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## **This Issue in the Journal**

### **Sources of satisfaction and dissatisfaction among specialists within the public and private health sectors**

Toni Ashton, Paul Brown, Elizaveta Sopina, Linda Cameron, Timothy Tenbensel, John Windsor

This study explores the level and sources of satisfaction and dissatisfaction of medical and surgical specialists with working in the public and private sectors in New Zealand. Overall mean levels of satisfaction were higher in the private sector than the public sector while levels of dissatisfaction were lower. While the public system is valued for its opportunities for further education and professional development, key sources of dissatisfaction are workload pressures, mentally demanding work and managerial interference. In the private sector specialists value the opportunity to work independently and apply their own ideas in the workplace.

### **Prevalence of diabetic retinopathy and maculopathy in Northland, New Zealand: 2011–2012**

Alistair T Papali'i-Curtin, David M Dalziel

Diabetic retinopathy is a serious complication of diabetes and remains the leading cause of blindness among working aged-adults in the developed world. National screening programmes are effective at detecting diabetic retinopathy and reducing visual impairment and blindness. The aim of this study was to determine the prevalence of diabetic retinopathy and maculopathy in the Northland screening programme. Rates of retinopathy and maculopathy detected by the Northland screening programme were comparable to rates reported in Waikato, lower than Wellington rates and lower than international averages. Māori were overrepresented in patients with retinopathy and maculopathy, but underrepresented within the screening population. The success of this programme was undermined by the high failure-to-attend rate despite attempts to improve access.

### **A retrospective review of notified human cryptosporidiosis cases in the Waikato region of New Zealand, 2004 to 2011**

George Cowie, Anita Bell

Cryptosporidiosis rates are higher in the Waikato than the national New Zealand average and other developed countries. Those who have contact with animals continue to be at risk of infection from *Cryptosporidium*. The data suggests that children who live on rural properties and have contact with animal faeces, either directly or via a contaminated drinking water supply, are at the highest risk of infection.

## **Review of capacity assessments and recommendations for examining capacity**

Heather Astell, Jae-Hyun Lee, Shankar Sankaran

We performed a review of the capacity assessments (assessments of patients informed decision making ability) performed by the Community Geriatrics Department at Middlemore Hospital over a three and a half year period. The number of assessments performed has been increasing with time. Most assessments were done on patients because of dementia. It is important that capacity assessments are focused on a particular problem. In our review the problems were grouped into capacity for personal welfare, financial capacity, capacity to appoint an enduring power of attorney, and capacity to write a will. We include a brief guideline on how to perform a capacity assessment.

## **Factors affecting vaginal birth after caesarean section at Middlemore Hospital, Auckland, New Zealand**

Anna-Marie van der Merwe, John M D Thompson, Alec J Ekeroma

Aiming for a normal delivery after a caesarean section has been advisable. Our study in Middlemore Hospital has shown that 52% of the women with a previous caesarean section tried to deliver normally and 74% of them were successful. Women who had a previous normal delivery had a better chance of delivering normally. Those who had not had a normal delivery were overweight and needed an intervention during labour.

## **Are you satisfied working as a specialist in a New Zealand public hospital?**

Job satisfaction among doctors has been in the news recently with a fall in job satisfaction and pay reported in the United States.<sup>1</sup> This week's issue of the *Journal* includes a timely article by Ashton et al entitled *Sources of satisfaction and dissatisfaction among specialists within the public and private health sectors*.<sup>2</sup> Not surprisingly the authors find that overall levels of job satisfaction were higher in the private sector than the public sector and that levels of dissatisfaction were lower there as well.

The authors go on to report that although specialists responding to their questionnaire valued the public system for its opportunities for further education and professional development they were more satisfied working in the private system.

The key sources of dissatisfaction with the public system are workload pressures, mentally demanding work and managerial interference—while in the private sector specialists value the opportunity to work independently and apply their own ideas in the workplace.

Income alone is not a factor in the satisfaction of private practice, although in reality it must have some role with some proceduralists earning as much as 4–5 times (or more) their public salary in the private sector. This gap is much bigger in some cases when compared with opportunities that exist for some at the nearby Australian doctor market.

Job satisfaction and work-life balance are discussed as non-medical media as being important today. So the concept that someone would do a job that is less than maximally satisfying is considered odd. As a result, after reading Ashton et al's paper, one could easily come to the conclusion that one should leave the public sector and move entirely into the private sector, where one would find job satisfaction and “happiness” as we would have more control and less managerial interference (and more pay)—or is this a delusion?

The public sector in New Zealand employs over 7000 doctors FTE (full time equivalent), most of whom are junior doctors (resident medical officers: RMOs). The study by Ashton et al was focused on specialist who in the public sector are called senior doctors (senior medical officers: SMOs) who are much fewer in number and have overall responsibility for patient care.

Questionnaires were sent to 1983 specialists from 28 specialties, not all of whom work in the public sector. 943 doctors returned the questionnaire of which 473 worked in both the public and private sector, while 306 worked in the public sector alone and 130 in the private sector alone. The 47% return rate is good for such studies, however the results are arguably open to biases as those returning the question may be the dissatisfied ones. It should also be acknowledged that the absolute scores for doctors' satisfaction appear to be very good.

To clarify the facts on what creates job satisfaction I thought I should “research” the concept of ‘job satisfaction’ and as such went as the ‘Google’ search engine as usual. A few surprising facts came to light such from sources such as “Wikipedia” where the authors state the following:<sup>3</sup>

“...job satisfaction is simply how content an individual is with his or her job.”

“Job satisfaction is thought by many to be important because it boosts work performance but and also because it increases our quality of life. However one common research finding is that job satisfaction is correlated with life satisfaction. This correlation is reciprocal, meaning people who are satisfied with life tend to be satisfied with their job and people who are satisfied with their job tend to be satisfied with life.

“An important finding for organizations is that job satisfaction has a rather tenuous correlation to productivity on the job. This is a vital piece of information to researchers and businesses, as the idea that satisfaction and job performance are directly related to one another is often cited in the media and in some non-academic management literature. A recent meta-analysis found surprisingly low correlations between job satisfaction and performance. Further, the meta-analysis found that the relationship between satisfaction and performance can be moderated by job complexity, such that for high-complexity jobs the correlation between satisfaction and performance is higher than for jobs of low to moderate complexity.

There appears to be many theories about what creates job satisfaction. Overall, however, most make a distinction between affective job satisfaction and cognitive job satisfaction.<sup>3</sup>

Affective job satisfaction is the extent of pleasurable emotional feelings individuals have about their jobs overall, and is different to cognitive job satisfaction which is the extent of individuals’ satisfaction with particular facets of their jobs, such as pay, pension arrangements, working hours, and numerous other similar aspects of their jobs.

There are other theories of course (3) as well such as the “Equity theory”(3) where it is argued that comparative fairness is important between employees (e.g. people are satisfied if people are paid the same for the same outputs); there is the “discrepancy theory” (3), which claims people work to avoid anxiety and dejection; and it is the gap between what they do and what they are expected to do that creates dissatisfaction.

There is also the “Frederick Herzberg’s two-factor theory (also known as motivator hygiene theory)” (3) so called as it describes “motivating factors” which are intrinsic to the job and which make people feel good about what they do and what they call “hygiene factors” such as pay and company policies and so on.

Trying to put all this together I am left with the conclusions from reading the heterogenic Internet Googlings that there are three aspects overall that appear important in job satisfaction, these are:

- The individual factors that we all bring to a job (partially genetic and partially environmental—home life, etc.). As we all know, some of us are happy people and easier to satisfy than others.
- There is the job itself; some jobs give us the sense of purpose and achievement (i.e. we feel good about doing them).
- Then there is the work environment itself. This, as suggested above, can be subdivided into two broad areas. This is (a) the work “fixed” environment or “cognitive” i.e. having an office, what we are paid, availability of parking,

policies about stuff etc, and (b) the “adjustable” environment such as communication with managers, relationships with staff, and what is called strategic employee factors.

If we accept that we want as doctors to have our best job satisfaction, but wish to stay in the public sector, then the aspects that appear to be adjustable are outlined in the paper by Ashton et al.

The public sector can't match the incomes of the private sector, any more than I expect management can stop interfering, so I would suggest that factors that might be considered in to retain SMOs are:<sup>6</sup>

- **Management should avoid unhelpful little hassles**—We all tend to downplay day-to-day irritations (e.g. car parking, office space, unexpected on-call gaps etc), but actually people's job satisfaction is surprisingly sensitive to daily hassles.
- **Perception of fair pay**—For a doctor to be satisfied, their pay should be fair and equitable.
- **Achievement**—Doctors need to feel more satisfied with their job if they've achieved something.
- **Feedback**—Most feedback we get is generally negative such as unmet waitlist times, patients needing to be seen in clinics that are already full, patients wanting surgery sooner than we can provide, complaints (hospitals, HDC, and letter to ACC), and so on. The positive feedback we get is generally from patients, which is part of the reason why we like seeing patients.
- **Complexity and variety**—To be satisfied, most of us need to be challenged a little and they need some variety in the tasks they carry out.
- **Control**—The more control we perceive we have in carrying out our jobs, the more satisfaction we experience.
- **Organisational support**—Doctors want to know that their employer organisation (DHB, university etc) cares about them.

It is most likely that the DHBs are well aware of the importance of retaining SMOs, as staff are their most valuable asset, and they are generally cheaper to retain than replace.

**Competing interests:** The author is a doctor in both the public and private sectors.

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## Sources of satisfaction and dissatisfaction among specialists within the public and private health sectors

Toni Ashton, Paul M Brown, Elizaveta Sopina, Linda Cameron, Timothy Tenbensel, John Windsor

### Abstract

**Aim** As in many countries, medical and surgical specialists in New Zealand have the opportunity of working in the public sector, the private sector or both. This study aimed to explore the level and sources of satisfaction and dissatisfaction of specialists in New Zealand with working in the two sectors. Such information can assist workforce planning, management and policy and may inform the wider debate about the relationship between the two sectors.

**Method** A postal survey was conducted of 1983 registered specialists throughout New Zealand. Respondents were asked to assess 14 sources of satisfaction and 9 sources of dissatisfaction according to a 5-point Likert scale. Means and standard deviations were calculated for the total sample, and for procedural and non-procedural specialties. Differences between the means of each source of satisfaction and dissatisfaction were also calculated.

**Results** Completed surveys were received from 943 specialists (47% response rate). Overall mean levels of satisfaction were higher in the private sector than the public sector while levels of dissatisfaction were lower. While the public system is valued for its opportunities for further education and professional development, key sources of dissatisfaction are workload pressures, mentally demanding work and managerial interference. In the private sector specialists value the opportunity to work independently and apply their own ideas in the workplace.

**Conclusion** Sources of job satisfaction and dissatisfaction amongst specialists are different for the public and private sectors. Allowing specialists more freedom to work independently and to apply their own ideas in the workplace may enhance recruitment and retention of specialists in the public health system.

As in many countries, most medical and surgical specialists in New Zealand have the opportunity of working as salaried employees in the public sector and/or on a fee-for-service basis in the private sector. Because the supply of specialists is fixed in the short to medium term, increasing time spent in the private sector inevitably means that less time is available for specialists to work in the public health system.<sup>1</sup> It is therefore useful to understand what factors may influence the decisions of specialists to work in one sector or the other.

The question of what influences specialists' decisions to work in the public and/or private sectors is especially pertinent in New Zealand because the specialist workforce faces tight constraints. While the absolute number of practising medical specialists has been increasing in recent years, the number of specialists per head of

population remains amongst the lowest of the OECD.<sup>2</sup> New Zealand also has the highest proportion of migrant doctors (42%) in the OECD countries.<sup>3,4</sup>

Factors such as the ageing of the professional workforce and the attraction of higher incomes offered in other countries are putting further pressure on this already constrained clinical workforce.<sup>3</sup> In addition, some district health boards (DHBs) are increasingly contracting elective surgical procedures out to the private sector<sup>5</sup> in an effort to meet the national target for improving access to elective surgery.<sup>6</sup> This increases the private sector work that is available to specialists and potentially puts further pressure on the public sector workforce.<sup>5</sup>

There is a growing body of international literature on the topic of dual practice in which specialists work in both sectors.<sup>7</sup> Most studies take a theoretical approach to examine issues such as the impact of dual practice on public sector labour supply<sup>1</sup> or on the incentives for dual practitioners to increase public sector waiting lists<sup>8</sup> or to 'cream-skim' profitable patients.<sup>9</sup> A common assumption underlying these theoretical models is that maximisation of income is a key objective for clinicians.

A few empirical studies have explored the factors which influence specialists' choice of sector or their division of time between the two sectors. One study, undertaken in south-east England, explored the motivations of specialists who work in dual practice.<sup>10</sup> It found that, in addition to the financial benefits, reasons for engaging in private practice included greater clinical autonomy and strategic influence, and a greater sense of being valued.

The authors concluded that the values and actions of these specialists diverged from a common belief (perceived to be held in the UK<sup>11</sup>) that private sector work is driven by professional self-interest while public sector work is underpinned by altruism and public interest. Another study, undertaken in Norway, also emphasised the importance of specialists' autonomy in their choice of sector.<sup>12</sup>

Overall, the empirical studies suggest that many motivations other than income influence specialists' choices of sector including working conditions, type of work, clinical autonomy, status, professional opportunities and a sense of social responsibility.<sup>7,10,13</sup>

Job satisfaction, including satisfaction with leadership roles and income security, has been found to be a predictor of staff retention.<sup>14</sup> Conversely, job dissatisfaction, including perceptions of inconvenient or inflexible work schedules and workload pressures, has been found to be a predictor of intent to leave a job.<sup>15-17</sup>

The aim of the present study was therefore to explore the sources and extent of satisfaction and dissatisfaction of specialists with the two sectors. Such information can inform health workforce planning and assist public sector managers in developing strategies for improving the recruitment and retention of specialists. The information will also be of interest to doctors and may assist in their career planning.

## Method

A directory of registered doctors working in New Zealand was obtained from an international health care management consultancy. From this we selected those specialties that offer work in both the public and private sectors. This provided a population of 1983 specialists from 28 specialties.

Specialties were sub-divided into procedural and non-procedural (see Table 5), although it should be noted that some specialties that we classified as non-procedural (such as dermatology) involve the performance of some procedures. The rationale for this sub-division was that procedural specialists may have greater opportunities to earn a higher income in the private sector. Since increased income has been considered to be a significant factor in deciding whether to work in the private sector, different levels and sources of job satisfaction might be reported.

A questionnaire was developed based on a set of questions used by Kankaanranta et al. (2007) in a Finnish study of satisfaction and dissatisfaction amongst physicians.<sup>18</sup> Questions were modified where necessary to reflect the New Zealand environment.

Satisfaction and dissatisfaction were assessed using two separate sets of questions, with levels being measured using a 5-point Likert scale in which a score of 1 ranked low while a score of 5 ranked high. Thus a high score for satisfaction would mean that the respondent was very satisfied, while a high score for dissatisfaction would mean that they were very dissatisfied. The questionnaire also covered personal information including demographic variables, area of specialty, place and time of training, and past and current place(s) of work.

The questionnaire was mailed to the 1983 specialists in October 2009 along with a covering letter explaining the objective of the study, and a stamped addressed envelope for returning the completed questionnaire. A reminder postcard was sent out in November 2009 thanking those who had already responded and requesting others to complete and return the survey. The study was approved by the New Zealand Ministry of Health Multi-Region Ethics Committee.

Summary statistics were calculated of frequency for the categorical variables and means and standard deviations for continuous variables. Two-tailed t-tests were performed to compare satisfaction and dissatisfaction scores between the two sectors. Results were considered statistically significant with a p-value smaller than  $\alpha=0.05$ .

## Results

Completed surveys were received from 943 (47%) of the 1983 invitees. A majority of respondents were male (78%), aged between 41 and 60 years (66%) and of European descent (73%) (Table 1). No respondents were New Zealand Māori. A majority (60%) were proceduralists, with a larger proportion of proceduralists being male (85%) than non-proceduralists (70%).

Half of respondents (50%) were working in both the public and private sectors, one-third (33%) were working solely in the public sector, and 14% worked solely in the private sector. The mean number of hours worked per week in each sector was 32 hours in the public sector and 23 hours in the private sector (Table 2).

Proceduralists reported spending a higher proportion of their total hours working in the private sector than non-proceduralists (45% v 32%,  $p<0.005$ ).

**Table 1. Characteristics of respondents**

Characteristic	Total respondents (n=943)		Proceduralists (n=566)		Non-proceduralists (n=335)		Speciality not-reported (n=42)	
	n	%	n	%	n	%	n	%
<b>Gender</b>								
Male	737	78	481	85	233	70	23	55
Female	191	20	77	14	97	30	17	40
Not reported	15	2	8	1	5	<1	2	5
<b>Age (years)</b>								
31–40	146	15	77	14	57	17	12	29
41–50	324	34	193	34	118	35	13	31
51–60	272	29	168	30	97	29	7	17
60+	156	17	100	18	51	15	5	12
Not reported	45	5	28	5	12	4	5	12
<b>Ethnicity</b>								
NZ European	693	73	436	78	228	68	29	69
NZ Māori	0	0	0	0	0	0	0	0
Pacific people*	4	<1	3	<1	1	<1	0	0
Chinese/Indian	45	5	29	5	15	4	1	2
Other	150	16	68	12	72	21	10	24
Not reported	51	5	30	4	19	6	2	5
<b>Workplace</b>								
Public and private	473	50	362	64	95	28	16	38
Public only	306	32	98	17	186	56	22	52
Private only	130	14	96	17	32	10	2	5
Not currently working	28	3	7	1	19	6	2	5
Not reported	6	1	3	1	3	1	0	0

\*Mostly of Samoan, Tongan, Niuean, or Cook Islands origin.

**Table 2. Mean number of hours worked per week in public and private sectors**

Sector	Total respondents (n=943)			Proceduralists (n=566)			Non-proceduralists (n=335)		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
<b>Public</b>	727	32	13.7	451	29	12.8	276	37	13.6
<b>Private</b>	580	23	13.8	454	24	13.6	126	18	13.3

The average mean satisfaction scores (out of a maximum of 5) for all respondents were 3.33 for the public sector and 3.57 for the private sector, indicating a slightly higher level of overall satisfaction with the private sector (Table 3).

Sources of high levels of satisfaction in the public sector were opportunities for further education (mean score = 4.05), interesting work (4.05) and opportunities for professional development (3.99).

In contrast, the private sector is valued for the opportunity to work independently (4.45), the freedom to apply ideas in the workplace (4.28) and the income earned relative to the workload (4.06). Income security scored relatively highly as a source of satisfaction in both sectors (3.92 for the public sector and 3.90 for the private sector).

**Table 3. Mean levels of satisfaction and dissatisfaction**

Source of satisfaction/dissatisfaction	PUBLIC SECTOR SCORES						PRIVATE SECTOR SCORES					
	Total		Proceduralist		Non-proceduralist		Total		Proceduralist		Non-proceduralist	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
<b>Satisfaction (overall)</b>	<b>3.33</b>	<b>0.54</b>	<b>3.31</b>	<b>.54</b>	<b>3.34</b>	<b>.55</b>	<b>3.57</b>	<b>0.62</b>	<b>3.57</b>	<b>.63</b>	<b>3.58</b>	<b>.62</b>
Opportunities for further education	4.05	.82	4.06	.82	4.02	.82	3.19	1.12	3.20	1.13	3.17	1.11
Interesting work	4.05	.75	4.07	.76	4.03	.75	3.68	.97	3.69	.99	3.66	.94
Opportunities for professional development	3.99	.83	3.99	.82	3.98	.84	3.26	1.11	3.26	1.11	3.26	1.12
Income security	3.92	.98	3.93	1.01	3.89	.92	3.90	.93	3.90	.94	3.91	.91
Leadership role	3.52	1.00	3.52	1.00	3.51	1.00	3.43	1.08	3.41	1.11	3.47	1.04
Regular and appropriate review of performance	3.34	.94	3.33	.94	3.36	.94	2.95	1.09	2.91	1.07	3.02	1.12
Prestige or respect for your position	3.31	.90	3.32	.91	3.31	.89	3.75	.87	3.73	.89	3.79	.82
Public recognition of accomplishments	3.03	.95	3.02	.95	3.04	.96	3.09	1.01	3.07	1.00	3.12	1.03
Predictable hours of workload	3.03	.98	2.98	.98	3.12	.98	3.70	.98	3.68	1.01	3.74	.91
Promotion prospects	2.97	.99	2.93	.99	3.04	.98	2.51	1.09	2.51	1.13	2.51	1.03
Opportunity to work independently	2.93	.93	2.91	.93	2.95	.94	4.45	.70	4.45	.71	4.44	.68
Income relative to workload	2.83	.98	2.78	.99	2.90	.96	4.06	.88	4.07	.90	4.05	.86
Amount of after-hours work	2.76	1.01	2.74	1.01	2.81	1.01	3.51	1.02	3.50	1.04	3.51	.99
Freedom to apply ideas in workplace	2.70	.98	2.68	.97	2.75	1.00	4.28	.77	4.29	.80	4.27	.73
<b>Dissatisfaction (overall)</b>	<b>3.07</b>	<b>0.46</b>	<b>3.08</b>	<b>.47</b>	<b>3.07</b>	<b>.47</b>	<b>2.44</b>	<b>0.45</b>	<b>2.47</b>	<b>.47</b>	<b>2.44</b>	<b>.41</b>
Workload pressures	3.59	.79	3.62	.77	3.53	.81	3.04	.86	3.06	.88	3.01	.83
Mentally demanding work	3.49	.75	3.52	.74	3.44	.76	3.20	.81	3.20	.81	3.20	.81
Managerial interference	3.40	.91	3.40	.90	3.40	.93	1.75	.72	1.75	.73	1.76	.69
Inconvenient or inflexible work schedule	3.14	.85	3.14	.86	3.15	.85	2.33	.84	2.31	.85	2.35	.83
Atmosphere in workplace	3.06	.91	3.03	.93	3.10	.87	2.65	1.21	2.70	1.24	2.57	1.15
Poor employee/employer relations	2.97	.93	2.97	.95	2.99	.90	1.91	.67	1.94	.70	1.86	.61
Ungrateful or non-compliant patients	2.92	.71	2.92	.74	2.94	.66	2.37	.61	2.38	.63	2.35	.59
Monotonous work	2.70	.75	2.67	.76	2.74	.74	2.63	.78	2.61	.78	2.66	.78
Fear of failure in work	2.42	.79	2.43	.80	2.42	.78	2.27	.82	2.30	.86	2.22	.74

**Note:** Scores are out of a maximum of 5, with 5 representing the most satisfied and the most dissatisfied.

The average mean dissatisfaction scores were 3.07 and 2.44 for the public and private respectively, indicating a higher level of dissatisfaction with the public sector. Interestingly, workload pressures and mentally demanding work ranked highest as sources of dissatisfaction for both sectors. Contrary to expectations, there were no significant differences between the mean scores of proceduralists and non-proceduralists for any of the 23 sources of satisfaction and dissatisfaction.

**Table 4. Mean difference in sources of satisfaction and dissatisfaction between the public and private sectors**

Variables	Mean difference <sup>#</sup>	SD	P value
<b>Sources of satisfaction</b>			
1. Freedom to apply ideas in workplace	1.59	1.33	<0.001
2. Opportunities to work independently	1.54	1.21	<0.001
3. Income relative to workload	1.25	1.38	<0.001
4. Amount of after-hours work	0.76	1.49	<0.001
5. Predictable hours of workload	0.69	1.46	<0.001
6. Prestige or respect for your position	0.40	1.28	<0.001
7. Public recognition of accomplishments	0.13	1.36	0.777
8. Income security	-0.03	1.47	0.591
9. Leadership role	-0.12	1.62	0.035
10. Interesting work	-0.37	1.26	<0.001
11. Regular and appropriate review of performance	-0.43	1.42	<0.001
12. Promotion prospects	-0.48	1.41	<0.001
13. Opportunities for professional development	-0.77	1.46	<0.001
14. Opportunities for further education	-0.89	1.45	<0.001
<b>Sources of dissatisfaction</b>			
1. Managerial interference	-1.66	1.15	<0.001
2. Poor employee/employer relations	-1.08	1.14	<0.001
3. Inconvenient or inflexible work schedule	-0.85	1.16	<0.001
4. Ungrateful or non-compliant patients	-0.56	0.86	<0.001
5. Workload pressures	-0.54	1.08	<0.001
6. Atmosphere in workplace	-0.41	1.25	<0.001
7. Mentally demanding work	-0.28	0.89	<0.001
8. Fear of failure in work	-0.15	0.78	<0.001
9. Monotonous Work	-0.07	0.96	0.047

<sup>#</sup> Paired t-test comparing private and public sector mean satisfaction and dissatisfaction scores.

In addition to knowing the absolute levels of satisfaction, it is helpful to know how levels of satisfaction compare across the two sectors. Mean differences in the sources of satisfaction and dissatisfaction between the two sectors are given in Table 4.

