An abdominal radiograph suggested there was free gas in the abdomen, and the clinical impression was either that of a rectal stump staple line dehiscence or a perforated peptic ulcer.

The patient was taken back to theatre for an exploratory laparotomy, which revealed an infected fluid collection without evidence of a perforated viscus. An internal jugular central venous line was placed using the Seldinger technique without the aid of ultrasound. Central line placement was checked with a chest radiograph and the position was thought to be satisfactory.

The patient progressed well on the first postoperative day, however the central line was difficult to flush and back-filled with blood. A blood sample was taken for blood gas analysis and was found to be arterial. After discussion, the central line was removed and pressure applied locally to the puncture site for 20 minutes. On the third postoperative day, the patient complained of a drooping eyelid and slightly blurred vision on the right side. Her pupils were also unequal. An ophthalmology opinion confirmed the presence of a right-sided Horner's syndrome and normal visual acuity. Three months after surgery, the Horner's syndrome had largely resolved.

Discussion

Horner's syndrome is a recognised complication of internal jugular venous catheterisation.[1] Risk factors for development of the syndrome appear to include: insertion of large bore haemodialysis[2] or Swan-Ganz[3] catheters, difficult catheterisation with repeated needling attempts, and accidental carotid artery puncture. All of these share the likely aetiology of carotid sheath haematoma with damage to the second-order sympathetic fibres in and around the cervical ganglia.

As in this case, most Horner's syndromes develop from a neuropraxia caused by a carotid sheath haematoma—often seen after internal carotid artery stenting.[4] Debate about the use of ultrasound to increase the rate of successful central venous catheterisation (CVC) continues,[5] but there is now increasing evidence that the use of a two-dimensional (2-D) ultrasound guidance increases the likelihood of success, thus decreasing the incidence of complications and the time spent on the procedure.[6,7]

In summary, the use of 2-D imaging ultrasound guidance should be considered in most clinical circumstances where CVC insertion is necessary (either electively or in an emergency situation).[8]

Author information: John Jarvis, Surgical Registrar; Angus J M Watson, Colorectal Fellow; Greg M Robertson, Consultant Surgeon, Department of Surgery, Christchurch Public Hospital, Christchurch

Correspondence: Mr J Jarvis, Department of Surgery, Norfolk and Norwich University Hospital, Colney Lane, NR4 7UY, Norwich, UK. Email: johnjarvis@paradise.net.nz

References:

1. Bell RL, Atweh N, Ivy ME, Possenti P. Traumatic and iatrogenic Horner syndrome: case reports and review of the literature. J Trauma. 2001;51:400–4.
2. Taskapan H, Oymak O, Dogukan A, Utas C. Horner's syndrome secondary to internal jugular catheterisation. Clin Nephrol. 2001;56:78–80.
3. Garcia EG, Wijdicks EFM, Younge BR. Neurologic complications associated with internal jugular vein cannulation in critically ill patients: A prospective study. Neurology. 1994;44:951–4.
4. Rosenkranz M, Eckert B, Niesen WD, et al. Horner syndrome related to ipsilateral carotid wall hematoma after stent placement for the treatment of carotid stenoses. Am J Neuroradiol. 2003;24:1508–11.
5. Scott DHT. The king of the blind extends his frontiers. Br J Anaesth. 2004;93:175–7.
6. Scott DHT. 'In the country of the blind, the one-eyed man is king.' Erasmus (1466-1356). Br J Anaesth. 1999;82:820–1.
7. Hatfield A, Bodenham A. Portable ultrasound for difficult central venous access. Br J Anaesth. 1999;82:822–6.
8. Calvert N, Hind D, McWilliams RG, et al. The effectiveness and cost effectiveness of ultrasound locating devices for central venous access. London: National Institute for Clinical Excellence (NICE); 2002. Available online. URL: http://www.nice.org.uk/Docref.asp?d=3019 Accessed May 2005.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Providing quality healthcare under funding constraints

Ian Powell

A feature of health systems is that periodically they reach certain crossroads.[1] This was the case in 1999 when a Labour-Alliance (now Labour-Progressive) 'centre-left' government was elected replacing the previous conservative (National-led) governments of the 1990s.

That crossroad was whether to make a significant break from the prevalent but unsuccessful ideology of the 1990s in which market forces were considered the most effective driver of the health system. That is what happened with the New Zealand Public Health and Disability Act 2000 (NZPHD), which marked a significant shift in direction, including the establishment of 21 district health boards (DHBs), and whose purpose can be summarised as:

- To provide for the public funding and provision of personal health, public health and disability services and to establish publicly owned organisations to ensure this provision.
- Pursuing the objectives 'to the extent that they are achievable within the funding provided.'
- Endeavouring to promote the 'integration of all health services, especially primary and secondary.'[2]

This shift of direction was predated by prioritisation and quality improvement initiatives. The main significance of the NZPHD was the provision of a new external morality replacing that of the previous legislation. It provided new parameters that medical practitioners and other health professionals were to work within. But sound parameters alone are insufficient for the provision of quality healthcare in an environment of funding constraints. Internal morality, in conjunction with a generative culture derived from the safety literature, is also required. To give this quality objective practical effect, the ethos of professionalism provides the basis for the alignment of external and internal moralities.

Prioritisation and quality improvement

Although the market experiment has ended, the challenge of providing quality healthcare under funding constraints remains unabated. As it became clear that the market experiment was failing to address this challenge, prioritisation or priority setting emerged as another response.

Following on from initial efforts to develop a surgical booking system based on fiscal thresholds and subjective clinical criteria that was unrealistically promoted by the government of the day as a 'cure-all' solution to lengthy waiting lists, the National Health Committee (a statutory body set up to advise the Minister of Health on health service priorities) recommended in 1997 that prioritisation decisions be explicit and transparent and based on effectiveness, efficiency, equity, and acceptability.[3]

Arguably the main benefit of prioritisation has been greater openness but it has been subject to strong criticisms, which go to the core of fiscal effectiveness and quality of care. Prioritisation has been implemented in a haphazard and unvalidated manner and is dangerous for quality standards and patient care in an environment of funding constraints because of its subjective and variable points system and its effect on access to essential services.

There are, however, interesting research projects currently underway that we should learn from. In the meantime, a series of papers to the New Zealand Orthopaedic Association's Annual Scientific Meeting (October 2003) highlight the serious limitations of prioritisation in reference to both quality and fiscal imperatives. They reported several negative effects such as high levels of internal inequity, significant medical (including mental health) and social problems for patients referred back to general practitioners, high levels of patient dissatisfaction, substantially increased paperwork for GPs, and diverting GPs from routine general practice.[4]

The current approach in New Zealand, building on prioritisation, has now shifted to quality improvement for which two reports commissioned in 2000 are critical.[5] A quality improvement approach offers discernible advantages in response to funding constraints such as being more likely to engage health professionals and the public, starting from the base of current service delivery and how it might be improved, and focusing on the process and outcomes of care.[6]

But, while in the right direction and a distinct improvement on misplaced reliance on prioritisation, a quality improvement strategy on its own is not enough and does not by itself bridge the critical gap between macro and micro issues and performance. For this, we need to draw upon, adapt, and borrow from the discussions and debates over safety cultures—including external and internal morality, and bureaucratic and generative cultures.[7]

External morality

External morality reflects the wider society's ethos and the parameters within which the internal morality of medical practitioners operates. In this context, New Zealand's legislative and policy framework has much going for it. Single-payer funding and the high level of public provision (particularly in secondary care) provide robust means of avoiding unnecessary fragmentation and promoting more effective integration. Also part of the external morality is the statutory position of the Health and Disability Commissioner responsible for the operation of the statute-derived Code of Patients Rights.

The DHBs objectives and functions are consistent with the provision of a universal public good that includes proactively (rather than simply reactively) confronting health needs. Of particular note in this respect is s23(1)(g) of the NZPHDA requiring DHBs to *regularly investigate, assess and monitor the health status of its resident population, any factors that the DHB believes may adversely affect the health status of that population, and the needs of that population for services*.[8]

That is not to say there are not legitimate debates over the form of the DHB system. There are differing views over the value and effectiveness of elected members comprising part of the board membership, the number of DHBs, and whether some

should be merged. These are, however, debates around the margins rather than the core of the system.[9]

At the level of policy (rather than legislation) is the initiation of a tripartite forum process based on the Government, DHBs, and the Council of Trade Unions (the central union organisation). This is significant given the high unionisation levels of health professionals in New Zealand. Although only in its formative teething days, if approached in the right way this has the potential to enable an improved contribution to more robust and practical national policies but, perhaps more importantly, stronger local bipartite (DHB-union) policy development and implementation.

New Zealand has an external morality framework that in the main is conducive to fronting up to the challenge of delivering quality healthcare against funding constraints. It is certainly superior to what it replaced. But it is the *doing* that is difficult. Despite several positive developments (including longer-term funding packages and a shift from time-limited to baseline funding),and nearly 3 years after the passing of the NZPHDA, we are at another crossroad. The gap between cup and lips, between the laudable long-term objectives of the orientation towards primary and population based healthcare, on the one hand, and the immediate demand driven healthcare imperatives that daily confront patients and doctors, on the other hand, is large indeed.

Internal morality and generative culture

This time the crossroad involves the culture of the health sector, including its decision-making process and engagement of health professionals. For those working at the front-line of health delivery there has not been a general discernible difference or improvement in the culture of the sector compared with the 1990s. This has a compounding effect as the longer a negative culture remains in place the more embedded and entrenched it becomes and it precludes the ability of the health system to use its greatest resource for ensuring quality of healthcare in an environment of funding constraints, the internal morality of health professionals, including the medical profession.

Excessive reliance on the external morality to deliver means that our health system continues to function largely in crisis management and short-term modes of decision-making. The capacity to shift to a medium-to-longer-term approach has not yet been achieved despite the external morality of the system requiring such an approach.

It is useful to raid and adapt the theoretical construct of Ron Westrum, as outlined by James Reason,[10] involving organisational cultures (pathological, bureaucratic and generative). This construct was in the context of the handling of safety information. While instances of the pathological culture unfortunately still exist in DHBs, the other two cultures are more prevalent and relevant to this discussion.

In summary, the differences between bureaucratic and generative cultures are:

- May not find out necessary information (bureaucratic culture) compared with actively seeking it (generative culture).
- Messengers are listened to if they arrive (bureaucratic) compared with training and rewarding messengers (generative).

- Responsibility is compartmentalised (bureaucratic) compared with sharing responsibility (generative).
- Failures lead to local repairs (bureaucratic) compared with failures leading to far-reaching reforms (generative).
- New ideas often present problems (bureaucratic) compared with new ideas being welcomed (generative).

New Zealand's DHB organisational culture is still largely bureaucratic, which contributes in no small part to our specialisation in fiscal ineffectiveness. Sustained pressures force DHBs into short-term decision-making in a sector where the best and most effective decisions are made when done so on a medium to long-term basis.

