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THE NEW ZEALAND MEDICAL JOURNAL



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EDITORIALS

Now Gisborne Hospital

The Health and Disability Commissioner, Mr Ron Paterson has just released his report on Gisborne Hospital.¹ "Traumatised, unhappy, marked by suspicion and distrust" are not words one would wish to see used to describe a public hospital service, but his report echoes Mrs Robyn Stent's earlier findings² of distrust and low morale in a dysfunctional and grief-stricken Christchurch Hospital. If these findings were in one city only, the quality of local management would be questioned, but their existence in two places points to an underlying general problem.

"My investigation team was not prepared for the visible distress shown by clinical staff during their interviews." "Senior doctors and nurses felt disenfranchised, unable to exercise an effective voice in management decisions. Suspicion and distrust was endemic". "The key driver for the change was the financial imperative for THL (Tairāwhiti Health Care Limited), to live within its budget".¹ These factors were the central problems in Christchurch as well² - and probably remain so in most hospitals in New Zealand.

The clash in Gisborne came between Board and Management on the one hand, who took financial imperatives laid down by Treasury and CCMAU as paramount, and health professionals on the other, concerned about standards and patient safety. "There were clear signals from Wellington that THL needed to work itself out of financial difficulties, as a priority. The shareholders and the board embarked on a process of reform ... business plans and company objectives were developed and endorsed by the board".¹ The Chief Executive explained, "while there was a high level of consensus processes among the Service Managers, this did not extend into the organisation".¹ In Christchurch there had been "sudden introduction of radical proposals for major change". Canterbury Health felt "compelled to push through changes in a manner that did not allow staff to work through the issues" ... "To attempt this change in an organisation where patient safety depended on consistent processes and the trust of long-standing relationships was foolhardy". "Trust ... was destroyed instantaneously".²

"In THL, the re-configuration of the adult medical surgical floors was never endorsed by staff, was carried out at great cost and has resulted in significant stress for staff, and inability to provide flexible services and risk to patient care".¹ A former Chairperson of the Board stated that she "believes there was a level of consultation, but how much notice was taken of people's comments is what begs the question." "Probably not a lot of cognisance was taken of concerns that were raised, because of the key driver to break even ..."¹ Consultation was therefore cosmetic - as it had been in Christchurch.

The Chief Executive in Gisborne accepted that "with the quantum of financial savings that had to be achieved and the timeframe available, the approach used was more top-down than is ideal".¹ Top-down planning was predicated by the systems imposed over the last eight or nine years by Government, Treasury, and the Ministry of Health. As well as this, Board

members and managers were selected for their likelihood of compliance with the directives of Treasury and CCMAU and for their acceptance of the theory that health professionals were guilty of "provider-capture" and not interested in the well-being of the organisation. The appointment of health professional Board members from outside the district was designed to reinforce this perceived need for independence of Board and management from the local clinical staff.

As increasing difficulties regarding patient safety arose in Canterbury Health, the Department of Health and management in Christchurch were strongly critical of senior medical and nursing staff who refused to give the names of patients and junior staff involved in episodes prejudicial to patient safety until an independent inquiry was mounted. The then Minister of Health threatened senior doctors with the full force of disciplinary action.³ Similarly at THL the Chief Executive stated "it is simply not acceptable (legally or ethically) for registered health professionals to refuse to disclose to the HHS (Public Hospital) relevant information, while complaining to other authorities ...".¹ The New Zealand Nurses Association stated that it was "absolutely aware of nurses' obligations to report adverse incidents (and) also aware of how risky this proves to be for individual nurses".¹ It stated that "we should be ashamed that the element of fear which permeated the New Zealand Health Service under the previous administration has resulted in nurses' inability to raise concerns with their own management".¹

A Clinical Director stated that "the management style of THL led to an adversarial relationship with medical and clinical staff and affected their behaviour ... Morale had been declining progressively over eight years ... The driving force to stay within budget and save money ... impinged on the quality of patient care and the focus and performance of clinical services".¹ A senior THL doctor commented: "Very few people want to speak out because they think the system will come down on them. Those people who want to stay are unwilling to participate in dialogue in an honest way." As well as this, senior nurses felt disenfranchised, having no Director of Nursing to take their concerns direct to the Chief Executive.¹ This was similar to the outcome of 'nursing restructuring' in Christchurch where nurses who had made legitimate criticisms lost their jobs.³ There was loss of a non-judgemental channel to voice concerns. Such a channel is critically important because concerns are likely to have a valid basis and management suppresses them at its peril.

Despite the fact that the investigation team heard the organisation described as "destructive, unappreciative, dysfunctional, and bureaucratic",¹ THL denied there was any management policy to refuse to listen to clinical issues. "Many of the decisions were made with the agreement of nursing or medical representatives". "THL feels that the complaints... derived from dissatisfaction with some outcomes, as opposed to process".¹ This exposes the stark lack of understanding of how unacceptable current processes in hospital management are to

health professionals. The selection of some medical advisers and managers on the basis of their willingness to comply with management's fiscally-driven agenda undermines open consultation and trust. The use of salary awards to encourage selected clinicians to support administrative decisions is divisive and damaging. The fact that most doctors continue in their jobs should not encourage hospital administrators or government to believe that all is well. Health professionals continue because of responsibility to patients, which prevents them from taking protest action to bring change.

Comparatively lower pay for health professionals in New Zealand did not in the past lead to the serious problems we now have in retaining nurses, medical staff and research workers, because the previous environment, being orientated to patients and excellence, was professionally satisfying. The adversarial relationship which has developed between management and junior medical staff has been particularly damaging. It has led to loss of loyalty to the hospital service, and young people have looked overseas for their future.

It is essential that the current government understands that the problems identified in Christchurch and Gisborne are general systems problems. As the Chief Executive of the New Zealand Nurses Organisation stated: "I recall over our concerns relating to Christchurch Hospital that twice Ministry of Health Medical and Nursing Advisers visited that establishment and said our issues were unfounded - it was not until the very public and lengthy review by the Health and Disability Commissioner that we were vindicated. We would not have confidence in a review undertaken by the Ministry".¹ At a government level, the dominating role of Treasury, unchecked by the Ministry of Health has had a profound influence on the aberrant behaviour of local health boards and their management. Mrs Stent found that "the Ministry of Health did not adequately meet its responsibilities" and the Crown Company Monitoring Advisory Unit and Treasury set a business plan for Canterbury health with high financial risks, "and the targets almost impossible".² They told the shareholding ministers, Hon W Birch and Hon P East that "it may be appropriate to set less stringent, more realistic targets ... Conveying such a message to the Board and management is not recommended as it will likely undermine their resolve to achieve the targets set".² This sort of secrecy and deceit can only lead to failure of services, danger to patients and even unnecessary deaths in dysfunctional organisations.

Under Mr Simon Upton, government adopted a business style of administration to improve decision making and save cost. It can now be argued it has had the opposite effect. The inquiries, over-use of outside consultants, poor planning systems leading to costly mistakes, resignations of Chief Executives, redundancy payments, the disinvestment by industry in New Zealand are signs of a chronic internal problem. The model of a Chief

Executive with virtually autocratic power has failed in the public health service. Although one doctor employed as a medical adviser felt "harassed by the suggestion that such roles (in administration) involved secrecy and deceit and lack openness, honesty and cooperation",⁴ the evidence in the reports on Canterbury Health and Gisborne Hospital argue that such perceptions are valid.

We believe it is only the government, encouraged by public opinion and health professionals, that can force a change to more sensible, open management arrangements. Autocratic managerial behaviour at a local level is no longer acceptable. Democratic staff organisations must once more play a central role if our hospitals are to become healthy again. Any other approach implies that the collective experience and expertise of local health professionals will continue to be discarded. The current government might have made a start, but since many incumbents in top administrative positions were selected for their willingness to support the approach of which we complain, how can government achieve effective change?

The trauma and expense of the investigations into Canterbury Health and Gisborne Hospital must not be in vain. Mr Ron Paterson has said: "it is time for clinical staff and management to make a fresh start in the co-operative endeavour that should be at the heart of any hospital: safe and effective care for patients".¹ Mrs Robyn Stent said: "It is time for all to work co-operatively in the interests of providing good service to the public ...".² Moller and Begg stated that such laudable sentiments "can only be realised if every group is satisfied with the openness and integrity of the administrative system".³ We must return to an administrative system in which appropriate local professional advice is assessed prior to management decisions being made. Foate et al pointed out persisting problems in Christchurch despite Stent's report, and the need for a fundamental change in attitude of the Board and administration.⁵ Given the striking similarities between the reports from Christchurch and Gisborne, the onus is now on the current government to insist on principles of governance that are acceptable to health professional staff, and consultation which is adequate to the public. Above all, this should restore an environment conducive to good relationships where excellent clinical standards, the economical use of resources, and co-operation are the norm. It would also help us to avoid the ignominy of future failures like those in Christchurch and Gisborne.

The Editors

1. A report by the Health and Disability Commissioner. Gisborne Hospital 1999 - 2000. Auckland: 2001 March.
2. A report by the Health and Disability Commissioner. Canterbury Health Limited. Auckland: 1998 April.
3. Moller PW, Begg EJ. Deaths at Christchurch Hospital. NZ Med J 1998; 111:237.
4. Morton J. Getting health back on track. NZ Med J 2000; 113: 474.
5. Foate J, Begg EJ, Anderson T et al. The Stent Report, one year on. NZ Med J 1999; 112: 278-9.

Molecule-to-Malady

This issue of the Journal contains another article in our Molecule-to-Malady series. We coined this term for the series as one that encapsulates our intention to provide user-friendly molecular information to those involved in treating the maladies. We were no doubt influenced in our choice by the International Union of Physiologists. 'From Molecule-to-Malady' is the name they have given to the 34th International Congress of Physiology, which is being held in Christchurch from 26-31 August this year. This is a major international meeting with an impressive array of international speakers, more information on which can be obtained on their website (www.iups2001.org.nz).

This issue's contribution to the series is a timely article by Dr Martin Kennedy, exploring the medical advances we can expect to come from the recent publication of the full sequence of the human genome. Dr Kennedy is a Health Research Council Senior Research Fellow at the Christchurch School of Medicine. He is a molecular geneticist who has been a leader in developing gene knockout technology in New Zealand. His current interests are in psychiatric genetics and pharmacogenetics, the expanding field of identifying genetic markers of drug responses.

Christine Winterbourn,
Deputy Editor.

Changing risk behaviours for non-communicable disease in New Zealand working men – is workplace intervention effective?

Christine Cook, *Public Health Dietitian*; Greg Simmons, *Public Health Physician, Public Health Protection, Auckland District Health Board*; Boyd Swinburn, *Associate Professor*; Joanna Stewart, *Biostatistician, Department of Community Health, University of Auckland, Auckland*.

Abstract

Aims. To evaluate the effectiveness of a health promotion programme targeting dietary behaviours and physical activity among male hourly-paid workers and to explore demographic and attitudinal influences on dietary patterns at baseline.

Methods. A controlled field trial compared workers at one intervention and one control worksite. The intervention comprised nutrition displays in the cafeteria and monthly 30-minute workshops for six months. Key outcome measures at six and twelve-months were self-reported dietary and lifestyle behaviours, nutrition knowledge, body mass index (BMI), waist circumference and blood pressure.

Results. 132 men at the intervention site and 121 men at the control site participated in the study and a high retention rate (94% at 6-months and 89% at 12-months) was achieved. At

baseline, 40% of the total sample (253) were obese, 30% had elevated blood pressure, 59% indicated an excessive fat intake and 92% did not meet the recommended vegetable and fruit intake. The intervention reduced fat intake, increased vegetable intake and physical activity, improved nutrition knowledge and reduced systolic blood pressure when compared to the control site. There was no difference in change in mean BMI or waist circumference. Reduction in BMI was associated with reduction in fat intake.

Discussion. Low intensity workplace intervention can significantly improve reported health behaviours and nutrition knowledge although the impact on more objective measures of risk was variable. A longer duration or more intensive intervention may be required to achieve further reduction in risk factors.