In this Table (and also in Table 5), positive mean differences reflect higher scores in the private sector relative to the public sector for both satisfaction and dissatisfaction. The private sector was rated more highly than the public sector for the 6 sources of satisfaction numbered 1 to 6 in this table, while the public sector was rated more highly for the 5 sources numbered 10 to 14.

While the private sector provides specialists with greater freedom to apply ideas in the workplace and greater opportunity to work independently, the public sector is valued more highly for its opportunities for further education and professional development,

and for its prospects for promotion. Levels of dissatisfaction were significantly higher in the public than the private sector for 8 of the 9 sources of dissatisfaction (numbers 15 to 22, Table 4) and most especially for managerial interference.

**Table 5. Mean difference in satisfaction and dissatisfaction by type of specialty**

Type of specialty	n	% of total	Mean difference#:			Mean difference#:		
			Satisfaction			Dissatisfaction		
			Difference	SD	P value	Difference	SD	P value
<b>All</b>	943	100	0.24	0.88	<0.001	-0.62	0.56	<0.001
<b>Proceduralists</b>	566	60	0.27	0.89	<0.001	-0.62	0.56	<0.001
Orthopaedics	113	12	0.37	0.92	<0.001	-0.73	0.54	<0.001
Obstetrics & gynaecology	92	10	0.35	0.86	<0.001	-0.63	0.57	<0.001
General surgery	85	9	0.14	0.96	0.198	-0.50	0.59	<0.001
Ophthalmology	59	6	0.21	0.72	0.038	-0.61	0.53	<0.001
Otorhinolaryngology	45	5	-0.06	1.02	0.723	-0.70	0.62	<0.001
Cardiology	41	4	0.29	0.89	0.052	-0.60	0.61	<0.001
Urology	30	3	0.39	0.97	0.056	-0.55	0.39	<0.001
Gastroenterology	29	3	0.13	0.81	0.434	-0.52	0.49	<0.001
Plastic surgery	25	3	0.41	0.83	0.031	-0.76	0.70	<0.001
Oral & maxillofacial surgery	14	2	0.65	0.93	0.021	-0.56	0.63	0.005
Paediatric surgery	8	<1	0.12	0.59	0.582	-0.57	0.75	0.068
Cardiac surgery	8	<1	-0.06	1.01	0.875	-0.70	0.56	0.017
Breast surgery	8	<1	0.66	0.57	0.022	-0.41	0.30	0.011
Neurosurgery	7	<1	0.33	0.64	0.221	-0.74	0.52	0.009
Vascular surgery	2	<1	0.39	0.97	0.728	-0.55	0.39	No data
<b>Non-proceduralists</b>	377	40	0.23	0.86	<0.001	-0.64	0.56	<0.001
General medicine	47	5	0.40	0.95	0.007	-0.55	0.56	<0.001
Emergency medicine	43	5	0.20	0.68	0.075	-0.80	0.60	<0.001
Geriatrics	33	4	0.36	0.98	0.046	-0.56	0.53	<0.001
Endocrinology	26	3	0.43	0.84	0.020	-0.56	0.59	<0.001
Neurology	22	2	-0.06	1.09	0.825	-0.74	0.59	<0.001
Dermatology	22	2	-0.06	0.98	0.764	-0.48	0.52	<0.001
Respiratory medicine	20	2	0.16	0.80	0.411	-0.77	0.51	<0.001
Rheumatology	20	2	0.02	0.88	0.928	-0.59	0.53	0.001
Haematology	19	2	0.23	0.83	0.200	-0.77	0.47	0.006
Nephrology	17	2	0.17	0.78	0.388	-0.52	0.40	<0.001
Sexual health medicine	5	<1	1.03	1.05	0.398	-0.81	0.68	0.339
Paediatrics	2	<1	0.89	0.35	0.174	-1.06	0.08	0.033
Other	59	6	0.21	0.74	0.040	-0.67	0.62	<0.001
<b>Missing</b>	42	4	-0.01	0.86	0.959	-0.46	0.58	<0.001

# Paired t-test comparing private and public sector mean satisfaction and dissatisfaction scores. Positive mean differences reflect higher scores in the private sector relative to the public sector for both satisfaction and dissatisfaction.

Mean differences in the levels of satisfaction and dissatisfaction by the specialty group are given in Table 5. The results for all specialty groups are presented in this table in the interests of completeness. However the number of respondents in some groups is very low and the results should be interpreted with caution.

The difference in satisfaction levels was statistically significant for only two of the 28 specialty groups: orthopaedics (mean difference = 0.37) and obstetrics and gynaecology (0.35). Four specialty groups rated the public sector more satisfying overall than the private sector: otorhinolaryngology (n=45), cardiac surgery (n=8),



neurology (n=22) and dermatology (n=22). However none of these differences were statistically significant.

All 28 groups reported higher levels of dissatisfaction with the public than with the private sector, 20 of which were statistically significant. The mean difference in dissatisfaction scores was greatest for specialists working in emergency medicine (-0.8), respiratory medicine (-0.77) and plastic surgery (-0.76).

We also examined whether the sector in which respondents were working affected levels of satisfaction and dissatisfaction. For the 14% of respondents working in the private sector only, the mean difference in satisfaction levels was greater (0.37) than for those working in both sectors (0.25) and those working only in the public sector (0.19).

The mean difference in levels of dissatisfaction was also slightly larger for those working only in the private sector (-0.67) than for those working in both sectors (-0.65) and those working only in the public sector (-0.63).

## Discussion

This study suggests that specialists are generally both more satisfied and less dissatisfied with working in the private sector than in the public sector, with differences in the levels of both satisfaction and dissatisfaction between the two sectors being statistically significant for 24 of the 28 sources included in our survey. Nevertheless, for the public sector, high levels of satisfaction were reported for the opportunities that it offers for further education and professional development as well as for the interesting work that it offers.

Key sources of dissatisfaction were workload pressures, mentally demanding work and managerial interference. In contrast, when working in private practice, specialists value the opportunity to work independently and to apply their own ideas in the workplace. They also have a good income relative to their workload and little managerial interference.

Satisfaction levels with income security were similar for both sectors. Moreover, non-pecuniary factors were important sources of job satisfaction. These findings raise questions about theoretical models of dual practice which are based upon an assumption that income maximisation is the key driver of workforce choices of specialists.<sup>1</sup> It also suggests that specialists working in private practice may be encouraged to allocate a greater share of their time to the public sector if non-pecuniary sources of satisfaction improved.

Our results support those of an earlier New Zealand study that explored the relationship between job satisfaction, job stress and psychological morbidity amongst New Zealand health professionals.<sup>19</sup> It found that overall levels of satisfaction were similar for both sectors but that specialists perceived public work to be more stressful than private practice.

Job stress has been shown to be inversely related to job satisfaction both theoretically and empirically.<sup>17</sup> While our survey did not include questions specifically related to levels of stress, dissatisfaction was higher in the public sector for all sources of



dissatisfaction. These included factors related to stress such as poor employer/employee relations, workload pressures and mentally demanding work.

The study by Kankaanranta et al. in Finland<sup>18</sup> was directed specifically at the question of what factors influence physicians' intentions to switch between the public and private sectors during the period 1988 – 2003. It found that increased job satisfaction decreased the intention to switch from the public to the private sector for all years except 1988.

Surprisingly, job dissatisfaction was not correlated with intention to leave the public sector except for the year 1988. This suggests that retention in the public sector might be improved if public sector managers focus on ways of strengthening the sources of satisfaction reported for both sectors. Of particular relevance here is our finding that specialists value the opportunity to apply their own ideas in the workplace - a finding that was also reported by Kankaanranta et al.<sup>18</sup> While this was ranked second highest as a source of satisfaction in the private sector (with a mean score of 4.28), for the public sector, it was ranked lowest of all of the 14 variables on the satisfaction scale, with a mean score of 2.70.

Since our survey was undertaken, many DHBs have worked towards building clinical governance and leadership following the release of the Ministerial Task Force Report on Clinical Leadership in 2009.<sup>20</sup> In a survey undertaken in 2012 of health professionals employed by DHBs, more than two-thirds of doctors agreed that health professionals in their DHB are engaged in shared decision-making with management, and that their DHB had sought to foster and develop clinical leadership 'to some or a great extent'.<sup>21</sup> However, only around one-third felt that their DHB was providing sufficient support for them to engage in clinical leadership activities.

Clinical leadership in the public sector may be more difficult if clinicians are too busy with their own practices, or if they have insufficient training to engage meaningfully with management to provide leadership in system improvement. This suggests that public sector managers need to continue to seek ways to encourage specialists to express their own ideas, and to open up opportunities for them to influence the process and direction of service development.

Unfortunately there are no national statistics which describe the demographic profile of the total specialist workforce in New Zealand against which we can assess the representativeness of our respondents. However, our sample contained a slightly lower proportion of women (20%) than the 27% of specialists reported as female by the New Zealand Medical Council.<sup>4</sup>

Our sample also contained no Māori, whereas 3% of the specialist workforce identify as Māori.<sup>22</sup> Considerable effort is currently being directed towards encouraging increased participation by Māori in the medical workforce in New Zealand. Information about sources of satisfaction and dissatisfaction amongst Māori specialists would be highly valuable for informing this process.

A further limitation to our study is that the numbers of respondents from some specialty groups were too small to produce any meaningful results. It is also possible that responses may have been affected by the fact that our survey included a greater number of questions relating to sources of satisfaction than to sources of dissatisfaction.

## Conclusion

The public sector specialist medical workforce in New Zealand currently faces many challenges including difficulties in filling vacant positions, increasing international competition for specialists, and a heavy reliance on immigrant doctors. At the same time, many specialists are working full-time or part-time in private practice.

Developing policies and practices which increase satisfaction and decrease dissatisfaction with working in the public sector should assist in alleviating pressures in the public system and secure a more stable workforce. In particular, allowing specialists more freedom to work independently and to apply their own ideas in the workplace may enhance their recruitment and retention in the public sector.

The findings of this study should also inform the wider debate about the relationship between the public and private sectors in New Zealand and about how the sectors can work together to secure a more efficient use of the specialist workforce.

**Competing interests:** None identified.

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## Prevalence of diabetic retinopathy and maculopathy in Northland, New Zealand: 2011–2012

Alistair T Papali'i-Curtin, David M Dalziel

### Abstract

**Aim** To determine the prevalence of diabetic retinopathy and maculopathy in the Northland Diabetic Retinopathy Screening Programme.

**Method** Retrospective analysis of the latest and most severe retinopathy and maculopathy grades from each patient in the programme.

**Results** Data from 7098 screenings from 5647 diabetics were obtained, which represented approximately 77% of the total number of diagnosed diabetics in Northland. The two main ethnic groups in our study were New Zealand European (56.5%) and Māori (39.3%). Retinopathy was present in 19% of the Northland diabetic screening population: 13.6% had minimal non-proliferative diabetic retinopathy (NPDR), 5.4% had NPDR and 0.4% had Proliferative Diabetic Retinopathy (PDR). Ethnicity data for NPDR was 57% Māori, 38% European, and PDR 50% Māori, 45% European. Maculopathy was present in 11%. Maculopathy requiring treatment was present in 1.4% (Māori 48%, European 44%). The mean failure-to-attend rate was 31%.

**Conclusion** Rates of retinopathy and maculopathy detected by the Northland screening programme were comparable to rates reported in Waikato, lower than Wellington rates and lower than international averages. Māori were over-represented in patients with retinopathy and maculopathy, but underrepresented within the screening population. The success of this programme was undermined by the high failure-to-attend rate despite attempts to improve access.

Diabetic retinopathy is a serious complication of diabetes and remains the leading cause of blindness among working-aged adults in the developed world.<sup>1</sup> The progression of visual loss can be reduced with timely detection and treatment with laser photocoagulation.<sup>2,3</sup>

National screening programmes are effective at detecting diabetic retinopathy and reducing visual impairment and blindness.<sup>4</sup> In New Zealand, it has been estimated that approximately 30% of people with diabetes have retinopathy and 10% have disease that is sight threatening.<sup>5</sup>

The Northland District Health Board (NDHB) services 3.6% of the national population. This equates to 159,160 people, making NDHB the tenth largest DHB in the country.<sup>6</sup> NDHB services the fourth largest Māori population in New Zealand with 30% of Northland identifying as Māori.<sup>6</sup> Sixty-three percent of Northland is European, 2.5% Pacific people (mostly of Samoan, Tongan, Niuean, or Cook Islands origin), and 4.5% Other.<sup>6</sup>

NDHB has some of the highest levels of deprivation in the country.<sup>7</sup> Over half of all Māori live in the most deprived quartile.<sup>7</sup> One-third of Northland's population live in an urban Whangarei, with the remainder living in towns and rural areas across the district.<sup>8</sup> Many communities are isolated and travel time is 5 hours from the most northern to southern extremities, and up to 2 hours east to west.<sup>8</sup> A mobile screening programme for diabetic retinopathy was therefore essential to access all diabetics in Northland.

Diabetic retinopathy screening in Northland started with direct ophthalmic examination by ophthalmologists at Whangarei Base Hospital. The Mobile Diabetic Retinopathy Screening Programme was quickly developed in response to the severity of initial retinopathy presentations.

Mobile screening was launched in 1994, screened 450 patients over the year and consisted of one medical photographer driving to 8 different locations across Northland taking photographs with a conventional fundus camera. Films were then developed and all images were assessed by the author (Dr Dalziel), as secondary grader at Whangarei Base Hospital. The mobile screening service has since grown with the population of known diabetics and today runs 22 screening clinics in 14 regions, in collaboration with local providers.

The aim of our study was to determine the prevalence of diabetic retinopathy and maculopathy in the Northland Diabetic Retinopathy Screening Programme.

## Method

**Research design**—The study accessed the Ophthalmology Digital Healthcare Database recently introduced in July 2011. This database recorded demographics, disease data and digital retinal photographs. All screening data from 10 February 2011 to 24 October 2012 was retrospectively assessed. The latest and most severe retinopathy and maculopathy grades of each patient were analysed.

**Screening centres**—Screening took place in 22 clinics in 14 regions including hospital outpatient clinics, medical centres, community centres and a correction facility. A qualified specialist medical photographer attended each venue and ran clinics in collaboration with local nurses.

**Data collection**—Data entered into the Ophthalmology Digital Healthcare Database were obtained through pre-screening questionnaires given to patients on arrival to each clinic. A local diabetic nurse double-checked answers, obtained visual acuity and consent, administered mydriatic drops (tropicamide 1% and phenylephrine 2.5%) and entered clinical data onto the database.

After pre-assessment and mydriatic administration, a Zeiss ProNM camera was used to take three digital photographs, each with a 45 degree field of view in accordance with National Guidelines.<sup>5</sup>

**Grading criteria**—Two grading systems were utilised in Northland. Initially, a local grading system was used that did not further define NPDR. In February 2012, this changed to the National Diabetes Retinal Screening Grading System.<sup>5</sup> To enable analysis, data graded using the national guidelines were converted to the local grading system used prior to February 2012. Table 1 and Table 2 correlate the two grading systems.

The primary and secondary graders consisted of a medical photographer and the designated ophthalmologist at Whangarei Base Hospital, respectively. For quality assurance purposes, 10 per cent of the primary grader's images were reviewed by the latter in a random fashion. Patients were then sent written screening results and informed of their next appointment according to National Guideline Screening Intervals.

**Table 1. Correlation between Northland and national grading criteria for retinopathy<sup>5</sup>**

Northland grade	National grade	Description	Clinical signs
<b>Retinopathy</b>			
NR	R0	No retinopathy	No abnormalities
M-NPDR	R1	Minimal	<5 microaneurysms or dot haemorrhages
NPDR	R2	Mild	>4 microaneurysms & dot haemorrhages Exudates >2DD from fovea
	R3	Moderate	Any features of mild Blot or larger haemorrhages
	R4	Severe	<1 quadrant of venous beading One or more of: – Definite IRMA – ≥2 quadrants venous beading – ≥2 quadrants blot or larger haemorrhages
PDR	R5	Proliferative	One or more of: – Neovascularisation – Sub hyaloid or vitreous haemorrhage – Traction retinal detachment or Retinal Gliosis

NR (No retinopathy); M-NPDR (Minimal Non Proliferative Diabetic Retinopathy); PDR (Proliferative Diabetic Retinopathy).

**Table 2. Correlation between Northland and national grading criteria for maculopathy<sup>5</sup>**

Northland grade	National grade	Description	Clinical signs
<b>Maculopathy</b>			
No M	M0	No maculopathy	No abnormalities within 2DD of fovea
M-NT	M1	Minimal	Microaneurysms & haemorrhages within 2DD but outside 1DD of fovea
	M2	Mild	Microaneurysms & haemorrhages within 1DD No exudates or retinal thickening No reduction in vision
	M3	Mild	Exudates (± retinal thickening) within 2DD but outside 1DD
M-T	M4	Moderate	Exudates or retinal thickening within 1DD Foveola not involved
	M5	Severe	Exudates or retinal thickening involving the foveola. Reduced vision

**Note:** No M (No maculopathy); M-NT (Maculopathy – No Treatment); M-T (Maculopathy – Treatment).

## Results

**Demographics**—From 10 February 2011 to 24 October 2012, a total of 7098 screens (14,197 retinal photographs) took place of 5647 diabetics. This represented approximately 77% of the diagnosed diabetes in the region.<sup>9</sup> The latest grading of each patient was analysed. The two main ethnic groups were NZ European (56.5%) and Māori (39.3%).

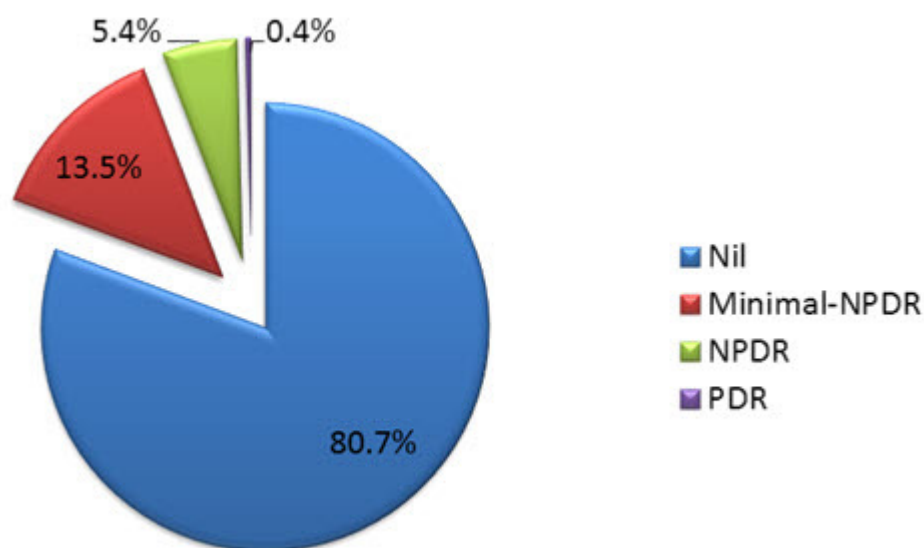
Age at screening ranged from 9 to 97 (mean±SD: 62.7±13.7; median: 64; interquartile range: 18). Data for the number of years between the date of diabetes diagnosis and screening was missing in 41.7% of cases, with available data ranging from 0 to 71 years (11.0±8.2; 10: 9). The mean failure-to-attend rate was 31%. The quality of retinal images was classed as good or adequate in 98.1%.

The type of diabetes within the population ranged between Type 2 (n=2829; 88.7%), Type 1 (348; 6.4%), Other (7; 0.1%) and Maturity Onset Diabetes of the Young (MODY) (1; 0.0%). There were 262 cases with no diabetes type noted (4.8%).



**Retinopathy grading**—81% of subjects had no retinopathy (Figure 1). A further 13.6% had minimal NPDR. The remaining 5.8% had either NPDR or PDR. Approximately 60 % of those with NPDR and 70% of those with PDR were screened outside of Whangarei.

**Figure 1. Prevalence of diabetic retinopathy in Northland**



Ethnicity data showed that 57% of those with NPDR were Māori. This corresponded to 7.8% of the total Māori population within the study. Fifty percent of the PDR population was Māori, corresponding to 0.5% of the study's Māori population (Table 3).

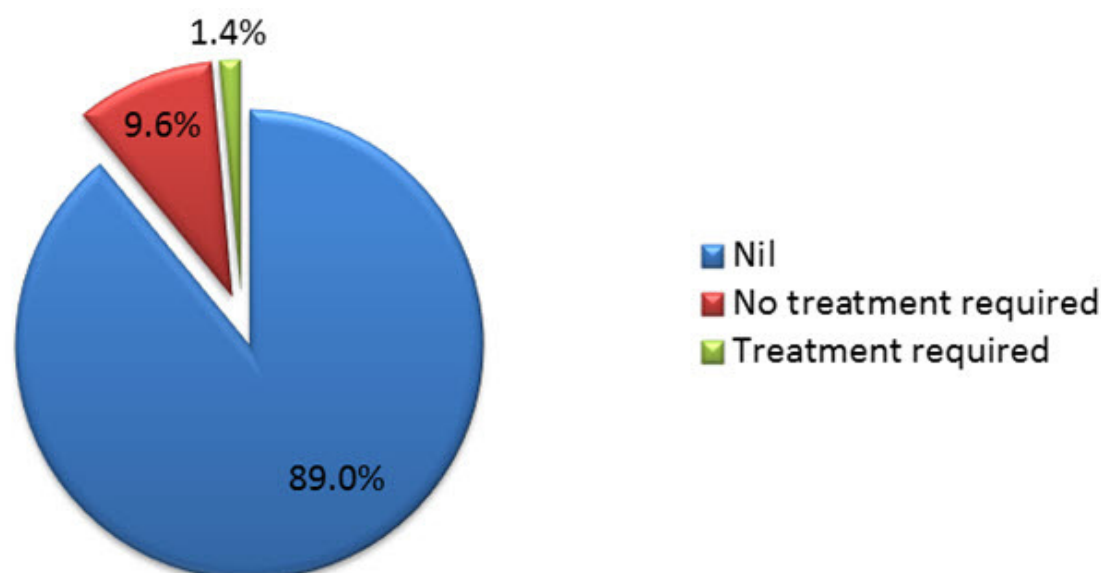
**Table 3. Distribution of retinopathy grading based on ethnicity**

Ethnicity	NR (%)	M-NPDR (%)	NPDR (%)	PDR (%)	Grand total (%)
European	2650 (83.0)	416 (13.0)	115 (3.6)	10 (0.3)	3191 (56.5)
Māori	1729 (77.9)	307 (13.8)	173 (7.8)	11 (0.5)	2220 (39.3)
Other	106 (76.3)	25 (18.0)	8 (5.8)	0 (0)	139 (2.5)
Asian	33 (68.8)	10 (20.8)	4 (8.3)	1 (2.1)	48 (0.9)
Pacific people	30 (71.4)	8 (19.0)	4 (9.5)	0 (0)	42 (0.7)
Unidentified	7 (100)	0 (0)	0 (0)	0 (0)	7 (0.1)
<b>Grand total</b>	<b>4555 (80.7)</b>	<b>766 (13.6)</b>	<b>304 (5.4)</b>	<b>22 (0.4)</b>	<b>5647 (100)</b>

NR (No retinopathy); M-NPDR (Minimal Non Proliferative Diabetic Retinopathy); PDR (Proliferative Diabetic Retinopathy).

**Maculopathy grading**—89% of patients had no maculopathy (Figure 2). Maculopathy requiring treatment (M-T) comprised 1.4% of the population. Approximately 60% with M-T were screened outside Whangarei.

**Figure 2. Prevalence of diabetic maculopathy in Northland**



Ethnicity data showed that 44% of those with M-NT were Māori, which represented 8% of the Māori population in our study (Table 2). Forty-eight percent of the PDR population was Māori, corresponding to 1.7% of the study's Māori population (Table 4).

**Table 4. Distribution of maculopathy grading based on ethnicity**

Ethnicity	No M (%)	M-NT (%)	M-T (%)	Grand Total (%)
European	2890 (90.6)	266 (8.3)	35 (1.1)	3191 (56.5)
Māori	1948 (87.7)	234 (10.5)	38 (1.7)	2220 (39.3)
Other	116 (83.5)	19 (13.7)	4 (2.9)	139 (2.5)
Asian	38 (79.2)	9 (18.8)	1 (2.1)	48 (0.9)
PI	34 (81.0)	7 (16.7)	1 (2.4)	42 (0.7)
Unidentified	7 (100)	0 (0)	0 (0.0)	7 (0.1)
Grand Total	5033 (89.1)	535 (9.5)	79 (1.4)	5647 (100)

No M (No maculopathy); M-NT (Maculopathy – No Treatment); M-T (Maculopathy – Treatment).