An inevitable outcome of 'short-termism' is to resort to crisis management and short-sightedness at the expense of longer-term investment in human capital. We don't know whether we spend enough on health or if we are about right in New Zealand. But health expenditure is expected to reach 19.7% of total government spending in 2006, a 60% increase on the 1993 share of government spending.[11] This requires New Zealand to reassess how effectively we are spending the health dollar in order to address the contradiction of overall increased health spending, increasing difficulties faced by health professionals in providing quality accessible healthcare at the clinical front line, and intensifying further demands increasing the fiscal pressures on the system.

Medical practitioners are obviously critical to this. Whereas managers play an important role in setting the scene, positively or negatively, in which fiscal value and effectiveness can be added, it is doctors and other health professionals who actually increase this value and effectiveness in particular in a form that is more likely to be longer term and sustainable. The application, for example, of doctors' routine daily responsibility of discharging patients can influence both readmission rates and 'bed-blocking'.

'Short-termism' and crisis management leads to the creation and perpetuation of unresolved time bombs. These include:

- The extent of unmet need is unknown with significant implications, including fiscal, down the track for the health system.
- The lack of an aggressive nationally coordinated recruitment and retention strategy causes excessive consequential reliance on costly alternatives.
- Failure to undertake work on further developing the capacity needs of DHBs to provide patient and other health services and taking advantage of the benefits and enhanced effectiveness of integrated provision.
- Addressing the high level of disharmony and distrust in the primary sector between medical practitioners and the Ministry of Health which is significantly undermining the ability to ensure that PHOs become effective organisations facilitating better health delivery and outcomes.

Using professionalism

This leads to the question of how effectiveness can best be provided. Internal morality (i.e. professionalism) is the generative culture. It provides the basis for bridging the gap between macro intent and micro performance, and gives substance to the external morality. The key issue is one of a working relationship of trust and confidence in which doctors are actively engaged and empowered in the engine-room of decision-making that goes beyond the level of rhetoric.

Doctors are the most critical resource, strategically and by location, but also the most untapped resource that the health system has available to it. They do not need to be motivated; they do not require crude incentives such as performance bonuses. Their motivation and the benefits that flow from it comes from being allowed to do what their professionalism drives them to want to do.

There are several ways, many of which are interconnected, in which our current crossroad can be navigated based on a generative culture in our health system, and within our DHBs based on the empowering of professionalism. These include:

- An assessment of the unmet need within the communities that make up New Zealand, and the consequential development of a strategy (inclusive of implementation plans) to address it.
- A coordinated and health professional-based independent taskforce approach, perhaps within the tripartite process discussed above, to examine the resource (personnel and non-personnel), organisational and delivery needs of the full range of services provided by—and through DHBs focussing on improving the effectiveness and alignment of services.

  This approach is an adaptation of the taskforce review of metropolitan acute services in New South Wales (now close to completion) which, for reasons of distrust, operates independently of the state health department. There are some variations of this approach already being underway in New Zealand (such as for cancer treatment services), but it is not part of a systemic approach.
- The question of workforce development and planning at the level of each DHB requires specific work and focus. While DHBs are discussing this nationally it is only at an embryonic outline stage, and without effective engagement with health professionals.

  This strategy would be more effectively achieved through active engagement with health professionals based on joint workforce development taskforces at an individual DHB level charged with developing agreed staffing plans (including the support staffing levels and resources required to meet these objective needs); recruitment and retention strategies to support these staffing plans; and agreed plans for the effective provision of and access to high quality professional development.
- Encouraging and supporting activities designed to address the vocational needs of non-specialist doctors (medical officers of special scale). This is an under-utilised part of the medical workforce that could be much better used to help meet workforce needs and to ensure quality of care.

The College of General Practitioners has taken the initiative with the development of special interests (largely secondary care) based on a generalist training framework. But it is important that such a development is a logical consequence of the evolution of medicine and shaped by the relevant professional college rather than determined by some external political or ideological persuasion.

- General practice offers a key foundation stone in helping address the staffing needs of New Zealand's public hospitals, including (but not confined to) rural and provincial. Along similar lines to the above discussion about medical officers of special scale, general practice coupled with supplementary special interests may provide good quality generalist care that many of our secondary care settings would benefit from. It is an attractive prospect that fits in well with current government support for workforce planning and development and primary and secondary care integration.
- The development of democratic and mandated models of clinical leadership within DHBs, including clinical boards with far-reaching reporting and advisory responsibilities. The most effective clinical leadership in an organisation is that which is based on the mandate of its peers. This includes, by whatever locally agreed means, some form of democratic election/selection.[12]

Aligning external and internal morality

In summary, external and internal morality are not opposites: one cannot do without the other, but both are critical to whether quality healthcare can be delivered in the context of funding constraints. An inherently weak, malign, inappropriate, or inefficient external morality erodes the professionalism of health professionals which is the internal morality most likely to generate fiscal effectiveness and maintenance of quality standards.

It is not just the effect of the evil extremes of Nazi Germany and apartheid South Africa, for example, that highlight how external morality can corrupt the internal morality of doctors. In 1990s New Zealand, the drive under the competitive commercial external morality for health providers to work only to their funding contract showed signs (fortunately not extensively) of extending to medical practitioners working only narrowly to their employment contract rather than the 'extra mile' underpinned by the values of professionalism.

It is fiscally inefficient and irresponsible to create an overarching morality that encourages any health professional to consider their employment as only a job and to confine their commitment to the health system in this way.

Today, New Zealand has a more or less reasonable and appropriate external morality. But we do not place sufficient importance to, or recognition of the necessary internal morality to give full effect to fiscally robust and responsible healthcare delivery—in part due to the corrosive ongoing legacies of a decade of market experimentation, but it is lazy to blame too much of this failure on this legacy. Ongoing reliance on external morality risks further eroding internal morality.

If New Zealand is to successfully and expeditiously work towards bridging the gap between current clinical imperatives and its longer term primary care and population health objectives, and if quality improvement is to be at the core of the health system,

then we are going to have to move beyond our prevailing bureaucratic culture to a generative culture based on the trust and confidence of and active engagement with medical practitioners and other health professionals.

This is what is required to have an internal morality aligned with our external morality and it is only with such an alignment that we will advance beyond 'lines on paper' assertions, and instead have a reasonable level of confidence that we can deliver quality healthcare under funding constraints.

Author information: Ian Powell, Executive Director, Association of Salaried Medical Professionals, Wellington

Correspondence: Ian Powell, Association of Salaried Medical Professionals, PO Box 10 763. Wellington. Fax: (04) 499 4500; email: ian@asms.org.nz

References:

1. This article is based on an address given by the author to the Second All-Ireland Health Conference in Belfast (27 November 2003) jointly organised by the British Medical Association and the Irish Medical Organisation. The address is available on the Association of Salaried Medical Specialists' website (www.asms.org.nz).
2. Sections 3(1), (2) and (4) of NZPHDA.
3. National Health Committee, *The best of health 3*, Wellington, 1997. Also Health Funding Authority, *How should we prioritise health and disability services?* Wellington, 1998, which also added Maori health to the four principles of effectiveness, efficiency, equity and acceptability, and Ashley Bloomfield and Robert Logan, *Quality Improvement perspective and healthcare funding decisions*, British Medical Journal, 23 August 2003, pp.439-443. Bloomfield and Logan make a misleading assertion that health funding in the 1990s flowed largely to secondary rather than primary care. In fact, considerable funding went to Independent Practitioner Associations and demand driven primary care. Secondary funding significantly increased in the second half of the decade which compensated for real per capita deceases in the first half of the decade and was primarily for time-limited prioritisation initiatives.
4. Jann Fielden, Geoffrey Horne and Peter Devane, *Hospital Waiting Lists – the GP Burden; D. Ardern and T. Lysnkey, Removing patients from an Orthopaedic surgery waiting list because they do not reach the financially sustainable threshold for access to publicly funded services*; and Jean-Claude Theis and others, *Equity of Access to Orthopaedic Surgical treatment in New Zealand – Improving Consistency of Clinical Decision Making*; papers to New Zealand Orthopaedic Association Annual Scientific Meeting, 19-23 October 2003.
5. *Quality Improvement Strategy for Public Hospitals*, Minister of Health advisory group, Wellington, 2001, and *Safe systems supporting safe care: Final Report on health care quality improvement in New Zealand*, National Health Committee, Wellington, 2002.
6. Bloomfield A, Logan R. Quality improvement perspective and healthcare funding decisions. BMJ. 2003 Aug 23;327:439–43.
7. In the discussion concerning safety cultures I draw upon the recent book by Peter Roberts, *Snakes and Ladders: The Pursuit of a Safety Culture in New Zealand Public Hospitals*, Victoria University, Wellington, 2003.
8. Coster G, Buetow S. Challenges for District Health Boards as needs assessors, N Z Med. J. 2002;115(1156). URL: http://www.nzma.org.nz/journal/115-1156/78
9. An interim report covering an independent three year study of the health reforms pursuant to the NZPHDA, of which DHBs are central, reports general support for the new system; *Interim Report on Health Reforms 2001*, Health Reforms 2001 Research Team, Health Services Research Centre, Victoria University, Wellington, November 2003. However, the findings of this report should be qualified by the fact that it was largely confined to the assessments of

those involved in Ministry of Health and DHB structures including bureaucracy and other organisations rather than health professionals. A survey of the public was conducted in the earlier stage of the reform process (June-July 2001).

10. As discussed in Peter Roberts' *Snakes and Ladders: The Pursuit of a Safety Culture in New Zealand Public Hospitals*, Victoria University, Wellington, 2003, pp.62-64.

11. Right Hon. Dr Michael Cullen, Deputy Prime Minister and Minister of Finance, *Issues in the finance portfolio*, Chen Palmer seminar, Wellington, 16 June 2003.

12. This approach was part of one of the key quality improvement reports to the Minister of Health; *Quality Improvement Strategy for Public Hospitals*, Minister of Health Advisory Group, Wellington, 2001.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Responsibility for pharmaceutical company samples

Shane Reti

On 1 October 2004, pharmaceutical company Merck Sharpe & Dohme (MSD) announced a voluntary worldwide withdrawl of Vioxx (rofecoxib). As part of the recall and audit process, patients were invited to seek further advice from their healthcare provider. This article will explore the wider issues of responsibility for pharmaceutical recalls, and more specifically, the responsibilities associated with pharmaceutical sample dispensing.

In the context of the Vioxx recall, the question a medical practitioner might ask is *Because I have prescribed this drug to patients, do I have any personal responsibilities for this recall?* Certainly, this has not been directly asked for by the Ministry of Health, and indeed the thrust of the recall has been for the pharmaceutical company to take prime responsibility for notifying patients via general media release. If an individual medical practitioner has no responsibility for being involved in a pharmaceutical recall, then the actions simply lie with the directions the pharmaceutical company receives from the Ministry of Health, and there would seem to be nothing more to do.