NZ Med J 2001; 114: 175-8

The high level of obesity and nutrition-related diseases in New Zealand is a significant public health issue.¹ It is of particular concern for men, especially Maori and Pacific men,^{1,2} and those working in lower paid jobs, all of whom are at high risk of non-communicable diseases.³ A manufacturing workplace is a key setting to access men in lower-paid jobs and influence risk behaviours, although male blue collar (hourly paid) workers may be less likely to participate in health education than female or white collar workers.⁴ Strategies to reduce health risk behaviour are more likely to succeed when health education is combined with changes in the worksite environment.⁵

This study tested the hypotheses that a relatively low intensity workplace intervention with male hourly paid workers could significantly improve dietary behaviours (more vegetables and fruit, less high fat food), increase physical activity and reduce blood pressure and body weight.

Methods

Design. A controlled field trial compared workers at one intervention and one control worksite. Two South Auckland manufacturing worksites with supportive management, a company canteen and a stable workforce of at least 200 men were chosen. Participation was voluntary and the study was open to all male hourly paid employees (310 at the intervention site and 260 at control site) except those known by management to be leaving within one year. Participants were assessed concurrently at baseline, six and twelve months. The six-month health promotion programme was implemented at the intervention site immediately after baseline data collection. The intention was to deliver the same intervention to the control site after the six-month data collection. Production pressure made it impossible to implement more than one session to 40% of participants, however cafeteria food was substantially improved to include lower-fat options and all employees received a leaflet on healthy eating. The intervention 'dose' was difficult to quantify and a decision was made to regard this site as a control for the duration of the study with acknowledgement that any resulting bias would reduce the apparent effect of the intervention at twelve-months. Ethics approval was obtained from the Auckland Ethics Committees.

Data collection. Height (to the nearest 5 mm) and weight (to the nearest 0.1 kg, Seca electronic balance) were measured without shoes and in lightweight work clothes. Waist circumference was measured next to the

skin at the umbilicus (to 0.5 cm). An automatic sphygmomanometer (Omron, HEM - 719 K) was used to measure blood pressure after sitting for five minutes. The mean of two measurements was recorded; treatment with blood pressure medication was not ascertained. Obesity was defined as BMI ≥ 30 kg/m² in European and Asian men⁶ and ≥ 32 kg/m² in Maori and Pacific men.⁷ Hypertension was defined as systolic ≥ 150 mmHg and/or ≥ 90 mmHg diastolic.⁸

Data on demographics and self-reported behaviours were collected using a ten-minute questionnaire. This included questions on fat, vegetable, fruit and alcohol intake, breakfast consumption, nutrition knowledge, stage of change in relation to readiness to lose weight, physical activity routine and attitudes to food and health. An interpreter fluent in Tongan and Samoan was available and participants were given the option of having the questionnaire administered to them. The Dobson short fat questionnaire (SFQ)⁹ was selected to measure fat intake because of its low respondent burden and comparatively high validity. The 17-item SFQ included foods commonly consumed in New Zealand but was modified to 19 items to better reflect food frequently eaten by Maori and Pacific men. A 14-item multiple-choice nutrition knowledge section was specifically designed as no suitable published questionnaire was found. Participants were asked if they undertook any moderate leisure time activity (eg brisk walking) or vigorous activity (causing a person to breathe hard or sweat) during a normal week, and if so, its frequency and duration.

Intervention. Intervention site participants were rostered to attend a 30-minute workshop session once a month for six months. Topics included nutrition and non-communicable disease risk, safe use of alcohol, and benefits of physical activity. Key workers were consulted during planning, and the stages of change model¹⁰ guided development and delivery. Six nutrition displays were rotated through the cafeteria. Additionally, illustrated point of choice messages promoting vegetables, fruit, lower fat items and water as a beverage were installed.

Statistical analyses. To examine the effect of intervention on outcomes, a mixed model (binary where appropriate) was fitted with the three time periods of baseline, six-months and twelve-months treated as repeated measures. The potential confounding variables of ethnicity, age, education and marital status were included and time, group interaction was the effect of interest. Where evidence of effect of intervention on change existed, the interaction contrasts of baseline versus six-months and twelve-months with group were tested. To investigate the influence of changes in intermediary variables on changes in outcome variables (BMI, waist circumference, systolic and diastolic blood pressure), a random coefficients model including the same four confounding variables and worksite was used. The intermediary variables examined were total fat score, nutrition knowledge score, vegetable and fruit intake, physical activity and alcohol intake. Regression techniques were used to

investigate relationships among demographic factors, attitudes and knowledge, lifestyle behaviours and health outcomes at baseline.

Results

132 of 347 eligible men employed at the intervention site and 121 of 262 men employed at the control site volunteered to participate in the study. A high retention rate (94% at six-months and 89% at twelve-months) was achieved. One participant withdrew due to ill-health, one elected to withdraw from the study and 25 had terminated their employment. Attendance at the workshops averaged 77% despite increasing production pressure.

Participant characteristics are shown in Table 1, and changes in lifestyle behaviours and knowledge in Table 2. Fewer than 20% of participants achieved the recommended fat score (approximately equal to 30-34% of energy as fat¹¹). A higher fat intake was associated with younger age ($p < 0.0001$), lower nutrition knowledge ($p = 0.0005$) and reduced belief in the importance of healthy eating ($p = 0.02$). Participants who anticipated difficulty in changing the food eaten at home, despite wishing to do so, also demonstrated a higher fat intake ($p = 0.03$). Vegetable and fruit intake was low with only 8.3% achieving the New Zealand goal (≥ 5 servings/day).¹¹ Higher nutrition knowledge score ($p = 0.04$) and ethnicity ($p = 0.02$, European higher) were associated with higher vegetable intake. Belief that healthy eating was important was associated with higher fruit intake ($p = 0.0003$). Mean nutrition knowledge was similar at both worksites. Ethnicity ($p = 0.002$, European higher) and higher education level ($p = 0.0002$) were associated with greater nutrition knowledge whilst lower knowledge was associated with higher BMI ($p = 0.02$).

Table 1. Baseline Characteristics of Study Participants by Worksites.

Factor	Intervention site (n=132)	Control site (n=121)
Ethnicity (%)		
Maori	12.1	29.7
European	25.7	39.7
Pacific	56.1	28.1
Other	6.1	2.5
Age (years)		
Mean \pm SD	35.0 \pm 11.2	42.9 \pm 11.7
Marital Status (%)		
Single	30.3	17.3
Married/partner	61.4	77.7
Other*	8.3	5.0
Educational level (%)		
<4 years high school	50.0	70.2
≥ 4 years high school	50.0	29.8
Smoking Status (%)		
Non-smoker	64.4	71.9
Current smoker	35.6	28.1
Drinking Status (%)		
Drinks less than 1x month	25.0	27.3
Drinks at least 1x month	75.0	72.7
Standard drinks per session[†]		
1-3	36.4	45.6
4-5	14.1	20.7
≥ 6	49.5	33.7

*Separated/divorced/widowed. [†]Applies to those drinking at least 1x/month.

There was little difference in attitudes to food and health between sites. Older age ($p = 0.03$), lower fat intake ($p = 0.0005$) and ethnicity ($p = 0.0001$, Pacific higher) were associated with belief that healthy eating was important. Anticipation of greater difficulty in changing the food eaten at home was associated with a higher BMI ($p = 0.02$), and

ethnicity ($p = 0.0007$, Maori/Pacific having greater degrees of difficulty) as well as a higher fat intake. Over 40% of participants with a BMI $> 30 \text{ kg/m}^2$ indicated that they were precontemplators, or not thinking about change,¹⁰ in relation to weight loss.

At baseline, 23.5% European, 31.2% Maori and 47.3% Pacific intervention site participants were obese compared to 27.1% European, 33.3% Maori and 67.6% of Pacific control site participants. Higher BMI was associated with poorer self-perceived health ($p = 0.0001$). Approximately one quarter (26%) of intervention site participants and one third of controls (35%) had hypertension. Higher dietary fat intake was associated with higher systolic blood pressure ($p = 0.03$).

Effects of intervention (Tables 2 and 3). There was a strong relationship of the intervention to change in mean fat score ($p = 0.0003$) with greater reduction at the intervention site between baseline and both six ($p < 0.0001$) and twelve-months ($p = 0.005$). There was also a significant difference in the change in vegetable intake ($p = 0.007$) with increase at the intervention site at both six ($p = 0.002$) and twelve-months ($p = 0.05$) compared to a decrease at the control site. However, the intervention did not significantly affect fruit intake. It also did not have a significant effect on alcohol consumption.

The change in nutrition knowledge differed ($p < 0.0001$) with a greater improvement in the intervention site at both six and twelve-months ($p < 0.0001$ and $p = 0.005$ respectively; Table 2). Attendance at more workshop sessions was associated with a significant increase in nutrition knowledge ($p = 0.006$). There was also a difference in the change over time in the level of physical activity ($p = 0.005$) with this increasing from baseline to twelve-months at the intervention site whilst decreasing at the control site ($p = 0.002$; Table 2).

There was a difference in change in systolic blood pressure at the worksites ($p = 0.0005$, Table 3) with a greater reduction at the intervention site from baseline to both six ($p = 0.001$) and twelve-months ($p = 0.0004$). There was no significant difference in the change in mean BMI or waist circumference (Table 3). Reductions in BMI within an individual were significantly related to decreases in fat score ($p = 0.05$) whereas reductions in waist circumference were related to both decreases in fat score ($p = 0.002$) and increases in fruit consumption ($p = 0.03$).

Discussion

The aim of this workplace intervention was to improve dietary patterns, increase physical activity and reduce risk factors for non-communicable diseases in hourly paid male workers. The failure to significantly change fruit consumption, whilst fat consumption decreased and vegetable intake increased, reflects the overall low intake of fruit in New Zealand,² mirrors the result from a worksite study of similar size,¹² and indicates that this is a more difficult behaviour to change. The workshop session on alcohol was held in response to participants' questions concerning the safety of their high alcohol intake, however it did not have a significant effect on self-reported alcohol consumption.

Similar overseas worksite studies measuring weight or BMI have reported mixed results ranging from modest losses to modest gains.¹³⁻¹⁵ Whilst the reduction in systolic blood pressure could not be associated with a specific behaviour change, the combined changes in fat and vegetable intake and physical activity may have contributed. Evidence for the combined effect of dietary changes is provided by the DASH study¹⁶ in which a reduced-fat diet rich in vegetables, fruit and low-fat dairy foods substantially lowered blood pressure.

Table 2. Changes in lifestyle behaviours and nutrition knowledge by worksite.

Lifestyle factor	Intervention site			Control site			Probability of difference in change
	Baseline (n=132)	6 months (n=124)	12 months (n=116)	Baseline (n=121)	6 months (n=114)	12 months (n=110)	
Consume 2-3 serves fruit/day (%)	21.2	28.9	23.3	26.4	29.2	31.8	0.78*
Consume 2-3 serves vegetables/day (%)	14.4	26.6	21.5	21.5	14.1	22.7	0.007*
Consume breakfast before work (%)	35.6	45.2	47.4	53.7	53.9	58.2	0.34
Consume \geq 6 drinks/session (%)†	49.5	31.8	35.4	33.7	21.7	23.7	0.32*
Vigorous activity/week (hours)‡	5.9 (7.9)	0.0 (9.6)	+2.8 (14.2)	10.6 (15.5)	-0.9 (16.4)	-2.6 (17.3)	0.005*
Moderate activity/week (hours)‡	4.5 (6.7)	+0.1 (10.2)	+0.9 (11.8)	6.53 (9.9)	-1.2 (11.6)	-1.7 (11.3)	0.005*
Fat score‡	31.0 (7.7)	-3.6 (7.2)	-3.4 (7.4)	30.9 (9.1)	-0.6 (6.0)	-1.1 (6.3)	0.0003
Nutrition knowledge score‡	8.5 (2.6)	+1.8 (2.2)	+1.4 (2.3)	8.3 (2.7)	+0.1 (2.4)	+0.5 (2.6)	<0.0001

*Probability applies to change in total quantity fruit or vegetables, total volume alcohol or total hours physical activity. †Applies to those drinking at least 1x month. ‡Mean (SD); 6 and 12-month values are changes from baseline.

Table 3. Change in biometric factors by worksite.