## Discussion

In New Zealand, approximately 5–7% of people have been diagnosed with type 1 or type 2 diabetes.<sup>10</sup> The rates for diabetes in Māori, Pacific and Indo-Asian people are two to three times higher than Europeans.<sup>10,11</sup>



Photographic screening programmes have an important role in reducing the burden of diabetic eye disease and rely on good coverage, quality and accessibility.<sup>4,12</sup>

The results of our study showed that retinopathy was present in 19% of the Northland diabetic screening population. Eighty-one percent had no retinopathy, 13.6% had minimal NPDR, 5.4% had no retinopathy and 0.4% had PDR. Maculopathy was present in 11%. Proportionately, Māori had more than twice the rate of NPDR, and two thirds more PDR compared to Europeans (Table 1).

Thirty-nine per cent of the screening population was Māori which was higher than the regional Māori population of 30%.<sup>6</sup> However, Māori appear to be underrepresented in the screening population, as national rates of diagnosed diabetes in Māori are up to three times higher than Europeans.<sup>10,11</sup> This is compounded by Māori also having high rates of undiagnosed diabetes.<sup>13</sup> The Asian and Pacific rates were high in our study, however the overall sample size was too small to assess significance.

The rates of retinopathy detected in Northland were lower than those reported in the Wellington region. Wellington data from 2002-2005 for first-visit screening of diabetics showed that 32% had some form of retinopathy. Sixty-eight per cent had no retinopathy, 20% had minimal NPDR, 10.5% NPDR and 0.2% PDR.<sup>14</sup> Maculopathy was present in 12.3%.

Wellington reported statistically significant differences between mean retinopathy grades of Māori and Europeans, but did not give total rates. Comparisons were limited by differences in overall time periods, and the timeframe used to assess grades (i.e. first-visit grade in Wellington compared to last-visit grade in our study).

Our overall rates of retinopathy were comparable to a Waikato study that analysed screening data from 1993-2001.<sup>15</sup> This study found that 22% of participants had some form of retinopathy: 78% had no retinopathy, 9.3% non vision-threatening retinopathy (NVR) and 3.1% vision-threatening retinopathy (VTR).

Proportionately, Māori had 39% more NVR and 72% more VTR than Europeans. However, differences in classification systems made further comparisons with our study difficult. We support the use of national guideline grading criteria as this will enable categorically comparison of rates in the future.

The rates of our study were lower than international data. A study in Newcastle, Australia, showed that out of 5519 diabetic patients 35% had some form of diabetic retinopathy.<sup>16</sup> Furthermore, a pooled analysis of 35 studies from around the world with a total of 22,896 individuals with diabetes, showed that the overall prevalence for any diabetic retinopathy was 34.6% (95% CI: 34.5-34.8) and PDR 6.96% (6.87-7.04).<sup>17</sup>

Strengths of our study included a large number of participants and a wide geographic representation. The retinal screening programme in Northland had a low proportion of non-assessable retinal images (1.9%). This was comparable to the 1.8% rate reported in Wellington<sup>14</sup> and was lower than the 6.2% rate reported in Waikato.<sup>15</sup> The rate of our study was well within the maximum failure rate of 5% recommended by the British Diabetic Association.<sup>18</sup> We attributed the high rate of assessable images in our study to the use of dilatation drops with every screen.

Other strengths of the screening programme included a high number of clinic locations providing many points of access, a high capacity to screen patients, improved ophthalmology clinic efficiency at Whangarei hospital and the ability to share screening information with other health professionals.

Our study did have several limitations. Failure-to-attend rates were high and averaged 31%. This was two thirds higher than the non-attendance rates of the Waikato screening population (18.7%).<sup>15</sup> Interestingly, other screening programmes within northland had much lower failure-to-attend rates, with 5% for breast cancer screening (non-published data, NDHB).

Screening for diabetic retinopathy does have several unique barriers to access. The use of dilating drops results in patients being unable to drive after screening, which has implications for time off work, social disruption and the added cost of arranging a driver. Steps to address attendance barriers have recently been put in place and include providing transport and extending clinic hours to allow individuals to attend screening after work.

Several other initiatives may also improve screening uptake. Improving public awareness levels of diabetic eye disease to match other well-known conditions, such as breast cancer, may increase motivation to attend screening. Streamlining regional screening programmes so that several types of screening clinics are run together on the same day may limit the amount of disruption to patients and their support networks caused by attending clinics.

The screening programme already works closely with Māori health providers and community health workers. By strengthening these partnerships<sup>19</sup> and facilitating other avenues for screening individuals who rarely access traditional primary care services,<sup>20</sup> the uptake of screening within the Māori community may be increased. Other limitations included incomplete data for diabetic type, date of diabetic diagnosis, HbA1c levels and blood pressure. These data would have helped to further characterise key risk factors present within our population.

In conclusion, the rates of diabetic retinopathy and maculopathy detected in Northland by this screening programme were comparable to rates reported in Waikato and lower than Wellington rates. Retinopathy rates were also lower than international averages.

Within our study, Māori were over-represented in patients with diabetic retinopathy and maculopathy, but were still underrepresented in the screening population as a whole. The success of this programme was undermined by the high failure-to-attend rate despite attempts to improve access.

Further input may be needed to increase public awareness about diabetic eye disease. There may also be the scope to collaborate with screening programmes with lower non-attendance rates to ultimately decrease the burden of diabetic eye disease in New Zealand.

**Competing interests:** None identified.

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## A retrospective review of notified human cryptosporidiosis cases in the Waikato region of New Zealand, 2004 to 2011

George Cowie, Anita Bell

### Abstract

**Aim** To retrospectively review notified human cryptosporidiosis cases in the Waikato region of New Zealand between 2004 and 2011 and to identify risk factors for human cryptosporidiosis infection.

**Method** Waikato cryptosporidiosis notification data for the period 1 January 2004 to 31 December 2011 were analysed to identify any trends in the rates and distribution of key variables. A comparison was made between urban and rural dwelling cases.

**Results** Annual Waikato cryptosporidiosis notification rates were consistently higher than national rates. Analysis showed a seasonal peak centred around September with most cases having direct or indirect contact with cattle. Comparisons between urban and rural cases showed similar probable causes of infection and higher rates of infection in rural cases.

**Conclusion** Those who have contact with animals continue to be at risk of infection from *Cryptosporidium*. The data suggests that children who live on rural properties and have contact with animal faeces, either directly or via a contaminated drinking water supply, are at the highest risk of infection.

Cryptosporidiosis is a widespread and common gastro-intestinal disease affecting people in both developed and developing countries.<sup>1-12</sup> The disease is caused by a protozoan parasites of the genus *Cryptosporidium*, which affect the intestines of vertebrates.<sup>13-19</sup>

*Cryptosporidium parvum* and *Cryptosporidium hominis* are the two most commonly identified species which affect humans. *Cryptosporidium parvum*'s main reservoir is animals and *Cryptosporidium hominis* seems to be a strictly human disease.<sup>20</sup>

For immunocompetent the most significant symptom is watery diarrhoea<sup>21</sup> but for the immunocompromised, such as those with AIDS, the symptoms can be much more severe and are often fatal.<sup>22-24</sup>

The parasite is transmitted through the faecal-oral route, via environmentally resilient cysts (oocysts), including person to person, zoonotic, contaminated water, foodborne and airborne transmission.<sup>25</sup> It has been estimated that as little as 10 oocysts may be sufficient to cause infection.<sup>21</sup> Although the cryptosporidium was first identified as far back as 1910<sup>26</sup> it was not until 1976 that the organism was linked to illness in humans.<sup>27</sup>

Previous reports on human cryptosporidiosis in New Zealand<sup>9</sup> and other parts of the world<sup>28-30</sup> showed seasonal patterns to the disease, with higher rates in the spring than other times of the year.<sup>9</sup> Rural areas, children under 10 years old and Europeans also had higher rates.

The Waikato region of New Zealand has one large urban centre and a significant rural population with approximately 22% of the population living in rural areas compared to 14% for the whole of New Zealand.

The aim of this study was to retrospectively review and describe notified cryptosporidiosis cases in the Waikato region of New Zealand between 2004 and 2011 and to identify risk factors for cryptosporidiosis infection.

## Methods

All confirmed cases of cryptosporidiosis notified to Waikato District Health Board between January 2004 and December 2011 were retrospectively reviewed.

Data was obtained from the EpiSurv database, which contains information on individual cases collected from general practitioners, hospital staff and public health staff, and includes information on a range of possible risks factors. The questionnaires originally used during the original case investigation to collect data for EpiSurv were also reviewed.

A confirmed case of cryptosporidiosis is defined as one with clinical symptoms compatible with cryptosporidiosis and is laboratory confirmed.<sup>31</sup>

Cases that do not meet this case definition are not considered to be a case and were not reviewed as part of this study. Laboratory testing is of faecal samples by ELISA and is not species specific.

All positive samples since 2007 have been directly notified to Population Health by laboratories. All confirmed notified cases were investigated either by Population Health staff or territorial authority (TA), environmental health officers (EHOs), using a standardised questionnaire, to try to identify possible sources of infection and to collect demographic information such as age, gender and occupation.

Possible sources of infection were determined from information on activities such as exposure to animals, contact with other symptomatic people and fresh water sources for 10 days prior to the onset of symptoms.

Data was entered into the EpiSurv database along with information from general practitioners and hospital staff. The original questionnaires for all of the cryptosporidiosis cases notified to Waikato District Health Board between 2004 and 2011 were also reviewed.

Incidence rates were calculated using population data for the Waikato District Health Board region from the 2006 New Zealand census. Group specific population data was used to calculate demographic specific incidence rates.

To identify potential differences in exposure between urban and rural populations, cases were split into urban and rural groups for the analysis of probable sources.

Urban cases were those residing in areas classed as main urban area, satellite urban area and independent urban areas according to definitions by Statistics New Zealand.

Rural cases were those living in areas classed as rural area with high urban influence, rural area with moderate urban influence, rural area with low urban influence and highly rural/remote.

Correlations between number of cases and a variety of exposure factors were examined using EpiInfo® version 3.3.2 and Microsoft Excel® software.

## Results

**Cryptosporidiosis cases**—A total of 1041 confirmed cases of cryptosporidiosis were notified within the Waikato DHB region between 1 January 2004 and 31 December 2011. Of these 50 cases were overseas during the incubation period and these were not investigated further for potential sources although the demographic information for these cases are reported. For 317 cases no confirmed or probable cause could be identified, most of these were lost to follow up and were not interviewed.

Fifty cases were hospitalised but no cases died as a result of the illness. The incidence rate was higher in Europeans than in any other ethnic group, in males (40.1 per 100,000 yearly average) than in females (36.7 per 100,000) and in those under 5 years of age (94.9 per 100,000 for 0 to 1 year and 60.5 per 100,000 for 1 to 4 years). See Table 1.

**Table 1. Confirmed notified cryptosporidiosis cases in the Waikato by key variable, 2004 to 2011**

Variable	Average annual number of cases (%)	Average annual rate (per 100,000)	95% CI
<b>Ethnicity</b>			
European	112 (86)	49.3	46.1–52.5
Māori	11.8 (9)	17.4	13.9–20.9
Pacific People	0.8 (1)	7.1	1.4–12.7
Asian	2.5 (2)	14.5	8.1–20.9
Other	1.6 (1)	10.0	4.6–15.4
Unspecified	1.3 (1)	–	–
<b>Gender</b>			
Male	66.6 (51)	40.1	36.7–43.5
Female	63.5 (49)	36.7	33.5–39.9
<b>Age group</b>			
<1	4.8 (4)	94.9	64.7–125
1 to 4	60.5 (46)	312	284–340
5 to 14	29.3 (23)	55.2	48.1–62.3
15 to 24	13.4 (10)	27.3	22.2–32.5
25 to 44	18.1 (14)	20.1	16.8–23.4
45 to 64	2.8 (2)	3.4	2.0–4.9
65+	1.4 (1)	3.2	1.3–5.1
<b>Location</b>			
Main urban	59.0 (45)	31.9	29.0–34.8
Satellite urban	2.8 (2)	29.0	16.9–41.2
Independent urban	15.9 (12)	22.3	18.4–26.1
Urban–All classes	77.6 (59.7)	29.2	26.9–31.5
Rural with high urban influence	5.6 (4)	74.1	52.5–95.8
Rural with moderate urban influence	11.4 (9)	70.8	56.2–85.3
Rural with low urban influence	31.8 (24)	74.7	65.5–83.9
Remote rural	3.8 (3)	51.4	33.0–69.8
Rural–all classes	52.5 (40.3)	71.5	64.6–78.3

Notified rates within the Waikato were typically higher than national notified incidence rates for the same period. The average Waikato annual rate was 38.3 cases per 100,000 population compared to 19.7 cases per 100,000 population for the whole of New Zealand.

There was no trend across the years during this period, but seasonal variations in case numbers can be seen with peaks between August and November, with September usually having the highest number of notifications. This pattern is also seen in the national rates (Figure 1).



There were 32 outbreaks during the study period. Most of these were household outbreaks with few cases; 19 had only two cases and the largest outbreak had only five cases.

**Sources of infection**—Only in 12 cases was a source of infection actually confirmed. Each of these was by person to person infection during close contact with another confirmed case. In all other cases only probable sources were identified.

The most common of the probable sources was contact with animals; a rate of 48.5 cases per 100,000 (Table 2). Contact was predominantly directly with farm animals, accounting for 84.4% of the animal contact cases, with calves identified as the most common animal type (63.8% of the farm animal contact cases). In 42.4% of these cases, animal contact was the only source of infection identified.

The second most significant probable source identified was the consumption of untreated drinking water with an average annual rate of 33.9 cases per 100,000 people. 10.9% of these cases had only one source of infection identified. Both animal contact and untreated drinking water had significantly higher rates than any other probable source identified.

Most cases had more than one possible source identified; some had three or more possible sources. For those with exposure to animals, 50.7% also had consumed untreated drinking water and of those where drinking water had been identified as a possible source 86.2% also had contact with animals.

The proportion of cases with only a single source of infection was relatively low: for food the proportion was only 7.7%; for person to person spread the proportion was 29.2% and for other sources, such as recreational water contact, the proportion was 25.9%.

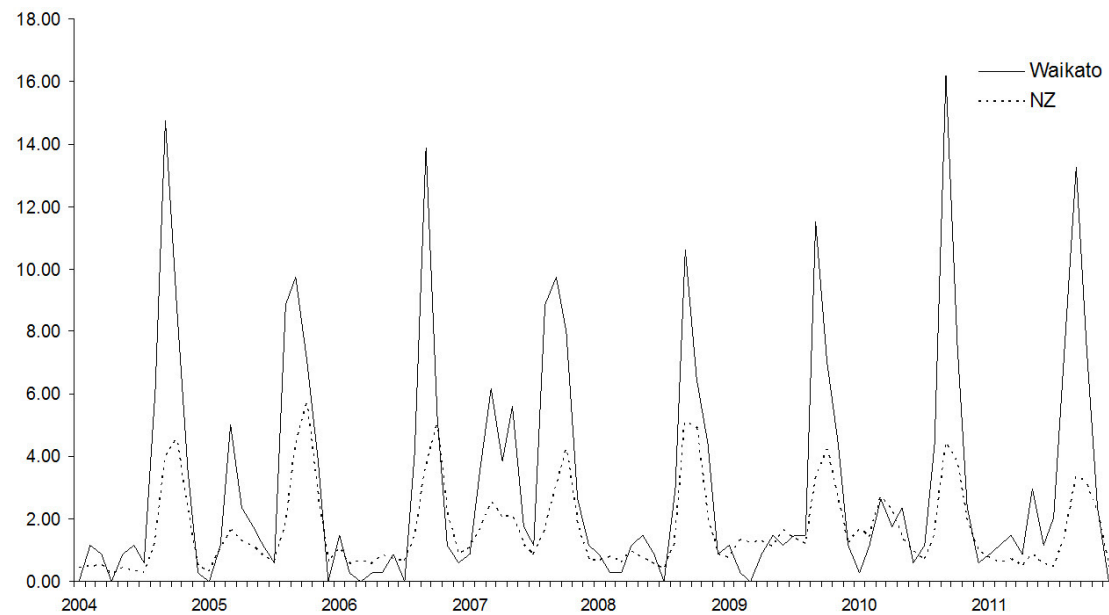
**Urban and rural comparison**—Although only 40% of cases were within rural areas the lower rural population means that rates of cryptosporidiosis in rural areas (yearly average of 71.5 cases per 100,000; 95% CI 64.6–78.3) were more than twice that of urban areas (yearly average of 29.2 cases per 100,000; 95% CI 26.9–31.5).

For all identified probable sources rates were higher for rural cases than urban ones (Table 2, Figure 3). However, the rates were only significantly higher for exposure to animals and consumption of untreated drinking water ( $p < 0.05$ ).

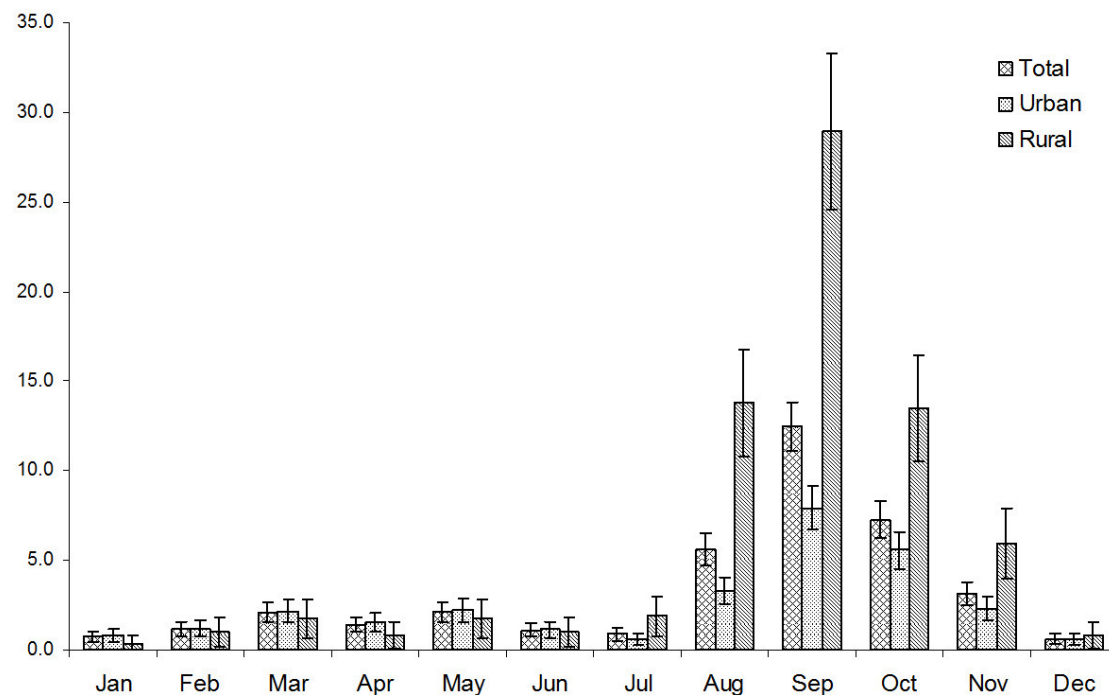
For rural cases the exposure to animals had a rate more than three times that of urban cases and for consumption of untreated drinking water the rates was over 5 times as high.



**Figure 1. Notified cryptosporidiosis cases per month for each year, Waikato District Health Board and New Zealand, 2004 to 2011**



**Figure 2. Average monthly cryptosporidiosis notification rates total, urban and rural cases, Waikato District Health Board, 2004 to 2011**



**Table 2. Waikato cryptosporidiosis cases by probable source type, Waikato District Health Board, 2004 to 2011**

Variable	Average annual number of cases (%)	Average annual rate (per 100,000)	95% CI
<b>Waikato total</b>			
Animal contact	72.5 (56)	21.4	19.6–23.1
Drinking water	42.6 (33)	12.6	11.2–13.9
Person to person	11.1 (9)	3.3	2.6–4.0
Food	3.3 (3)	1.0	0.6–1.3
Overseas	6.3 (5)	1.8	1.3–2.4
Other	3.9 (3)	1.1	0.7–1.6
Not identified	39.6 (30)	11.7	10.4–13.0
<b>Urban</b>			
Animal contact	36.9 (48)	13.9	9.4–18.4
Drinking water	17.8 (23)	6.7	3.6–9.8
Person to person	7.9 (10)	3.0	0.9–5.0
Food	1.3 (2)	0.5	-0.4–1.3
Overseas	4.3 (5)	1.6	1.1–2.1
Other	1.9 (2)	0.7	-0.3–1.7
Not identified	28.6 (37)	10.8	6.8–14.7
<b>Rural</b>			
Animal contact	35.6 (68)	48.5	42.9–54.1
Drinking water	24.9 (47)	33.9	29.2–38.6
Person to person	3.3 (6)	4.4	2.7–6.1
Food	2.0 (4)	2.7	1.4–4.1
Overseas	2.0 (4)	2.7	1.4–4.1
Other	1.5 (3)	2.0	0.9–3.2
Not identified	11.0 (21)	15.0	11.8–18.1

## Discussion

As expected for an area with a relatively high agricultural population cryptosporidiosis rates in the Waikato were higher than the national New Zealand average.

When rates are compared between urban and rural cases a clear difference is apparent with rates within the rural population being significantly higher than the urban population, although the rate for urban cases was still higher than the national average and that of other developed countries.<sup>9</sup>

True rates within the community will, of course, be higher as only a small proportion of cases will seek medical attention and provide faecal samples for testing.<sup>32</sup>

A seasonal peak in spring was clearly evident from the data and was present for both rural and urban cases. This peak is also apparent in the national data but is more pronounced within the Waikato. Direct contact with animals, typically calves, was the most important sources of infection identified during this study for both urban and rural cases.

Although this peak is in line with other studies which demonstrate the zoonotic nature of cryptosporidium infection<sup>3,5,10,11,33,34</sup>, a difference in between urban and rural cases

could have been expected in both the seasonal pattern and the most commonly identified sources of infection.

However this study suggests both urban and rural cases were most likely to have acquired the parasite from calves or from the consumption of untreated drinking water. For the rural population exposure to these risk factors is more likely, hence the higher rates, but within the Waikato the majority of the urban cases were also exposed to the same risk factors during visits to rural properties.

In other studies differences in infecting species of cryptosporidium are apparent between the rural and urban populations<sup>28</sup> as sources of infection differ but this is less likely to be the case within the Waikato as the most likely sources identified are the same for both populations. However more widespread speciation of cryptosporidium in diagnostic sampling, within New Zealand, may shed further light on the epidemiology of the parasite.

The risk posed by cryptosporidium in untreated or inadequately treated drinking water is well understood.<sup>35-40</sup> In this study it has been difficult to isolate different potential sources of infection, as most cases who consumed untreated drinking water also had direct contact with animals. However the consumption of untreated drinking water has been shown to be widespread amongst cryptosporidiosis cases in the Waikato and has to be considered a significant potential source of infection. Further study is necessary to determine the full significance of the consumption of untreated drinking water on cryptosporidium infection.

Although Waikato District Board provided a standard questionnaire for to completion during case investigations the data returned varied in quality. Many investigators used the questionnaire provided but some did not and not all sections of the questionnaire were completed. In many cases where contact with a farm animal was determined no information on additional potential sources was provided. This is apparent in the higher proportion of animal contact cases where only a single source was identified. This is likely to have underestimated the significance of other likely sources and hidden the true impact that these sources may have on the disease.

It is difficult to fully understand the necessity of collecting data when you are not fully aware of why it is collected. Increasing the understanding of why the data is collected, amongst those who collect it, may lead to an improvement in the quality and usefulness of the data.

Prevention messages regarding reducing transmission during and after contact with animals, particularly during Spring time, may prove beneficial although difficult to implement. Similarly action on reducing the consumption of untreated drinking water may also help reduce the incidence of cryptosporidiosis and other water borne communicable diseases in the Waikato.

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## Review of capacity assessments and recommendations for examining capacity

Heather Astell, Jae-Hyun Lee, Shankar Sankaran

### Abstract

**Aim** To audit the capacity assessments performed since December 2007 by Community Geriatric Services (CGS), Middlemore Hospital, and to develop a resource kit for training health professionals.

**Method** 1343 clinical letters were reviewed. Demographic data, reason for assessment and outcome of assessment were recorded. Data was analysed to reveal trends.

**Results** There were 87 capacity assessments on 82 unique patients. The numbers of referrals for capacity assessments have increased since December 2007. 63% of patients were female, and the majority were European (75.6%). The mean age was 80.3 years. 66.7% of patients were referred by their general practitioner (GP). Dementia was the most common diagnosis.

Fifty patients had more than one reason for referral. Thirty-seven were assessed for appointing an enduring power of attorney (EPOA), 44 for financial welfare, 73 for personal welfare, and two for testamentary capacity. Forty-five lacked capacity for all aspects assessed. Twenty-three did not have an EPOA and appointment of a guardian was recommended for 16 patients.