However, this may not be the case. Medical practitioners who prescribed or dispensed Vioxx may have some responsibility for being involved with the Vioxx recall, over and above the actions taken by MSD. For example, the Health and Disability Commissioner Act 1994 and the Code of Health and Disability Services Consumers' Rights (the Code) could possibly require medical practitioners to be involved in a pharmaceutical recall such as that for Vioxx.

Advice on the issue of responsibility was sought from the Health and Disability Commissioner Ron Paterson (personal communication with Ron Paterson, Health and Disability Commissioner, 2004).[1]

The Commissioner's reply was that under Right 6 of the Act, there is a requirement to provide ongoing provision of information, but that fulfilment of that requirement will depend on the circumstances surrounding the recall. The Commissioner writes:

> If due to the nature of the medication or the reasons for recall, there is very little or no risk of harm to patients, then it is unlikely that a general practitioner would be expected to contact patients about the recall (although most recalls occur because there is a risk of harm). However, if the nature of the medication and/or the reason for recall is such that there is a risk of harm to patients then general practitioners should:
>
> - Notify patients of the recall within a reasonable time;
> - Tell patients what steps to take in response to the recall; and
> - Advise patients where to go for further information (often this will be the manufacturer)

While the Commissioner also states

> Clearly the primary responsibility for initiating, publicising and managing recalls lies with the pharmaceutical companies,

it would seem that with most recalls therefore, under Right 6 of the Code, medical practitioners will generally have an obligation to contact patients on the basis of the

general level of potential patient harm required to initiate a medicines recall in the first place. In the case of Vioxx, the potential patient harms related to cardiovascular events of heart attack and stroke, both of which would likely meet a criteria for serious patient harms, and therefore would likely require medical practitioner involvement in the recall process.

Having determined that under a medicine recall scenario, medical practitioners may have an obligation to contact patients, there needs to be some exploration of exactly how that contact might occur. In terms of the example in question, exactly how might a medical practitioner contact patients to whom they have given Vioxx ? It is important for the following discussion to differentiate the term 'given' a medicine into the two most common ways to give a medicine—prescribed and dispensed.

Most prescribed medicines today are electronically prescribed via a patient database management system (PDMS). Most PDMSs have the ability to identify patients prescribed any given medicine, so a credible audit and recall mechanism exists. Furthermore, prescribed medicines are also electronically recorded by the pharmacist at the point of dispensing, and so a second audit trail exists. This second mechanism would also provide some follow-up ability for the many after hours clinics where doctors are manually writing prescriptions.

It is in the area of dispensed medicines (such as pharmaceutical samples) that this article will particularly focus on, as it is this author's experience that (in general) most dispensed samples are not recorded in a manner that facilitates suitable monitoring and audit processes. To provide scope to the discussion, MSD correspondence indicates that tens of thousands of Vioxx samples have been made available to New Zealand practitioners over the past few years—a not insignificant volume to attempt to recall [personal communication with Gerry Fitzgerald, Franchise Group Manager, MSD, 2004].[2]

While Vioxx is the example used here, the discussion is equally relevant to other practitioner dispensed medicines, whether dispensed from an after-hours bag or an after-hours drug cupboard, or stat dispensed medicines such as the morning-after pill, or steroid injection.

It may well be that these medicines are currently recorded in a PDMS clinical notes area, or maybe even in a manual log, but neither mechanism has the same rapid electronic recall and audit mechanisms afforded to medicines that are prescribed.

If current practitioner practice for the monitoring of pharmaceutical samples is indeed deficient, what legislative obligations or professional body guidelines define what suitable practice should be?

A suitable starting point to an audit trail examining sample monitoring would be with pharmaceutical representatives. The distribution of samples from the pharmaceutical company to the medical practitioner, usually via pharmaceutical representatives, is encompassed in the requirements for a licence to hawk medicines. These requirements, which include a record of medicine description and numbers, are detailed under the Medicines Act 1981, the Medicines Regulations 1984, and the New Zealand Regulatory Guidelines for Medicines.

The Researched Medicines Industry (RMI) Code of Practice contains further monitoring requirements specifically relating to samples under Principle 11, as follows:

> 11.4.6 Medical representatives are required to record the issuing of any Sample/Starter Pack and gain a signature of receipt from the health professional receiving the Sample/Starter Packs3

The audit pathway for samples, from pharmaceutical representative to medical practitioner, would therefore seem to be well covered by legislation and an industry code of conduct.

What similar legislation and professional body guidelines exist then for the monitoring of samples dispensed from the medical practitioner to the patient ?

Correspondence with Medsafe, the regulatory body of the Ministry of Health responsible for pharmaceutical regulation, confirms that the legislative authority exists for practitioners to dispense sample medicines, but that record-keeping is not specifically covered in the legislation [personal communication with Bridget Naylor, Medicines Control Advisor Medsafe, 2004].[4]

Medsafe also points out that even though the relevant legislation, Medicines Act 1981 and the Medicines Regulations 1984, are mostly framed in terms of a person who 'supplies in circumstances corresponding to retail sale', that this still applies to practitioners giving patients samples. This is because under the Medicines Act 1981 Section 2 (c), supplying a sample is interpreted as 'to sell'.

From a sample perspective, these regulations could potentially require practitioners to meet very detailed and stringent labelling requirements under Regulation 13 of the Medicines Regulation Act 1984. This would include labelling with the name of the patient, the name and address of the seller, dose and frequency instructions, and one of the following statements *Caution: Not To Be Taken*, or *For External Use Only*. In practice, however, pharmaceutical companies are required to meet the labelling requirements of Regulation 13 before they are given a licence to distribute, and as long as the sample is not altered from its approved licensing format, Regulation 23 of the Medicines Regulation Act 1984 states that medical practitioners do not have to comply with Regulation 13.

Guidelines from professional bodies such as the Royal New Zealand College of General Practitioners (RNZCGP) also do not exist in the area of pharmaceutical management and monitoring. The RNZCGP is currently working on a standards based practice accreditation programme, with various key indicators and criterion detailed in the document *Aiming for Excellence*.[5] In that document, Indicator D.7.1 examines what an adequate medical record might display, and Indicator B.4.6 details authorised access to medications and pharmaceutical products, however the document does not deal with sample monitoring issues.

The opportunity to dispense samples may also arise in hospital settings, however most hospitals have sample policies requiring the involvement of hospital pharmacists, who in turn have professional body guidelines on sample management from the New Zealand Hospital Pharmacists Association (NZHPA). These guidelines provide for quite rigorous monitoring of samples (including protocols for accepting samples, labelling, and storage) and monitoring their distribution [personal communication with Bruce Hastie, Chairperson NZHPA].[6] In hospital settings then, for all intents and purposes samples are treated as prescribed medicines.

A review of the literature shows very little published international data examining dispensed pharmaceutical sample management and monitoring; and where it is reported, compliance seems to be a problem.[7] The protocols for pharmaceutical management in United States (US) hospitals are particular rigid, with one study suggesting that such standards could never be applied in the community:

> Full compliance with the JCAHO (Joint Commission on Accreditation of Healthcare Organizations) regulations for prescription drug samples may be practically impossible in a busy private practice; fortunately, these JCAHO drug sample standards only apply in a hospital environment[8]

In another US hospital study, compliance with dispensed sample protocols was only 10%; and even after an educational programme, compliance was still only 26%.[9] Drug samples were removed from the institutions involved in this particular study. In non-hospital settings in the US, the 'Society of Teachers of Family Medicine' have developed guidelines that specifically detail the recording requirements that should accompany samples dispensed by medical practitioners.[10] Again, however, compliance is a problem with one study describing how the designated pharmaceutical sign out sheet was 'frequently not used'.[11]

In New Zealand then, there are no clear guidelines either in legislation or professional body recommendations addressing pharmaceutical sample monitoring. This needs to be addressed, and the first step would seem to be recording in an identifiable manner, exactly what and to whom samples are given. An initial suggestion would be to treat a pharmaceutical sample the same as a prescription medicine, and to record dispensed samples in the patients formal electronic medications list, just as one would with any other unique electronically prescribed medicine.

However, several issues arise with this approach:

- Often samples are for newer medicines or formulations of medicines that are not on the current PDMS drug database, and updates are generally infrequent.
- PDMS based pharmaceutical cost and volume analysis becomes inaccurate if a PDMS is not able to differentiate between prescribed and dispensed medicines.
- There is a small, but cumulatively significant time resource involved in entering dispensed sample information.

One response to this would be for PDMS vendors to include a single default generic-type-sample medicine in their standard drug database—e.g. 'Pharmaceutical Sample'. Practitioners could then record this default medication in a patient's formal medication list when pharmaceutical samples are dispensed—*viz:* formally prescribe the default sample medicine.

A downside to generic default electronic coding of this type, is that data retrieval is of all patients assigned this code, and not just medicine specific retrieval. Another disadvantage in generic default coding is that drug interaction warnings would not be available.[12] These reservations aside, from the practical perspective of developing a simple (albeit broad) tracking mechanism for dispensed samples that incorporates software resource sustainability over time, prescribing a generic default sample medicine from a PDMS database would seem to have more advantages than disadvantages.

Standards New Zealand are currently at the stage of public consultation on a document that examines software standards for primary practice management systems (PPMS). Indeed, 13 Section 7.7.1 confirms the requirement for PPMS to be able to search on prescribed data for 'audit or for review of each patients prescribing history'. The management of dispensed samples is not considered or covered by this document, but would be if samples were prescribed as a default medicine in the format previously described.

In summary, the Vioxx recall has provided a timely review of the responsibilities associated with dispensing pharmaceutical samples. There is a clear expectation for practitioner involvement in pharmaceutical recalls. A software vendor solution towards the interface of these two activities has been presented. In the case of Vioxx, it is probably fortunate that the offending medicine appears to require regular use over a period of 18 months or more, and so is likely beyond the practical use of most sample volumes.

That aside, if this discussion was about thalidomide, then we might all have reasons to be even more urgently reviewing sample management and monitoring.