Biometric factor	Intervention site			Control site			Probability of difference in change
	Baseline*	Change 0-6 Months†	Change 0-12 months†	Baseline*	Change 0-6 months†	Change 0-12 months†	
BMI (kg/m ²)	30.0 (6.0)	+0.1 (0.1)	0.0 (1.2)	30.6 (5.2)	+0.2 (1.3)	0.0 (1.1)	0.68
Weight (kg)	92.1 (20.9)	+0.2 (3.1)	0.0 (3.8)	92.4 (17.0)	+0.5 (3.8)	0.0 (3.3)	0.63
Waist circumference (cm)	98.8 (15.5)	-0.5 (3.6)	-0.1 (6.2)	100.7 (13.5)	+0.2 (3.8)	+0.4 (4.2)	0.22
Systolic blood pressure (mmHg)	135.8 (18.2)	-5.0 (16.5)	-5.8 (15.3)	134.3 (18.8)	+1.5 (11.9)	+1.9 (13.5)	0.0005
Diastolic blood pressure (mmHg)	83.4 (12.2)	+0.5 (10.3)	-0.2 (10.8)	85.9 (12.2)	+2.1 (9.0)	+1.7 (9.9)	0.17

*means (SD). †means of difference (SD).

At baseline, belief in the importance of healthy eating and greater nutritional knowledge were associated with desirable eating behaviours. In contrast, increased difficulty with changing habitual food intake was associated with higher fat intake and higher BMI. Additionally, 43% of obese participants were not contemplating losing weight. These findings confirm the importance of strategies utilised in workshop sessions, namely, raising awareness about problem behaviours, personalising health risk and favourably influencing decisional balance (the weighing up of advantages and disadvantages associated with changing behaviour).

Self-reported measures of dietary intake and physical activity are subject to reporting bias and it is possible that intervention site participants may have sought to please the interviewer and underreported fat intake. However, the SFQ had been previously validated, intra-individual reduction in BMI and waist circumference was significantly related to decreases in fat scores, and data were collected at each time-point and responses analysed later (rather than directly asking the participants for reported changes). Based on the actual number of participants recruited and using the standard deviation of the mean intra-individual change, the study had an 80% power to detect changes of 0.66 kg in weight, 0.4 kg/m² in BMI, and 1.27 cm in waist circumference at the 5% level of significance. A more intensive, individually oriented intervention may have been able to demonstrate a further reduction in risk factors, however small changes achieved by a large number of people add up to a significant public health benefit.¹⁷

A standardised biometric measurement protocol was used to minimise error. Inter-observer error in waist circumference measurement was minimised by using one operator. Observer error in blood pressure measurements was eliminated by the use of a previously

validated digital monitor.¹⁸ If blood pressure was elevated, respondents at each worksite were counselled in the same manner by the same researcher. It is possible, though unlikely, that the difference in change between the worksites was due to intervention site participants seeking medical intervention more avidly than control participants.

Only 42% of the employees volunteered to participate in this study. Since, however, it was a controlled study to assess the effect of an intervention, any bias introduced by this is of less importance. The study had a comparatively high respondent burden and the numbers participating do not necessarily reflect the number who would be attracted to a similar education programme without the data collection burden. As only one worksite was included in each arm of the study, variation in the effect of the intervention at different sites could not be investigated. The commitment shown by the companies was vital to the programme's effectiveness and their support and tangible contribution, particularly at the intervention site, was considerable. These companies are perceived to be 'good employers' and the wider ability of New Zealand companies to support and sustain health promotion programmes in paid time has not been tested. The ethnic diversity of the population makes it more representative of a manufacturing worksite in Auckland than in other areas of New Zealand.

In conclusion, this study has shown that a manufacturing worksite is potentially a valuable setting for primary prevention of non-communicable disease and that a low intensity intervention can improve nutrition knowledge and change important lifestyle behaviours in a population who are difficult to reach. A longer or more intensive individually oriented intervention may have been able to demonstrate further reduction in the prevalence of risk factors.

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Cost-effectiveness of spinal cord stimulation in patients with intractable angina

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Abstract

Aim. To review the cost of healthcare utilisation by patients suffering from intractable angina, unsuitable for coronary revascularisation, before and after treatment with spinal cord stimulation.

Methods. Data were collected for eight patients treated for intractable angina with spinal cord stimulation at Green Lane Hospital before April 1999. Information on consumption of specified medical resources for the twelve months preceding implantation, the implantation period, and the twelve months following implantation was collected. Where available, data were also collected for the eighteen months preceding and following treatment.

Results. In six patients successful permanent stimulation was established; in two it proved technically

impossible to implant a stimulator. The six patients with successful stimulation spent fewer days in hospital ($p=0.028$) and consumed fewer resources ($p=0.046$) following implantation than in the period before implantation. The two patients for whom spinal cord stimulation was unsuccessful spent more days in hospital and consumed more resources in the twelve months following, than in the twelve months preceding attempted implantation. Extrapolation of data for all eight patients suggests that, on average, the cost of implanting a spinal cord stimulator will be recovered in approximately fifteen months.

Conclusion. Spinal cord stimulation is a cost-effective treatment for intractable angina pectoris.

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Angina pectoris is disabling with serious implications for quality of life and ability to carry out every-day activities. For an identifiable group of patients, surgery carries high risk or is technically impossible, and medication may fail to control symptoms. In 1994, the number of patients with such intractable angina was estimated as almost 30 000 in the US alone.¹ A treatment which could safely relieve suffering and improve the quality of life of these patients, would be of benefit. Spinal cord stimulation (SCS) may be such a treatment.

SCS was first used for angina in 1985, after success with pain relief in peripheral vascular disease indicated its utility for pain of ischaemic origin.² Since the first trial in the literature in 1987,^{3,4} there has been growing interest in this treatment. By 1994, 500 patients with angina in Europe had been treated with SCS.¹

Although the mechanisms of action of SCS remain incompletely understood, many investigations have concluded that the reduction of angina is secondary to an anti-ischaemic effect.^{2,5-10} Published results on the efficacy of SCS in angina are promising, indicating reduced ischaemic burden,^{2,10} reduction in angina episodes,^{6,11,12} increased working capacity and exercise tolerance,^{2,8,9} improved myocardial lactate metabolism,^{9,10} reduction in intake of nitrates,^{11,13} and improved quality of life.^{13,14} Studies have reported SCS to be effective in about 80% of patients with intractable angina.^{8,15}

Since July 1997, fourteen patients with intractable angina who were unsuitable for coronary surgery were referred by their cardiologists for consideration of treatment with spinal cord stimulation (SCS) at Green Lane Hospital. They were asked to undergo a screening procedure, in which a trial SCS lead was inserted, but externalised. If technically satisfactory stimulation was achieved, with relief of angina, the patients had implantation of a permanent stimulator.¹⁵ Results were encouraging, but SCS is a costly procedure (NZ\$13 300 for the implanted components alone), and in New Zealand its use has been restricted on economic grounds. In fact, there are limited data on the economic consequences of SCS.^{16,17} It is clear that such patients will continue to utilise expensive healthcare resources if untreated, so it is possible that such economic restriction is misguided. Therefore the present study reviewed the cost of healthcare utilisation by patients suffering from

intractable angina unsuitable for coronary revascularisation, before and after treatment with SCS at Green Lane Hospital.

Methods

Data were collected in April 2000 on patients (eight) for whom at least twelve months' follow-up information was available. Using patient notes, data related to the consumption of medical resources were collected for the twelve months preceding implantation, the implantation period itself, and the twelve months following implantation. When available, the same information was collected for the eighteen months preceding and following implantation. The implantation period was defined as beginning on the day of the first procedure related to SCS, and ending on the day of discharge, either after implantation of a permanent stimulator or failure of the screening procedure. Information was collected on the following designated components of healthcare utilisation: number of days of cardiac-related hospitalisation in a ward or in a coronary care unit (CCU), outpatient clinic visits, echocardiograms, ultrasound investigations, exercise tolerance testing, admission into the intensive care unit (ICU), and operative sessions (angiography, percutaneous transluminal coronary angioplasty (PTCA) with or without stents, coronary artery bypass grafting (CABG) and SCS related procedures). Each component was allocated a value in dollars, obtained (on a confidential basis) from current hospital pricing, and the mean times and costs were calculated for each period.

Results

Eight patients had a trial SCS lead implanted before April 1999 (Table 1). Of these, six proceeded to successful implantation of a permanent stimulator, while in two it was impossible to obtain technically satisfactory stimulation. In six of the eight patients, (coincidentally, the six in whom stimulation was successful) data were available for eighteen months before and after implantation. The average age of the eight patients was 65 years, and all were Canadian Cardiovascular Society (CCS) angina class four. All had undergone at least one bypass grafting procedure and seven had undergone one or more PTCA procedures. Their average ejection fraction was 60%. Full medical treatment for angina, including perhexiline, had been tried in all patients and five had received anticoagulation at some stage.

The six patients in whom SCS was successful underwent two operative sessions during the implantation period: initial trial screening and permanent implantation (Table 2). The mean total cost for this period was NZ\$24 523 (range NZ\$22 590 - 27 793). Patients in whom implantation of a stimulator was unsuccessful had a screening procedure only. The mean cost

Table 1. Demographic and other patient-related information.

Sex	Patients receiving SCS before April 1999							
	M	M	M	M	M	M	F	M
Age (years)	55	71	65	69	69	63	58	71
Ejection fraction (%)	51	70	44	57	68	50	76	61
CABG (no. operations)	2	1	1	2	2	1	2	2
PTCA (no. procedures)	3	4	4	3	0	2	1	3
Perhexiline (daily dose, mg)	200	200	100	200	200	100	200	100
Anticoagulation therapy (heparin/warfarin)	H	-	W	-	-	H	H	H
Angina class (CCS)	4	4	4	4	4	4	4	4
Successful SCS implant	Y	Y	Y	Y	Y	Y	N	N
Follow up (months)	25	22	21	27	28	21	12	12

CABG = coronary artery bypass graft; PTCA = percutaneous transluminal coronary angioplasty; CCS = Canadian Cardiovascular Society; SCS = spinal cord stimulation.

for the implantation period for these two patients was NZ\$6782.

Patients in whom SCS was successful required fewer days in hospital ($p=0.028$, Wilcoxon signed-rank test) and consumed fewer resources in the twelve months post-implantation than in the twelve months before implantation (Table 2; $p=0.046$, Wilcoxon signed-rank test). Compared with the twelve months preceding implantation, the post-implantation period was associated with at least a four-fold reduction in CCU admissions, operative sessions and total cost. Cardiology ward admissions dropped from an average of 18.3 to 6.2 days per year.

The two patients in whom the trial of SCS was unsuccessful showed an increase, post-procedure, in all

measured outcomes except CCU admissions and operative sessions (Table 2). Total cost was similar for pre- and post-implantation periods for these two patients.

The decrease in resource consumption and hospitalisation seen in the initial twelve month post-implant period were maintained until eighteen months in the six patients with sufficient follow-up data (Table 3). The mean cost for the eighteen months post SCS implantation was NZ\$26 935 less than that for the eighteen months prior to treatment, a net saving of NZ\$2412 after subtracting the mean cost of SCS implant treatment (NZ\$24 523).

For all eight patients, the average cost of SCS insertion (successful or unsuccessful) was NZ\$20 088. Combining the

Table 2. Hospital admissions and resource consumption costs for twelve months before and after SCS implantation.

	Pre-implant	Implant period	Post-implant
Successful implant (n=6)	Days in CCU Mean (range)	9.1 (2-17)	0 (0-5)
	Days in ward Mean (range)	18.3 (5-32)	11 (7-18)
	Operative sessions Mean (range)	2.17 (1-4)	2 (2)
	Cost per patient NZ\$ Mean (range)	28 072 (13 413-56 845)	24 523 (22 590-27 793)
	Total cost NZ\$	168 436	147 142
Unsuccessful implant (n=2)	Days in CCU Mean (range)	5 (0-10)	1 (0-2)
	Days in ward Mean (range)	1.5 (0-3)	1.5 (0-3)
	Operative sessions Mean (range)	1.5 (1-2)	1 (1)
	Cost per patient NZ\$ Mean (range)	10 915 (9887-11 943)	6782 (6519-7044)
	Total cost NZ\$	21 830	13 563
Total (n=8)	Days in CCU Mean (range)	8.13 (0-17)	0.25 (0-2)
	Days in ward Mean (range)	14.13 (0-32)	8.6 (0-18)
	Operative sessions Mean (range)	2.25 (1-4)	1 (1-2)
	Cost per patient NZ\$ Mean (range)	23 783 (9887-56 845)	20 088 (6519-27 793)
	Cost per patient per month NZ\$	1982	-
	Total cost NZ\$	190 266	160 705
	Total cost per month NZ\$	15 856	-

data for successful and unsuccessful SCS, the average total cost including SCS implantation for the eight patients after twelve months was NZ\$27 903. The cost per month in the post-implantation period was NZ\$10 646 less than during the pre-implantation period, for all eight patients (ie an average saving of NZ\$1330 per patient per month). Assuming that this benefit was maintained, a net saving would occur after approximately fifteen months (Figure 1).