**Conclusion** The CGS is performing more capacity assessments over time. The majority of the patients are elderly and have dementia. There is a need to train specialist nurses and general practitioners to perform capacity assessments. A resource kit has been developed for this purpose.

The principal of autonomy relies on individuals being able to make informed decisions which involve the four domains: to understand the relevant information, to appreciate the nature of their situation and the consequences of their decision, to consider and reason through the alternatives, and to be able to express their decision to others.<sup>1-6</sup>

If patients are unable to perform all these domains of informed decision making (often due to cognitive impairment) to an acceptable degree, they lack capacity. Capacity is rarely all or nothing and patients may be able to perform these domains to some extent, in which case they may be considered to be partially competent.

Where a patient lacks capacity, another individual may need to make decisions on behalf of the patient. In New Zealand the next of kin does not automatically have the right to make decisions on behalf of the patient. Instead, prior to losing capacity, patients can appoint someone to act on their behalf (an Enduring Power of Attorney) which can then be enacted by having the patient declared incompetent by a medical professional.



If the individual did not appoint someone as their EPOA and they are declared incompetent, the family court can appoint someone to act on their behalf through the Protection of Personal and Property Rights (PPPR) Act 1988.<sup>7</sup>

Capacity assessments are assessments done by medical professionals to determine whether a patient is competent to make a particular decision where there is potential risk to the patient due to lack of capacity. It is important that there is a particular aspect of capacity in question, rather than a general concern regarding capacity, as capacity can vary across different types of decisions. The most common decisions can be roughly grouped into those related to personal welfare, financial welfare, testamentary capacity, or appointing an EPOA.<sup>6</sup>

Historically, in New Zealand capacity assessments have been done by psychiatrists, however recently geriatricians are increasingly performing capacity assessments. In fact, all doctors may perform capacity assessments as it is considered within their scope of practice.<sup>7</sup>

Counties Manukau District Health Board (CMDHB) is a tertiary hospital serving the South Auckland region. Part of the Adult Rehabilitation and Health of Older People department, the CGS was set up in December 2007 to perform geriatrics home visits, support aged residential care facilities and promote enhanced integration with primary care. The CGS frequently performs capacity assessments at the request of other health care professionals or if the need for a capacity assessment is evident while reviewing a patient for another reason.

Capacity assessments are also performed by other departments from CMDHB, notably Mental Health Services of Older People (MHSOP) and the Geriatrics department, and these capacity assessments are not included in the data below.

This audit aimed to review the trends in capacity assessment by the CGS over the last 3½ years, and to review the literature regarding capacity assessment to form a resource kit for health professionals to use.

## Methods

This was a retrospective study. Ethics approval for this study was obtained. (NTX/11/EXP/235). A list of all patient contacts made by the CGS between 1 December 2007 and 30 June 2011 was obtained from the hospital database. The clinical letters for each patient were reviewed. The initial referral was not always solely for the purpose of capacity assessment, but the patient was included in this study if the clinician who saw the patient considered a capacity assessment necessary and performed one.

A set of data was recorded on a password-protected spreadsheet; gender, ethnicity, date of birth (age at the time of assessment were calculated using Microsoft Excel 2003 software), date of assessment, diagnosis, referrer, reason for referral, assessor, degree of competence, existence of EPOA, whether referral under the PPPR Act was recommended and the presence of any complex family situations.

Diagnosis was categorised into the most commonly seen clinical causes of cognitive impairment; dementia, mental disorder, intellectual impairment, and delirium. Other diagnoses seen in the study group included various forms of stroke with or without dysphasia, Parkinson's disease, meningioma, severe chronic obstructive pulmonary disease (COPD), alcoholism, and general frailty.

The degree of capacity was recorded in four separate categories; capacity for personal welfare, financial welfare, ability appoint an EPOA, and testamentary capacity, and the subject was recorded as competent, partially competent or incompetent for each category. Not applicable was recorded if an assessment was not done for a particular category.

The data was analysed to reveal trends. The number of assessments performed for each 6 month interval was calculated.

## Results

1343 visits were made by the CGS between 1 January 2008 and 1 July 2011, which included 87 capacity assessments. Of the 87 visits, 12 were made as part of recruitment to another study rather than a referral to the CGS and therefore these visits were excluded from the analysis of the number of capacity assessment referrals.

Four patients had a capacity assessment on more than one visit. One patient had a capacity assessment done on three occasions while three had two assessments each. Consequently, there were 82 unique subjects in this study.

**Figure 1. Number of capacity assessment referrals in each 6-month period**

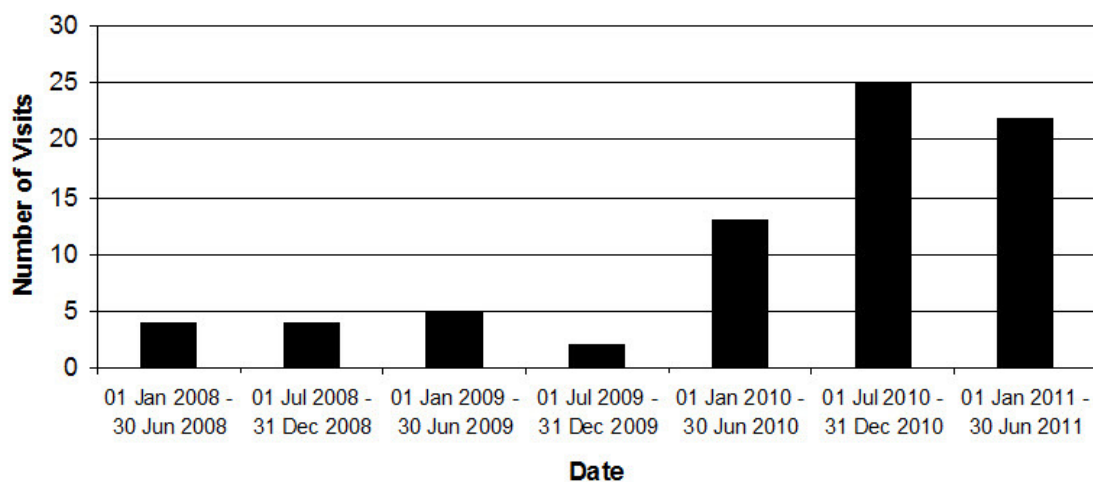


Figure 1 shows the number of capacity assessments referred to the CGS between 1 January 2008 and 1 July 2011 in six month intervals. There was a sharp increase in January 2010 and a peak of 25 capacity assessments between 1 July 2010 to 1 January 2011.

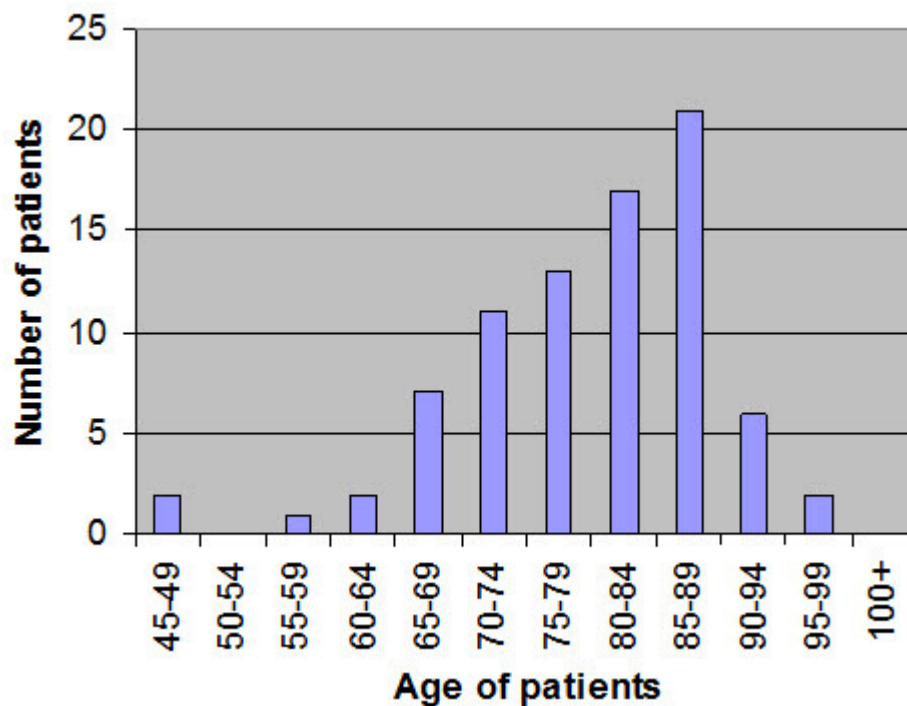
Figure 2 shows the age distribution of the 82 patients at the time of capacity assessment. The mean age was 80.3 years and the age group with the most capacity assessments was 85-89 year olds. This is similar to the patients seen by CGS for any reason who have a mean age of 83.8 years old and a peak number of assessments for patients aged 85-89.

Fifty-three of the 82 patients (64.6%) were female. The majority (62 or 75%) of patients were European, nine were Maori (11.0%), six were Pacific Islander (7.3%), three were Indian (3.7%) and two were other ethnicities (2.4%).

This compares with 67% female, 82% European, 2.5% Maori, 6.6% Pacific Islander, 1.8% Indian, 1.8% Chinese and 5.6% other ethnicities for the total CGS sample.

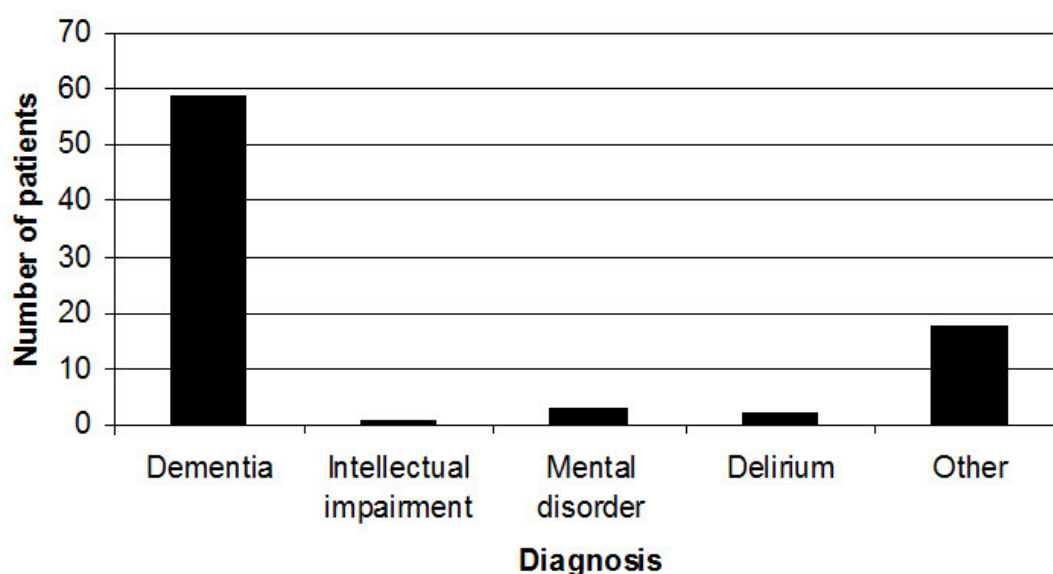


**Figure 2. Age distribution of patients who had a capacity assessment**



Fifty-eight (66.7%) were referred by GPs, five (5.7%) by Allied Health, 15 (17.2%) by the needs assessment services coordination (NASC) team, eight (9.2%) by the geriatrics department and one (1.1%) by a lawyer. Four patients (5%) had complex family situations triggering the assessment with concerns of financial and personal welfare abuse.

**Figure 3. Diagnosis of patient indicating a need for a capacity assessment**

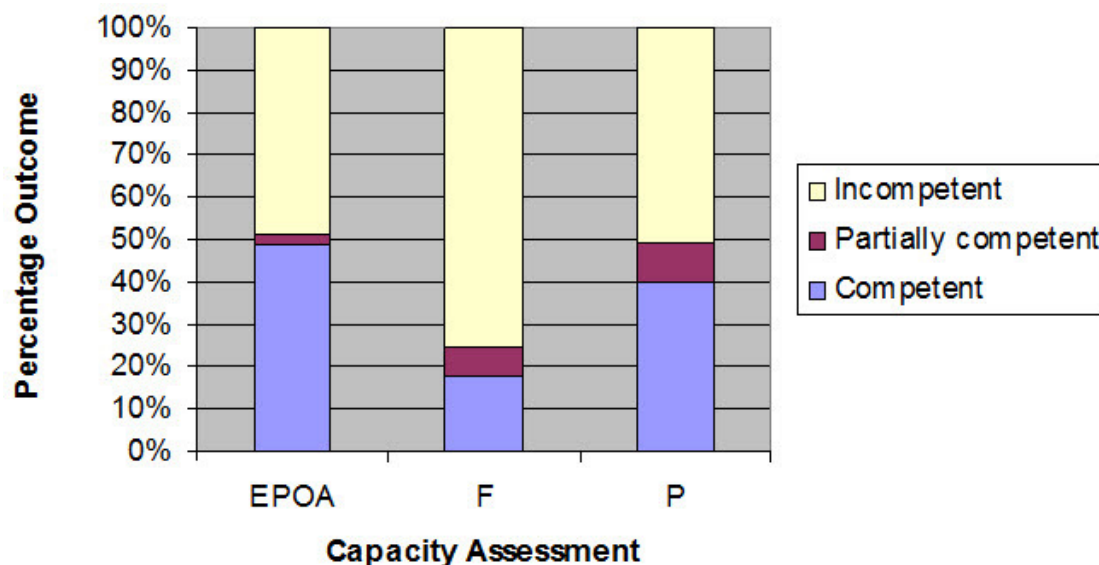


Fifty-nine of the 82 patients seen by the CGS for capacity assessment had a diagnosis of dementia, one had intellectual impairment, three had a mental disorder, two had delirium, and 18 other diagnosis. One patient was diagnosed with both dementia and delirium.

Thirty-two (36.8%) of the 87 capacity assessments were done by consultants, 54 (62.1%) by registrars and one (1.1%) by a geriatrics nurse specialist.

Fifty of the 87 (57%) visits were for assessment of more than one category of capacity. Seventy-three patients (84%) were assessed for capacity for personal welfare, 44 (51%) were assessed for financial capacity, 37 (43%) were assessed for capacity to appoint an EPOA and two (2%) patients were assessed for testamentary capacity.

**Figure 4. Graph showing the outcomes of each category of capacity assessed**



**Note:** EPOA is capacity to appoint enduring power of attorney, F is financial capacity, P is personal welfare capacity.

Eighteen (48.6%) were competent to appoint an EPOA, 18 (48.6%) incompetent and one partially competent.

Eight (18.2%) were competent for financial decisions, 33 (75.0%) incompetent and three partially competent.

Twenty-nine (39.7%) were competent for personal welfare, 37 (50.7%) incompetent and seven partially competent.

One of the two patients assessed for testamentary capacity was competent, the other patient was not willing to participate in the assessment and therefore the degree of competence could not be assessed.

Forty-five patients (52%) who were tested lacked capacity for all categories tested. Twenty-three of these patients did not have an EPOA and proceeding under the PPPR act was recommended to 16 patients.

No patients who were competent in some categories tested and incompetent in other categories were referred to the courts under the PPPR Act.

**Table 1. Capacity assessment outcome for patients with dementia and non-dementia diagnosis**

Diagnosis	Capacity assessment outcome*			EPOA status**	
	Competent	Mixed competency	Incompetent	No	Yes
Dementia	18 (31%)	8 (13.8%)	32 (55.2%)	29 (50%)	29 (50%)
Non-dementia	13 (56.5%)	2 (8.7%)	8 (34.8%)	12 (52%)	11 (48%)

**Note:** One patient with dementia had unknown competency for testamentary capacity and therefore was excluded from this table.

Where 'competent' means competent for all categories tested, mixed competency means competent in some categories tested, and incompetent or partially competent in other categories, and incompetent means incompetent for all categories tested.

\* Fisher's exact test was used to assess the associations between diagnosis and capacity assessment outcome,  $p > 0.90$ .

\*\* The Chi-squared test was used to assess the associations between diagnosis and EPOA status,  $p = 0.76$ .

Patients diagnosed with dementia performed markedly worse in capacity assessment with 55.2% determined incompetent, compared to patients without dementia where 34.8% were incompetent (but this was not statistically significant).

## Discussion

The number of capacity assessments have increased since 2007 indicating the demand for capacity assessment is increasing. As the population ages we expect the demand for capacity assessment will continue to rise.

Two-thirds of capacity assessments are performed on request by GPs (often because the patient's lawyer suspects incompetence and asks the GP for a medical certificate or because of family member's concerns). This indicates that there is a need for general practitioners to be trained in this assessment.

Training for capacity assessment is not usually included in most medical or nursing qualifications. As such, many medical professionals lack training to perform capacity assessments, and therefore patients are frequently referred to specialist services. Another reason for referral may be the limited time GPs can spend with a patient in a consultation. However, it is advantageous for the GP to perform capacity assessments as they are often the health professional who knows the patient, their medical conditions, and their cultural and religious views best. They also have an ongoing relationship with the patient which will allow for a more thorough assessment and the opportunity to re-evaluate capacity in the future.<sup>4,8</sup> Patients also have improved access to their GP and therefore capacity assessments can be performed promptly without waiting for a specialist appointment.

Referrals for specialist capacity assessments could be reserved for more complicated cases; for example where neglect or abuse is suspected. In this data the investigators identified four (5%) patients that were complicated and needed specialist input.

The majority of the patients on whom capacity assessments were performed had dementia (71.9%). Not all patients with dementia lack capacity. Patients may have partial capacity and may have varying degrees of capacity in different types of decision as each requires different skills.<sup>4</sup> Each type of decision should be assessed separately.

As dementia is a progressive condition, a patient's capacity is expected to deteriorate with time. Consequently, some patients may need to be assessed more than once. In our data four patients were assessed more than once. Alternatively, some patients with dementia develop an overlying delirium and could be expected to have improved capacity after the delirium has settled.<sup>5</sup>

Considering the often predictable progress of dementia the investigators expected a higher proportion of patients with dementia to have appointed an EPOA. However there was no significant difference in EPOA status between the patients with dementia and non-dementia diagnoses. This highlights a need for more effective public education on the importance of appointing an EPOA especially in early dementia.

Family members of cognitively impaired patients often (erroneously) believe that if they have EPOA for their relative they are legally entitled to act on their behalf. However until the patient is declared incompetent, they are not entitled to make decisions for the patient (unless the patient specified at the time of setting up the EPOA that it would take effect immediately). As such, it is important for medical staff to obtain copies of the relevant documents to ascertain what specifics they contain in order to safeguard a patient's autonomy.

Competent patients have the right to make autonomous decisions that as medical professionals we may regard as imprudent, and sometimes such decisions are a reflection of the patient's longstanding personality, beliefs or lifestyle. This right is described in the Health and Disability Consumers Rights Act.<sup>9</sup>

To some extent a patient's capacity is assessed at any interaction with a health professional as we have a duty to ensure that patients make valid decisions.<sup>4,8</sup>

There have been attempts to standardise capacity assessments to improve the inter-rater reliability. The Mini Mental Status Examination (MMSE) does correlate with judgments of incapacity at the high and low range of the spectrum, however capacity for those with scores between 19-26 is highly variable.<sup>1</sup> While this cannot determine capacity alone, it provides useful information in the assessment of capacity. Other cognitive tests may be useful such as the Executive Interview (EXIT) or the Revised Addenbrooks Cognitive Examination (ACE-R)<sup>3</sup> however language, education and culture can all affect the results of cognitive tests such as these.<sup>6</sup>

A semi structured interview may be the most clinically applicable method of determining capacity. This is where a clinician raises a functional problem with the patient, discussing in detail the possible options and consequences and asks the patient to make and explain their choice of solution.<sup>3</sup> Frequent reversals of choice and lack of insight or denial of the problem are often associated with lack of capacity.<sup>1</sup>

A variety of assessment tools (e.g. Aid to Capacity Evaluation, Decision-making Instrument for Guardianship, MacArthur Competence Assessment Tool) have been developed, however many deal with hypothetical scenarios and therefore may not be clinically applicable. Others assess the same skills as a semi-structured interview and still require the clinician to make a clinical judgment of capacity.<sup>1-3</sup>

Collateral information is important in capacity assessment to determine the accuracy of what the patient says, and to provide information that the patient may not volunteer. However, capacity cannot be decided on collateral information alone. In addition there are other factors such as conflicts of interest that may influence the information obtained.<sup>3</sup>

## **Guidelines for capacity assessment**

### **Step 1: Gathering information**

- Find out the reason for the capacity assessment as this will guide the questions asked. Examples include entering a financial contract, managing accommodation, paying bills, appointing an EPOA or writing a will.
- Establish the trigger – Discuss with the referrer and other relevant sources what events led to concerns about capacity and what the risks are as a result. Capacity assessments are invasive; is there any other way to resolve the issue?
- Obtain information about the patient's cognitive condition.
- Determine the likely timeline of the cognitive impairment
- Decide on the best time to perform the assessment. If the decision does not need to be made immediately and if the patient's cognition is likely to improve, the assessment could be delayed until the patient is more likely to be competent.
- Conduct the assessment in a private location free from interruption.

### **Step 2: Performing the assessment**

- A translator or other aide to communication such as written information may be required. Patients should be asked if they would like family/whānau/cultural support during the assessment.
- Try to engage the patient in the process, explain what is being done and why.<sup>5,6</sup>
- Perform a cognitive assessment using a recognised scoring system such as ACE-R or MMSE.

Consider other assessment questionnaires e.g. EXIT or Geriatric Depression Score.

### **Part A: Assessing the ability to understand the situation and its consequences**

- Discuss the relevant issue with the patient.

For example when assessing capacity for **personal welfare decisions**, ask detailed questions about the patient's living arrangements and care needs.

Assess nutrition and medication compliance. Assess potential risks to the patient and ask how they would get medical help. Are they at risk of abuse from others?<sup>5</sup>

When assessing **financial capacity** ask details about the patient's finances such as which bank they bank with, the value in their accounts, their assets or debts, how they pay their bills, and how much would they expect the bills to be for? If they don't know the answer to any of these questions ask them how they would find out.

How do they protect themselves from being taken advantage of financially?<sup>5</sup>

When assessing **testamentary capacity** check that the patient understands the nature and effect of making a will, the extent of their estate and the claims of those who might expect to benefit under the will. Ask about and review previous wills and question any changes.<sup>5,6,10</sup>

When assessing **capacity to appoint an EPOA** ensure the patient understands what an EPOA is, when it will take effect and who they are appointing and why.<sup>5</sup>

- Discussing the issue with the patient may reveal that the patient lacks the knowledge needed to make decisions, in which case they should be educated so that they fully understand the issues.<sup>6</sup> After educating the patient ask questions to check their understanding and registration of the issue.

### **Part B: Assessing the ability to understand relevant information**

Ask the patient to discuss what options are available and the benefits/risks of each option, and what may happen if no intervention were staged.

### **Part C: Assessing the ability to reason and express a choice**

- Ask the patient to discuss which option they prefer and how they reached that decision.

Parts B and C test the patients' ability to manipulate information.

### **Step 3: Acting on the results of the capacity assessment**

- Decide if the patient's decision-making is sufficient for this particular situation, taking into account the importance and complexity of the decision at hand. Patients are legally considered competent until proven otherwise. Note that the legal test of competence differs depending on which part of capacity is being examined. This is described in sections 10, 25(2)b, 12, and 94(1) of the PPPR act 1988.<sup>7</sup>
- If the patient is competent they may need advice or extra supports arranged. They should be encouraged to appoint an EPOA if they have not done so already.
- If the patient is incompetent and already has appointed an EPOA, the EPOA should take over decision making in this area.

If there is no EPOA, the patient's capacity to appoint one should be assessed. If capable of appointing an EPOA, one should be appointed and start acting in

this role immediately. If incompetent to appoint an EPOA, an application to the family courts may need to be made for a welfare guardian, property manager or personal order.

Alternatively, if the patient is not competent to give informed consent and there is no one entitled to consent on their behalf Right 7(4) of the Code of Health and Disability Consumer's Rights<sup>9</sup> may justify emergency treatment.

- Advice can be given to the substitute decision maker for example whether placement in residential care is required etc.
- If patients lack capacity health professionals involved with assessing their capacity have a duty of care to manage any capacity deficits. This may involve ensuring that any overlying delirium is managed, cognitive enhancers considered for dementia and vascular risk factors are optimally controlled. Health professionals should also ensure that patients have community supports such as home help where needed.

#### **Step 4: Documenting the assessment**

Capacity assessments should contain detailed descriptions of the assessment date, sources of information, medical and cognitive history, current living arrangements and care needs. The capacity assessment should include examples of questions asked and the answers obtained to justify why the assessment on capacity was reached.

Recommendations based on the result of the assessment should be given.