Author information: Shane Reti, Medical Practitioner and Researcher, Whangarei

Correspondence: Dr Shane Reti, 15 Rust Ave, Whangarei. Email: vioxx@selectpost.com

References:

1. Paterson R. Personal Communication. Health and Disability Commissioner, Private Bag, Wellington, 2004.
2. Fitzgerald G. Personal Communication. Franchise Group Manager, Merck Sharp & Dohme (NZ) Ltd, 109 Carlton Gore RD, Newmarket, Auckland, 2004.
3. RMI. Researched Medicines Industry Association of New Zealand Incorporation Code of Practice; 2003. Available online. URL: http://www.rmianz.co.nz/html/publications/publications-3-3.asp Accessed May 2005.
4. Naylor B. Personal Communication. Medicines Control Officer, Medsafe, PO Box 5013, Wellington, 2004.
5. RNZCGP. Aiming for Excellence: An Assessment Tool for General Practice. Royal New Zealand College of General Practitioners, Private Bag, Wellington, 2002.
6. NZHPA. New Zealand Hospital Pharmacists Association Statement on the Conduct of Pharmaceutical Industry Representatives in Hospitals; 1995.
7. Traska MR. Drug samples: tightening controls to support patient safety initiatives... part 1 of 2. PMA. 2001;34:16–20.
8. Coolidge MP. Drug samples: friend or foe? J Drugs Dermatol. 2002;1:49–52.
9. O'Young T, Hazlet TK. Removal of drug samples from two teaching institutions. Am J Health Syst Pharm. 2000;57:1179-80.
10. STFM (Society of Teachers of Family Medicine). Guidelines for the Residency Program Relationships with Pharmaceutical and other Proprietary Companies. Available online. URL: http://www.stfm.org/guidelines.html Accessed May 2005.
11. Westfall JM, McCabe J, Nicholas RA. Personal use of drug samples by physicians and office staff. JAMA. 1997;278:141–3.
12. Scott L. Controls sought on drug samples. Modern Healthcare. 1996;26:45.

13. SNZ. Standards New Zealand Primary Practice Management Systems: Publicly Available Specification PAS P8170. Wellington: Standards New Zealand; 2004.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Miscellaneous Notes

This extract comes from the New Zealand Medical Journal 1905, Volume 4 (14).

The *New Zealand Medical Journal* is the title of a high class quarterly published by the British Medical Association, New Zealand Branch. The editor is J. Malcolm Mason. The number before us contains several excellent original articles. The most striking characteristic of the journal is that extremely limited space has been given to advertisements – *Practical Medicine,* July, 1904.

An illiterate young man once got a friend to write a letter for him to his sweetheart. The letter was rather prosaic for a love letter, and he felt that an apology was due to his sweetheart for its lack of tenderness. It was as follows: "Please excuse the mildness of this here letter, as the chap wot's writin' it is a married man, an' he says he can't abide any soft-soaping – it allus gives him the spazzums."

At the Christchurch Hospital Board meeting on the 4th May it was decided to defer decision on a motion proposing the closing of the casualty ward at Lyttelton until it was ascertained what amount the shipping companies would be prepared to contribute to its maintenance. A committee was set up to consider the question of the establishment of consumptive sanatoria and to convene a conference of other Hospital Boards in the district to discuss the details. The Board decided to object to the proposal of the Justice Department to repeal the Christchurch Hospital Act of 1887, which vests the land on which the hospital stands in the Board. A proposal that members of registered friendly benefit societies in the hospital district should receive hospital treatment at half usual rates was rejected.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Proceedings of the 177th meeting of the Otago Medical School Research Society, 19 May 2005

A blinded randomised controlled trial of patch closure over the ligated sapheno-femoral junction to prevent varicose vein recurrence: preliminary results.

Mohammad Amer, I Thomson, R Pettigrew, S Packer, G Hill, R Christie, GT Jones, AM Van Rij. Department of Medical and Surgical Sciences, Dunedin School of Medicine, University of Otago, Dunedin.

Neovascular regrowth of the sapheno-femoral junction (SFJ) is a known contributor to recurrence of varicose veins following surgery. Mechanical prevention of such regrowth using a physical barrier placed over the ligated SFJ has therefore been proposed. This study is the first blinded, randomised controlled trial to investigate the efficacy of such a technique.

Three hundred and five patients were randomised independently to receive standard surgery with or without the insertion of a secured PTFE (polytetrafluoruethylene) patch over the ligated SFJ stump. Preoperative investigations (duplex venous scanning, air plethysmography (venous function), clinical scoring and patient self assessment) were repeated postoperatively at 1 month to ensure surgery was adequate, and at 6, 12 and 36 months to determine recurrence. Patients and assessors were blinded to study group throughout. Neoreflux (on duplex scanning) at the previously confirmed obliterated SFJ was the primary endpoint, and constituted the definition of recurrence.

A total of four hundred and eight limbs were included. The PTFE patch reduced recurrence rates significantly at 6 months and 1 year, with cumulative recurrence rates of 7% and 18% respectively (cf. 22% and 38% in the no patch group; $P = 0.0003$ (chi-squared)). This trend persisted at 3 years, with 35% of participants assessed at this time point thus far. Results also show the patch is most effective in reducing recurrence in more severe disease (12% recurrence in limbs with a past or present ulcer at 1 year, vs. 45% in the no patch arm for the same sub-group; $P = 0.0001$).

These results show that placing a PTFE patch over the ligated SFJ stump significantly reduces the rate of neoreflux, probably by mechanically inhibiting neovascularisation. The PTFE patch is most effective in cases of severe disease. Use of a PTFE patch is therefore a useful adjunct to varicose vein surgery.

Supported by a grant from the Health Research Council of New Zealand and a Summer Studentship funded by the Surgery Department, Dunedin School of Medicine.

Lipoprotein (a) : A risk factor for stroke?

Jean-ha Baek, G Jones, M Deng, A van Rij, G Hammond-Tooke, J Cole, S Cleveland, S McCormick. Department of Medical and Surgical Sciences, Department of Biochemistry, Otago School of Medical Sciences, University of Otago, Dunedin.

Stroke is a common cause of mortality and long term disability. Apart from the well established risk factors for stroke such as age, hypertension and diabetes, lipoprotein

(a) (Lp(a)) is emerging as a "newer" risk factor for stroke. Lp(a) consists of a low density lipoprotein (LDL), which is covalently attached to the plasminogen-like protein, apolipoprotein(a) (apo(a)). Several studies have shown that Lp(a) levels are elevated in stroke patients. Elevated Lp(a) levels are commonly associated with small apo(a) isoforms. The aim of this study is to examine the level of Lp(a) in stroke patients and to determine if there is a specific size of apo(a) that is associated with stroke.

Two hundred and thirteen samples were obtained from patients enrolled in the Otago Vascular Disease Study who showed clinical evidence of stroke. The average plasma Lp(a) level from the stroke group was significantly higher than controls (63.3 vs 47.1 nmol/L, $P < 0.05$) and was consistent with that observed in other vascular disease populations. The Lp(a) level of the cardioembolic subgroup of stroke patients was significantly higher compared to controls (76.0 vs 47.1 nmol/L, $P < 0.04$). Although large vessel-related stroke patients had slightly higher Lp(a) level than small vessel-related stroke patients (63.0 vs 52.3 nmol/L) both were not significantly different from controls. Determination of all apo(a) isoform sizes could not be completed due to the short experimental period, however results from those that were analysed showed a diverse range of apo(a) isoform sizes. In addition, some subjects with a low Lp(a) level presented no Lp(a) gene.

From the current study, it seems that Lp(a) is a risk factor for stroke. As stroke poses a tremendous burden on health resources throughout the world, improved detection and modification of risk factors such as Lp(a) could reduce the impact of this disease.

Summer Studentship funded by the National Heart Foundation.

Expression of a key regulatory protein in clinical isolates of *Pseudomonas aeruginosa.* Catherine Bear, IL Lamont. Department of Biochemistry, Otago School of Medical Sciences, University of Otago, Dunedin.

Pseudomonas aeruginosa is a Gram-negative bacterium that can infect immuno-compromised individuals and cystic fibrosis patients. Crucial to this pathogenicity is the ability of *P. aeruginosa* to obtain iron by secreting the iron-scavenging compound pyoverdine. The expression of all pyoverdine synthesis genes depends upon the presence of a transcription factor PvdS. The expression of the gene encoding this pivotal protein was previously investigated in a laboratory strain of *P. aeruginosa*. In this strain, *pvdS* expression increased while the bacteria were actively growing and leveled off as the bacterial growth neared maximum. The present study aimed to examine *pvdS* expression in clinical isolates of *P. aeruginosa,* and compare these with each other and the laboratory strain.

Eleven isolates of *P. aeruginosa* obtained from separate infected individuals were engineered to have the *pvdS* promoter fused to a luciferase reporter gene within their chromosome. When the *pvdS* promoter was active i.e. the bacteria were synthesising pyoverdine, the luciferase genes were expressed, resulting in bioluminescence. Bioluminescence, bacterial growth and pyoverdine production were measured.

Most isolates had similar gene expression patterns to the laboratory strain, and the amount of pyoverdine produced was about the same for the majority of isolates. However some differences in the quantity and timing of *pvdS* gene expression were

observed. Two strains expressed *pvdS* at a level approximately three times higher than the laboratory strain. Two strains did not down-regulate *pvdS* expression when the bacteria stopped growing. One strain that was unable to synthesis pyoverdine had an extremely low level of *pvdS* expression that occurred very late in growth. The variations observed likely reflect differences in gene regulation amongst individual clinical isolates. The conservation of gene expression across infectious strains reinforces the importance of PvdS during bacterial growth and infection.

Funding for this research was supplied by the Otago Medical Research Foundation.

Finding a genetic susceptibility for panic: a candidate gene approach.
Charmaine Chan, M Lill, A Fitches, RJ Olds. Department of Pathology, Dunedin School of Medicine, University of Otago, Dunedin.

Cholecystokinin (*CCK*) is a neurotransmitter in the central nervous system, as well as a peptide hormone in the gut. We have previously found that the -36T allele of a single nucleotide polymorphism (SNP) in the *CCK* gene is associated with panic symptoms in families with bipolar affective disorder (BPAD). In the current study, we aimed to clarify if it was the -36T *CCK* allele, or a nearby allele, that was responsible for the susceptibility to panic.

A subset of SNPs (tag SNPs) around CCK, accounting for most genetic variation of the locus, were identified by analysing data obtained from the International HapMap Project using Haploview software. Genotyping assays were then designed for each tag SNP identified. Allele-specific PCR amplifications were carried out on the DNA of seven individuals identified in the previous study, each of whom was homozygous for the -36T *CCK* allele.

Haploview displayed seven tag SNPs within 40 kb of *CCK*. Analysis of genotypes derived from each of these seven tag SNPs did not reveal a common haplotype among the seven individuals genotyped. This suggests that the -36T allele is not contained within a block of strong linkage disequilibrium. This is consistent with the analysis from Haploview. In the absence of a common haplotype, our results suggest that it might be the -36T allele itself that confers susceptibility to panic disorder in families with BPAD, rather than the allele being in linkage disequilibrium with another susceptibility allele elsewhere in the vicinity of the *CCK* locus.

Further work will seek to confirm the association in independently ascertained populations of patients, and to determine if the allele has a functional effect on *CCK* expression. The latter work would involve reporter gene studies, allowing a comparison of transcriptional control in neural cell lines.

Supported by a summer scholarship from the Dunedin School of Medicine.

Gene expression profiling of Wilms tumours with chromosomal abnormalities.
Thomas Clendon, R Heathcott, A Reeve, A Dunbier. Cancer Genetics Laboratory, Department of Biochemistry, Otago School of Medical Sciences, University of Otago, Dunedin.