Table 3. Hospital admissions and resource consumption costs for eighteen months before and after SCS implantation (for patients with successful implantation).

	Pre-implant (n=6)	Implant period (n=6)	Post-implant (n=6)
Days in CCU Mean (range)	10.5 (2-25)	0	2.3 (0-6)
Days in ward Mean (range)	19.8 (5-32)	11 (7-18)	6.2 (0-24)
Operative sessions Mean (range)	3.17 (1-7)	2 (2)	1 (0-4)
Cost per patient NZ\$ Mean (range)	35 222 (13 443-88 318)	24 523 (22 590-27 793)	8287 (30-25 302)
Total cost NZ\$	211 335	147 142	49 727

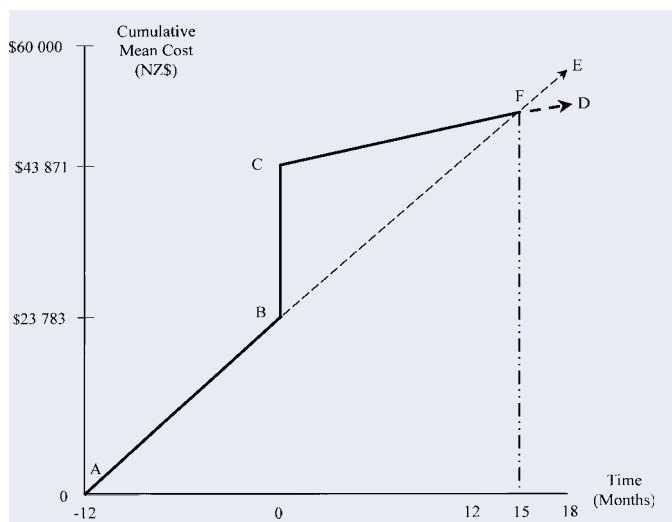


Figure 1. Rates of resource utilisation (mean cost per patient in NZ\$) before and after SCS insertion. AB=Pre-implantation cost by time, BC=Cost of implantation, CD=Post-implantation cost by time, BE=Extrapolated pre-implantation cost by time, F=Break even point for SCS insertion. *After twelve months data are extrapolated.

Discussion

Our data suggest that the costs to the healthcare system of implanting spinal cord stimulators are likely to be recovered after fifteen months on average. The clinical benefits of SCS have been extensively documented.^{2,6-14,18} Therefore, SCS is justifiable on both economic and clinical grounds.

Post-implantation costs in the two unsuccessful patients were not reduced, suggesting that the savings seen in the others were attributable to SCS, and not simply coincidental. Our conclusion takes account of the costs related to patients in whom stimulation was unsuccessful, as well as those in whom it was successful, which clearly it should. A higher failure rate would reduce the savings made overall. However, the literature suggests a success rate of 80% with SCS for angina,^{8,15} so our proportion of good results (six out of eight) is likely to be achievable on an ongoing basis.

One barrier to offering this treatment in the current public health system in New Zealand is the lack of an appropriate

Diagnostic Related Group (DRG) code for SCS implantation for angina. At present these procedures are coded as a treatment for back pain, unrelated to the principal diagnosis of angina, and are allocated too low a value to cover the costs of providing the treatment. Under the current code (DRG 950) the hospital is left with a net loss in respect to implantation of the stimulator of approximately NZ\$15 000. In the light of our results, this situation is irrational and should be addressed urgently.

The main limitation of our study relates to the comprehensiveness of the cost estimates. The cost information was obtained from current Green Lane Hospital pricing data, and applied in the same way to pre- and post-operative periods. Any omitted costs are likely to follow the same trends as those we have included. Even if the exact dollar amounts were disputed, the central conclusion seems secure. SCS does lead to a reduction in the level of resources used by patients with angina, and eventually to saved money.

The exact place of SCS in the management of angina is uncertain. In addition to the patients described in this paper, for whom surgery was not an option, there is a group of patients in whom coronary artery grafting is feasible but associated with very high risk. It may well be that these patients would be better treated with SCS. Only one study has subjected SCS for angina to the rigours of a prospective randomised comparison with surgery. In this study, the effects of the two treatments were similar, but mortality was lower in the SCS group in an intention-to-treat analysis.¹⁹ We have begun a randomised prospective comparison of SCS with surgery in patients for whom the latter is possible but poses a higher than usual risk. The results of this study will help to refine our understanding of the indications for SCS. In the meantime there is a steady demand for SCS in patients for whom surgery is not an option. Our data justify continuing to meet this demand if possible.

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Stereotactic radiosurgery in New Zealand

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Abstract

Aims. To explain the use of Stereotactic Radiosurgery for intracranial lesions and report Dunedin Hospital's early experience with this treatment.

Methods. Review of a prospective computer database and departmental clinical files.

Results. 74 patients underwent 78 radiosurgical procedures between 30 July 1994 to 18 December 1997. 28 patients with arteriovenous malformations were treated with an obliteration rate of 82% (95% CI: 48% to 98%) at two years. Seventeen vestibular schwannomas (acoustic neuroma's) were treated, with follow-up magnetic resonance imaging available in eleven in whom there was no tumour progression after a mean period of twelve

months. There was preservation of some hearing in all patients not already deaf, but one developed a new facial palsy and another had worsening palsy as late side effects. Other tumours, including selected metastases, gliomas and skull base tumours have been treated in smaller numbers.

Conclusion. Rates of arteriovenous malformation obliteration, vestibular schwannoma control, and side effects of radiosurgery in Dunedin are comparable to those reported in other uncontrolled series. Radiosurgery is quick and has a low procedure-related morbidity but does have important limitations and delayed side effects, which means the decision to treat needs to be based on thorough multidisciplinary review.

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Stereotactic radiosurgery is focused irradiation of intracranial lesions based on three-dimensional images derived from CT or MRI. Therapeutic irradiation of the target while preserving adjacent tissue is achieved with the delivery of megavoltage multiple non-coplanar beams affording greater targeting accuracy than conventional radiotherapy.

The system involves positioning of a head frame to provide reference co-ordinates in three dimensions for brain structures seen on imaging. The Cosman Roberts Wells III (CRW) frame is fixed by pins to the outer table of the skull. The head frame remains in place during scanning, subsequent computer planning and irradiation. The Gill Thomas Cosman (GTC) relocatable head frame, which may be used instead of the fixed head-ring, was introduced to our unit in 1997. Images are imported to the Unix-based X-knife 3 radiosurgery planning software (RSA Boston) and reconstructed so as to provide a three-dimensional image of the brain. Arcs of radiation are used to deliver acceptable radiation doses to both the lesion and surrounding sensitive structures. The greater the lesion volume, the greater the risk to surrounding tissue. In most situations, this limits radiosurgery to lesions of three centimetres or less.

Once the treatment plan is complete, radiation is generated by a modified linear accelerator, the treatment taking between 30-40 minutes. The head frame is removed and the patient can usually be discharged the same day.

Methods

Linear accelerator radiosurgery has been used in Dunedin Hospital since 30 July 1994. 78 procedures have been performed for 74 patients up to the end of 1997. The unit caters for all New Zealanders, with 56 (76%) patients having come from outside Otago. 79 other patients were assessed for radiosurgery but were deemed unsuitable (on the basis of 'eloquence' of site, too large size or inappropriate indication) and were therefore declined. The mean (and median) age of those undergoing radiosurgery was 45 years (range, 3-80). Indications have comprised arteriovenous malformations (AVMs) and a wide range of intracranial tumours (Figure 1). The mean waiting time was thirteen weeks from booking to the date of the procedure and 95% were treated as outpatients. The mean lesion diameter was 2.3 cm, the largest 4.5 cm. The mean peripheral radiation dosage was 1407 cGY (minimum 1000 cGY, maximum 2500cGy) over the spectrum of lesions treated.

Results

Interpretation of both the clinical and radiological results of radiosurgery is very much dependent upon the indication for therapy. The aim of radiosurgical treatment for patients with AVMs is to prevent future haemorrhage whereas in tumours it is to arrest growth and prevent recurrence.

Radiosurgery may be associated with three distinct types of morbidity: head-frame pin-site problems, acute neurological side effects occurring within several weeks and late neurological side effects which begin months after radiosurgery. The neurological side effects depend upon the anatomical location of the irradiated lesion and the volume irradiated.

Pin-site morbidity was independent of the lesion being irradiated and included bruising, swelling of eyelids, controllable bleeding, resolving scalp numbness or infection in thirteen of the 70 patients (19%) who had radiosurgery with the CRW head frame. Similar problems occur commonly with use of the skull fixation in neurosurgical procedures. However, this problem has so far been avoided in suitable patients by the recent introduction of the GTC relocatable head frame which has been used in four patients.

Arteriovenous malformations. AVMs represent the largest group of pathologies treated (Figure 1). Although none of the 28 patients had medical contraindications to surgery, radiosurgery was considered safer in 25. In many cases this was due to the 'eloquence' of adjacent brain tissue. Six patients had undergone previous incomplete resection, two had received unsuccessful conventional radiotherapy, and one patient had prior therapeutic embolisation. Median follow-up was fifteen months and includes those recently treated patients with no follow-up information and one patient seen 36 months after treatment. There was MRI evidence of complete obliteration at 24 months in nine out of eleven (82%, 95% CI: 48-98%) patients with more than two years follow-up. The specificity of MRI in detecting AVM closure may approach 100%.¹ Angiography was performed in eight of these patients and confirmed complete obliteration.

There were acute neurological side effects in two patients consisting of a few hours of dysphasia in one and a single tonic-clonic seizure in the other. Late neurological side

effects occurred in seven patients and included one or more of headache, diplopia, memory loss, ataxia, temporary hemiparesis, sensory disturbance, facial palsy and quadrantanopia. These symptoms completely disappeared in two patients and were still present to some degree at the most recent follow-up consultation in the remainder. One patient suffered post-radiosurgery haemorrhage at six months with full neurological recovery. Another died of pre-existing but unknown intestinal worm infestation.

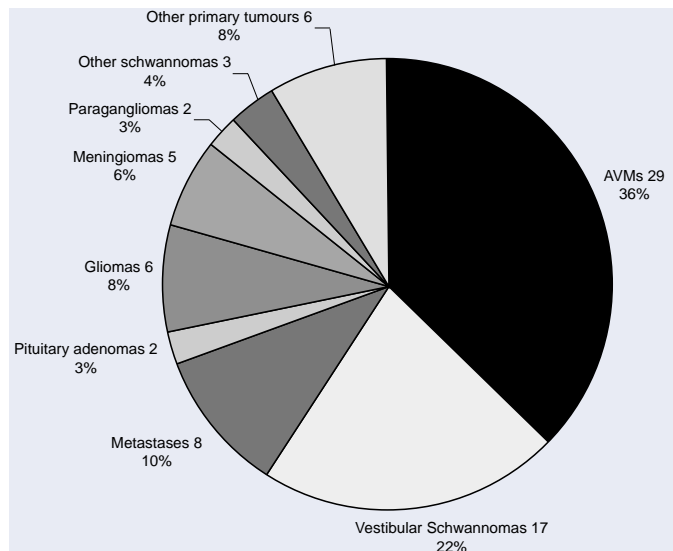


Figure 1. Pie chart showing the distribution of the 78 lesions treated in this series.

Vestibular schwannomas. Sixteen patients with seventeen vestibular schwannomas were treated ranging in size from 0.5-3.5 cm. Reasons for radiosurgery included medical contraindications to surgery (four patients), patient preference (five patients) and referring specialist opinion that radiosurgery would be more likely to preserve cranial nerve function (six patients). One patient's lesion was considered too small to warrant surgery but ideal for radiosurgery. Another had radiosurgery for residual tumour after incomplete surgical resection. Of the eleven vestibular schwannomas followed up with post-radiosurgery MRI, ten had remained the same size and one was smaller (follow-up range: 4-18 months).