A form can be obtained from the family court website for documentation of the assessment. <http://www.justice.govt.nz/courts/family-court/forms/list-of-forms/forms-for-proceedings-under-protection-of-personal-and-property-rights-act-1988>

**Competing interests:** None identified.

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## Factors affecting vaginal birth after caesarean section at Middlemore Hospital, Auckland, New Zealand

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### Abstract

**Aims** To determine factors associated with vaginal birth after caesarean section (VBAC) in women delivering at Middlemore Hospital (MMH).

**Method** Retrospective descriptive study. All women in 2008–2009 who had a previous caesarean section and was deemed suitable for a trial of labour (TOL).

**Results** Of the 1543 women who had one or more previous caesarean sections, 806 (52.2%) were deemed suitable for a TOL by an obstetrician and self-selected to have a VBAC. Of the 806 women who had a TOL, 592 (73%) had a VBAC. Of women who had a previous VBAC, 257 (91%) delivered vaginally again compared to 332 (64%) without such a history (OR 3.69; 95%CI 1.83–7.43). Increasing parity increased the chances of another vaginal delivery. Variables that led to a failed VBAC were: a BMI  $\geq 25$  in women of single parity (OR 0.47, 95%CI 0.24–0.91), labour augmentation (OR 0.63, 95%CI 0.43–0.93) and epidural analgesia (OR 0.18, 95%CI 0.12–0.28).

**Conclusion** The VBAC rate at MMH in 2008–2009 was 73% and was higher in women who had a previous VBAC. The VBAC rate is lower in women with a high BMI of single parity and where progress of labour was slow. This information is important in counselling women with a previous caesarean section who are considering a VBAC.

The New Zealand Guidelines Group recommended that women without additional risk factors with a previous caesarean section should be offered a vaginal birth after caesarean section (VBAC).<sup>1</sup> However, a recent large cohort study has shown that an elective repeat caesarean section (RCS) significantly reduced the risk of fetal death or infant death compared to those women who had a VBAC.<sup>2</sup>

An earlier survey of Australian and New Zealand (NZ) obstetricians found that 96% agreed that an option of VBAC should be offered although only 40% agreed that it was the safest option for the woman.<sup>3</sup>

Our study from a large tertiary hospital in a low socioeconomic area is important because an uncertainty in management has persisted. There has been one other recent NZ study<sup>4</sup> which found a lower VBAC rate in Asians and those with a high Body Mass Index (BMI). However, they did not include other variables which include previous vaginal deliveries, augmentation epidural analgesia and maternal morbidity. An understanding of local factors that may affect women's chances of a successful VBAC will assist informed consent and counselling.

The aims of this study were to determine the VBAC rate and evaluate the importance of ethnicity, body mass index (BMI), parity, previous vaginal delivery and the

conduct of labour as factors that may determine the success of a VBAC. Serious maternal and perinatal outcomes were also determined.

## Methods

**Study design**—A retrospective study was conducted at MMH, a tertiary referral centre in South Auckland, New Zealand. Ethics approval was obtained from the Northern X Ethics Committee (NTX/10/EXP/003).

Included in the study were women who delivered a singleton baby in 2008 and 2009, with at least one previous lower segment caesarean section who chose to have a VBAC and were assessed eligible by an obstetrician for a TOL. TOL is defined as a planned labour after a previous caesarean section delivery in an informed woman.

A previous VBAC is defined as a woman who had a vaginal delivery after a caesarean section and a previous NVD were those who had a vaginal delivery prior to a caesarean section.

Exclusions were an elective caesarean delivery due to the woman's personal choice, non-vertex presentation, gestation of less than 24 completed weeks, classical caesarean section, severe pre-eclampsia, placenta praevia, maternal medical condition necessitating urgent delivery and multiple gestation.

Severe pre-eclampsia is the presence of one of the following symptoms or signs: systolic BP  $\geq 160$  mmHg or diastolic BP of  $\geq 110$  mmHg; proteinuria  $> 5g$  in a 24-hour collection; pulmonary oedema or cyanosis; oliguria ( $< 400$  ml in 24 h); persistent headaches; epigastric pain and/or impaired liver function; thrombocytopenia; oligohydramnios; decreased fetal growth; or placental abruption.

**Data sources**—Data was collected from the Delivery Suite Birth Register, electronic hospital databases (Healthware, Concerto and Patient Information System) and selected case notes by a single data collector (AMvdM).

Data on women with previous caesarean sections were extracted from Healthware and cross-checked with the data from the Birth Register. Data on age, weight, height, ethnicity, obstetric and medical history, intrapartum events and neonatal outcomes were obtained from the relevant databases and medical records where the data was absent in Healthware.

Indications for previous caesarean delivery, previous uterine incision (if available), history of previous vaginal delivery (defined as a delivery preceding a previous caesarean section)<sup>5,6</sup> or previous VBAC (defined as any vaginal delivery after a caesarean section) and where there was a presence of maternal disease (hypertension, diabetes, asthma, epilepsy, renal disease, thyroid disease or collagen vascular conditions) was recorded from the Healthware and Concerto databases.

Obstetric factors related to the present pregnancy such as spontaneous labour, induction, augmentation, epidural use and VBAC success, were also recorded in a Microsoft Excel 2007 spreadsheet.

Neonatal factors including the birth weight, gestational age, gender, 5-minute Apgar score were also documented. Neonatal and maternal complications were also collected from Healthware and Concerto.

There were 16,051 deliveries in Counties Manukau DHB in 2008 and 2009 and all women with a previous caesarean section were referred to MMH for delivery. Of the 16,051 women, 1543 (9.6%) had one or more previous caesarean section deliveries.

Women were excluded due to an elective caesarean delivery (679), of which was usually due to the woman's preference after discussion with a specialist, non-vertex presentation (33), unclear plan (6), medical conditions (6), placenta praevia (5), multiple pregnancy (4), and classical incision (4). After exclusions, 806 (52.2%) women were eligible for analysis.

**Statistical analysis**—Analysis was performed using SAS v9.1 (SAS Institute, Cary, NC) and odds ratios (OR) was estimated using logistic regression. Statistical analysis was conducted using Chi-squared for categorical variables and Student's t-test for normally distributed continuous variables.

Factors potentially affecting VBAC success were initially analysed in univariable analysis. Following this, multivariable logistic regression was performed to evaluate the likelihood of successful VBAC during a subsequent trial of labor controlling for gender, ethnicity, previous vaginal delivery, previous VBAC, maternal BMI, induction of labour and epidural use.

Parity was not included in the multivariable model because of its close relationship to previous vaginal delivery and previous VBAC. Augmentation was excluded from the multivariable model due to its

close association with IOL, which was found to be the stronger of the two variables in relation to VBAC.

Confidence intervals and p values of  $\leq 0.05$  were considered statistically significant.

## Results

Of the 806 women who planned a vaginal delivery, 592 (73.4%) had a vaginal delivery and the remaining 214 (26.6%) had a RCS delivery, albeit an emergency one. The factors associated with a successful or failed VBAC at the univariable level were parity, previous vaginal delivery, previous VBAC, induction of labour, augmentation and epidural (Table 1).

**Table 1. Variables associated with a VBAC or a RCS delivery**

Variables	VBAC (n=592)	RCS (n=214)	OR (95%CI)	P value
<b>Age</b> (mean) 17–44 years 30.2±5.3	30.1±5.7	30.4±5.2		p=0.71, p=0.48
<b>Sex</b> (n/%)				p=0.95
Male (409/50.7)	292 (50.7)	109 (50.9)	0.99 (0.72–1.35)	
Female (397/49.3)	300 (49.3)	105 (49.1)	1.00	
<b>Ethnicity</b> (n/%) missing 11				p=0.30
European (164/20.3)	120 (20.6)	44 (20.8)	1.00	
Maori (162/20.1)	128 (22.0)	34 (16.0)	1.38 (0.83–2.30)	
Pacific (355/44)*	254 (43.6)	101 (47.6)	0.92 (0.61–1.40)	
Other (114/14.1)**	81 (13.9)	33 (15.6)	0.90 (0.53–1.53)	
<b>Parity</b> (n/%) missing=0				p<0.0001
1 (392/48.6)	241 (40.71)	151 (70.6)	1.00	
2 (172/21.3)	142 (24)	30 (14)	2.97 (1.90–4.62)	
3+ (242/30)	209 (35.30)	33 (15.4)	3.97 (2.61–6.04)	
<b>Gestation</b> (n/%) missing=0				p=0.08
≤37	63 (10.6)	20 (9.3)	0.80 (0.44–1.44)	
38	54 (9.1)	24 (11.2)	0.57 (0.32–1.01)	
39	98 (16.6)	39 (18.2)	0.64 (0.39–1.03)	
40	198 (33.4)	50 (23.4)	1.00	
41	121 (20.4)	51 (23.8)	0.60 (0.38–0.94)	
≥42	58 (9.8)	30 (14)	0.49 (0.29–0.84)	
<b>Previous NVD</b> (n/%)				p<0.0001
No (417/51.7)	257 (43.4)	160 (74.8)	1.00	
Yes (389/48.3)	335 (56.6)	54 (25.2)	3.86 (2.73–5.47)	
<b>Previous VBAC</b> (n/%) missing=3				p<0.0001
No (521/64.7)	332 (56.4)	189 (88.3)	1.00	
Yes (282/35)	257 (43.6)	25 (11.7)	5.85 (3.74–9.16)	
<b>Induction of labour</b> (n/%) missing=1				p=0.002
Spontaneous (654/81.1)	496 (83.8)	158 (74.2)	1.00	
IOL (151/18.7)	96 (16.2)	55 (25.8)	0.56 (0.38, 0.81)	
<b>Maternal BMI</b> (n/%) missing=116				p=0.15
<25 (167/24.2)	131 (26.1)	36 (19.2)	1.00	
25–29.99 (161/23.3)	112 (22.3)	49 (26.1)	0.69 (0.45–1.07)	
30+ (362/52.5)	259 (51.6)	103 (54.7)	0.63 (0.38–1.03)	
<b>Augmentation</b> (n/%) missing=7				p=0.019
No (652/80.9)	492 (83.1)	160 (74.8)	1.00	
Yes (147/18.2)	97 (16.4)	50 (23.4)	0.63 (0.43–0.93)	
<b>Epidural</b> (n/%)				p<0.0001
No (510/63.3)	451 (76.2)	59 (27.6)	1.00	
Yes (296/36.)	141 (23.8)	155 (72.4)	0.12 (0.08–0.17)	

\* Tongan, Samoan, Fijian, Cook Island Maori, Tokelauan, Niuean, and Other Pacific Islander.

\*\* Other Asian, Indian, Vietnamese, Sri Lankan, Chinese and Other.

Of the 389 (48.2%) women who had a previous vaginal delivery, 335 (86%) had a vaginal delivery again. Of the 417 (51.7%) women who did not have a previous vaginal delivery, 257 (61.6%) had a vaginal delivery. Of the 282 (35.0%) women who had a previous VBAC, 257 (91.1%) delivered vaginally again whilst 332 (63.7%) of the women who had not had a VBAC before had a vaginal delivery. Thus the increased Odds Ratio associated with having another successful VBAC was 5.85 (95%CI 3.74–9.16).

In multivariable analysis several factors remained significantly associated with the successful completion of a VBAC (Table 2). A previous VBAC was still associated with an increased VBAC success after adjustment for confounding factors (OR 3.69; 95%CI 1.83–7.43). Whilst a similar effect was seen in univariable analyses for a previous vaginal delivery, this did not remain significantly associated with a successful VBAC in multivariable analysis.

After adjusting for confounding factors the Odds Ratios in the overweight BMI category was 0.44 (95%CI 0.25–0.79) and obese BMI category was 0.43 (95%CI 0.24–0.78). In 116(14%) eligible women data on height, weight, and BMI was not available.

In women of single parity (P1) however, VBAC success was reduced after multivariate analysis in overweight (OR 0.47; 95%CI 0.24–0.91) and obese women (OR 0.43; 95%CI 0.22–0.86).

Spontaneous labour was not associated with greater VBAC success (OR 0.81; 95%CI 0.50–1.31) and this was also found in P1 (OR 1.09; 95%CI 0.58–2.02). Labour augmentation statistically reduced VBAC success in the univariable analysis (OR 0.63; 95%CI 0.43–0.93).

Epidural anaesthesia was associated with a reduced VBAC success (OR 0.18; 95%CI 0.12–0.28) and this was also found in P1 (OR 0.20; 95%CI 0.12–0.34).

No effect was seen in relation to ethnicity in univariable analysis or after controlling for other factors associated with VBAC.

Those with an unsuccessful VBAC were more likely to deliver a baby with a birth weight  $\leq 3000\text{g}$  (OR 0.65; 95%CI 0.44–0.97) or  $\geq 4001\text{g}$  (OR 0.47; 95%CI 0.32–0.69).

Of the 592 women who had a VBAC, 29 (4.9%) had a postpartum haemorrhage (PPH) of  $>1000\text{ml}$ , 18 (3.0%) had a 3<sup>rd</sup> or 4<sup>th</sup> degree vaginal tear, 12 (2.0%) had a manual removal of placenta (MROP) and 2(0.3%) women had a peripartum hysterectomy due to PPH.

Of the 214 women who had an emergency caesarean section delivery, 19 (8.9%) had an estimated blood loss of  $>1000\text{ml}$  and none had a hysterectomy. Infection morbidity was similar in the two groups (0.3% of VBAC and 1% of RCS). None of these outcomes was statistically significant. There was no uterine rupture in this study, which was not adequately powered to investigate this outcome.

Most of the repeat caesarean sections (105, 48%) were performed for failure to progress either in the first or second stage of labour, followed by fetal distress (56, 26%) (Table 3).

**Table 2. Multivariate logistic regression of variables for all women and women of single parity**

Multivariable regression	All subjects OR (95% CI)	Para 1 OR (95% CI)
<b>Ethnicity</b> (missing=11)	P=0.23	p=0.21
European	1.00	1.00
Maori	1.21 (0.64–2.26)	1.36 (0.63–2.95)
Pacific	0.72 (0.40–1.28)	0.68 (0.34–1.36)
Other	1.10 (0.58–2.08)	1.19 (0.59–2.41)
<b>Previous vaginal delivery</b>	p=0.35	
No	1.00	
Yes	1.33 (0.74–2.41)	
<b>Previous VBAC</b> (missing=3)	p=0.0003	
No	1.00	
Yes	3.69 (1.83–7.43)	
<b>Maternal BMI</b> (missing=116)	p=0.091	p=0.028
<25	1.00	1.00
25–29.99	0.44 (0.25–0.79)	0.47 (0.24–0.91)
30+	0.43 (0.24–0.78)	0.43 (0.22–0.86)
<b>Induction of labour</b> (missing=1)	p=0.39	p=0.79
Spontaneous	1.00	1.00
Induction	0.81 (0.50–1.31)	1.09 (0.58–2.02)
<b>Epidural</b>	p<0.0001	p<0.0001
No	1.00	1.00
Yes	0.18 (0.12–0.28)	0.20 (0.12–0.34)

**Table 3. Indications for repeat caesarean section**

Indications for repeat caesarean section	N (%)
Failure to progress, 1 <sup>st</sup> stage	85 (39.2)
Fetal distress	56 (25.8)
Failure to progress, 2 <sup>nd</sup> stage	20 (9.2)
Failed induction of labour	9 (4.2)
Antepartum haemorrhage	5 (2.3)
Failed instrumental delivery	5 (2.3)
Other	7 (3.2)
Not specified in case notes	27 (12.4)
<b>Total</b>	<b>217 (100)</b>

## Discussion

The number of caesarean section births in NZ has been increasing in the last two decades and in 2009, 15.3% of all first deliveries in NZ were by caesarean section.<sup>6</sup> MMH has, for many years, had a lower caesarean section rate compared to other referral hospitals in NZ<sup>8</sup> and this may be because about 57% of all deliveries annually were to women of Maori and Pacific ethnicities who had higher parities than other groups.<sup>9</sup> It may also be due to a different clinical practice at MMH.<sup>10</sup>

But whereas the cyclical debate on the reasons for the increase in caesarean section deliveries has continued, what has come to the fore is the discussion on the subsequent management of these women given the recent publication of the Australian trial by Crowther et al showing a significantly higher maternal and neonatal morbidity in women having a VBAC compared to those who have elective RCS.<sup>2</sup> They found that 53% of the 2323 women with a previous caesarean section elected to have a TOL and only 57% of them achieved a VBAC. In our study, 806 (52.2%) of women agreed to a TOL and 592 (73.5%) achieved a VBAC. The Auckland Hospital study<sup>1</sup> cohort were women without normal deliveries therefore a TOL and VBAC rate cannot be compared with ours.

The MMH VBAC rate of 73% lies within the 60–80% VBAC rate of studies as reported in the NZ guidelines although reported VBAC rates reported in the literature have ranged between 25 to 93%.<sup>5,12,13</sup> We found the VBAC rates for women having a first delivery after a caesarean section and for those who had a previous VBAC were 64% and 91% respectively. These findings were similar to those of an American study by Elkousy et al<sup>6</sup> which found a VBAC rate for women of single and multi-parity were 65% and 83–94% respectively.

There was no difference in VBAC success rates between Pacific, Maori and European groups, which is similar to the findings of the Auckland Hospital Study.<sup>1</sup> American studies had shown women of Caucasian ethnicity had a better chance of a VBAC compared to other ethnic groups.<sup>5,12,14,15</sup>

Increasing parity, previous vaginal delivery and a previous VBAC have been shown to be strong predictors for a successful VBAC<sup>7,12–14,16,17</sup> and this was also evident from our findings. The increasing VBAC rate with the increase in parity is most likely an association with an increasing number of previous vaginal deliveries, whether they were before or after the original caesarean section.

Whereas a previous vaginal delivery and a previous VBAC significantly increased the chances of a VBAC, the difference remains significant only for the latter group on multivariable analysis. Landon et al<sup>12</sup> found in their large study, a significantly higher VBAC rate of 87% in women with a previous vaginal birth compared with 61% in women without such a history. Although they did not find a VBAC rate difference between those who delivered vaginally before or after a caesarean section, a smaller study<sup>17</sup> confirmed the difference found in our study.

The likelihood of a VBAC is less likely in women with increased BMI and was significant in women of single parity who had not had a vaginal delivery. This confirms similar findings in other studies<sup>5,12,19,20</sup> and the Auckland Hospital study.<sup>1</sup>

Data for the calculation of BMI came from the booking weight and height and 14% of that data was missing. Although this may not be the most reliable data, a significant effect in the multivariable analysis suggests that this effect is real.

In the conduct of labour, we found that induction of labour was not statistically significant but augmentation of labour and an epidural analgesia were found to be significant factors in reducing the chances of a VBAC compared to those who did not have labour augmentation or an epidural analgesia. These findings have also been found in other studies.<sup>2,16,12,22</sup> The reason for this could be that once the labour is



dysfunctional requiring augmentation and an epidural, then the chances of a VBAC diminishes.

Our results demonstrated a reduction in VBAC success in babies that ended up weighing less than 3001g or more than 4001g ( $p=0.0005$ ). In a study by Peaceman et al,<sup>23</sup> only 38% had a VBAC if the birth weight exceeded the preceding pregnancy birth weight by more than 500 grams.

Elkousy et al<sup>5</sup> demonstrated a systematic decline in VBAC success with increasing birth weight (68% <4000g; 52% 4000–4249g; 45% 4250–4500g and 38% >4500g). An explanation as to why babies of less than 3000g were more likely to be delivered by caesarean section could be because of prematurity, intrauterine growth restriction and the increase likelihood of fetal distress and malpresentation that accompany these scenarios.

The indications for RCS had similar percentages to the background rate of caesarean sections for failure to progress and fetal distress at MMH.<sup>6</sup> There was no uterine rupture in our study, which was not adequately powered to investigate the incidence which has been estimated to be 0.2–1.5%.<sup>1</sup> The considerable maternal morbidity is a concern in those who had a VBAC and these included PPH (5%), 3<sup>rd</sup>/4<sup>th</sup> degree vaginal tears (3%), MROP (2%) and the two women who had hysterectomies.

The Crowther et al study<sup>2</sup> confirmed the high rate of PPH in the VBAC group but it seems that there was a higher total morbidity rate (11%) in our study. Thirty women (5%) needed procedures in the operating theatre to have either a vaginal repair or MROP. The Crowther et al study<sup>2</sup> did not mention MROP and had only two cases of “perineal haematomas”.

Neonatal morbidity defined as Apgar scores  $\leq 7$  was higher in the caesarean group and may be explained by the fact that these were not elective caesarean section procedures. The Crowther et al study<sup>2</sup> found significant neonatal morbidity but there was no difference in Apgar scores at 5 minutes between the planned VBAC and elective caesarean section groups.

The main limitation of our study is its retrospective nature, which meant that some of the variables could not be collected due to the incompleteness of the database and case notes. For example, 14% of the BMI data was not available. The strength of our study was in the large number of women.

Our study’s findings, would contribute to the continuing discussion on the management of women with previous caesarean sections in the NZ context. We have identified factors that affect the VBAC rate in our setting and a prospective study may identify or clarify more.

The significant maternal morbidity in the VBAC group is a concern and we will need to address these if a TOL and VBAC are to be made safer and continue to be offered as a viable option to women.

**Competing interests:** None identified.

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## Futility of medical treatment in current medical practice

John Botha, Ravindranath Tiruvoipati, David Goldberg

### Abstract

Intensive care provides support for acute reversible organ failure and most patients who receive intensive care recover from their illness. In some patients organ failure may become irreversible and in these patients further treatment or organ support may be considered futile. Emerging technologies and expertise can enable the medical profession to prolong life / death indefinitely without curing or controlling the underlying disease process. Introduction of ultramodern organ supports such as extracorporeal life-support systems, ventricular assist devices and organ transplantation surgeries have introduced some degree of ambiguity in defining futility of care. Furthermore medico legal implications of futility of care introduce further complexities in defining and instituting futile treatments.

In this review we discuss the evolution of the concept of futility of care, review the various meanings of the term “futility of care”, explore the complexities of management when care is considered futile, offer suggestions as to how such patients and their families could be managed. We also review the legal framework when consensus is not achieved.

*To cure sometimes, to relieve often and to comfort always – this is our work*

Intensive care may provide support for acute reversible organ failure and most patients who receive intensive care recover from their illness. In some patients however, organ failure may become irreversible and in these patients further treatment or organ support may be considered futile.

In developed countries with well-funded health care systems, new technologies and expertise can enable the medical profession to prolong life / death indefinitely without curing or controlling the underlying disease process.

In sustaining life when the probability of leaving the intensive care unit or hospital is unlikely, many would reason that this constitutes futility of care. Furthermore, the introduction of ultramodern organ supports such as extracorporeal life-support systems, ventricular assist devices and organ transplantation surgeries have introduced some degree of ambiguity in defining futility of care

The implications for a patient when prolonged “futile” care is administered may be profound particularly if they are exposed to prolonged mechanical ventilation, renal replacement therapy and other invasive therapies. Such treatments may cause anxiety, be uncomfortable and sometimes induce pain.

Where more invasive procedures or surgery is performed the patient’s discomfort may be even greater, often requiring medications that may have substantial side effects.

Despite prolonging life, the consequences of prolonged intensive care therapy and sedative drug administration may render patients unable to communicate with their family and friends. During such times many of the simple pleasures of life are removed and the implications of physical and emotional isolation may be profound.

Furthermore the emotional and physical implications on relatives of patients who are unlikely to recover can be intense. Such an approach may increase the costs of health care systems and may potentially deny lifesaving treatments from those who are likely to recover from their illness.

In this article, we:

- Discuss the evolution of the concept of futility of care,
- Review the various meanings of the term “futility of care”,
- Explore the complexities of management when care is considered futile,
- Discuss the patient-centred approach, the role of ethics committees and institutional policies when discussing futile treatments with patients and their families, and finally
- Consider the legal framework in Australia and New Zealand when consensus is not achieved.

## **Futility of care**

### **Evolution of futility of care**

Historically the earliest suggestion that physicians should withhold medical interventions from terminally ill patients probably dates back to Hippocrates injunction to “refuse to treat those [patients] who are overmastered by their disease realizing that in such cases medicine is powerless”.<sup>1</sup>

In 1835 Bigelow suggested to members of the Massachusetts Medical Society to withhold “therapies” such as cathartics and emetics from hopelessly ill patients.<sup>2</sup>

In North America in the late 1980s and early 1990s the view was held by some that physicians could ethically terminate futile treatments.<sup>3</sup> Despite the perceived advantages of such an approach there were inconsistencies in the use of the term ‘futile’.<sup>4-6</sup> Initiatives to achieve uniformity on the term futility of care remain problematic as the term will remain subject to ethical, religious, clinical and legal considerations.

Medical futility must be contrasted to passive or active euthanasia, advanced care planning (although the importance of advanced care planning to medical futility is undeniable) and situations in which life prolonging treatment may be considered medically appropriate but is not supported by the patient (or by a substitute decision-maker).