Wilms tumour is an embryonic kidney tumour that has been used to identify genetic abnormalities in tumorigenesis. The frequency of trisomy 12, trisomy 7, and 16q LOH

in Wilms tumours suggests that these events increase the tumorigenic potential of cancer cells. The present study sought to analyse and confirm previously obtained microarray data which suggested that there was an over-expression of cellular proliferation genes in tumours with trisomy 12.

To investigate the genetic profile of Wilms tumour, cDNA microarray analysis was used to measure the expression levels of 6017 genes in 42 Wilms tumours. These results indicate that there is significant differential expression of 73 genes in tumours with trisomy 12 relative to tumours without trisomy 12 ($P < 0.005$, n = 42, two-tailed t-test). Real time quantitative PCR was used to analyse expression levels of four of these differentially expressed genes; minichromosome maintenance protein 3 (*MCM3*), cyclin dependent kinase 4 (*CDK4*), replication factor C 5 (*RFC5*), and Integrin Alpha E precursor (*ITGAE*), in tumours with and without trisomy 12. These genes were selected for a combination of high significance values and a functional interest; *MCM3*, *CDK4*, and *RFC5* all have roles in cellular proliferation. *MCM3*, *CDK4*, and *RFC5* were all differentially expressed ($P < 0.0008$, $P < 0.007$, and $P < 0.0002$, n = 60, two-tailed t-test), while *ITGAE* expression was not significant ($P = 0.44$).

Our findings suggest that Wilms tumours with a trisomy of chromosome 12 have increased expression levels of some genes involved in cellular proliferation, which may confer a proliferative advantage over other cells. This could provide a selective benefit which accounts for the relatively high frequency of trisomy 12 amongst Wilms tumours.

Supported by the Functional Genomics, Gene Expression, and Proteomics Theme Summer Studentship and the Health Research Council of New Zealand.

Characterisation of the expression of karyopherin alpha-1 and alpha-2 in gonadotropin-releasing hormone neurons. Deborah Friberg, C Jasoni, A Herbison. Department of Physiology, Otago School of Medical Sciences, University of Otago, Dunedin.

The gonadotropin-releasing hormone (GnRH) neurons are the critical neuronal cell type regulating reproduction. Pulsatile secretion of GnRH is gender-specific and controls the secretion of pituitary reproductive hormones. Previous DNA microarray analysis of GnRH neurons identified karyopherin alpha 2 (Kpna2) as one of the molecules expressed only by GnRH neurons in females. Karyopherins function in dendrite-to-nucleus signalling, a mechanism recently appreciated to be involved in plasticity and which may play a role in oestrous cycle-dependent changes in female GnRH neuron output.

In situ hybridisation and immunocytochemistry were used to characterise the expression of Kpna2 and the related karyopherin alpha-1 (Kpna1) in GnRH neurons of the female C57BL6/J mouse. Single-label radioactive *in situ* hybridisation (n = 3 animals) for Kpna2 mRNA revealed heavily labelled cells in the rostral migratory stream and positive, but lightly labelled, cells in the medial septum and cerebral cortex (grain counts at least 2.5 times above background). Single-label immunocytochemistry (ICC) for Kpna2 produced a similar distribution pattern (n = 3 animals). The finding of similar labelling patterns between these two techniques indicated that there was a good correlation between mRNA and protein levels and

confirmed that the antibody used in these studies was specific for Kpna2. Double-label chromagen ICC for GnRH and Kpna2 provided preliminary evidence of co-expression of the molecules in a subpopulation of GnRH neurons (n = 3 animals). Double-label fluorescent ICC for the two molecules revealed clear co-expression in a sub-population of GnRH neurons (n = 4 animals). By contrast, there was no evidence that Kpna1 was located within GnRH neurons (n = 8 animals).

These results suggest that Kpna2 is expressed by a subpopulation of GnRH neurons of the female, where it may be part of the signalling mechanism used to generate cyclical patterns of activity across the oestrous cycle.

Supported by a summer research scholarship from the Otago Medical Research Foundation.

Dietary fibre in conservative management of faecal incontinence in adults; a randomised double-blind cross-over trial. Mel Lauti, M Thompson-Fawcett, D Scott. Department of Surgery, Dunedin School of Medicine, University of Otago, Dunedin.

Faecal incontinence affects >1% of the healthy adult population and significantly impairs quality-of-life. Most patients are managed medically with a constipating agent, which is often prescribed concurrently with either fibre supplementation or low-residue diet. Clinician opinion is divided as to which regime is best and there are no randomised trials comparing these treatments. The aim of this study was to compare the effectiveness of these treatments for faecal incontinence in routine clinical practice.

Patients referred to a colorectal surgeon for incontinence to mucus, liquid or stool were randomised in a cross over design to six weeks of loperamide with promotion of a low residue-diet then crossed over to six weeks of loperamide with fibre supplementation, or alternatively randomised to treatment in the reverse order. The primary outcome measured was the Faecal Incontinence Severity Index (FISI), a patient based symptom severity score. Secondary outcomes included generic (SF-36) and condition-specific (FIQL) quality-of-life measures. The treatments were compared using paired t-tests.

Over three years, 63 patients consented to participation and were randomised, 31 to low-residue diet first and 32 to fibre supplementation first. Patients had a mean age of 59±15 years, 57 (90%) were female. Fifty-nine (94%) participants completed questionnaires at baseline, 49 (78%) at six weeks and 49 (78%) at twelve weeks. Forty-seven participants completed questionnaires after both treatments. After treatment the mean (s.d) FISI was improved over the untreated baseline of 31.2 (10.3), and was 18.4 (13.8) for the low residue diet and similar at 18.8 (14.1) for fibre supplementation (mean difference between the two treatments, -0.8, 95%CI -4.9 – 3.3, *P=0.79)*. Similarly there was no statistically significant difference for any secondary outcomes.

This study provides good evidence that loperamide with either low-residue diet or fibre supplementation has similar clinical effectiveness for the treatment of faecal incontinence, at least in the short-term. Further studies are required to confirm this finding and to determine long-term effectiveness.

The Otago Medical Research Foundation and Dunedin School of Medicine and Otago School of Medical Sciences provided funding for a summer studentship. Research funded by a University of Otago Research Grant.

Clinical characteristics of a Dunedin rheumatoid arthritis cohort. Andrea McDonald, J Highton[1], T Merriman[2], V Markham. Department of Medical and Surgical Sciences[1], Dunedin School of Medicine, Department of Biochemistry[2], Otago School of Medical Sciences, University of Otago, Dunedin.

This study was designed to clinically characterise 279 Otago/Southland patients with rheumatoid arthritis (RA) and compare them to a 1981 Dunedin cohort of 110 consecutive outpatients. We expected to find fewer patients with poor prognostic indicators because of improvements in treatment.

Patients had previously been recruited through Dunedin (n = 256) or Invercargill (n = 23) hospital outpatient appointments as part of several previous studies. Additional information on each patient was collected from hospital notes, hospital database, laboratory enquiries and phone interviews.

Compared to 1981, the current cohort of patients had disease of longer duration (mean 17.4 vs. 10.2 years) and they were older (62 vs. 57 years). Using chi square analysis it was found that, compared to the 1981 cohort, there were significantly more patients with a positive rheumatoid factor (94% vs. 85%, $P = 0.005$), rheumatoid nodules (57% vs. 28%, $P < 0.001$) and bone erosions (95% vs. 84%, $P < 0.001$). More were being treated with disease modifying anti-rheumatic drugs (DMARDs) (89% vs. 53%, $P < 0.001$), and prednisone (43% vs. 3%, $P < 0.001$). Of the patients currently taking methotrexate 63% had nodules compared to 48% not on methotrexate ($P = 0.016$). Smoking prevalence at disease onset was more than the national average and was higher in rheumatoid factor positive patients (58% vs. 25%, $P = 0.028$).

Although patients are now taking more DMARDs, the proportion with nodules, erosions and seropositive RA is more than the 1981 cohort and recent overseas studies. This is contrary to expectations and suggests that current outpatient therapy is focussed on patients with more severe disease. The data on smoking are consistent with the proposition that smoking is a factor predisposing to RA, and in particular seropositive RA.

The financial support of the Otago Medical Research Foundation is gratefully acknowledged.

Construction of *E. coli* expression clones from *Wilms Tumour 1* cDNA mammalian vectors for DNA binding studies. Poh Ooi, RD Fagerlund, SM Wilbanks. Department of Biochemistry, Otago School of Medical Sciences, University of Otago, Dunedin

Located on human chromosome 11, the Wilms tumour 1 gene (*WT1*) plays a critical role in both organ-specific differentiation and cancer development. Encoding a transcription factor, the *WT1* transcript undergoes alternative splicing to generate four different isoforms. The WT1 protein is able to activate or repress transcription of its target genes by differential DNA-binding, of which the specific mechanisms remain unknown. This study aims to generate *E. coli* expression clones of three isoforms so as to further investigate WT1's DNA-binding properties.

DNA sequences of three isoforms (WT1(+,+), WT1(-,+) and WT1(-,-)) were amplified from cDNA clones and cloned into the Gateway® "entry vector", pENTRII, which contains λ recombination sites. From the entry vector, the gene can be moved via site-specific λ recombination reactions to any "destination vector" containing appropriate recombination sites.

The *E. coli* expression vector, pET21d+, was converted into a Gateway® destination vector via restriction digestion, followed by blunt-end ligation with a Gateway® cassette containing the necessary recombination sites. The plasmid pET21d+ encodes a C-terminal His-Tag which can facilitate subsequent purification of soluble WT1 using affinity columns. Via site-specific λ recombination reaction, *WT1* was transferred from the entry clone to the destination vector , generating a *WT1* expression clone.

Putative clones were subjected to screening by restriction digestion. Of the putative entry clones, WT1(-,+) gave 4 positive clones out of 6, while WT1(+,+) and WT1(-,-) gave 1/5 and 3/7 positive clones respectively. Further verification of the clones was done via DNA sequencing. Two expression clones from each of the isoforms were analysed, and all displayed expected restriction digestion profiles, revealing that *E. coli* expression clones have been successfully generated for all the isoforms.

With the successful construction of the expression clones, functional protein expression can now be carried out and the binding mechanism of the various isoforms further characterised.

Supported by a grant from the Child Health Research Foundation.

Milling causes a solid state transformation of ranitidine hydrochloride. MV Talekar, DJ Saville, T Rades. School of Pharmacy, University of Otago, Dunedin.

The solid state of a drug, when presented in a dosage form may influence its release, absorption and plasma levels and therefore may affect the therapeutic response. Particle size reduction, formulation and stabilisation of an amorphous drug (without crystal structure) and/or production of a particular crystal form (polymorph) of a drug may all occur during preformulation and potentially in the manufacturing process.

The present study investigated the effect of milling on the solid state properties of the H2-antagonist ranitidine hydrochloride, a drug that can exist in two polymorphic forms, and describes techniques by which solid state changes can be monitored.