Audiograms were performed 8-26 months after radiosurgery in thirteen ears to yield Gardner-Robertson² hearing scores (Table 1). Deterioration occurred in ten, which was by one class in seven ears and by two classes in the other three (one of which dropped from 'non serviceable' to 'none' in one ear). There was no hearing to preserve in two, and no change for the remaining patient who had 'poor' hearing in one ear before radiosurgery.

Table 1. Gardner-Robertson hearing class (based on pure tone average) before and after radiosurgery for vestibular schwannoma in thirteen ears.

	Clinical description	Pure tone average	No. of patients before	No. of patients after
I	Good	0 to 30 dB	5	0
II	Serviceable	31 to 50 dB	2	3
III	Nonserviceable	51 to 90 dB	3	4
IV	Poor	91 dB to max. loss	1	3
V	None	No response	2	3

There were two lower-motor-neurone facial-palsies, tinnitus in one, and resolving facial pain in another with a mean

follow-up of twelve months (excluding four recent patients in whom follow-up information is not yet available). One had new facial palsy with a House Brackmann³ grade of two ('slight weakness on close inspection'). The other had a pre-existing grade two upper-motor-neurone facial weakness that deteriorated to grade four ('obvious weakness and/or disfiguring asymmetry') after radiosurgery but is now improving.

Other tumours. There were 30 other patients with a range of intracranial tumours (Figure 1). Six patients had intracranial metastases: melanoma (two patients), choriocarcinoma, bronchogenic adenocarcinoma, bowel adenocarcinoma, and adenocarcinoma of unknown origin. Gliomas treated were of all grades. Two unsuccessfully resected pituitary adenomas were included: one non-functional macroadenoma and the other secreting adrenocorticotrophic hormone. Surgically difficult meningiomas, parangliomas, vagal, and trigeminal schwannomas were treated. Other lesions included primitive neuroectodermal tumour, cerebellar haemangioblastoma, chondromyxoid fibroma of the cavernous sinus, pineocytoma, craniopharyngioma and cerebello-pontine angle sarcoma.

The largest maximum tumour diameter was 4 cm. In many cases, radiosurgery was used as an adjunct to surgery, conventional radiotherapy or chemotherapy. Reasons for radiosurgery included difficulty of surgery due to the eloquence of adjacent brain structures in 24 and medical contraindications to surgery in two patients.

The mean clinical follow-up for patients with other intracranial tumours was thirteen months. There were no follow-up data available for five patients. Imaging data were available for eighteen tumours and showed that two were bigger, eleven were the same size, and five were smaller after an average time to imaging of sixteen months. The only acute neurological side effect occurred when a radiation field overlapped the area postrema in one patient and caused vomiting during treatment. Six patients had late neurological side effects that included improving hemiparesis, ataxia, vomiting, blurry vision, headache, muscle twitches and acute coma (resolved). Radionecrosis occurred in the cerebellum of one patient causing ataxia and morning vomiting which prompted surgical resection of the area. Four patients died due to sequelae or progression of disseminated cancer and one from high-grade astrocytoma.

Discussion

The most established indication for radiosurgery is AVMs.⁴ Radiosurgery is best suited to AVMs with a nidus diameter of less than 3 cm. Deeply situated AVMs or those bordering on eloquent brain structures have been targeted because of the difficulty of resection. Radiosurgery causes obliteration of AVMs and removes the risk of haemorrhage. In contrast to surgery, however, there is a variable latency period of continued risk at a pre-treatment level until obliteration occurs.⁵ Other series have shown that 68-100% of stereotactically irradiated AVMs are fully obliterated at two years.^{6,7} Our two-year obliteration rate of 82% (95% CI: 48-98%) is within this range. Two patients had elective hypofractionation and planned future dosing with no expectation of obliteration within two years. Under usual circumstances, failure of obliteration within three years is an indication in the Dunedin unit to consider repeat radiosurgery or resection.

Radiosurgery offers an alternative in the primary treatment of vestibular schwannomas, leaving open the possibility of future surgical intervention.⁸ Early studies have shown either reduction in size or arrest of tumour growth in

over 90% at one year and up to 89% at four years,^{8,9} with rates of cranial nerve damage comparable to the best surgical series.^{10,11} No tumours have enlarged so far in our series. Although some hearing has been preserved in all but one patient who had hearing preoperatively, there was a significant fall-off in hearing (Table 1) in those tested. The incidence of facial palsies is comparable to other series¹² but patient numbers are small.

The standard treatment of high-grade glioma is surgical biopsy or debulking followed by conventional radiotherapy. Evidence for success with radiosurgery in the treatment of low-grade gliomas is incomplete from retrospective studies: it is possible there is survival benefit with combination therapy in this group.¹³ High dose radiosurgery boosts after relapse with conventional treatment may give similar results to radioactive implants.¹⁴

Radiosurgery may emerge as an alternative to the conventional surgical, chemotherapeutic and radiotherapeutic treatments for brain metastases. Uncontrolled series with follow-up from several months to one year show tumour growth can be arrested or reversed in 84-97% of patients with a range of intracranial metastatic lesions.¹⁵⁻²⁰ Radiosurgery has been successfully used as a primary treatment and after relapse, with results comparable to those of combined surgery and conventional radiotherapy. Its role still must be regarded as uncertain. Radiosurgery may provide an alternative to surgery for patients with small meningiomas in surgically difficult areas such as the cavernous sinus or skull base. The largest study of radiosurgery reports only short-term results with a 96% control rate at two years for meningiomas less than 5 cm in diameter, but it is uncertain whether this represents an improvement over the natural history.²¹

The close proximity of pituitary tumours to the relatively radio-sensitive optic chiasm means that radiosurgery poses a significant theoretical risk to vision. It is unlikely that conventional medical and surgical management will be challenged although there may be a role for radiosurgery after failed pituitary resection or in hormonally active tumours. Radiosurgery may be the non-surgical treatment of choice for secretory pituitary tumours when surgery has failed and in those that extend into the cavernous sinus.²² Although radiosurgery has been used to treat a number of other tumours, there is considerable uncertainty as to its efficacy. However, it is still used on a case-by-case basis in special circumstances.

In conclusion, radiosurgery is useful for the primary obliteration of small AVMs and intracranial tumours for

patients with relative or absolute contraindications to surgery. Radiosurgery may also offer significant benefits as an adjunct to other treatment modalities. Advantages over surgery include low morbidity and pain, no craniotomy scars or hair cut, no need for general anaesthetic, no resection or retraction of normal brain tissue and return to the community the day after treatment. Despite these advantages, it is clear that appreciable acute and delayed morbidity is associated with radiosurgery and a multidisciplinary team is needed to balance these risks during treatment planning.

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Doctors pay out £77m in compensation

Doctors paid a record £77m in compensation to patients last year – almost double the amount paid out in 1996, when £41m was distributed.

The Medical Defence Union, which represents doctors in negligence claims, warned that the dramatic rise in cases could result in a similar situation to that in the United States, where surgeons in high-risk areas of medicine become increasingly nervous about carrying out life-saving procedures, for fear of being sued.

Last week the MDU said the rise in payouts was due to higher awards and the fact that more patients were suing, rather than poorer care. Michael Saunders, its chief executive, said: "The rise in litigation is not attributable to a fall in clinical standards – quite the opposite. But it is indisputable that the medico-legal climate has changed dramatically over the last 10 years".

"Patients and their relatives are bringing more claims, and the amounts awarded in compensation are getting higher, principally because of the increasing costs of caring for damaged patients. Recently a brain-damaged patient received £3.5m in compensation from the National Health Service."

Keith Parry. *Guardian Weekly* 10-16/8/2000,

Rehabilitation that works - vocational outcomes following rehabilitation for occupational musculoskeletal pain

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Abstract

Aims. To describe the short term vocational outcome for accident compensation claimants with disabling musculoskeletal pain following a comprehensive, interdisciplinary rehabilitation programme.

Methods. A telephone follow-up audit of clients who had undertaken a rehabilitation programme characterised by a cognitive-behavioural approach with self-management, reconditioning, vocational rehabilitation and psychological pain management.

Results. Of 62 clients who had undergone a rehabilitation programme, we obtained follow-up information on 49 (79%). These were predominantly male, aged in their mid 30s, manual workers with low back pain and a median sick leave of twelve months. At a median of five months a

vocational success was achieved in 75%: working full time (47%), part time (12%) or actively looking for work (16%). Of those in work, 48% went back to the same job, 7% went back to the same job but with a different employer and 15% went to a different job that used the same skills. Logistic regression analysis showed that duration of work disability was the major predictor of vocational success (OR 0.36, 95% CI 0.18 to 0.78, for a difference of twelve months).

Conclusion. Despite the uncontrolled nature of these results, it is likely that the rehabilitation programme had a significant impact in getting compensation claimants back to work. Only a minority require substantive retraining and early intervention is associated with a better outcome.

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Chronic musculoskeletal pain is a major source of community disability and unhappiness with significant financial costs to employers, insurers and patients.¹⁻³ Occupational musculoskeletal pain in the context of a workers' compensation environment may be especially problematic. New Zealand has had a relatively unique compensation system which has been characterised until recently as being a universal, 24 hour, no-fault, unfunded liability scheme with responsibility for partial wage replacement and medical and rehabilitation costs for personal injury. We have presented data that suggest claimants with low back pain in New Zealand may recover more slowly than people in alternative compensation environments.⁴ This may have become worse over the last decade.⁵

Although the majority of people with an acute episode of low back pain stop seeking health care within a short period of time, a number continue to experience symptoms and some become disabled.⁶ This group contributes most to the overall burden of musculoskeletal pain in the community, both in terms of personal suffering and societal costs.⁷ It is important to know how best to manage this group to relieve their suffering and restore functional ability.

'Multidisciplinary rehabilitation' has been one approach to this problem but the term is not especially well defined. It is difficult to know which combination of interventions and which method of delivery is correct for which patient. It is also difficult to know from the published evidence which approach might be effective in the New Zealand workers' compensation environment. We are aware of a single New Zealand based report on the outcomes of rehabilitation for low back pain.⁸

In response to a perceived lack of appropriate rehabilitation services for compensation patients with disabling musculoskeletal pain in the Wellington region, a multidisciplinary service was established at Hutt Hospital in late 1997 and the first programme commenced in February

1998. This report describes the initial vocational outcomes of the first 62 patients rehabilitated over the first year who were at least three months from the end of their rehabilitation programme.

Methods

During early 1999, all patients who had undergone a rehabilitation programme at WorkWell, a multidisciplinary rehabilitation service for compensation claimants with musculoskeletal pain, and who were at least three months from the end of their programme, were contacted by telephone and underwent a structured interview.

The rehabilitation programme was based around an interdisciplinary rehabilitation team and cognitive-behavioural model adhering to a number of principles: focus on teaching self-management skills and adaptive attitudes and beliefs (especially fear avoidance beliefs), developing a sense of personal control over one's health condition and one's environment, shared and congruent goals, and emphasis on increasing functional ability rather than palliating symptoms (particularly occupational function).

The programme consisted of a screening assessment phase, a three week intensive phase where clients attended daily for six hours each day as part of a group (the 'treatment' phase), followed by a three week 'integration' phase where clients met with therapists individually to translate any skills or attitudes learnt into real-life situations at home or the workplace. The content of the treatment phase consisted of graduated exercise, tuition and practice in relaxation and other cognitive pain management techniques, education especially in regard to job seeking skills, stress management, assertiveness, health psychology, and family sessions with an overall orientation of adult-learning and sports-coaching rather than a traditional 'therapy' orientation. The integration phase was particularly important in providing a time for detailed return to work planning, work place visits or vocational counselling to quickly direct clients into a structured return to work programme.