### **Futility of care**

The medical literature currently refers to futile care as care that is physiologically, qualitatively or quantitatively futile.

**Physiological futility**—Physiological futility is less complex to define and implies a therapy that will deliver no physiologic effect. An example of this may be to rush a patient to the emergency department after two hours of resuscitation in the field has failed to return spontaneous circulation. An emergency physician could confidently convey to the family that further chest compressions would be medically futile.

Another example may be an elderly patient in cardiogenic shock from end stage dilated cardiomyopathy who has not responded to maximum inotropic support.

**Qualitative futility**—Qualitative futility describes a situation in which the intervention may produce a result that may be “Lacking in purpose”.<sup>3,7</sup> An example of this may be to prescribe statins to a 90-year-old bedridden patient with ischaemic cardiomyopathy.

**Quantitative futility**—Quantitative futility refers to an intervention that has a very small chance of benefiting the patient; the most commonly used number is less than 1% chance of success”.<sup>3,7</sup> This would be the case of considering urgent coronary artery bypass surgery in a patient who had just completed 50 minutes of cardiopulmonary resuscitation before any return of spontaneous circulation.

Societal expectations may focus on active treatment in the ICU even when clinicians anticipate that recovery is not possible.<sup>8</sup> As convenient as it may be for some hospitals to enact a unilateral physician driven not for resuscitate policy, even when consensus is not reached with families, some would argue that this process is flawed. Those that argue that futility should only be physiologically defined hold the view that health care professionals should avoid imposing their values on families and patients and that patient autonomy should be seen as inviolable.<sup>9</sup>

When considering the concept of physiological futility and applying this definition when making end-of-life decisions we should be aware of the limitations of such an approach. If physicians were confined to adhere to dying patients autonomous wishes in the critical care unit they would function as technicians “body mechanics” completing tasks of organ support under the instruction of patients and their families.

In contrast to a physiological definition of futility, a patient centred approach argues that the provider should deliver therapy that the patient can appreciate. With such an approach, where therapy aims at benefiting patients there is an emphasis on beneficence while still maintaining patient autonomy.

### **The complexities of considering futility**

Only after futility of care is considered does the complexity of this proposal become apparent. There are numerous barriers to engaging in futility of care discussions and these are complex and diverse. There may be regulations that make futility of care discussions problematic and these may be institutional, local, regional or at state or national level.

Existing regulations at many levels may lead to a pervasive fear of prosecution by physicians for prescribing medications aimed at the relief of pain and symptoms. In some institutions reimbursement and financial considerations may influence a physician’s decision to engage in futility of care discussions.

Some physicians are influenced by the financial conditions attached to their activities and cognitive and counselling activities remain the least remunerative. Individual attitudes toward end-of-life care may represent a substantial barrier to initiating futility of care discussions.

For the concept of futility to be accepted by all concerned requires unequivocal confidence by the treating physician of a patient’s prognosis and likely outcome,



agreement between physicians on the prognosis and outstanding communication between the care givers, the patient and their family. Under such circumstances it may be possible to reconcile the medical, ethical and religious views of patients, families and their surrogate decision-makers. There are numerous factors that compound the acceptance of medical futility by all parties concerned.

The medical staff may have a fear of failure should futility be considered. In interviews with nurses and physicians, 47% of all respondents reported acting contrary to conscience in providing care to the terminally ill, with many providing excessive rather than under treatment.<sup>10</sup> The religious view of death may have been replaced with attitudes that find little solace or meaning in death.<sup>11</sup>

Indecision or avoiding hard decisions regarding futility may further confound the process. Some physicians may perceive that their role extends into the domain of health economics and that their responsibility should include the financial realities of delivering healthcare.

There may also be situations in which the delivery of futile care may be considered harmful to other patients.<sup>12</sup> It could be argued that the use of antibiotics for those receiving futile care can be considered unethical by egalitarian theory because it can lead to antibiotic resistance that may make the treatment of other patients impossible. It has also been established that nurses have powerful emotional responses that may cause distress when witnessing medically futile care.<sup>13</sup>

The patient and family emotions that may be elicited during discussions of futility of care are often powerful, inconsistent and unpredictable. The determinants of such emotions may be fear, anxiety, denial, anger and guilt. There is also no consensus among patient surrogates about whether physicians should routinely provide a recommendation regarding life-support decisions for incapacitated patients.<sup>14</sup>

Doubt about a physician's ability to predict medical futility is common among surrogate decision-makers.<sup>15</sup> The nature of the doubt may have implications for responding to conflicts about futility in clinical practice. A survey from Japan revealed that there is no support for the physician's unilateral decision-making on futile care.<sup>16</sup> In this survey the majority of respondents (67.6%) believed that a physician's refusal to provide or continue a treatment on the ground of futility judgement could never be morally justified.

Whilst some commentators deny the concept of medical futility and the resultant consequences to the nature of future care to be provided, Pellegrino states: "Those who call for the abandonment of the concept [of futility] have no substitute to offer."<sup>17</sup> They persist in making decisions with, more or less, covert definitions.

The common sense notion that a time does come for all of us when death or disability exceeds our medical powers cannot be denied. This means that some operative way of making a decision when 'enough is enough' is necessary. It is a mark of our mortality that we shall die. For each of us some determination of futility by any other name will become a reality".

Pellegrino's above dissertation adds to a persuasive body of medical ethics that underpins the notion that a medical practitioner must cease treating a person at a point in time where such treatment serves no benefit to the patient.



It is evident that to fully understand and resolve these complexities the important communication skill required by the medical staff is listening, and that focussing on this skill may help in unravelling the issues involved in discussions on futile care.

For some families a percentage chance of success may add meaning to their understanding of medical futility. This percentage is difficult to establish but most definitions of quantitative futility offer a less than 1% chance of success as a suggestion.

## **Discussing futility of care with patients and or their families**

**The importance of a patient-centred approach**—In 1988, the Picker/Commonwealth Program for Patient-Centred Care (now the Picker Institute) coined the term “patient-centred care” to call attention to the need for clinicians, staff, and health care systems to shift their focus away from diseases and back to the patient and family. The term was meant to stress the importance of better understanding the experience of illness and of addressing patients' needs within an increasingly complex and fragmented health care delivery system.

The Institute of Medicine (IOM) defined patient-centred care as “care that is respectful of and responsive to individual patient preferences, needs, and values” and that ensures “that patient values guide all clinical decisions.” The importance of this definition highlights the importance of a symbiosis between physicians and patients when making decisions about administering or withholding or withdrawing medical care.<sup>18</sup>

In an influential article on clinical practice guidelines, David Eddy argued that an intervention should be considered a “standard” only if there is “virtual unanimity among patients about the overall desirability. Of the outcomes.”<sup>19</sup>

With many decisions in intensive care regarding futility it remains unlikely that there is a “standard” therefore making a patient centred approach an imperative. Shared decision-making occurs when the patient and the treating medical team share information. The treating team outline management plans with the associated risks and benefits and patients or their surrogate decision-makers express preferences and values.<sup>18</sup>

Through shared decision-making, clinicians can help patients understand the importance of their values and preferences in making the decisions that are best for them. This interest is shared by patients worldwide, as demonstrated by the recent release of the Salzburg statement endorsing shared decision-making, authored by representatives from 18 countries.<sup>20</sup>

Clinicians need to relinquish their role as the single, paternalistic authority and train to become more effective coaches or partners — learning, in other words, how to ask, “What matters to you?” as well as “What is the matter?”<sup>18</sup>

It is only when the treating team has informed those entrusted to their care what the strengths and limitations of their therapies are can genuine negotiation begin between patients, their surrogate decision-makers and the medical team.

Regional culture shall always play an important part in the end-of-life decision-making<sup>21</sup> and as the world has become a global village, attempts to standardise policy

have become more difficult. Furthermore, an increasingly educated public has made a unilateral declaration of futility by the physician untenable. Medicine has changed from being a scientific art to a contractual market place enterprise, with consequential erosion of trust between patient and physician.

Considering the numerous treatments now available for the critically ill, it has become very difficult for a patient or a patient's surrogate decision-maker to fully anticipate or understand the intricacies, burdens and benefits of all available options.<sup>22</sup>

The implications of the above are that the treating physician should openly and honestly explain the treatment options and likely outcomes when futility becomes evident and communicate consistently and frequently with the patient and their surrogate decision-makers.

Billings and Krakauer<sup>23</sup> have presented an approach that suggests a physician should first determine the patient's desire for information, and then assess the patient's values, goals and beliefs to determine the outcomes that would be acceptable to the patient. With this knowledge, the physician should propose a plan of treatment that is likely to achieve the patients goals, expressed in a manner that is easily comprehensible to the patient.

The complexity of the situation mandates that a senior and experienced clinician initiates discussions related to futile care. Too often we hear of the junior resident stating "your loved one is dying, would you like everything done to try and save her?" Such an immature statement may create ambiguity in relatives and can cause significant distress to the already stressed relatives. Furthermore "everything" is something that is elusive to define or explain to relatives who are distressed.

It is sometimes necessary and appropriate to have different physicians evaluate a patient's management and prognosis and communicate their views to all parties concerned. It is likely that different personalities and styles of communication may be required to communicate a view that advocates palliation on the grounds of medical futility. Should it be the wish of the family to have an external opinion from a different institution, this should be provided. Involvement of social workers and others such as the chaplain may prove vital in fostering communication and in facilitating the change from active to palliative/comfort treatment.

In some situations a limited period of administering futile care is required. Such an approach may have substantial benefits and may enable friends and family to travel long distances to pay their respects to the dying patient. For others ongoing care may provide them with time to grieve and reflect, restoring their sense of autonomy as they are no longer forced into acceptance of palliation through time constraints determined by the intensive care staff.

Decision aids, which can be delivered online, on paper, or on video, can efficiently help patients and their families absorb relevant clinical evidence and aid them in developing and communicating informed preferences.<sup>24</sup> The time afforded to patients and their families to process and interpret their own emotions and intellectualise endless information and data may be crucial in achieving agreement regarding ongoing management. It is this time of reflection and exploration that may enable families to walk out of the hospital with a feeling of wholeness.

There may be differences between acute and slowly evolving scenarios of potential medical futility. Examples of these differences may be prolonged resuscitation after cardiac arrest in a previously healthy 42 year old as compared to arrest in an 84 year old with metastatic cancer. The latter example illustrates a case of futility where the probability of the patient returning home is remote and next of kin have had time to interpret the slow transformation to death.

To the contrary in case of the younger patient, time for education, discussion and reflection would be expected and necessary. As the nature of the pathology in chronic situations of potential futility is often advanced malignancy or cardio vascular disease the likelihood of cure and restoration of health remains improbable. In such situations management of patients may be under the auspices of oncologists or palliative care physicians, where there has been the time and opportunity for ongoing patient centred care. These circumstances contrast sharply with the acute unexpected deterioration of younger well-functioning patients.

**The role of palliative care**—Palliative care is often the end-of-life pathway for elderly patients with undeniable incurable disease. The role of palliative care becomes less clear when clinical deterioration is acute, unexpected and the outcome less predictable. It is the exception to have routine palliative care consultation in intensive care units and referral by intensive physicians to their palliative care colleagues is infrequent. Furthermore the end-of-life approach of intensive care physicians and palliative care physicians may differ. In a European qualitative study intensivists favoured an indirect and stepwise disclosure of the prognosis whilst palliative care clinicians focused on a candid and empathetic information strategy.<sup>25</sup>

A recent study reviewed administrative claims and clinical data for critically ill older adults. Multivariable regressions examined the associations between palliative care types and hospital outcomes by advance directive status.

The authors found significantly lower hospital costs and in-hospital deaths with higher hospice discharges in integrative palliative care compared to consultative palliative care. However, these findings were diminished with the presence of advance directives.<sup>26</sup> These data support the notion that advanced directives may impact on patient outcomes and that integrative palliative care may have cost and clinical implications.<sup>26</sup>

Palliative care should play an integral role in the management of terminal conditions, particularly when futility-of-care discussions are considered. The recent policy document of The Australian National Health and Medical Research Council underpins the importance of integrating palliative care principles into the management of advanced chronic or terminal conditions.<sup>27</sup>

**Ethical considerations and the role of ethics committees**—The ethical considerations in cases where futility is contemplated remain complex and deserve further discussion. To quote from Dunstan “You should not judge- the success of intensive care is not to be measured only by the statistics of survival, as though each death were a medical failure.”<sup>28</sup>

It is to be measured by the quality of lives preserved or restored, the quality of the dying in those whose interest it is to die and by the quality of the relationships

involved in each death.” He argues that if death is inevitable, the dying process dignified and the family accepting, death has been good.

Adherence to the above mantra can only be achieved when sensitive communication has been maintained between all the relevant members of the medical team, the patient and / or their family. Such a process enables professional reflection on decisions and recommendations made, empowers the family to contribute to the decision-making process and provides time for the acceptance of end-of-life decisions.

The intensive care unit (ICU) is where patients are given some of the most technologically advanced life-sustaining treatments, and where difficult decisions are made about the usefulness of such treatments. End-of-life care is associated with increased burnout and distress among clinicians working in the ICU.<sup>29</sup>

To make end-of-life and futility of care decisions requires adequate training, good communication between the clinician and family, and the collaboration of a well-functioning interdisciplinary team. Facilitative ethics consultations can be helpful in resolving conflicts when physicians and families disagree in end-of-life decisions.

Ethics committees are allowed to make such decisions in one state of The United States of America when disagreements cannot be resolved otherwise. This so-called due process approach was incorporated in 1999 into an amendment to the Texas Advance Directives Act. It allows a physician to ask a hospital ethics committee to review a patient or family request for treatment the physicians consider futile or inappropriate. If the committee agrees that the request is inappropriate and no other physician or hospital will accept the patient in transfer within a 10-day time period, the treatment may be withheld or withdrawn.<sup>30</sup>

When families and physicians disagree over continuing treatment, physicians sometimes choose to withdraw life support unilaterally, although they run the risk of being sued for malpractice and accruing defence costs whether or not the suit is successful.

In the United States when clinicians and health care facilities have asked courts to sanction such withdrawal before it is performed, the courts have traditionally sided with families. This contrasts with cases in Canada and Australia wherein the courts allowed physicians to make end-of-life decisions over family objections.<sup>31</sup>

A recent multicentre study demonstrated that ethics consultations were associated with reductions in hospital and ICU lengths of stay and life-sustaining treatments in patients who ultimately did not survive to discharge.<sup>32</sup> These data suggest that Ethics Committees may have the ability to play a significant role in medical futility discussions when patient management consensus is elusive.

**Institutional policies**—In Australia the Respecting Patient Choices Project is funded under the National Palliative Care Programme and is supported by the Australian Government Department of Health and Ageing. This project aims to encourage advance care planning in individuals irrespective of their current state of health and has been recently implemented in a number of Australian Hospitals. The choices offered to patients regarding end-of-life decisions under this program facilitates limitation of therapy and resuscitation guidelines.

It remains unclear what the implications of such a policy will be on futility of care discussions and institutional bias will continue to limit widespread acceptance of such initiatives

### **Legal framework in futility of care: some Australian and New Zealand perspectives**

As a final resort, when all attempts to gain consensus on a decision have been exhausted alternative strategies may be considered. This could include referral to a tribunal or deferral for legal advice. This process may differ from state to state, country to country and may not always assist the process of trust and communication required by all parties concerned.

Despite this, the importance of the law in end-of-life decisions is profound, because ultimately the sources of duties in end-of-life decision-making emanate substantially from the obligations imposed by legislation and common law. Many and varied scenarios may face health practitioners and patients in end-of-life decision-making.

In the United States some states have enacted medical futility laws. In Texas, for example, if both the hospital ethics team and medical team are in agreement that treatments should be discontinued and if the patient's family disagree, the hospital should seek another centre willing to provide treatment.<sup>33</sup> If such an initiative is not successful after 10 days the family may appeal to a state court.

The law in the Australian state of Victoria in relation to futility of care is ambiguous and does little to guide practitioners. Yet, even if the law were clear and well defined, the complexities and emotions of end-of-life decisions will always play a significant role in the course of action to be undertaken. In the state of Victoria, neither legislation nor common law has defined futility. As such, the concept of futility is a medical construct, borne primarily out of medical ethics.

Whilst the definition of benefit may differ amongst commentators, we submit the notion of medical futility at some point cannot be denied. Further, whilst it may sound flippant, there is no such concept as "medicine on demand". That is, a patient or patient representative cannot demand a certain course of treatment, and a medical practitioner must not provide a course of treatment merely for the reason that it is demanded by a patient. Extending this to the futility context, a medical practitioner must not continue treatment that he or she considers futile merely because the patient or the patient's representative requests it.

**Who determines medical futility?**—Medical futility is determined by a medical practitioner. Such determination is as far as possible, an objective view that treatment would be unjustifiable. As there is no legal definition of futility in Victoria in legislation or at common law and no established medical definition of futility, the determination of medical futility can be a very difficult one to make.

Where a decision is made by a treating team to extend futile (and therefore medically unjustified) care, it can be difficult to later "reverse" that decision. A decision that future medical care would be medically futile, and the consequential effect of that decision on a patient, can be challenged by a patient (or patient advocate) in the Supreme Court of Victoria. There are broad powers available to the Supreme Court,

including ordering treatment to occur or not to occur, or awarding an injunction against a proposed course of action.

Australian courts have demonstrated a general reluctance to interfere in medical decision-making, but more readily intervene to safeguard the fairness and justice of the process to ensure that the correct medical decision and approach is made. For example, the Courts are unlikely to state that a properly qualified medical practitioner has made an incorrect medical decision, but will more likely require an additional independent opinion or additional time, where to not do so may cause an injustice against a patient.

**Once a determination of medical futility has been established, what obligations exist?**—The common law position in Australia is that a medical professional is under no obligation to provide treatment where “no benefit at all would be conferred”. However, it is important to note that treatment in this context does not include palliative care. Palliative care is defined under the Medical Treatment Act 1988 of Victoria<sup>34</sup> as including the provision of reasonable medical procedures, food and water for the relief of pain, suffering and discomfort. Such care must be provided where appropriate.

**Are there legal risks in medical futility cases?**—Where a medical practitioner makes a decision to withhold or withdraw treatment on the basis of futility that decision, like any other decision, is subject to review by a court. In particular, if the decision of medical futility is a decision that falls below the standard of practice of a reasonable medical practitioner, a doctor may be liable in negligence.

Further, there is at least a theoretical possibility that a medical practitioner could be charged with murder or manslaughter as a result of death arising from the act of withdrawing treatment, or withholding treatment. However, criminal intervention is unlikely for a number of reasons that this analysis will not explore. If, on the other hand, treatment is provided to a patient once such treatment is seen to be futile, it is arguable that the provider of such treatment could be liable for the tort of battery or crime of assault.

**What legal tools are available in end-of-life medicine?**—It is clear that the clear expression by a competent patient of their future care needs is immensely valuable. In some cases, a patient can make such expression using formal legal tools. In other cases, such expression can be made by a person appointed to act on behalf of a patient in circumstances where the patient loses the capacity to make his or her own decisions, under the *Guardianship and Administration Act 1986* (Victoria).

There are a number of legal tools available to a patient (and sometimes to a substitute decision-maker) in relation to advanced care planning and end-of-life decisions, including refusal of treatment certificates and advanced care directives. Refusal of treatment certificates are statutory instruments under the *Medical Treatment Act 1988* (Victoria), but their application is limited to “current conditions”.

Advanced care directives are common law expressions by a patient of their desires. There is some debate as to the applicability of advanced care directives in Victoria. However, the New South Wales Supreme Court case of *Hunter and New England Health Service v A*<sup>35</sup> has upheld that advanced care directives can be enforceable if it is both *valid* and *applicable*.



For an advanced care directive to be valid, it must have been made by a competent person, acting free of undue influence at the time of the directive. For it to be applicable, the advanced care directive must relate to the situation contemplated in the directive.

Whilst use of guardians, refusal of treatment certificates and advanced care directives may offer some legal certainty to end-of-life decision-making, they are by no means definitive. Therefore, in the absence of explicit legal guidance, the role of health practitioners remains central to end-of-life decision-making, in circumstances of medical futility.

Intensive Care practice and Resources in New Zealand may be different when compared to many other nations.<sup>36</sup> Consumers in New Zealand have a “Right to Services of an Appropriate Standard.”<sup>37</sup> Health care “consumers” in New Zealand have statutory rights, specified in the above “Code of Rights” accompanying the relevant legislation; the code also defines corresponding duties of health care “providers”. However, these rights do not include a right to any possible health care service. Not all possible services are “options” in the sense that the word could imply a “free choice from an unlimited menu”.

Hospital Ethics Committees in New Zealand are seldom involved in end –of –life disputes and decision- making, possibly because of a lack of apparent need for such a role.

A landmark case in New Zealand was heard in the High Court of New Zealand in 1992 .The patient was suffering from chronic Guillain-Barre syndrome and he was totally paralysed ,ventilator dependent and deaf for one year at the time of the hearing. The medical specialists involved in his care had sought overseas expert opinion and the medical consensus was unanimous. It was concluded that his prognosis was hopeless and his condition irreversible .Under these tragic circumstances, the doctors caring for the patient had decided to withdraw ventilator support. They had the full support of the patient’s wife and the judge stated that the medical staff had meticulously followed a cautious procedure in reaching their decision.

The doctors involved in the patient’s management were concerned that if they proceeded with withdrawal of ventilator support they would be prosecuted for murder or manslaughter under the New Zealand Crimes Act of 1961.

The Judge ultimately delivered an order in the following terms:

If,

- the doctors responsible for the care of the patient, taking into account a responsible body of medical opinion, conclude that there is no reasonable possibility of the patient ever recovering from his present clinical condition; and if
- there is no therapeutic benefit to be gained by continuing to maintain the patient on artificial ventilator support , and to withdraw that support accords with good medical practice, as recognised and approved within the medical profession; and if



- the patient's wife and ethics committee of the relevant Health Board concur with the decision to withdraw ventilator support,

Then, ss 151 and/or 164 of the Crimes Act 1961 will not apply, and the withdrawal of the artificial ventilatory support from the patient will not constitute culpable homicide for the purposes of that Act.

Concluding from this judgment it would appear there is a good prospect that New Zealand health professionals will be able to deal with such difficult issues without undue concern of criminal prosecution if patient management accords with good medical practice.

## Conclusions

There has been significant evolution in the concept of medical futility yet there remain many unanswered questions. The debate about how to resolve cases in which patients and families demand interventions that clinicians regard futile have been in evolution over the past 20 years.

A recent publication argues that the futility debate can be divided into three generations. The first generation was characterized by attempts to define futility in terms of certain clinical criteria. The second generation was a procedural approach that empowered hospitals, through their ethics committees, to decide whether interventions demanded by families were futile. The authors predict emergence of a third generation, focused on communication and negotiation at the bedside.<sup>38</sup>

It is clear when reviewing the history of the futility debate that clinical criteria and procedural approaches to unravel the complexities of futility remain problematic. The view of Burns and Truog<sup>38</sup> that an era of communication and negotiation may well improve the processes around futility seems plausible.

The future and evolution of medical futility may depend on open frank communication with a focus on the patient centred approach.

We argue that the leadership required when discussing futility should allow all involved to accept and understand that in some circumstances, death is inevitable.

Death will come to all of us and it is how patients and their families walk that final journey that will determine their lasting memories.

Care for the critically ill should remain decisive, gentle and inclusive. Why should this change when management includes evaluation and discussion regarding potentially futile therapy?

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## Point-of-care testing governance in New Zealand: a national framework

Samarina M A Musaad, Geoff Herd

### Abstract

Point-of-care testing (POCT) devices are in-vitro diagnostic devices used near the patient and for the most part distant from the pathology laboratory. By definition they have a large scope of settings and user profiles. POCT optimises care pathways and overcomes geographical barriers but has a high potential for adverse incidents.

A successful POCT service needs good clinical governance and a comprehensive quality management system. In New Zealand, Medsafe regulates medical devices including POCT devices in accordance with the Medicines Act 1981. A number of regulations impact on the use of devices but none address analytical and clinical performance.

In 2015 PHARMAC will assume responsibility for management of medical devices. We propose a governance framework that optimises patient safety and maximises benefit from this indispensable technology. This is the first of two articles; the second will address point-of-care governance at healthcare provider level.

### Clinical governance and the need for it

“First do no harm” is a cornerstone of medical practice, however clinical mistakes are inevitable. One of the challenges of modern-day medicine is to develop principles to minimise these mistakes. In 1997, in response to medical misadventure incidents including the Bristol Heart Scandal,<sup>1,2</sup> the National Health Service (NHS) first introduced the concept of clinical governance.<sup>3</sup>

The NHS defined clinical governance as “a framework through which NHS organizations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish”.<sup>3</sup> It ensures up-to-date clinical practice, continuous education of health carers, cost-effective health care delivery, effective clinical management pathways, clinical audit and transparent feedback of performance and outcomes, continuous process improvement, risk management and information management culminating in a safe effective medical service.<sup>4</sup>

Clinical governance has since been adopted by several international healthcare communities as being a robust foundation for high quality healthcare delivery and patient safety. However, it needs to be applied judiciously to safeguard against an autocratic “top down” approach.