Ranitidine hydrochloride polymorph form 1 (1 g samples) were milled in a small vibrational mill for periods of up to 10 h. Samples were independently milled for each time point. Powders were recovered and evaluated using X-ray powder diffraction (XRPD), differential scanning calorimetry (DSC), diffuse reflectance infra-red spectroscopy (DRIFTS) and scanning electron microscopy (SEM). In the first two hours upon milling an increase in the content of amorphous drug was observed by XRPD. With increasing time, form 1 disappeared and form 2 appeared, with the amorphous content decreasing. Substantial transformation of form 1 to form 2 had occurred after five hours. DRIFTS and DSC provided supporting evidence for this transformation, while SEM showed some particle size reduction. The transformation

from the meta-stable form 1 to the stable form 2 thus appeared to occur via an amorphous state.

The current study showed that milling can cause polymorph transformation. Since milling is a part of the manufacturing process, pharmaceutical scientists should take this into account.

Summer studentship supported by a grant from the Formulation and Delivery of Bioactives Research Theme.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Damp Digits

A 68-year-old male had a motor vehicle accident and abandoned his car. He was located confused after enduring two nights in the bush.

On examination, he was noted to have black toes. (Figure 1 and Figure 2).

Figure 1. Right foot

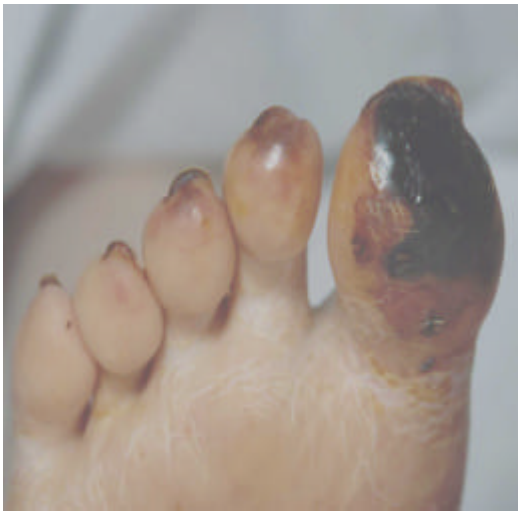
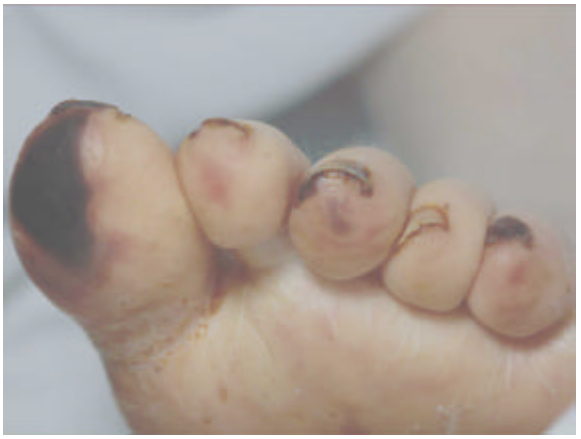


Figure 2. Left foot



Questions

What is the diagnosis and how does this disorder differ from frostbite? (see the answers on the next page)

Answers

The diagnosis is *trench foot*, a condition associated with exposure to moisture (but not immersion) and cold, resulting in erythrocyte extravasation and necrosis.

It differs from frostbite, as trench foot does not involve freezing of the tissues and therefore can occur in supra zero temperatures. The maximum temperature it will occur at is unknown.

Author information: Ben Wilkinson, Radiology Registrar, Department of Radiology, Christchurch Hospital, Christchurch

Correspondence: Dr Ben Wilkinson, Department of Radiology, Christchurch Hospital, PO Box 4710, Christchurch. Fax: (03) 364 0620; email: BenW1@cdhb.govt.nz

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Brave new world

Should parents be allowed to use preimplantation genetic diagnosis to choose the sex of their children to "balance" their families? A 10 member committee of the British House of Commons was split 50–50 on this matter. If they want a casting vote they can have mine—NO.

And the BMA's view? Michael Wilkes, chairman of the BMA's ethics committee said: "We are particularly opposed to proposals which would allow parents to select the gender of their children for social reasons."

BMJ 2005;330:745

The value of physical signs

Accuracy in history-taking and physical examination are the keystones of medical diagnosis. In a very interesting recent paper the reliability of physical signs have been evaluated.

And the key positive points are:

- Do try to elicit hepatojugular reflux. It is a useful sign of cardiac failure when other signs may be equivocal.
- Do listen for an S3 to confirm your suspicion of cardiac failure.
- Do ventilatory manoeuvres (such as held inspiration and expiration) to confirm your suspicions about the nature of cardiac murmurs.
- Do percuss the splenic bed before palpating for the splenomegaly.
- Do be reasonably confident that a patient with a positive Murphy's sign has cholecystitis.
- Do count the respiratory rate carefully because clinicians often disagree about tachypneoa.

And Methuselah would add:

- Do take the blood pressure yourself—don't delegate it to someone else.
- And do take it lying and standing if there is the slightest hint of postural hypotension.

Internal Medicine Journal 2005;35:178–87

The advance of electronic technology

Apparently there are 85 million mobile phone owners in Japan. Not content with using mobile phones to text and email, play games, take photographs, shop and check the news and weather, Japanese youngsters now have another reason to stay glued to their handsets: full-length novels. Hundreds of titles are on offer on subscription

websites, with new releases appearing every month. Traditionalist bookworms may be appalled, not to mention a little dizzy, at the thought of reading a classic novel on a tiny screen, but devotees of the medium say it is a habit that is easily acquired.

Not by me! Would Alexander Graham Bell be pleased?

Guardian Weekly, 29 April–5 May 2005. p21

Venous thromboembolism after hip and knee replacement surgery

Deep-vein thrombosis (DVT) and pulmonary embolism (PE) are significant complications of total knee replacement (TKR) and total hip replacement (THR) surgery. In a recent Australian study, 5999 such patients underwent ultrasonography of both legs before discharge from hospital. All patients had received prophylactic compression elastic stockings or intermittent pneumatic compression of their legs and chemical prophylaxis (anticoagulant) against VTE. In spite of these measures, subclinical deep vein thrombosis (DVT) was detected in 9%, 26% and 37% of patients after hip, knee or bilateral knee replacement, respectively.

In an editorial commentary it was noted that hospital prophylaxis alone is not enough. Many would argue that extended prophylaxis is likely to be the simplest, cheapest and perhaps safest solution. Indeed, the American College of Chest Physicians now recommends at least 10 days prophylaxis after major joint surgery, extending to 28-35 days after hip arthroplasty or hip fracture.

Sounds like a good idea.

Med J Aust 2005;182:154–9 and 149–50

Personal Digital Assistant (PDA)

Old timers like Methuselah used to wonder what PDA meant. Finding out what the acronym stood for caused speculation about possible surgical procedures. However, we now know that a PDA is a small portable computer.

PDAs come in many forms, with a variety of capabilities, but all share some basic characteristics: they are small and lightweight; have small, touch sensitive screens; and run a variety of software, including personal organizers (phone and appointment books), electronic references (ranging from “cheat sheets” to textbooks), and data collection forms.

Rapid access to prescribing information probably represents the single most visible and widespread effect of PDAs on health care today. Apparently 25% of US physicians were using them in their practice in 2003, and Methuselah has been told that about 40% of the junior doctors in his hospital are so equipped.

How to cope? Buy a PDA—no make sure your junior colleagues have one.

N Engl J Med 2005;352:860–2.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Regarding 'Is PHARMAC's sole-supply tendering policy harming the health of New Zealanders?' editorial

I was surprised to read an editorial written by Pippa MacKay (Chair of the Research Medicines Industry [RMI] Association) that appeared in the 5 May 2005 issue of the New Zealand Medical Journal (http://www.nzma.org.nz/journal/118-1214/1433). The relationship between the pharmaceutical industry and the medical profession is a minefield of conflict of interest. That is why there are codes of conduct around receipt of inducements from companies by doctors, and why editors of reputable journals require information from authors of research papers on whether they have any commercial relationship with organisations that might create conflict of interest.

By accepting the Chair of the RMI as an editorial contributor you are aligning the NZMA's position with the RMI. I cannot see how this is acceptable, and in my view undermines the credibility of the NZMJ as an independent reputable professional journal.

Dr Ben Gray
Wellington

NZMJ response: pharmaceutical industry and medical publishing

The relationship between the pharmaceutical industry and medical publishing industry has been an area of conflict, contractions, and self interest (by both groups). The NZMJ in the last 3 years has not published (as far as I am aware) any pharmaceutical industry adverts. Rather, the NZMJ has published a considerable amount on the effects of such advertising and its influence on doctors (see articles in this issue), and there is more to come.

As the author of the above letter correctly states, the relationship between the pharmaceutical industry and medical profession in general is a minefield of conflict of interest. That is why, as he states, there are codes of conduct around receipt of inducements from companies by doctors, and why editors of reputable journals require information from authors of research papers on whether they have any commercial relationship with organisations that might create conflict of interest.

It is clearly stated in Pippa MacKay's editorial (which is of concern to the letter writer) what her professional role is, and thus it is a clear declaration of potential conflict of interest. If the conflict of interest is unclear, then we have a separate potential conflict of interest statement included; however, in this case, the potential for conflict of interest is so clear, and the statement of the professional role of the author appears quite adequate.

Frank A Frizelle
Editor, NZMJ
Christchurch

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Low back pain and occupation: a response to the article by McBride et al

The study by McBride et al[1] (based on a cohort of nearly a 1000 young adults aged 26) presents a cross-sectional picture of their experience of low back pain (LBP) over the previous 12 months. Their findings are entirely consistent with the data on the epidemiology of LBP in the industrialised world. Although *acute* LBP is normal (in that over 50% of the cohort reported LBP over the 12 months—most commonly 3 or more times), only 1 individual of those 969 was *chronically disabled* by LBP (being unable to work for most of the year). And they found that LBP was unrelated to occupation: McBride et al report a similar proportion of individuals with LBP in the employed as in the non-employed group; and, of those currently working, "there was no difference in the distribution" of LBP between different types of work. They found that LBP has major economic and other costs to the individual and society.

In view of these quite predictable findings, it is surprising that McBride et al then ignore their own findings (that occupation was not related to LBP), and the rest of the large body of international epidemiology on LBP, to discuss the role of occupation in LBP! There are several important errors in their discussion of the role of biomechanical factors in LBP:

McBride et al refer to an article[2] listing various "pain generators" in the low back, including the disc, facet joint, sacroiliac joint, and soft tissue. But they do not make the fundamental distinction between acute and chronic LBP. In *acute* LBP, we simply do not know the anatomical origin of the pain in general, let alone in the individual patient. There are no clinical features, or clinically available investigations, to enable the tissue generating the pain to be identified.