Demographic variables were collected that included age, gender, occupational type, length of time off work, and site of pain. Health status was measured at first assessment and immediately following the programme using the Short Form 36 questionnaire.⁹ The scores were expressed in number of standard deviations from the mean of an age and sex matched normal UK population.¹⁰

At telephone follow-up a structured interview gathered data mainly related to occupational function. Clients who are not working but who might be capable of work ('work-ready'), pose a difficult measurement problem. We define work-readiness in behavioural terms. That is, clients

who had applied for more than one job in the previous month were felt to be demonstrating job-seeking behaviour and could be deemed work-ready. We thus defined four categories of vocational outcome: working part-time, working full-time, actively seeking work and neither working nor looking for work. A successful vocational outcome was defined as any of the first three categories.

Clients were asked how useful they found the programme and to rate this on a five point scale (1=not useful, 5=very useful). They were also asked whether they had consulted a health professional for their back condition or used pain medication since the programme (none, rarely, regularly, always).

Descriptive (mostly ordinal) data are presented as the median and interquartile range. Bivariate correlation analysis using Kendall's tau-b for ordinal and continuous variables was used to identify factors associated with vocational outcome ($p < 0.05$). Vocational outcome was then dichotomised into success or not (success being defined as working at least part time or actively seeking work). Multiple logistic regression analysis was used to select (stepwise forward and backward method, $p < 0.05$ for entry and 0.10 for removal) factors that were associated with a successful vocational outcome in the multivariate case. SPSS version 7 for Windows was used for the statistical analysis.

Results

From January 1997 to January 1998, 127 clients were referred for assessment. Of these, 50 (39%) did not proceed to either assessment or rehabilitation because funding was not approved by the ACC case-manager. Clients and staff agreed that a further 14% of assessed clients were unsuitable for the rehabilitation programme. Of the remainder, 62 entered the rehabilitation programme and were at least three months from the end of their programme; they form the study sample. Of these, we were able to contact 49 (79%) clients by telephone for the follow-up survey.

There were no statistically significant differences between clients whom we could trace and those whom we could not, in terms of demographic features or pre rehabilitation SF-36 scores (Tables 1 and 2). Clients were generally male, mid thirties, out of work for months and were manual workers. Nearly all had low back pain but the few that did not, had musculoskeletal arm or neck pain and their management was virtually identical.

Approximately three-quarters of the cohort obtained a successful vocational outcome. Twelve (24.5%) were neither working nor seeking work. The remainder were actively job seeking (8, 16%), in part time work (6, 12%) or in full time work (23, 47%). Of those who were working full or part time (29), only 30% were in a job that required different skills from their most recent employment. The others went back to the same job (48%), went to a different employer but the same job (7%) or found a different job that used the same skills (15%).

Table 1. Demographic features.

	Clients contacted (n=49)	Clients not contacted (n=13)	p value
Age (mean, 95%CI)	39 (37, 42) years	35 (30, 40) years	NS
Gender (% male)	76%	69%	NS
Site of pain (% back)	84%	92%	NS
Occupational type (% manual)	71%	85%	NS
Time off work (median, IQR)	13 (0, 54) months	9 (0, 71) months	NS
Time from programme to follow up telephone call (median, range)	5 (3, 13) months		

The factors significantly associated with vocational outcome are shown in Table 3. A separate logistic regression analysis to predict a successful vocational outcome (defined as working at least part time or actively job seeking), found that only gender and time off work prior to rehabilitation contributed significantly to the model (Table 4). Time off work appeared to be the most important factor (Figure 1).

Table 2. SF-36 scores prior to rehabilitation programme.

	Clients contacted (n=49)	Clients not contacted (n=13)	p value
Physical function	-3.0 (-3.4, -2.6)	-3.4 (-4.2, -2.6)	NS
Physical role limitations	-2.9 (-3.2, -2.5)	-2.4 (-3.4, -1.5)	NS
Mental health	-1.2 (-1.7, -0.8)	-1.2 (-2.2, -0.2)	NS
Mental role limitations	-1.6 (-2.1, -1.1)	-1.1 (-2.2, 0.0)	NS
Pain	-2.6 (-2.8, -2.3)	-2.4 (-3.2, -1.5)	NS
Energy/vitality	-1.2 (-1.5, -0.9)	-0.9 (-1.5, -0.2)	NS
Social function	-2.4 (-2.9, -2.0)	-1.3 (-2.4, -0.2)	NS
General health perception	-0.8 (-1.1, -0.5)	-1.8 (-2.7, -0.8)	NS

Scores are expressed as mean (95% CI) z-scores, which represent the number of standard deviations away from an age and sex matched population average.

Table 3. Bivariate correlation coefficients for potential associated factors with vocational outcome. Only factors which demonstrate statistical significance are shown (Kendall's tau-b).

Factor	Correlation coefficient	p value
Age	-0.23	<0.05
Personal rating of programme usefulness	0.41	<0.01
Contact with health professional	-0.49	<0.01
Medication use	-0.30	<0.05
Time off work prior to programme	-0.43	<0.01
Post programme SF36 Pain	0.31	<0.01
Post programme SF36 Physical function	0.35	<0.01
Post programme SF36 Social	0.44	<0.01

Discussion

The claim exit rate for ACC claimants of more than twelve months duration is about 20% (ACC Annual Report 1998). Clearly, the vocational success rates of the rehabilitation approach we described compares very favourably. Despite the absence of a control group, we know enough about the natural history of compensated musculoskeletal pain to be fairly confident that the people treated by the rehabilitation programme achieved better outcomes than if they had not received rehabilitation. Internationally, there are substantial data to support the effectiveness of a cognitive-behavioural approach to chronic pain and disability and some support for the approach that has been termed 'functional restoration'.¹²⁻¹⁵

Table 4. Results of the logistic regression analysis for successful vocational outcome (model fit chi square=17.57, df=2, $p < 0.05$).

Factor	Regression coefficient (SE)	OR (95% CI)
Time off work prior to programme (years)	-0.08 (0.03)	0.36 (0.18, 0.78)
Gender (male/female)	-3.53 (1.89)	0.03 (0.00, 1.20)
Constant	6.48 (2.41)	

We have also confirmed a large body of work that suggests duration of work disability is not only a *measure* of outcome, but represents a *key predictor* of poor outcome in that the longer the duration of disability, the less likely is a return to employment. Intervention prior to the development of chronic pain behaviour and maladaptive beliefs is probably of critical importance.¹⁶ Furthermore, we have shown that most people who do obtain work by three months post rehabilitation are able to use preexisting skills rather than re-train. Only 30% of people in employment were in a job that required different skills from their previous occupation. This has important implications for the focus of vocational rehabilitation services.

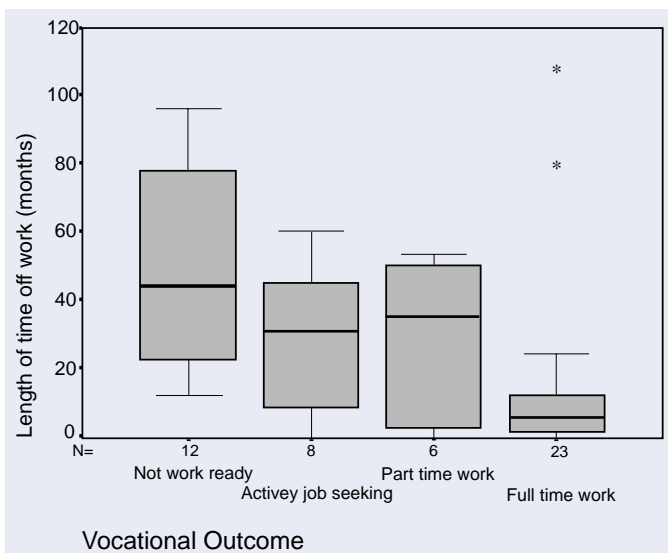


Figure 1. Relationship of time off work to vocational outcome. Box plots show median, interquartile range, and extremes (values greater than 3 box-lengths beyond the box). The whiskers denote the range of values that are not extremes or outliers.

Although the univariate correlation analysis suggested a number of factors that might be associated with vocational success, only time off work remained statistically significant in the multiple logistic regression analysis. This is probably because time off work is strongly correlated with many other prognostic factors (data not shown). Although the logistic regression analysis found gender to be of some additional predictive value, this did not reach conventional statistical significance. Gender was not statistically significant in the bivariate analysis. The reason for the discrepancy is probably due to small numbers, a different distribution of vocational outcome amongst males and females and the different way in which vocational outcome was defined in the two analyses.

Why should this programme work, when the experience of many health professionals is that compensation claimants are so difficult to manage? Possible reasons include: first, rigorous assessment, orientation to the goals of the programme and commitment of the client prior to commencement of the treatment phase; second, re establishment of a work like daily structure; third, integration of physical exercise, psychological pain management, vocational training and health education as a complete package; and fourth, the synergy that occurs through true interdisciplinary practice. If these elements are important, then clearly it will often be beyond the resources of isolated health professionals to manage chronic musculoskeletal pain and disability effectively.

Patient selection is a potent source of bias in uncontrolled observations. Access to assessment or rehabilitation was denied by the insurer in 39% of referrals. It is possible that claimants whom their insurer judged unsuitable for our programme did not need this intervention, but it is more likely that claimants denied rehabilitation cover have a worse prognosis than those not denied cover. The success rates we have observed may therefore be an overestimate in less selected populations.

We endorse the ACC Low Back Pain Guideline recommendation to refer people with low back pain and work disability that are slow to recover, to appropriate multidisciplinary teams. However, this intervention is expensive and adequate resources need to be available for effective implementation. Our experience has been that such a service is barely sustainable in the New Zealand

compensation environment. From January 1999 to June 1999, referral rates dropped below what was felt to be clinically or financially viable. Although it may be the case that fewer patients are developing chronic work disability, there are insufficient data to be sure about this. An equally plausible hypothesis is that patients who 'pass' the Work Capacity Test move from ACC wage replacement to Income Support, rather than receive adequate rehabilitation. We are unaware of data that could verify either position.

The Work Capacity Test formalises the 1996 amendment to the ARCIC Act that changed the exit criterion from needing to be able to work in the previous occupation to being able to work 30 hours in any suitable occupation: "to engage in any work for which the person is suited by reason of experience, education or training".¹⁷ With the introduction of this legislation, 'claim exit' is not the same as 'return to work': clearly it is important for outcomes to be defined carefully. We should note that the Work Capacity Test is only supposed to be invoked once all rehabilitation is complete, and not as a substitute for adequate rehabilitation. The courts have clearly placed Work Capacity Test at a point once "...various objectives of vocational rehabilitation and/or retraining have been carried out and that there appears to be no impediment, either occupational or medical for that person remaining".¹⁸ However, it may be difficult for case-managers to know when such a point has been reached.

Despite the effectiveness of our programme, it is no longer in operation. We suggest that purchasers of services for people with occupational musculoskeletal pain and disability carefully monitor the effect of policy and legislative changes upon such people. We believe that this audit sets a standard for adequate rehabilitation of New Zealanders with disabling musculoskeletal pain; it is to be hoped that insurers and case-managers will find such a standard helpful when deciding that rehabilitation is 'finished'.

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Prescribing the pill: obligations of health professionals

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NZ Med J 2001; 114: 188

For some time now, all who prescribe the pill have received the clear message that women have the right to be informed of the risks associated with combined oral contraception, and it is essential to take a careful personal and family history before initiating pill use.¹ An investigation I concluded into a complaint about a general practitioner (GP) who prescribed a third generation combined oral contraceptive pill (COC), highlights these issues.²

During consultation, the patient requested an oral contraceptive for relief of dysmenorrhoea. She was prescribed a third generation COC. The prescribing GP failed to take a careful family or personal history or advise the patient of the risks. He felt that his brief consultation with this fit active 20 year old in a walk-in clinic setting was sufficient, as the patient's needs related to dysmenorrhoea rather than contraception. He said he had intended to review the patient's use of the COC after three months and that he had not informed her of an increased risk of blood clots with this third generation COC: "no such increased risk exists, or if it does exist, for practical purposes it is immeasurably small".

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), Ministry of Health, issued a publication 'Oral Contraceptives and Blood Clots' in February 1999, with an attached letter outlining the risks of third generation oral contraceptives and the link with blood clots. The publication advised that taking COCs increases the risk of blood clots to two in 10 000 women, that is, six times the risk in non-users and twice the risk with second generation oral contraceptives.