### Governance of in-vitro diagnostic devices in New Zealand

In-vitro diagnostic devices (IVDs) comprise a spectrum of laboratory medical devices including POCT devices.

At the time of writing this article Medsafe (New Zealand Medicines and Medical Devices Safety Authority), a government regulatory body, is responsible for governance of medicines and medical devices in New Zealand (NZ) in accordance with the Medicines Act 1981. It defines medical devices as “... *any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, that is manufactured, imported, sold, or supplied for use wholly or principally on or by one or more human beings for a therapeutic purpose...*”. IVDs “*have a therapeutic purpose of diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition and are considered as medical devices in the Medicines Act 1981.....*”.<sup>5</sup>

POCT devices are IVDs that are used for testing outside of the laboratory and in the vicinity of the patient—e.g. urine pregnancy tests, glucose meters, International Normalised Ratio meters and urine dipstick kits. It is a requirement that information on all medical devices in NZ is entered into a dedicated database, the Web Assisted Notification of Devices (WAND). IVDs however are exempt from this requirement under schedule 1(i) of the Medicines Regulations 2003, notification being optional. Risk classification has been cancelled since 2011.<sup>5</sup>

IVDs in NZ can be bought, used, and sold by any client or patient as long as they comply with the Medicines Act 1981 and its regulations. The regulations cover legal definitions and interpretation, powers of the Minister of Health (MoH), restrictions on sale and requirements for advertising and compliance with standards.<sup>5,6</sup>

These regulations are enforced by Medsafe. Although other device regulations may impact on IVD supply in the NZ market, none of the above mandates any requirement for analytical quality specifications or validation of assays/methods in NZ. Suppliers of IVDs are advised to keep records for recall purposes but not required to comply with any pre-defined analytical quality standards.<sup>5</sup>

Adverse incidents or “reportable events” are required to be reported to Medsafe within pre-defined time frames depending on the type of event. Reportable events include “incorrect or out of specification results”, “discovery of a serious public health threat”, “malfunction or deterioration in characteristics...” and “inaccuracy in labelling, instructions for use.....”.<sup>5</sup> It can only be assumed that since there is no legislative requirement for independent validation the “specification” is defined based on manufacturers’ information.

Whereas this may not be a concern within medical laboratories or for POCT devices subject to a quality management system (QMS) where it is standard practice to independently validate devices and their tests to ensure fitness for purpose, it is however inadequate for POCT devices sold and used freely in the community where there is no immediate oversight.

The Integrated Healthcare Model proposed by the IT Health Board links general practitioners (GPs) and electronic prescribing within primary health care to national specialty systems and medicines reconciliation within secondary and tertiary care under a common theme of shared care.<sup>7</sup> It fails, however, to establish a link between users of POCT at all levels with each other and with primary, secondary and tertiary care and hence omits a vital element of patient care.

Inadequate governance of POCT devices allows the utilisation of inappropriate instruments that are sometimes not fit for purpose, by poorly trained individuals, in unsuitable settings, with lack of accountability and potential for adverse patient outcomes. Whereas POCT is part of medical laboratory testing it poses different challenges.

A POCT device is used to perform tests near the patient, geographically distant from the main medical laboratory and intellectually remote from the trained laboratory scientist and pathologist. By definition it can be performed in numerous settings and by multiple users of varying expertise ranging from health professionals to lay people. The scope of tests and devices is varied and is still expanding. With its benefits come potential risks. There is sufficient evidence to demonstrate the risks and patient harm that POCT poses in case of lack of regulation and flawed QMSs.<sup>8-13</sup>

## **Proposed changes to governance of POCT in New Zealand**

It is our view that the current regulatory environment in NZ does not provide an adequate framework that optimises the quality and safety of POCT devices that are used in the health system.

The pharmaceutical management agency (PHARMAC) is a Crown entity instituted in 1993 that has been responsible for prioritising funding of pharmaceuticals and commenced management of hospital pharmaceutical purchasing since 2002.<sup>14</sup>

In 2010 Cabinet announced that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices. A timeline for process building was released with clinical and stakeholder consultation until 28 March 2013 with management of devices planned to formally commence in 2015. PHARMAC partners with Health Benefits Limited in securing cost savings.<sup>14,15</sup>

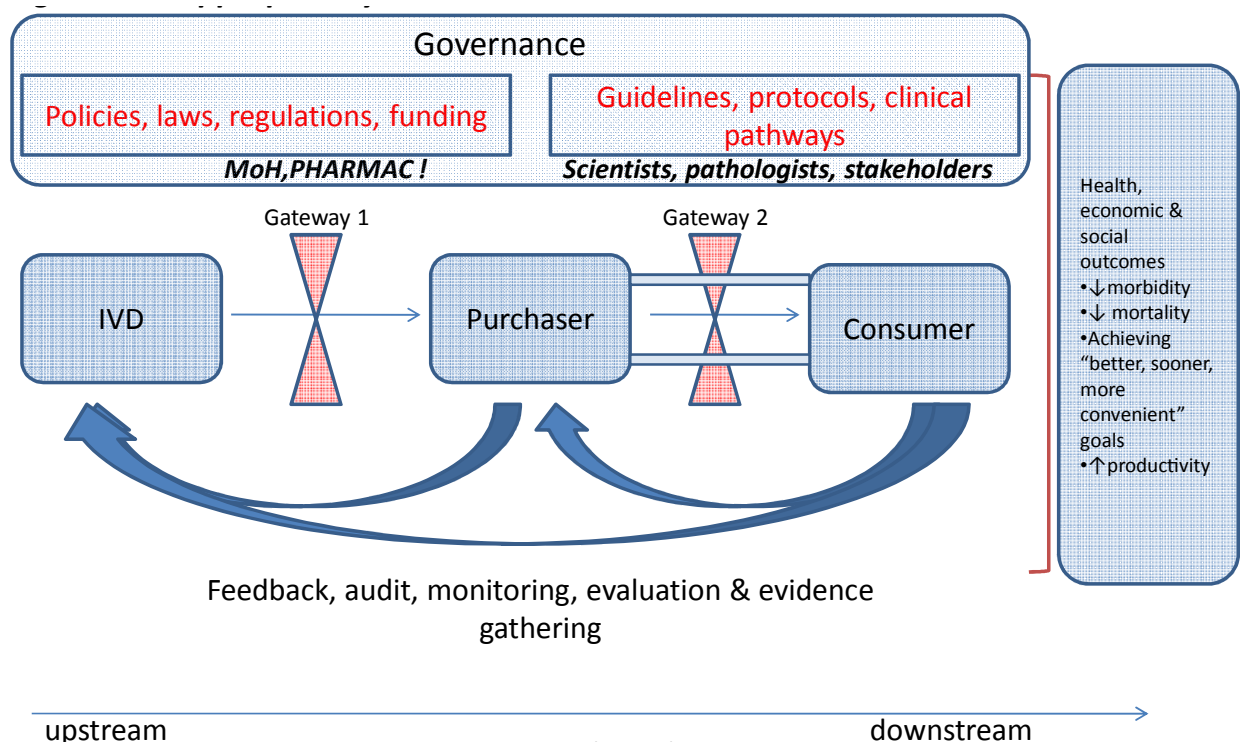
A national framework for the governance of POCT in NZ, inclusive of all stakeholders is proposed in Figure 1.

Figure 1 depicts a POCT service overseen by a governing body, controlled by gateways, fluid and cyclical by nature with clear objectives. The governance group includes stakeholders with PHARMAC, accountable to the MoH, acting at a regulatory level (Gateway 1). Legislation and evidence based policies that PHARMAC adopts, determine the quality of POCT devices available to the NZ healthcare system. This will subsequently aid in prioritising funding for POCT devices.

PHARMAC will be informed by partnering with the scientific community, consumers and relevant stakeholders. Pathologists and medical laboratory scientists are experts in device and method validation to ensure “fitness-for-purpose”. Their expertise is vital to inform PHARMAC of which devices are accurate, precise, safe and cost-effective for the NZ population. Their recommendations to PHARMAC are informed by professional body guidelines, up-to-date literature, and tried and tested clinical pathways and laboratory protocols.



**Figure 1. A national governance framework and expected outcomes**



**Key:** MoH: Ministry of Health; IVD: *In-vitro* diagnostic device manufacturers; PHARMAC: Pharmaceutical Management Agency.

It is expected that IVD companies endeavour to provide devices of the highest calibre of quality. Manufacturers evaluate their instruments before marketing but often small numbers of samples are studied, in patient populations that are sometimes different from a NZ demographic.

Evaluation frequently takes place in controlled environments under resource constraints and the literature referenced may not be applicable for local needs. The information provided by manufacturers therefore cannot form a solid foundation for the unequivocal use of a device. There are professional international guidelines (independent of IVD industry) for the study, validation and choice of instruments that are adhered to by NZ medical laboratory health-carers.<sup>16-22</sup>

The concept of a checkpoint or gateway (Gateway 1) to ascertain “fitness-for-purpose” is fundamental. The ideal set up would be to establish a system of formal device validation in NZ, enabled by legislation, and provided by pathologists and medical laboratory scientists. A National Reference Laboratory for validation of all POCT devices available in the NZ market can be a starting point.

Currently each laboratory service validates all POCT devices to be used in the laboratory and/ or within the relevant hospital service to ensure good analytical and clinical performance. Pre-defined quality goals are assessed centred on local needs and professional scientific guidelines. This is time consuming for scientists and



pathologists and costly in terms of reagents and disposables yet is essential. The instrument may eventually be deemed adequate or if not, further analyses are performed on another device.

A national laboratory would consolidate these efforts saving valuable time and potentially reduce cost. A catalogue of all validated devices, whatever the outcome of validation, would serve as a reference for POCT users and as a funding guide for a regulator such as PHARMAC. Certification of devices based on local validation would encourage compliance with regulations and allow users to make informed decisions.

Expert groups like the New Zealand Point-of-Care testing Advisory Group (NZPOCTAG) are key to the success of a governance scheme. The NZPOCTAG had been formed in 2009 under the chairmanship of the point-of-care coordinator at Whangarei Hospital, Northland District Health Board and coauthor of this article (GH).

Its core membership includes POCT coordinators, senior medical laboratory scientists, laboratory managers and pathologists from all around NZ. It includes representation from the Medical Sciences Council, the Royal College of Pathologists of Australasia (SM, coauthor) and International Accreditation New Zealand. The group possesses the scope of expertise and professional links to practically assess, advise and guide the choice of POCT devices, settings, application and cost effectiveness of POCT instruments and services. NZPOCTAG is therefore an obvious resource to include in POCT governance.

For simplicity, as shown in Figure 1, district health boards (DHBs), health organisations and pharmacies are classed as purchasers while patients and lay people as consumers. The second Gateway between the latter 2 groups serves to facilitate the rational and patient centred approach to the application of POCT. The roles of pathologists and medical laboratory scientists is to implement robust QMSs to ensure the reproducibility of accurate test results, continuous training and certification of users of POCT devices, application of internal and external quality controls (IQC and EQC) and risk management.<sup>23</sup>

Clinicians have an essential role to incorporate POCT results within effective clinical pathways that maximise the benefit from a valid POCT analysis.<sup>9</sup> The net result is improved delivery of care.

A large proportion of POCT devices are sold in community pharmacies where pharmacists train lay people on the use of the devices. This makes pharmacists important players in the governance of POCT. Other stakeholders that should be involved in governance include community nurses and midwives, and the commercial sector with their duty to inform of any relevant variables that may affect the test performance.

The NZPOCTAG can act as an interface between the regulator (PHARMAC) and all other stakeholders (clinicians, health organisations, pharmacists and industry). Its membership can be expanded to involve representatives from respective interested parties.

Feedback enables the assessment of target attainment. This entails open lines of communication, transparency and efficient information technology (IT) systems in place. Forms of feedback include incident reporting, audit, monitoring, evaluation and evidence gathering. It will inform decision-makers and ensure continuity of quality improvement. Equally, processes in place should ensure timely response to consumer needs.

## **Connectivity in integrated care**

Connectivity of POCT devices entails that all results of a POCT assay are available and displayed in the patient's electronic health record. Though arguably essential, this is not the current state of affairs because not all POCT devices possess connectivity technology and possibly because it is not a mandatory requirement. The gap is demonstrated in the current Integrated Healthcare Model.<sup>7</sup>

Connectivity is a feature that laboratory professionals seek in all POCT devices.<sup>8,9,11</sup> It allows all professionals involved in the care of a patient to access all information needed for a comprehensive care plan. The unavailability of POCT results creates knowledge gaps leading to replication of testing, delays in diagnosis and management, frustration of both patient and health carer and increased expenditure. It is therefore prudent to foster connectivity if not legislate to implement it.

## **What the proposed framework means**

Health leadership takes several forms and there is no place for observational leadership in POCT. Its scope of applications, settings, users and safety concerns dictates interventional leadership measures. This needs to be balanced by consumer leadership by means of challenging policies and regulations that impact negatively on the quality of healthcare delivery.

The collective goal is an effective, deliverable, safe and equitable health care system nationwide. The framework supports plans for improved primary healthcare such as the "Better, sooner, more convenient" initiative.<sup>24</sup> It also advocates for a whole system approach recognising that decisions made at higher levels have a downstream effect and those made at ground level have an upstream effect. It makes a clear distinction between first- and second-order governance (2<sup>nd</sup> and 1<sup>st</sup> gateways respectively) clearly defining roles and systems. Furthermore, by ensuring adequate QMSs in place, it fosters proactive rather than reactive health service delivery.

The framework adheres to the principles of evidence based laboratory medicine (EBLM),<sup>25</sup> the concepts of effective clinical governance and public health safety. It encompasses all layers of provision of a POCT service from manufacturers and importers to the use of a POCT device by a lay person. By ensuring involvement of all relevant stakeholders and continuous clinical outcome feedback it partners "bottom up" with "top down" hence creating a balanced approach.

The NZ market should be open to state of the art technology. Local validation and certification is not meant to restrict choices, stifle market availability nor curb competition. It aims to provide an evidence based and scientifically sound means to allow informed decisions. It will ultimately have fiscal implications but this is not a

disadvantage because this is needed for governing potentially costly services such as POCT within the constraints of a healthcare budget.

Commercial leadership should continue charting new technology frontiers and balance the pursuit of profit by responding to consumer expectations and local population and market needs.

## Summary

In summary, POCT is an essential limb of mainstream pathology laboratory testing. There is no mature health care delivery service that can operate without POCT to various degrees.

Due to its varied nature, risks associated with POCT are higher than those associated with testing in the environmentally controlled pathology laboratory. It therefore necessitates robust regulatory measures at a political/governmental level, implementation of vigorous QMSs at an operational level and efficient patient care pathways at a clinical level.

We propose a framework that is all-inclusive in an attempt to maximise the benefit from an indispensable technology. We recommend reliance on local expertise such as the NZPOCTAG and not to alienate the commercial sector. We recommend balancing short-term costs with long-term gain in relevant health outcomes and uniting the “top down” with the “bottom up” approach.

Furthermore we recommend that PHARMAC and Medsafe actively engage with international bodies enabling NZ to be a global player in healthcare delivery and device regulation.

**Competing interests:** None identified.

**Note:** The views expressed in this article are those of the authors and do not represent views of any particular organisation.

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## Beware of paracetamol use in alcohol abusers: a potential cause of acute liver injury

Achala Manchanda, Christina Cameron, Geoffrey Robinson

### Abstract

There may be under-recognition of acute liver injury following reported therapeutic use of paracetamol in alcoholics. We present the case of an alcoholic patient who developed acute liver injury suspicious for chronic paracetamol toxicity on two occasions. The likely contribution of chronic paracetamol was not recognised at her second presentation, reflecting a need for increased awareness of this potential cause of acute liver injury.

The biochemical hallmark of the syndrome is the 'towering' aspartate-aminotransferase (AST), often in the thousands; transaminases above 500 U/L should never be dismissed as secondary to alcoholic liver disease alone. Whether alcoholics are at increased risk of toxicity from therapeutic doses of paracetamol remains controversial, although many cases have been described for over 30 years.

Randomised controlled trials to date have failed to show significant hepatic derangement in newly abstinent alcoholics exposed to short courses of paracetamol. We argue that these studies do not reflect the realities of paracetamol use in this population. In addition, alcoholics are at risk of accidental 'staggered overdoses', or repeated supra-therapeutic ingestions. In cases of suspected paracetamol toxicity, administration of the antidote n-acetyl cysteine (NAC) should be considered, even when the patient's serum paracetamol level is normal.

It is 20 years since the *NZMJ* published a case report of paracetamol hepatotoxicity in a heavy drinker taking no more than 6 grams of paracetamol daily.<sup>1</sup> Sporadic cases of life-threatening liver necrosis in heavy drinkers continue to be encountered in those taking alleged therapeutic doses of paracetamol, prompting us to report on a recent case.

### Case report

A 52-year-old woman with a 12-year history of alcohol dependence was admitted electively for detoxification in December 2011. Her past medical history included possible seizure disorder (not treated with anticonvulsants), gastric bypass (admission weight 61 kg, body mass index 23 kg/m<sup>2</sup>), previous DVT, asthma and depression.

She was regularly drinking two bottles of wine per day up to the day of admission; breath alcohol on admission was 680 mcg/L. Examination showed mild tachycardia, tremor and right upper quadrant tenderness; there was no delirium, seizures or signs of liver failure.

Liver function tests (LFTs) 1 month earlier were consistent with alcoholic liver disease, with an ALT (alanine amino-transferase) of 146 U/L(<28), GGT (gamma-glutamyl transpeptidase) 212 U/L(<36), INR (international normalised ratio) 1.3,

albumin 40 g/L (34-46), mean cell volume 103 fL, platelets  $177 \times 10^9$ /L; an AST (aspartate-aminotransferase) level was not taken.

On admission, her AST was markedly elevated at 1453 (<27 U/L), ALT 332, GGT 732, INR 2.5, albumin 27. Transaminases peaked the next day (AST 8015, ALT 1260). Serology for hepatitis B and C, Epstein-Barr virus and cytomegalovirus, and ANA were unremarkable. No contributing medications were noted; on admission she was taking omeprazole, citalopram (20mg daily), Symbicort® (budesonide with eformoterol) inhaler, zopiclone and multivitamins, and was treated for alcohol withdrawal with diazepam.

On enquiry, the patient reported using paracetamol for neck pain, as prescribed by her general practitioner (GP) at 4 grams a day for the preceding month. This was consistent with her pharmacy's dispensing records. Paracetamol was ceased on admission and she was administered the antidote NAC. Her LFTs improved markedly; by day 6 AST had fallen to 333, INR 1.4. She was discharged with strong advice to avoid paracetamol.

Unfortunately, she relapsed into alcohol abuse the next day. Two months later, a follow-up blood test by her GP revealed further hepatic insult with an AST of 3322, ALT 595 and INR 1.7. Remarkably, she admitted to resuming paracetamol at 4 grams a day for 2 weeks while concurrently drinking alcohol. She was referred to the acute medical service and assessed by a different team. A liver ultrasound was normal. She was not treated with NAC on the basis of an undetectable paracetamol level on admission.

Paracetamol was ceased and her LFTs improved after 2 days (AST 291, ALT 176). She continues to struggle with abstinence but her transaminases have never exceeded the low hundreds since.

## Discussion

We have reported a case of acute liver injury in an alcoholic woman taking paracetamol with therapeutic intent. Other causes of acute liver injury were considered but felt less likely, including viral hepatitis, ischaemia, autoimmune liver disease, and other drug-induced hepatotoxicity.

At her second presentation, the potential role of paracetamol was discounted based on a falsely reassuring paracetamol level. In chronic hepatotoxicity, paracetamol levels are frequently 'therapeutic'.<sup>2</sup> They are dependent on the time from last dose to medical presentation, and therefore cannot be used to exclude toxicity in the setting of chronic use.

This patient's LFT derangement is similar to that described in previous case reports, with a markedly raised AST, said to 'tower' over the relatively less elevated ALT. In one case series, ASTs ranged from 3000 to 48,000 U/L in 90% of subjects.<sup>3</sup> In contrast, transaminases are only moderately raised in alcoholic liver disease (usually AST <500, ALT <200), with an AST:ALT ratio in the order of 2:1 or greater.

Similar cases have been described for over 30 years. One case series in 1995 identified 67 cases of hepatotoxicity in alcoholics taking paracetamol with therapeutic



intent, alarmingly associated with a 20% mortality rate.<sup>3</sup> This effect has been dubbed the ‘alcohol-paracetamol syndrome’.<sup>4</sup>

Therapeutic doses of paracetamol are predominantly metabolised into non-toxic metabolites by glucuronidation or sulfation; a small proportion is metabolised by the cytochrome-P 2E1 (CYP2E1) enzyme into the hepatotoxic metabolite n-acetyl-p-benzoquinone imine (NAPQI). With excessive doses of paracetamol, the glucuronidation and sulfation pathways become saturated, resulting in the accumulation of toxic NAPQI.

Chronic alcohol ingestion induces CYP2E1 up to threefold; the effect of which persists in the early days of alcohol abstinence.<sup>5</sup> Acute ingestion of alcohol in fact has a protective effect as it competes with paracetamol for CYP2E1; therefore, newly abstinent alcoholics who continue to take paracetamol may be most at risk.<sup>6</sup>

Alcoholics are also less able to clear NAPQI, as its breakdown is mediated by glutathione, stores of which are decreased with chronic alcohol ingestion and malnutrition.<sup>7</sup>

In the United States, the Food and Drug Administration has mandated that all paracetamol packets sold over-the-counter carry an alcohol warning: ‘If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen (paracetamol)’.

Critics argue such warnings are unfounded. Some call into question the validity of case reports of the ‘alcohol-paracetamol syndrome’, in particular, pointing to incomplete dosing histories and instances when measured paracetamol levels imply higher dosages ingested than reported.<sup>8</sup>

A recently published meta-analysis cites five randomised controlled trials where paracetamol was given at up to 4 grams a day to newly abstinent alcoholics for up to 10 days; no statistically significant increase in ALT was seen at day 4.<sup>9</sup>

All trials in the meta-analysis excluded alcoholics with baseline transaminases greater than 200, and only two allowed patients with ALTs greater than 120; thus severe alcoholic liver disease was excluded. Paracetamol was given in short courses only (for up to 10 days). However alcoholics are more likely to use paracetamol for extended periods; one study suggests alcoholics are twice as likely than non-regular drinkers to use paracetamol on a daily basis.<sup>7</sup> It may be that a longer period of paracetamol use increases the risk of developing toxicity.

We argue that these clinical trials do not reflect the realities of paracetamol use in the most vulnerable or malnourished alcoholics. It is also likely that alcoholics are at increased risk of taking medication unreliably, and therefore clinical trials do not simulate risk in practice.

While the ‘alcohol-paracetamol syndrome’ is controversial on a purely pharmacological level, there is evidence that alcoholics are at increased risk of non-intentional ‘staggered overdoses’, i.e. repeated supra-therapeutic ingestions.<sup>10</sup> In a prospective study of at-risk drinkers, 31.9% of 128 alcoholic subjects were found to use paracetamol at supra-therapeutic doses.<sup>7</sup>



Alcoholic patients are over-represented in the most severe cases of chronic paracetamol toxicity; in 2012, authors at the Scottish Liver Transplant Unit reported that of 663 patients admitted there with liver failure from paracetamol, one-quarter were due to staggered overdoses; of these cases, half involved alcohol abuse.<sup>10</sup>

The contribution of the antidote NAC to our patient's initial recovery is uncertain; her improvement may have been due to paracetamol cessation alone. Nevertheless, the New Zealand National Poisons Centre advises that patients with repeated supra-therapeutic ingestions of paracetamol with a raised ALT be treated with the antidote NAC even when the serum paracetamol level is undetectable.<sup>11</sup>

In summary, we recommend caution in the prescribing of paracetamol to alcoholic abusers, especially in longer courses and to those with known alcoholic liver disease or malnutrition. Diagnosing paracetamol toxicity in the alcoholic requires a high index of suspicion. The diagnosis may be missed by physicians, due to insufficient history taking, incorrect interpretation of liver function tests, and false reassurance by blood paracetamol levels.<sup>12</sup>

When staggered paracetamol overdoses, or therapeutic dose paracetamol toxicity are suspected, treatment with the antidote NAC is recommended, even when the serum paracetamol level is undetectable.

Unintentional acute liver injury from paracetamol in heavy drinkers is not new, having been reported in the medical literature for over 30 years. Nevertheless, we believe the awareness of the potential life-threatening interaction remains low within health professionals and the community, and believe it is important to raise the issue.

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## Kikuchi-Fujimoto disease—an unusual mimicker?