But in *chronic* LBP there is more data: it has been shown that the disc is responsible for about 40% of chronic low back pain; the sacroiliac joint for about 20% (this applies only to patients with chronic LBP below the lumbosacral junction, but not more proximal LBP); and the facet joint for 40% of the elderly with chronic LBP, but only about 10–15% of younger injured workers.[3] There are no grounds for "assuming" that the remaining 40–50% of chronic LBP in working age adults is due to "soft tissue injuries or a combination of pathologies".

On the contrary, such chronic non-specific LBP (ie without any identifiable source of nociception) is probably due to a central neural sensitisation disorder,[4] as occurs in other chronic musculoskeletal pain syndromes, whether or not they follow trauma.[5]

It is even more important to correct the unfounded and harmful concept of what McBride et al refer to as the "cumulative trauma model" of LBP. Having correctly stated that "our data do not support any clear association between occupation and risk", the authors immediately—and inexplicably—add "occupational factors are important"! Because psychosocial factors have been well shown to be crucial in the development and persistence of chronic LBP disability, outweighing the explanatory significance of biomedical factors in spinal pain,[6] it is important to be aware of the evidence from the published studies on the relationship between occupation and low

back pain: if popular belief can be aligned with the evidence, it will help allay unfounded (and harmful) beliefs amongst the workforce, patients, society at large including news media and the legal system, and healthcare professionals.

McBride et al refer to a review[7] that does indeed provide good evidence for a relationship between low back pain, and physical factors at work. Several later published reviews have, not surprisingly, reached the same conclusion.[8,9] All 3 reviews report strong evidence for an association between physical demands at work, and reports of low back symptoms.

However, there is a trap here for the unwary. It is important not to confuse "strong evidence of association" (which there is in this case), with "evidence of strong association" (which there is not).

The Faculty of Occupational Medicine Review[9] looked not only at the strength of the evidence of the association between work and LBP, but also at the strength of the association: how strongly do physical factors at work predict the experience of LBP? They found that physical demands of work were a risk factor for the onset of LBP, but that the size of this effect was less than that of other individual, non-occupational, and unidentified factors.

Even more importantly, their review found strong epidemiological and clinical evidence that disability due to LBP was more strongly related to complex individual and work-related psychosocial factors than to clinical features or the physical demands of work. They found only limited and contradictory evidence that the length of exposure to physical stressors at work (i.e. cumulative risk) increases reports of back symptoms or of persistent symptoms. So there is no solid evidence to support the idea that chronic LBP disability can be explained by a "cumulative trauma model".

This epidemiology is therefore consistent with the *findings* of McBride et al, that work is not strongly related to LBP; but this evidence is at odds with McBride et al's subsequent *speculations* on this. Their statement that "occupational factors are important in low back pain" thus needs to be qualified: physical factors at work have been well shown to be related, although not strongly, to the initial onset of LBP; but when LBP becomes chronic and disabling, psychosocial factors (both individual and work-related) have been shown to be far more important than physical exposures at work.

It is this evidence, as opposed to speculation, that underlies the modern approach to the management of acute non-specific low back pain, which involves normalising and demedicalising the common experience of acute low back pain, and maintaining or returning as quickly as possible to normal function.

But, without any supportive evidence, McBride et al challenge this internationally accepted and well-founded approach:[10] McBride et al believe there is "a danger" if we "ignore the biomechanical model" of LBP. On the contrary, there are well-established significant dangers in the biomechanical model. The evidence shows that, although there is some truth in the biomedical model of LBP, it is not a major factor even in explaining the onset of acute LBP. Even more importantly, the evidence does not show that the "the biomechanical model" is related to chronic low back pain and disability. Instead, the data[6] shows that psychosocial factors, including prolonged time off work, and fear of returning to work, result in a higher risk of subsequent chronic

pain and work disability. Thus, although McBride et al suggest paying attention to the neglected "biomechanical model", doing so may do more harm than good, ie to cause more chronic low back pain and disability, by encouraging time off work, and fear of returning to work.

To avoid causing harm, it is important to base management on the evidence, as the international guidelines on the management of acute LBP do; it is important not to base management on unproven hypotheses, especially when these hypotheses are wrong and have harmful effects.

McBride et al ask whether the high rate of LBP they found in their group of young adults "might therefore be viewed as a source of concern". To avoid causing undue concern, it is worth placing their results in the context of LBP internationally.

A recent review[11] concluded that most international studies of adult back pain report a point prevalence of 15–30%, a 1-month prevalence of 19–43%, and a lifetime prevalence of 60–70%. Similar prevalence rates seem to occur in native populations.[12] As discussed by Waddell,[10] LBP is ubiquitous across the world, and there is no evidence that the rate is increasing. The problematic epidemic that afflicted, but was restricted to, the industrialised west over the second half of the 20th century, was not of the *incidence* of LBP; it was of a dramatic increase in *chronic LBP and disability*, which occurred despite increasing mechanisation and decreasing physical loads at work, and can be explained by psychosocial factors in the western world over this time, rather than by biomechanical factors.

A World Health Organization survey[13] found that 22–25% of 15-year-old Europeans reported weekly backache. A 3-year prospective study of Norwegian adolescents[14] found that 58% reported LBP at baseline (aged 14.7 years), and 39% at follow-up 3 years later; 31% reported LBP on both occasions. LBP lasting more than 7 days was reported by 32% at baseline, 26% at follow-up, and by 18% on both occasions. In the context of this international data, McBride et al's findings should not cause any alarm.

The other crucial point is that the problem of LBP is not so much the high incidence of acute LBP; this would not be a significant problem were it not for that very small proportion of those with acute LBP who go on to develop chronic LBP with disability. And, rather than being grounds for concern, the findings of McBride et al are reassuring on this point, and again consistent with the international data: they found that only 1 out of nearly a 1000 of these 26 year olds "was chronically disabled by back pain and unable to work for most of the year".

The main strength of the paper by McBride et al is that it provides a snapshot of the problem of LBP amongst young New Zealand adults, showing that it is consistent with the data internationally. Even better is their statement that, using the large amount of data from this birth cohort, they will be able to search prospectively for risk factors for their cohort's experience of LBP. This may turn up new risk factors, as yet unidentified.

In particular, it would be interesting if the Dunedin Multidisciplinary Health and Development Study team were to look at whether there is a similar functional polymorphism in the promoter region of the serotonin transporter gene which has been identified in women with fibromyalgia,[15] in the Dunedin subjects with chronic

musculoskeletal pain, such as chronic LBP or chronic widespread pain and abnormal pain sensitivity—i.e. fibromyalgia.

Dr John Alchin
Pain Management Centre, Burwood Hospital
Christchurch

References:

1. McBride D, Begg D, Herbison P, Buckingham K. Low back pain in young New Zealanders. N Z Med J. 2004;117(1203). URL: http://www.nzma.org.nz/journal/117-1203/1099
2. Shelerud R. Epidemiology of occupational back pain. Occup Med. 1998;13:1–22.
3. Adams M, Bogduk N, Burton K, Dolan P. The biomechanics of back pain. Churchill Livingstone; 2002.
4. Doubell TP, Mannion RJ, Wolfe CJ. The Dorsal Horn: State-dependent sensory processing, plasticity and the generation of pain. In: Wall P.D, Melzack R, editors. Textbook of Pain. 4th edn. Churchill Livingstone; 1999, Chapter 6, p165–81.
5. Banic B, Petersen-Felix S, Andersen OA, et al. Evidence for spinal cord hypersensitivity in chronic pain after whiplash injury and in fibromyalgia. Pain. 2004;107:7–15.
6. Linton SJ. A review of psychological risk factors in back and neck pain. Spine. 2000;25;1148–56.
7. Bernard BP. Musculoskeletal disorders and workplace factors. Cincinnati, Ohio: National Institute for Occupational Safety and Health; 1997, Chapter 6, p1–96 (Report No. 97–141).
8. Hoogendoorn WE, van Poppel MN, Bongers PM, et al. Physical load during work and leisure time as risk factors for back pain. Scand J Work Environ Health. 1999;25:387–403.
9. Waddell G, Burton AK. Occupational health guidelines for the management of low back pain at work – evidence review. London: Faculty of Occupational Medicine; 2000.
10. Waddell G. The Back Pain Revolution. Edinburgh: Churchill Livingstone; 2nd edition; 2004.
11. Nachemson AL, Waddell G, Norlund AI. Epidemiology of neck and low back pain. In: Nachemson AL, Jonsson E. (eds). Neck and back pain: the scientific evidence of causes, diagnosis and treatment. Philadelphia: Lippincott, Williams and Wilkins; 2000, p165–88.
12. Honeyman PT, Jacobs EA. Effects of culture on back pain in Australia aboriginals. Spine. 1996;21:841–43.
13. Currie C, Hurrelmann K, Settertobulte W, et al. Health and health behaviour among young people. Copenhagen: WHO; 2002.
14. Sjolie AN. Persistence and change in non-specific low back pain among adolescents. Spine. 2004;29:2452–57.
15. Offenbaecher M, Bondy B, de Jonge S. Possible association of fibromyalgia with a polymorphism in the serotonin transporter gene regulatory region. Arthritis Rheum. 1999;42:2482–88.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Response to 'Exceptional circumstances and heart transplantation' letter

Dr Arthur Coverdale has suggested in his letter *Exceptional circumstances and heart transplantation* (NZMJ. 2005;118(1209). URL: http://www.nzma.org.nz/journal/118-1209/1290) that both mycophenolate and sirolimus are "first-line" standard treatments for heart transplantation.

Although applications for subsidy for these treatments were initially considered by the Community Exceptional Circumstances (CEC) scheme, it became obvious that this was not the appropriate funding mechanism. CEC was never intended to be used for the provision of "first-line" treatments. CEC has always been about providing funding in truly "exceptional" cases; the definition of "exceptional" generally referring to a national prevalence of less than 10 patients.

Applications to the Exceptional Circumstances Panel for the use of either sirolimus or mycophenolate in heart transplant patients have been made in such numbers that these cases can no longer be considered "exceptional". PHARMAC and the Exceptional Circumstances Panel wrote to all District Health Board (DHB) transplant groups in both 2003 and 2004 to indicate that the frequency of applications for sirolimus was such that the criteria of rarity could no longer be applied. Instead, as rescue therapy for a functioning transplant is cost-saving to the DHB, the Hospital Exceptional Circumstances (HEC) mechanism could be used. All reasonable requests have been recommended for funding under this mechanism. This funding scheme is more explicit, being a direct cost to the DHB involved and allows funds from the limited CEC budget to be used for other exceptional cases.

Mycophenolate has been considered for listing as first-line therapy for heart transplantation and is in the process of further clinical and economic evaluation. As mycophenolate is much more expensive than its comparator azathioprine, PHARMAC and Pharmacology and Therapeutic Advisory Committee (PTAC) have to ensure that this medicine is both cost-effective as well as safe and efficacious in this role. Factors such as progressive renal impairment, transplant coronary vasculopathy and graft failure, as well as gout, all need to be taken into account, but must be evaluated in properly constituted clinical trials designed to assess these endpoints. Such trials are currently ongoing.