My opinion found that the GP breached Right 4(l), Right 6(l)(b), Right 6(2) and Right 7(1) of the Code of Health and Disability Services Consumers' Rights. In my opinion the GP did not provide services with reasonable care and skill by failing to undertake a careful history and blood pressure check. Nor did the GP provide sufficient information about

side effects and specific information about the particular contraceptive pill that she was to be prescribed.

A common concern is that it is not always feasible or practical to inform patients about all possible adverse effects of a course of treatment, and that "an overly-alarmist response where actual risk is remote might lead patients to reject a form of treatment and inadvertently expose themselves to greater risks in other ways".³

My opinion accepted that a reasonable patient would not ordinarily expect to be told about absolute risks of a magnitude of 2 in 10 000. However, where there has been extensive publicity about the six-fold increase in the risk of blood clots with third generation COCs, compared to non-use, fuller disclosure was required. The patient did not receive sufficient information to enable her to make an informed choice.

My opinion also recognised that there is a continuing debate about the true extent of the risk of blood clots associated with the third generation oral contraceptive pills. However, in accordance with the Medsafe advice, and in keeping with the reasonable expectations of consumers in such circumstances, health professionals in New Zealand are required to inform women about the debate and the heightened risk of blood clots. The Medsafe publication 'Oral Contraceptives and Blood Clots' is far from alarmist in nature and is an effective tool for health professionals to ensure that this obligation is fulfilled.

A full version of my anonymised opinion of case number 99HDC03 994 may be viewed at www.hdc.org.nz.

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VIEWPOINT

The RUB

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There are a number of difficult ethical issues in making decisions about withholding and withdrawing life saving treatment. The situation in which these occur often involves a patient admitted relatively acutely having suffered a medical catastrophe. The other common situation involves a decision concerning Cardio-Pulmonary Resuscitation (CPR). In such cases we often think only of the simple alternatives - life and death but there is another significant category - survival in an unacceptably bad state for the patient concerned. There is always, in such decisions this

third factor - the risk of unacceptable badness. The RUB is an acronym for the Risk of Unacceptable Badness and captures the third possibility in life threatening situations. It therefore has a satisfying resonance with its literary source in Shakespeare's Hamlet. Hamlet, in the crucial soliloquy, muses:

To sleep, perchance to dream, Aye, there's the rub.

He is worried about what he should do having been told by a ghost that his uncle (who has since married his mother) murdered his father. He cannot decide whether he should

take revenge on the basis of this possibly suspect information or leave things as they are. If he acts on demonic information and commits a mortal sin he will of course be damned, but if he fails to avenge his father he cannot live with himself. He thinks about suicide and the release of eternal sleep that that would promise but then he contemplates the possibility that in death one dreams. The prospect of spending eternity dead, and therefore, impotent, but wracked with the moral torments that have provoked his suicidal thoughts is, to him, an unacceptably bad prospect. He recognises that there is a risk of falling into this unacceptably bad state. He therefore faces the RUB.

Shakespeare's Hamlet faces the RUB as a crucial factor at one point in his story but doctors face this problem time and again. Patients and relatives are often told that there is a probabilistic chance of surviving a serious catastrophe if a certain course of action is taken. The image created is a small chance of life on the one hand and a black hole - death - on the other. Faced with this stark choice many will say "Well, doctor, go for it; after all, any chance is better than none." But this decision is not always made in the light of the real probabilities. The realities of survival may be that the person, if saved, will be left in an unacceptably bad state. The RUB expresses this fact in terms of the probability of survival in an unacceptable rather than an acceptable state of living.

For instance, a patient with a severe brain injury may have a 5% chance of survival but, if he survives may have only a 10% chance of living in a state he would find acceptable and a 90% chance of living in a state he would consider unacceptably bad. The RUB takes this risk into account. It acknowledges the 5% chance of survival but then says "The reality is that, if he does survive there is a nine to one chance that he will not thank us for having saved his life." The realities of this wager are very sobering. It is hard to imagine a telling analogy to bring it home to the decision maker involved but perhaps the following is helpful. Imagine that you are standing in front of a pair of doors. You are told:

If you choose the left hand door you will die. If you choose the right you will immediately be tipped into one of ten chutes. Nine of these will leave you demented, bedridden, with tubes in your nose and veins and bladder and unable to do anything for yourself but one will allow you to recover to something like your normal self Which door do you choose?

This is a very significant choice and should provoke deep ethical consideration, especially when somebody else is making it for you or you are making it for somebody else.

In fact the role of relatives or other surrogate decision makers is not widely appreciated among doctors. In most jurisdictions the relatives have some say, whether binding or not, on the treatment that is given to an incompetent patient suffering a medical or traumatic catastrophe. But the ethics of the decision require that those making the decision try and do what the person at risk would have wanted to happen to him or her and not what they think should happen. This applies as much to medical staff as to relatives and it puts the role of relatives into the right perspective. Their role is solely to inform the decision-makers of what they know the person to have been like and what they think he or she would have wanted. Of these two types of information the first is the most valuable in that it allows the care-giving team to form their own unprejudiced opinion of what it is best to do. It is very clear, in terms of potential conflicts of interest, perhaps over property or perhaps for some other reason, why this is the key. The ethical responsibility is to make the best decision in the light of what the patient would have wanted, acknowledging that this involves a degree of uncertainty when the patient is unable to take part in the discussion. We should also acknowledge that there may be considerable medical uncertainty about the unfolding reality in an acute care situation.

As a profession we are bad at admitting uncertainty in that we fear that patients will lose confidence in us if we do so. There is, however, no evidence that that is so and anecdotal evidence to support the opposite view. If one is uncertain, one should say so. That initial step of openness is particularly important in acute care where a period of intervention may be required in order to gather the information required for a good prognosis to be arrived at. There is a further widespread and mistaken belief among doctors that beginning treatment and then stopping it is worse than not beginning it at all. But again this does not bear up under rational scrutiny. The need for the best information - for instance, about the initial insult and its response to treatment - implies exactly the opposite. What is important however, is that clear signals are given that treatment is being trialled and that the patient's response is an important indicator of how long the trial should continue. If the uncertainties of acute care are acknowledged and the idea of a trial of treatment is communicated then withdrawing becomes a decision which must be faced by all and not just a "bolt from the blue" signalling a change in management policy. People in general are, very good at coping with this kind of thing if they are informed about what is going on and the withdrawal of lifesaving treatment becomes an issue to be revisited and not just part of a clandestine medical process from which the patient and relatives are excluded. It is in this context that the RUB can be mooted and considered by all parties.

The RUB implies that we cannot take a simplistic 'two options' line in life and death situations and say: "Well, any chance of living is better than none." Once we see that the chance of survival might only be bought at the cost of a very high risk of an unacceptably bad survival, the reasons for going beyond simplistic thinking are pellucidly clear to all. This ought to give pause to anybody with the best interests of the patient at heart because we have a responsibility to do what he would want if he were able to choose. Of course, the best way of getting at what his assessment of an unacceptably bad state might be is by asking the relatives and others that knew him. In the case of an incompetent patient, this questioning is in the service of trying to ascertain the values and interests that he or she had before the catastrophe in question. Even if there is not an explicit advanced directive, there is usually enough evidence to be able to form some judgement about these things. In an entirely analogous way we can, in a discussion of CPR with the patient him or herself, clearly convey the RUB so that the "any chance is better than none" line is much less attractive than it seems on first pass.

A commitment to paying attention to the RUB entails that life and death decisions in critical and other situations are seen for what they truly are and not just as a choice between two alternatives- life (to be valued positively) and death (to be valued negatively). The RUB captures the third alternative: life to be valued negatively. Once that is put into the moral balance along with the other two the balancing act changes its nature.

The RUB is not necessarily a concept explicitly to be used with patients and relatives. But it is a concept which should inform the ethical advice given by clinicians and, where appropriate, clinical ethicists who are dealing with the life and death decisions that are all too common in clinical practice. To be aware of these things does not make life and death decision-making easier and may even make it harder. But it also makes it more responsive to the hopes and fears of any person faced with the mortal perils that often wait at a hospital door.

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What does the human genome project mean for medicine?

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We have heard a great deal about the promise and perils of genome knowledge, particularly since the announcement in June 2000 of a draft human genome sequence. This reflects progress over the past 25 years in our understanding of the detailed structure of human chromosomes and genes, fuelled by the discovery and application of genetic modification methods. In 1975 we knew of only a small number of human genes and the chromosomal location of few were known. Now we have the DNA sequence of all our chromosomes, and this spells out the detailed structure and precise location of every gene. A good analogy is like moving from a view of the world as a group of continents with only a handful of identified landmarks, to one where every detail of interest in each continent is precisely marked and described.

This extraordinary technological feat must surely rank as one of the greatest in human history, but what does it really mean for medicine? There is little doubt that knowledge of the genome sequence of humans, and other organisms including various laboratory animals and many pathogens, will lead to significant improvements in medical practice and human health. Equally, there is little doubt that the acquisition of this knowledge brings with it ethical risks that need to be carefully considered and well managed. In this article I consider how, where, and when genome knowledge will impact on patients.

Inherited disorders

Part of the motivation for genome sequencing was to provide more effective tools for identifying genes that underlie inherited disorders, some 4000 of which are documented.¹ In the absence of detailed genome sequence knowledge, isolation of each gene responsible for a Mendelian condition requires massive effort. The human genome sequence was viewed as the ultimate gene map, and the rate of identification of genes underlying rare inherited illnesses has matched the growing accumulation of genome sequences over recent years.²

The identification of a causative gene for an inherited condition often leads to development of DNA tests that allow carrier detection and prenatal or presymptomatic diagnosis in affected families. As a consequence of the genome project, the technology for performing such tests is evolving rapidly.²⁻⁴ Many of the newer methods and equipment being developed aim at high-throughput, automated analysis of DNA variation. This means that genetic testing for multiple disorders should eventually become a realistic proposition.

Identification of the causative gene also provides fundamental insights into the molecular basis for a disorder, and accelerates the acquisition of basic knowledge so vital to the understanding of a disease and its potential treatment. However, because of the small markets for treatments aimed at rare conditions, this work will continue to depend on academic laboratories with specialist research interests.

Despite the wealth of human gene sequence knowledge now available, the connection between an inherited disease and a gene can only be made, with rare exceptions, when

additional strong clues exist. These clues will come from identification and detailed analysis of families in which the condition is segregating, and the development of animal models that mimic the illness. The mouse is a valuable source of such information, as it is genetically very similar to humans and amenable to a range of genetic modifications. Genetically modified mice developed in the course of basic functional analysis of genes occasionally exhibit phenotypes with similarity to human conditions, providing novel insights for the understanding of human disease.

For families suffering from very rare inherited diseases, the provision of accurate and useful advice relevant to their condition is often difficult. Unfortunately, the human genome sequence does little to immediately alter that situation, although it illuminates the route by which we will discover the genes responsible for these inherited disorders.

New tools for diagnostics and disease management

One of the immediately useful products of the genome project is a catalogue of human genes. The DNA sequence and cloned copies of most human genes are readily available, although it is true that we have few clues to the function or identity of the vast majority of these genes. There is still disagreement about the precise number of human genes, which may range from 35-120 000, as many of the estimates are guided by imperfect computer-based analysis of DNA sequence.^{5,6} Despite these issues, collections of isolated gene sequences make it possible to survey *en masse* changes in expression patterns resulting from disease, drug treatment, or other environmental or biological insults.⁷⁻⁹

The principle of these microarray methods is that gene sequences are applied to glass slides using very precise robotic systems. The resulting grids of gene sequences can then be probed with fluorescently labelled copies of cellular RNA derived from tissues of interest. The patterns of fluorescence generated on the microarray can be captured by fluorescence microscopy and automatically interpreted by computer algorithms, to indicate which genes are up-regulated or down-regulated in different states.

We are starting to see the application of microarrays as a tool for better understanding drug effects and in drug discovery.^{9,10} and there is an explosion of basic research applications for microarray methodology.^{7,11} Furthermore, microarray systems are showing great promise for clinical applications. Using acute leukaemia as an example, Golub et al showed that microarray analysis alone could accurately define the difference between acute myeloid and acute lymphoid leukaemia, indicating the feasibility of such approaches with other cancers.¹² More recently Alizadeh et al used microarrays to identify two molecular sub types of diffuse large B-cell lymphoma, one of which had a significantly better overall survival than the other.¹³ Similar studies have been performed in breast cancer and melanoma.¹⁴

As the utility of these methods is established, how can we begin using them in New Zealand? Several research laboratories in this country are establishing microarray

systems, and these may facilitate adoption of this methodology in clinical practice, particularly oncology. However, it is likely that commercially produced microarrays or commercial service providers will, over the next few years, become available for a range of clinically important applications. Moreover, it is quite possible that microarrays will be supplanted by other methods as genomic technology is a rapidly changing landscape and the market for new and improved methods or equipment is large and very competitive.