PHARMAC is not able to list an unregistered product or indication in the Pharmaceutical Schedule due to a lack of adequate safety and efficacy data. Sirolimus is not registered for use in heart transplant patients in New Zealand and it therefore cannot be promoted in this context. Indeed, there are important serious adverse effects, including death, that have been associated with this product.

Dr Coverdale also alludes to the Immunosuppressant Subcommittee of PTAC, which has now met and produced guidelines for the use of sirolimus in the New Zealand context. These guidelines will shortly be available.

Paul Tomlinson
Chair, Transplant Immunosuppressant Subcommittee
Member, Exceptional Circumstances Panel
Invercargill

Peter Moodie
Medical Director
PHARMAC
Wellington

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1214 ISSN 1175 8716

Michael Robert Miles

We are sorry to have to farewell Michael Miles (QSO, JP), a highly respected paediatric colleague and friend at Rotorua Hospital. One of "nature's gentlemen," Michael died at home from cancer on 7 March 2005, aged 73.

Born in Gisborne, Michael was the eldest of three children. A diligent student at school, he was awarded a Barrington Miller scholarship to study medicine at Otago University.

Michael qualified in 1956 and moved to Auckland for house surgeon and registrar posts, prior to going to Great Ormond Street Hospital, London to specialise in paediatrics and obtain the London Diploma of Child Health.

While working in Aylesbury/High Wycombe, UK he met his future wife, Ann-Elise, whom he married in 1963.

Following his UK experience, Michael worked for a year in Nigeria, before returning in 1965 for 2 years as a tutor specialist in Auckland . Michael had by then become (to our knowledge) the first successful FRACP (Paediatrics).

In 1967, Michael was appointed as the first Paediatrician at Rotorua Hospital, although his role was as one of four physicians caring for all medical patients, adults and children. In 1970, Michael went to American Samoa as the Medical Director of Paediatric public health at the LBJ Tropical Medicine Center, and spent 14 months there before returning to Rotorua where he developed the paediatric unit and worked as the sole paediatrician for 13 years. He was then on acute call most of the time, receiving help from physicians and interested general practitioner colleagues.

Michael's clinical interests/focus included childhood allergy and child development. Neonatology was a significant and stressful part of the workload, and Michael established a very good level II unit in a pioneering relationship with the regional level III centre in Hamilton. The General Paediatric Service which developed was also very well regarded and Michael encouraged a high level of integration with community services (undefined community paediatrics).

Michael had a leadership role with the Child Potential Unit (a residential facility to treat children with cerebral palsy and other physical disabilities) and he introduced conductive education (learnt from the Peto Institute in Hungary) to New Zealand for the physical management of cerebral palsy here.

Michael was involved in several community health services, including Crippled Children's Society, IHC, and Plunket. His emphasis on teamwork, his ability to approach situations with fairness, his compassion, and his sense of humour made him a much-loved member of the local community.

Michael was an excellent paediatrician, passionate about child health and highly respected both by the local medical network and throughout the paediatric community nationally. He is described as "someone who had a twinkle in his eye and was a man

with a very good heart." He had a wonderful sense of the ridiculous, which appealed to children and adults alike.

After his retirement in 1997, Michael worked again in American Samoa for a further few years, before illness forced him and Anne-Elise to return home to Rotorua. Michael continued his involvement in the local community, became chairman of the Rotorua Arts Village Trust, was President of the Friends of the Rotorua Museum of Art and History, and commenced a role as a Justice of the Peace (JP).

Michael was made a Companion of the Queen's Service Order (QSO) for Public Services in 1997 and a tree was planted in his honour at Centennial Park by the Rotorua Tree Trust in 2002. He loved nature, and was an enthusiastic sailor and gardener.

Michael was a devoted family man and was very proud of his children and their achievements. Always considerate, hospitable, and a loyal friend, he engendered great loyalty from those he was with.

Michael will be sorely missed but has left a great legacy in his family and in the child health service that he evolved. He is survived by his wife Anne-Elise, three children (Andrew ,Elizabeth, and Fiona), and five grandchildren.

We are grateful to Johan Morreau (Paediatrician) and Geoff Lamb (retired Orthopaedic Surgeon) for this obituary.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Tristram Peter Dennitts Willcox

As was one of the last generation of graduates from Otago University under the tutelage of Sir Charles Hercus, Peter (1931–2005) always took for granted that general practice was a community service.

A firm believer in taking responsibility for his own continuing medical education, he took time out from full-time practice to study at Great Ormond Street in London (1965) and at Auckland Hospital's Ward 10 psychiatric unit (1970).

One of the founding members of the Royal NZ College of General Practitioners, he was elected Fellow (1996).

Peter was also active in medical politics, first as a member of the NZ branch of the BMA then on the executive of both the NZMA and MANZ.

Whilst in rural practice at Lincoln, Canterbury (1959–69), he campaigned vigorously for public health issues, such as the institution of a village sewerage scheme to protect against hepatitis and a nationwide practice nurse subsidy for rural practice.

As a city GP based on Auckland's North Shore (1970–1981) he spoke out strongly in support of the absolute confidentiality of patient records, women's rights in the abortion debate, and breaking down the stigma associated with mental illness. He liked working with young people, and enjoyed his role in student health at Lincoln and later (part time) at Auckland University.

After a decade of working long hours on call (with partner Lance Austin) in a large rural area—10,000 patients to care for, driving 40,000 miles on home visits, and delivering hundreds of babies a year—the move to Auckland brought opportunities to join a larger group practice and begin a more balanced life. On the North Shore, Peter was one of the initiators of comprehensive after-hours care, culminating in the establishment of 'Shore Care.' For Peter, this meant a chance to indulge his love of sailing. He could combine precious family times with the excitement of exploring the Hauraki Gulf and northern coast by sea. It was a passion that led, inevitably, to the challenge of racing.

From 'round the buoys' club racing, he progressed to the South Pacific Half Ton regatta in Sydney (1972), where he finished third, and finally to the World Half Ton Cup in 1977 (also in Sydney) where Peter and his talented crew on *Gunboat Rangiriri* finished first—New Zealand's first-ever win in this international event.

Personally, he never wanted to continue in practice once the total commitment he felt for his calling had begun to dissipate and so, from his earliest years, Peter planned an early retirement from general practice medicine to focus his considerable energies on his other great passion—farming. As planned, he was able to achieve this objective by the time he turned 50. However, he did maintain contact with his profession for a

further 10 years (1986–1996) working part-time for the Auckland Blood Transfusion Service collection team.

Peter is survived by his wife (Wensley), three sons (David, Hamish, and Robert), and five grandchildren (Samuel, Daniel, Anna, Leilani, and Finley).

We are grateful to the Willcox family for this obituary.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

David Burke

Dr David Burke died recently at the age of 43. His death was unexpected.

Born in Christchurch and educated at St Bede's College, he was graduate of the University of Otago. After qualifying, he did house jobs at Christchurch and Greymouth, then he did GP locums until he purchased a practice in Innes Road almost opposite his father's pharmacy. The strip of road became known as Burke's Pass, and he soon built up a strong local following.

In parallel with his general practice, he became increasingly involved with high-performance sport and sportspeople. He was the first medical advisor to the Crusaders Super 12 Rugby Team, and many of that team remained friends and patients. He was also medical advisor to the New Zealand Cycling Team and was the official doctor to the New Zealand Rugby League Team for 4 years back in the 1990s.

David worked closely with the South Brighton Life Saving and Surf Club, and he was a consultant to several endurance athletes. A feature of his work was the enduring personal relationships he established. Perhaps this is because he remained essentially a GP in touch with people from all walks of life.

David's death has been referred to the Coroner as a suspected suicide. It is a sad irony that one so well qualified in recognising depression in others could, in the end, find no way to cope with his own.

As Father Kevin O'Grady said at the funeral, David Burke gave too much time to other people and not enough free time to himself

This obituary was compiled by Roy Holmes (Coordinator of NZMJ Obituaries) and was based on an obituary (in *The Christchurch Press* by David McCarthy) with notes from the eulogy delivered by Father Kevin O'Grady

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

University of Otago Faculty of Medicine / Freemasons Postgraduate Fellowships in Paediatrics and Child Health for 2006

The above Fellowships or Scholarships are open to University graduates who intend to pursue long-term work in Paediatrics or Child Health within New Zealand. The Fellowships include full-time salary for 1 year, with provision for a further year.

Applications close on **24 June 2005** with the Manager of the Faculty of Medicine,
University of Otago Medical School,
P O Box 913,
Dunedin,
from whom further details may be obtained.

THE NEW ZEALAND MEDICAL JOURNAL
Vol 118 No 1215 ISSN 1175 8716

Better than well: American medicine meets the American dream

Carl Elliott. Published by WR Norton & Company Inc, 2003. ISBN 039305201X. Contains 320 pages. Price US$26.95 (US$16.98 on Amazon.com)

This book explores the paradoxes of self-improvement. The author is a professor of bioethics and philosophy. Its major subject is the increasing use of "enhancement technologies" such as drugs, surgery, and therapy in an attempt to improve our happiness and wellbeing. The book shares some features with any number of others such as *Listening to Prozac* (whose author, Peter D Kramer, contributes the Forward) and focuses on the ambiguities in its subtitle "American medicine meets the American dream". Unlike many similar books, however, it is well worth reading.

Elliott grasps that historical and philosophical concepts lie behind the American (and to an increasing degree all Western countries) ideology of happiness and self fulfilment. He refers the reader to an array of literary philosophical and scientific readings to back up his assertions. Even better, he is humorous and sardonic and at times almost bleak in a rather un-American way (perhaps his 4 months sabbatical at the University of Otago contributed to this).

His central argument is that American culture sees the power of individual authenticity as the moral ideal. Within this, conscience is incorporated as the moral guide and the concept of self-fulfilment is seen as a democratic right to pursue ones own vision of the "good life".

The problem with this vision is that the fulfilment is largely self reverential and therefore there are constant doubts over whether this fulfilment is adequate. The lack of any fixed or agreed upon success or failure imparts a sense of unease; we are constantly wondering whether we could be better—i.e. could be more fulfilled. This unease leads to the increasing use of enhancement techniques to ensure that we are near the top in being self fulfilled or at least reasonably competitive. The recurring problem is that we can never be sure; there is no way of validating our happiness in relation to others' happiness.

Elliott also challenges the consolation that while these enhancement technologies apply to others they do not apply to us. He points out that we all moralise about enhancement technologies except the ones we use ourselves. He suggests that it is similar to people "living in the suburbs but pretending they are not real suburbanites".

Finally he refuses to let us off the hook by blaming drug companies, advertising, the government or other controlling agencies. He suggests that what we grasp at is the result of free choices made in the search for some peculiar kind of American happiness.

Recommended.

Roger Mulder
Professor of Psychological Medicine
Christchurch School of Medicine and Health Sciences