Improved prescribing

Adverse drug responses are a significant cause of morbidity and mortality.¹⁵ The differential response of patients to drugs is significantly influenced by genetic factors,^{16,17} and the study of genes underlying such differences is known as pharmacogenetics.¹⁸ Genetic variation in many proteins that metabolise, transport, or are the target of drugs may contribute to inter-individual variability that underlies adverse drug responses.¹⁰ With some notable exceptions, few of the genes that contribute to adverse drug responses are known. The genome project offers great potential for identification of these genes and application of this information to improve the safety and efficacy of drug prescribing. Although this is a promise rather than reality, a significant proportion of the world's biotechnology industry is now focusing on the development and application of pharmacogenetics knowledge.^{19,20}

The key to pharmacogenetics is the recognition that the most common type of variation in the human genome occurs at single nucleotide positions in the DNA. These so-called single nucleotide polymorphisms (SNPs, pronounced 'snips') appear to account for much of the inter-individual differences attributable to genetics.^{21,22} Genome analysis has revealed that SNPs are abundant, and they have the desirable attribute of being easily assayed in automated systems. Much of the hardware and expertise dedicated to genome sequencing is now being focused on the search for SNPs and much of the impetus for this work comes from pharmaceutical or biotechnology companies. The SNP consortium²³ is discovering and publishing these markers directly on the internet for immediate access by all researchers and interested parties (<http://snp.cshl.org/>). By October 2000, the consortium had lodged in its internet database information on close to a million human SNPs.

It is anticipated that detailed genetic maps based on subsets of SNPs will provide a digital guide to differences throughout the human genome, and allow the identification of genetic differences between groups of individuals who respond differently to drugs.^{24,25} This may lead to prescriptions that are tailored by type of drug or dosage for different genotype groups, on the basis of a DNA test. It seems likely that such DNA tests will, over the next few years, become routinely available and will be justified for a proportion of patients and drugs in order to avoid adverse reactions.

Impact on drug discovery and development

The major pharmaceutical producers have embraced genome knowledge because it offers novel approaches to drug discovery, design and development.²⁶ Many biotechnology start-up companies are based around the application to drug discovery and development of high throughput analysis of DNA sequences (genomics) and proteins (proteomics).^{20,27} The rationale underlying these approaches, generally referred to as pharmaco-genomics, is that detailed molecular understanding of all cellular drug

targets should permit design of drugs with high specificity for only the desired targets. It is anticipated that pharmacogenomics will lead to a new generation of more specific, more effective and safer drugs.²⁴ Again, this is more promise than reality, and given the 10-15 year development period of most pharmaceuticals, it is unlikely that we will begin to see many such drugs before the next decade.

Unravelling genetic determinants of common diseases

The human genome project has great potential to clarify the basis of common illnesses, most of which have a significant genetic component.^{28,29} These common disorders, such as heart disease, depression, diabetes, and asthma, are multifactorial and are precipitated by a combination of environmental and genetic factors. In these conditions there appear to be some genes that have a major effect, and several or many other genes that contribute minor risk for the condition. Identifying even the major risk genes is not proving straightforward,²² despite early successes such as the discovery of the apolipoprotein E variant (Apo E4) that determines the risk and age of onset of Alzheimer's disease and the Factor V Leiden polymorphism that predisposes to deep venous thrombosis.

Discovery of susceptibility alleles or 'risk genes' for common disorders is, for obvious reasons, a major focus for the biotechnology and pharmaceutical industries. This is a two-edged sword: progress will probably be rapid because of intense commercial pressure but, conversely, knowledge of these susceptibility alleles may not enter the public domain until intellectual property and other commercial issues are resolved.

With the pace of SNP accumulation and improvements in data handling there is considerable optimism that a number of significant risk alleles for common diseases will be found within a decade.^{22,30} What is less certain is when and under what circumstances tests for these alleles should be applied, and in what form will these tests be made available for clinical use. Knowledge of risk alleles could offer considerable potential for disease prevention or risk reduction, such as lifestyle modifications, early intervention, more intensive clinical surveillance for early symptoms, or prophylaxis. Decisions about the application of DNA tests for susceptibility alleles will need to weigh up the degree of risk conferred by the allele, and the likely value or harm that knowledge of increased genetic risk may bring to the individual. The likely increase in availability of such tests, and their potential application to many people, raises urgent privacy issues particularly relating to requests for such tests by insurers and employers. Furthermore, the resultant increasing demand for specialist medical genetics and counselling services is almost certain to exceed the limited capacity of such services in this country. It is fair to say that there has never been a stronger case for bolstering the genetics content of undergraduate medical curricula and continuing medical education programmes.

The challenges ahead

The unravelling of the human genome is the start of a new era in genetics research. It has created many new challenges for medical science, foremost of which is interpreting the vast amount of sequence data in a way that is clinically beneficial. We need to rapidly identify the subset of genes that are of the greatest clinical relevance - those involved in Mendelian disease, susceptibility alleles that confer major risk of common disease, and pharmacogenetic loci. This will require the concerted and collaborative efforts of molecular

biologists, biochemists, and clinicians, and increasingly the input of people with specialist skills in bioinformatics.

Some technical issues remain. The draft human genome sequence requires a good deal more work before it can be considered definitive. The vast amounts of data about the sequences, expression and function of genes housed in numerous computer databases needs to be linked in a fashion that optimises access and use of the data. Finally, the cost of genetic analyses must come down and the throughput increase if we are to take full advantage of genome knowledge in the diagnosis, prediction and management of disease.

Ethical challenges will arise from the increased application of genome knowledge, particularly with insurers or employers. While it is important to guard against misuse of data, the potential positive applications of genome knowledge are remarkable and we must strive to extract maximum benefit with minimum acceptable risk. New Zealand should focus its resources on resolving ethical and cultural ramifications of genome knowledge peculiar to our country, rather than tackling generic issues already well studied offshore. Finally, institutional ethics committees would do well to contemplate in advance how to handle clinical research proposals that deal with the simultaneous analysis of tens or hundreds of genes, rather than one or a few.

Conclusion

We can expect to see increasing numbers of molecular diagnostic tests for Mendelian conditions, although identification of genes for very rare conditions will remain problematic. The economic reality of establishing tests for such rare conditions will also probably ensure that they remain in the domain of interested research laboratories. This decade we are likely to see the implementation of DNA tests to stratify patients who may or may not respond to a drug, or may show side effects, or perhaps even to indicate an appropriate dose of the drug. Methods and equipment for mass-analysis of genes are evolving very rapidly, and we are witnessing the start of an evolving succession of systems, kits and services that centre on analysis of expression patterns of large sets of genes for clinical purposes. Microarrays and related technologies will be used for staging cancer and classifying other diseases, and perhaps for guiding treatment. Over the next few years it is likely that many more predictive genetic tests for common illnesses like depression, asthma, diabetes, and migraine will be developed, although quite how useful they will be depends on the advent of better preventative measures, prophylaxis, or therapy. Whether or not knowledge of risk alleles proves of immediate clinical utility, such information will almost certainly contribute fundamental insights of longer-term value for human biology and the understanding of disease. Finally, within another decade we can expect to see a wide range of drugs that are designed on the basis of precise molecular knowledge of their targets. These drugs should be safer and

more effective, and they may prove to be the real bounty of the human genome project.

Despite the scientific and ethical challenges that remain, and uncertainties in the rate of technology transfer from laboratory to clinic, completion of the human genome project is undoubtedly a defining moment for our species. It is not difficult to envisage a time when total genome information is an integral part of each patient's medical record, highlighting genes of relevance to disease or pharmacogenetic characteristics. Whatever the uncertainties of the future, it is clear that genome technology is poised to become a fundamental and enduring component of health care.

Two landmark papers, published in February 2001,^{31,32} fully describe the human genome and indicate that about 30-40 000 genes exist.

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Mandatory reporting of incompetence

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Later this year the Government is likely to introduce the Health Professionals' Competency Assurance Bill ('the Bill'). The Bill proposes repealing the eleven existing occupational regulation statutes which cover eighteen health and disability sector professions to replace them with a single Act to govern all health professionals.

Under the Bill, health professionals will be required to report a colleague to the registering authority (e.g. the Medical Council) if they believe that the colleague is "practising below an acceptable standard". This change places a positive duty on health professionals to take action against incompetence. Health professionals who do not report incompetent colleagues may themselves be criticised and potentially subject to disciplinary proceedings for their failure to act. The notifying practitioner will be protected from civil and criminal liability, provided they have not acted in bad faith or without reasonable care.

Whilst there is nothing at present which either encourages or requires health professionals to report incompetence, doctors are required to report colleagues if they have reason to believe that the colleague is not fit to practise because of some mental or physical condition. In such circumstances, the practitioner must notify the Medical Council as soon as is reasonably practicable.¹ If the doctor does not report a colleague when he or she should have done so, then that doctor commits an offence and can be fined up to \$10 000.²

The impetus for the change has come from recent and high profile medical scandals. Action does need to be taken to ensure that incompetent health professionals are prevented from harming patients. Mandatory reporting of incompetence is seen as an obvious solution.

There are however, a number of reasons why the primary goal of ensuring the care, treatment and safety of patients is not best served by mandatory reporting. Some of these reasons are:

1. A duty on health professionals to report incompetence will be open to subjective interpretation. Health professionals are likely to have difficulty in differentiating between the type of mistakes that anyone can make, and the type of mistakes which amount to conduct "below an acceptable standard" that must be reported.
2. In order to assist in resolving problems and to ensure quality of care, health professionals must be able to share information firstly with their colleagues, and secondly with the hospital's senior management. Health professionals may be less likely to approach mistakes and problems with this openness if they know that their colleagues, or management, will be required to investigate the matter in a way that establishes whether there are grounds for disciplinary action. The danger

with a punitive or legalistic approach is that problems will not be brought into the open but will be driven underground.³

3. Health professionals who are suspicious about a colleague's conduct may not want to delve too deeply, because if they know too much, they will have to take action.
4. There is the danger of health professionals acting in bad faith. Personalities and professional competitiveness or jealousies must have no place in determining whether conduct is of the type that warrants reporting.
5. If health professionals know that they themselves may be criticised for failing to report incompetence, there is the danger that the 'reporting threshold' will be too low. The consequences to a practitioner's career in the event of a false or unjustified complaint will be serious.
6. Mandatory reporting would be difficult to enforce. It is likely that a great number of health professionals would resist it. Without co-operation from health professionals, incompetence may be pushed underground.

The primary responsibility for ensuring good medical practice lies with individual health professionals and the clinical teams within which they work (ie at the local level). Members of clinical teams, who constantly monitor the performance of team members, will be in the best position to ensure that any signs of wrongdoing or incompetence are dealt with promptly and in a positive way. The Bill places no emphasis on team-based self-regulation. More emphasis should be placed on the role to be played by clinical teams in the monitoring of professional standards.

Mistakes will occur, but if they are managed properly they should provide some of the best guidance to health professionals on how to minimise future errors. We should have more, not less, confidence in health professionals who are prepared to discuss their mistakes with colleagues. There needs to be an environment created where health professionals can openly discuss and learn from their own and their colleague's mistakes.

Some of the concerns mentioned above may be alleviated by comprehensive guidelines so that all health professionals are aware of exactly what type of conduct should be reported, and the procedures that should be followed. However, in attempting to create the open, trusting and learning environment that will ultimately benefit patients, mandatory reporting may well be a step in the wrong direction.

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1. Medical Practitioners Act 1995, section 76(2).
2. Medical Practitioners Act 1995, section 142.
3. Liam Donaldson. Medical mishaps: a managerial perspective. In: Rosenthal M, Mulcahy L, Lloyd-Bostock S, editors. Medical mishaps: pieces of the puzzle. Buckingham: Open University Press; 1999. p217.