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### Abstract

We describe the case of a 27-year-old Chinese female diagnosed with Kikuchi-Fujimoto disease in Ireland. It principally occurs in Asian populations, but is being increasingly reported in non-Asian populations. This rare, benign disease may potentially be misdiagnosed as lymphoma, and has an association with the subsequent development of systemic lupus erythematosus. Clinicians and pathologists need to be aware of the clinical and histological features of this rare disorder to avoid misdiagnosis.

### Case report

A 27-year-old female of Chinese descent was admitted for investigation of a 19-day history of intermittent fevers, cervical lymphadenopathy, anorexia, weight loss, pruritis, abnormal liver enzymes (ALT=1099, alkaline phosphatase=89, GGT=175, bilirubin=15), neutropaenia and thrombocytopaenia (WCC 2.4, neutrophils  $1.22 \times 10^9$ , lymphocytes  $1.01 \times 10^9$ ).

Multiple serological, immunological and autoimmune blood tests were completed as was a Mantoux test and liver ultrasound which were all normal. Her symptoms and lymphadenopathy began to resolve after 1 week with reduction in elevated liver enzymes. She was discharged with a suspected viral aetiology of unknown cause and a planned outpatient follow up.

She reattended 10 days later, with recurrent fevers, cervical lymphadenopathy and anorexia. In addition, she had developed nausea and vomiting. LDH was now noted to be 600 I/U. She remained febrile, and was initially managed with doxycycline, piperacillin/tazobactam and gentamicin.

CT neck, thorax, abdomen and pelvis demonstrated extensive left-sided cervical lymphadenopathy (Figure 1). A cervical lymph node biopsy was subsequently ordered, which was 5 days after her readmission.

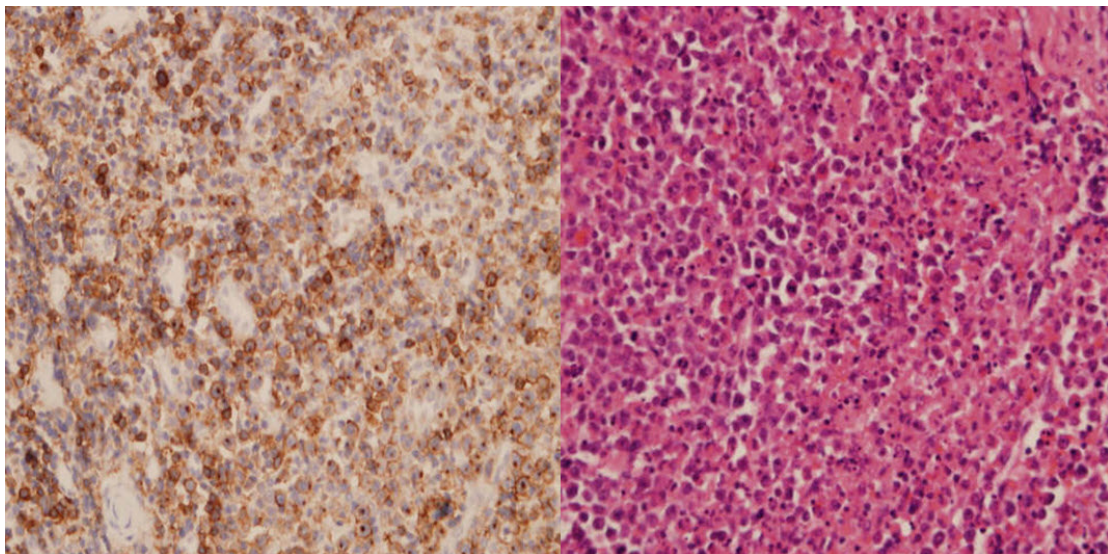
The preliminary verbal report was suspected lymphoma, however the official pathological report became available 3 days after she underwent the biopsy and demonstrated subacute necrotizing histiocytic lymphadenitis (Figure 2) confirming the result of Kikuchi-Fujimoto disease.

Ibuprofen was initiated and her symptoms started to resolve. She was discharged 1 week later (6 weeks, 1 day post first admission) with normal laboratory results and resolving symptoms. There were no clinical or laboratory abnormalities at review 3 months later and she is now being followed up yearly.

**Figure 1. Multiple enlarged lymph nodes in the posterior cervical triangle**



**Figure 2. In Kikuchi-Fujimoto disease, biopsies in the necrotizing phase show necrosis with abundant histiocytes but without a neutrophilic infiltrate. In this photomicrograph of a lymph node, we see areas of necrosis (pink area) and immunoblast in the periphery of the necrotic area (black dots). There are also a number of histiocytes containing apoptotic debris in this picture. On the right side, we see atypical lymphoid cells showing positive reactivity for CD8 which implies evidence for Kikuchi-Fujimoto disease**



## Discussion

Kikuchi-Fujimoto disease is a rare, benign, generally self-limiting disease of unknown cause, usually characterised by lymphadenopathy and fevers.

Lymphadenopathy is the most common symptom and is isolated to one region in approximately 83% of cases.<sup>1</sup> A flu-like prodrome has been reported in 30–50% of cases.<sup>2</sup> Other clinical and laboratory findings reported are rash (10%), arthritis (7%), hepatosplenomegaly (3%), leucopaenia (20–32%), elevated ESR (40%), anaemia (23%) and increased LDH suggesting hepatic involvement.<sup>3</sup>

Systemic symptoms are more likely with extra nodal involvement and include night sweats, nausea and vomiting, thoracic and abdominal pain, diarrhoea, weight loss, headache, rigors and myalgia.<sup>4</sup>

The potential for misdiagnosis of Kikuchi-Fujimoto disease as lymphoma or systemic lupus erythematosus (SLE) has been widely reported. In Dorfman and Berry's series, 40% of patients were initially diagnosed with malignant lymphoma and received chemotherapy of varying durations until Kikuchi-Fujimoto disease was finally diagnosed.<sup>5</sup> This may be due to the morphologic features being suspicious for lymphoma based on the florid immunoblastic proliferation and the presence of necrosis. It may also be due to its similar presentation to lymphoma.

Patients with Kikuchi-Fujimoto disease are at increased risk of subsequently developing SLE and need to be followed carefully. The only definitive diagnostic procedure is a lymph node biopsy (Figure 2).

Non-steroidal anti-inflammatory drugs (NSAIDs) are used for symptomatic relief of lymph node tenderness, fever and other pains. Corticosteroid use (50–60 mg po od) is recommended for severe extra nodal disease, hepatic and neurological involvement and severe lupus-like syndrome.<sup>6</sup>

Glucocorticoids with intravenous immunoglobulins have been used for persisting symptoms with apparent benefit.<sup>7</sup> Patients rarely suffer from recurrences of Kikuchi-Fujimoto disease (3%).<sup>8</sup> There has been one reported case of successful treatment of recurrent Kikuchi-Fujimoto disease with hydroxychloroquine.<sup>9</sup>

Kikuchi-Fujimoto disease was originally reported as a female predominant disease of Asian populations. The Census of 2006 reported that there were 354,552 Asians resident in New Zealand and clinicians practicing in New Zealand may rarely encounter this condition.

More recently it has been reported that Kikuchi-Fujimoto disease is not confined to the Asian population. In a review of 108 cases worldwide, 68 of these were reported in the United States<sup>2</sup> and a subsequent study by the same authors noted that 75% of 88 US patients with Kikuchi-Fujimoto disease were Caucasian.

Clinicians should consider Kikuchi-Fujimoto disease in the differential diagnosis of both Asian and non-Asian patients with unexplained lymphadenopathy and fevers.

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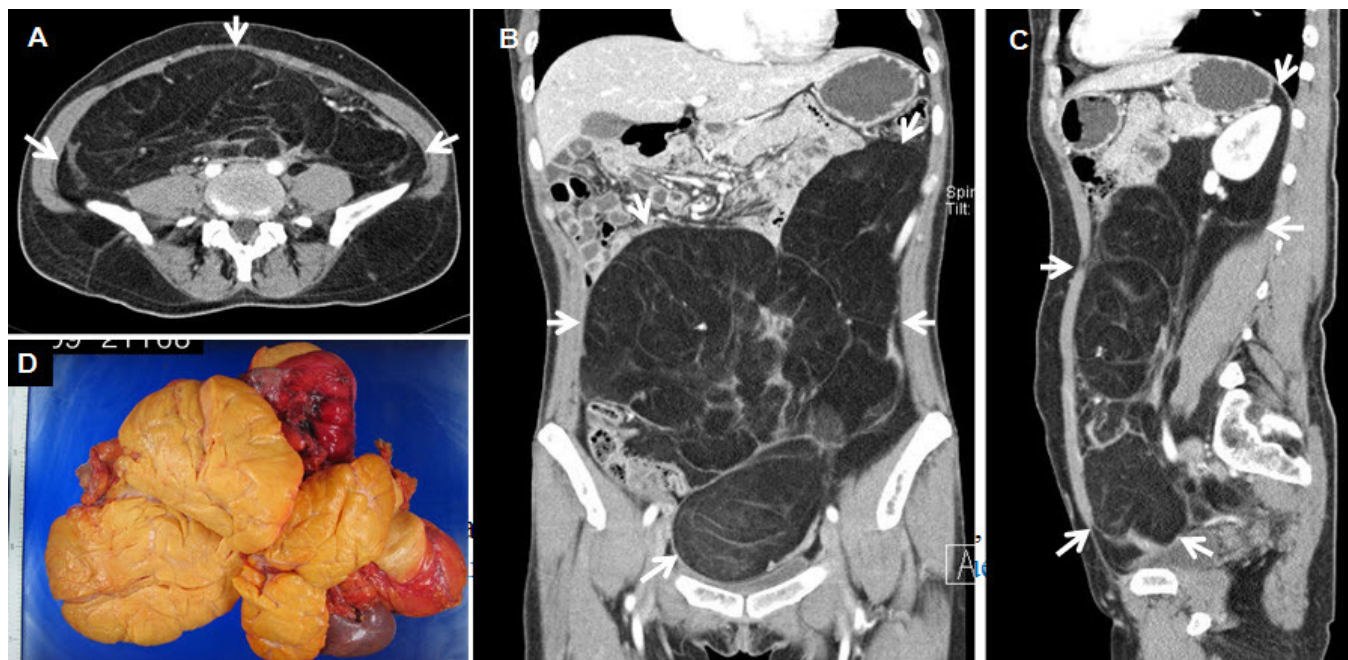
## Giant retroperitoneal mass occupying nearly the whole abdomen

Myung-Won Lee, Sang Il Lee, Hyo Jin Lee

**Clinical presentation**—A 48-year-old woman presented with an abdominal mass with insidious onset. Computed tomographic scans of abdomen and pelvis (Figure 1A–1C) revealed a huge fatty tissue mass extending from the retroperitoneum to the pelvis. It occupies entire mid to lower abdomen and pelvis displacing bowel loops to the right upper quadrant of the abdomen.

She underwent a complete excision of the tumour with concomitant resection of the left kidney, the left hemicolon, and the left ovary (Figure 1D).

**Figure 1. Computed tomographic scans of abdomen and pelvis (A, horizontal; B, coronal; C, sagittal; arrows indicate the extent of a huge fatty tissue mass) and resected tumour (D)**



*What is the diagnosis?*



**Answer and Discussion**—*Retroperitoneal liposarcoma* is a rare tumour that may grow to a considerable size before causing clinical symptoms.<sup>1</sup> It has been reported that 20% of the tumours are >10 cm at the time of diagnosis. Clinically, these tumours tend to present with diffuse abdominal pain accompanied by anorexia, weight loss and increased abdominal girth.

The most characteristic sign is a painless abdominal mass in ~78% of the cases. Abdominal symptomatology is due to compression of the organs. Aggressive surgical resection of the tumour together with adjacent structures, if necessary, is the mainstay of treatment.<sup>2</sup>

Regarding prognosis, retroperitoneal liposarcoma is significantly better than other retroperitoneal soft tissue sarcomas such as leiomyosarcoma, malignant peripheral nerve sheath tumour, and malignant fibrous histiocytoma. Histologic grade, status of resection margin, and tumour invasion of adjacent structures are known to affect prognosis of retroperitoneal sarcoma.<sup>3</sup>

In this patient, histologic examination of the specimen confirmed that the lesion was well-differentiated liposarcoma. Her postoperative course was uneventful. Any adjuvant therapy was not given.

After 3 years of treatment, the patient was well.

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## **The sickness of the USA model of healthcare—is it a contagious disease?**

I write this letter after attending the Preventing Overdiagnosis Conference in Dartmouth, New Hampshire, USA. The conference focused on a relatively new field of research, which investigates the harms and costs associated with overdiagnosis and overtreatment, and the extent to which this is adding considerably to the cost and resource burden in healthcare.

I presented my research findings into patterns of off-label prescribing of atypical antipsychotics (AAPs) in Christchurch, New Zealand.<sup>1,2</sup> That study found that 96% of psychiatrists in Canterbury prescribe AAPs off-label, 58% do so at least weekly and that overwhelmingly the drug of choice is quetiapine, which is prescribed for (non-psychotic) conditions for which there is very little evidence of efficacy and safety. The direct cost burden for this type of use in 2010 was \$9.5million. Other presenters found similar patterns of off-label AAP and other medication use in the USA and Europe, and strongly criticised this practice expressing concern about public harm and cost.<sup>3</sup> Part of my motivation in writing is to alert colleagues to the research into overdiagnosis and overtreatment and to encourage clinicians to consider what role this plays in their area of practice.

I also write to sound a cautionary note, based on my personal experience of healthcare in the USA and to point out the potential pitfalls of following their model, with its emphasis on private health insurance. This at a time when the New Zealand Government is keen to promote privatisation (ACC), arguing that it will improve performance, access, quality, and greater efficiency in healthcare.

Within days of arriving in the US I developed moderately severe symptoms of Bell's palsy (unilateral facial paralysis). As I was scheduled to deliver a number of presentations this was a particularly inconvenient context in which to develop this condition. Bell's palsy is a diagnosis of exclusion and as I was not keen to be subjected to exhaustive investigations in the US I largely ignored the symptoms for several days. However as these progressed I finally accepted the inevitable wisdom of seeking treatment. I was told to contact the local hospital (Dartmouth-Hitchcock), who directed me to the "ER".<sup>4</sup> There I went through the customary triage process.

I then waited for 2 hours to be ushered into the medical examination room where I met the billing clerk who was armed with a series of questionnaires and questions, which I had to complete before I could proceed to the medical examination. The completion of this task required a high degree of cognitive functioning as I not only needed to provide a comprehensive medical history, proof of identity and detailed financial information, but also had to decide whether I wanted to be "resuscitated" and what my advanced directives were in case of a medical emergency. As I appear fit and healthy, take no regular medications and have no medical history of serious illness it all seemed a little over the top.

Finally after signing a number of medicolegal documents (which were largely unintelligible to me, despite my training in forensic psychiatry) I met the duty doctor, who quickly diagnosed Bell's palsy and prescribed the standard prednisone, acyclovir combination treatment, without any physical examination or investigations.

Armed with my script I was anxious and ready to leave, but was told that I had to again see the billing clerk before "discharge". She asked whether I could pay for the bill and presented me with a hospital invoice amounting to \$USA1000 (\$857 plus taxes)!! I then realised why she had gone to so much trouble to ask whether I wanted to be resuscitated—the invoice was sufficient to provoke a heart attack or stroke in the most robust individual, even in the absence of other risk factors.

I made discrete enquiries but no one could clarify how a simple 10-minute medical consultation could lead to such an exorbitant bill. Had I been more anxiety prone or uninformed about Bell's palsy I may have asked or been advised to have a number of investigations, such as brain CT and blood tests to rule out a stroke, Lyme's disease or middle ear tumours—the bill then would surely have caused a coronary, leading to further interventions and wildly escalating costs (I should have opted out of "resus").

Without a hint of irony the clerk confirmed that I wasn't charged excessively because I was a tourist and that the charge is the same for any of the 46 million residents (15%) in the US who are uninsured and do not qualify for Medicaid or Medicare. A recent investigation into the costs of healthcare in the US by Time Magazine shows this is the norm.<sup>5</sup> Given that the minimum wage in the US is \$8/hour this equates to 120 hours work to pay for a 10-minute medical consultation!

Reviews have repeatedly found that despite having the most costly healthcare system in the World (US\$7960 per person cf. US\$2983 in NZ), the United States consistently underperforms on most dimensions of performance, relative to other countries. Compared with five other nations—Australia, Canada, Germany, New Zealand, the United Kingdom—the US healthcare system ranks last or next-to-last on five dimensions of a high performance health system: quality, access, efficiency, equity, and healthy lives.<sup>6</sup>

Because of its long-term experience with private health insurance, in my opinion the US presents a compelling real-world case study of the likely long-term disadvantages of introducing competing private health insurance to improve performance and efficiency in the health sector in New Zealand.

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## Prostate cancer screening in New Zealand

Simon van Rij et al's paper<sup>1</sup> on the use of PSA screening is an excellent illustration of the problems of ad hoc screening programmes. The National Screening Unit<sup>2</sup> lists the requirements to justify setting up a national screening programme and observes that to justify a screening programme some criteria need to be met including: there is effective treatment, the health system is capable of supporting all the necessary elements, social and ethical issues are considered and cost benefit issues are considered.

I applaud research aimed at determining whether PSA screening is effective...but also how cost-effective such screening is. Given that the jury is still out on effectiveness, cost-effectiveness cannot be determined. Doing 1271 PSA tests to find one case of prostate cancer (as reported in 40–49 year olds) or a total of 18,469 tests in men over 80 years of age can't be seen as cost-effective in anyone's language.

Ad hoc screening programmes such as this inevitably increase health outcome disparities by servicing the worried well, and because the public system has become burdened with biopsy work more of the treatment is done in private.

I am one of the GPs who was surveyed who does not initiate discussion about PSA testing in asymptomatic men. I work at Newtown Union Health Service that is a Very Low Cost Access Practice. Our budget was cut 7.8% this year. We cannot afford to employ enough staff to adequately treat diagnosed problems. According to the NZ Health Survey<sup>3</sup> nearly 1 million people had an unmet need for primary health care last year.

We cannot afford to waste health spending on useless (testing 80-year-old men) or marginally beneficial tests that increase our already bad health outcome disparities. This money would be better directed to improving access to primary care for the most disadvantaged in our community.

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## Doctors discussing PSA screening with their male patients

Reducing numbers of doctors in New Zealand are now initiating discussion about PSA screening with their male patients. In my opinion, this decline results from a misunderstanding of the research, which has been inadequate in several ways.

I have had no medical training, but I think, nevertheless, that I have something to bring to the debate on prostate cancer screening: a Men's Rights centred approach. At Law School students of the New Zealand Bill of Rights Act 1990 have been encouraged to take a rights-centred approach to cases. What is very rare in the World today is a Men's Rights centred approach, and that is what I bring to the table.

Moyer (2012) reports on two major studies of PSA-based screening for prostate cancer: the U.S. PLCO (Prostate, Lung, Colorectal and Ovarian) Cancer Screening Trial, and the ERSPC (European Randomized Study of Screening for Prostate Cancer). The latter is the focus of Bangma (2009) and of Schroeder et al. (2009).

Moyer (2012) states that:

The U.S. trial did not demonstrate any reduction of prostate cancer mortality. The European trial found a reduction in prostate cancer deaths of approximately 1 death per 1000 men screened in a subgroup aged 55 to 69 years. This result was heavily influenced by the results of 2 countries; 5 of the 7 countries reporting results did not find a statistically significant reduction (page 122).

The obvious thing to do, on reading this, is to investigate why:

- The two studies produced different results; and
- Two of the countries in the European study produced different results from the other five countries.

As regards the first question, Bangma (2009, page 2) states that, in the U.S. PLCO Cancer Screening Trial, “a large proportion of men in the control arm of the study had already undergone a PSA determination before or during the study, and therefore that arm of the study has to be regarded as contaminated.”

As regards the second question, I note that Moyer (2012) states that the two countries involved are Sweden and The Netherlands (page 125). Well, what is particular about those two countries that might account for the discrepancy?

As far as Sweden is concerned, Schroeder et al (2009) state (on page 1322) that:

The screening interval at six of the seven centers was 4 years (accounting for 87% of the subjects); Sweden used a 2-year interval. In Belgium, the interval between the first and the second rounds of screening was 7 years because of an interruption in funding.

Although prostate cancers are generally slow-growing, some prostate cancers grow fast, and it may be that a four-year screening interval is not frequent enough to detect these cancers in time to prevent them from killing the patient. There is a need for studies to investigate this possibility, in my opinion.

As far as The Netherlands is concerned, Bangma (2009, page 3) states that offering screening to the individual is allowed in most European countries, with the exception of The Netherlands.

In both the U.S. PLCO Cancer Screening Trial and the ERSPC, the issue of contamination of the control group of non-screened men (because control-group men got themselves screened outside the framework of the study) was a serious one.

In The Netherlands, it would probably have been much harder for men in the control group to be contaminated in this way, with the result that statistical comparisons between the screened group and the control group would have been much more valid than in the other countries (including the USA). There is a need for studies to investigate ways of dealing with the issue of contamination, in my opinion.

Two other questions that need to be addressed are the harms of diagnosis and treatment, and also the associated costs. As far as the harms are concerned, I believe that any decision as to whether the harms outweigh the benefits is one that the individual man needs to be allowed to make after consulting a doctor.

This is not a decision that researchers (especially females such as Virginia Moyer) or governments have the right to make on their behalf. The decision as to whether the financial costs are bearable is a political one which should take into account the balance between the amounts spent on research into, teaching about, prevention of, and treatment of men's health conditions, in comparison to women's health issues.

The above remarks, in my opinion, cast serious doubt on the validity of the recent conclusion of both Moyer (2012) and of the Health Committee of the New Zealand House of Representatives that PSA-based population screening for prostate cancer should not be implemented.

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## Usage of renal function equations to guide prescribing in general medicine

We recently surveyed doctors working in the Department of General Medicine, Christchurch Hospital/Princess Margaret Hospital (Christchurch, New Zealand) regarding their usage of equations for estimating renal function in the setting of drug dosing. The Department managed 14,000 acute admissions in 2012 (MSS Lee, Christchurch Hospital, NZ, personal communication, 2013).

Estimating an individual's renal function is a key step in the individualisation of the dosage of renally-cleared drugs.<sup>1,2</sup> This is especially important for those drugs with a narrow therapeutic index, such as dabigatran and gentamicin. The Cockcroft-Gault equation<sup>3</sup> has been in use for several decades<sup>4</sup> and is part of the guidance from the Food and Drug Administration for pharmacokinetic studies in the setting of renal impairment.<sup>5</sup> However, values of estimated glomerular filtration rate (eGFR), which are routinely reported by laboratories in association with plasma creatinine concentrations,<sup>6</sup> represent a convenient alternative for clinicians to use.

The laboratory-reported eGFR is typically calculated either using the Modification of Diet in Renal Disease Study (MDRD) equation,<sup>7</sup> or more recently, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.<sup>8</sup> The performances of these equations for drug dosing have been debated in the literature, and it is unclear whether any particular equation is superior in all settings.<sup>9</sup> It is also unclear what equation(s) clinicians use during prescribing. Knowledge of this could help guide efforts in improving the use of renal function estimation for dose-adjustment.

An electronic questionnaire (<http://www.surveymonkey.com/s/Q2CC359>) was sent to all 67 doctors working in the Department in April 2013. There were 34 responses (51% response rate), including 13 specialist general physicians and 21 junior doctors.

When prescribing renally-cleared medications, most doctors (20/34, 59%) reported mainly using the laboratory-reported eGFR to guide dosing (Table 1). Significantly more respondents used the laboratory-reported eGFR for guiding the dosing of dabigatran (71%) compared with gentamicin (35%) (McNemar's  $\chi^2(1) = 8.6$ ,  $P = 0.0018$ ). These results reflect local prescribing guidelines that highlight the use of the Cockcroft-Gault equation when prescribing gentamicin, but not dabigatran.

**Table 1. Usage of renal function equations by medication (total n=34 respondents)**

Renally-cleared medication	Mainly laboratory eGFR*, n (%)	Mainly Cockcroft-Gault equation, n (%)	Both equally, n (%)	Other, n (%)
Any <sup>†</sup>	20 (59)	5 (15)	8 (24)	1 (3) <sup>‡</sup>
Dabigatran	24 (71)	3 (9)	1 (3)	6 (18) <sup>§</sup>
Gentamicin	12 (35)	16 (47)	2 (6)	4 (12) <sup>§</sup>

\* Estimated glomerular filtration rate; <sup>†</sup> Examples of commonly prescribed renally-cleared drugs were provided in the survey; <sup>‡</sup> Respondent stated using a combination of creatinine, age, body weight and gender; <sup>§</sup> Responses consisted of "not prescribed yet" and "pharmacy consultation".

The survey also included a question asking respondents to recall the units of the laboratory-reported eGFR value. A minority (7/34, 21%) correctly stated that these were mL/min per 1.73 m<sup>2</sup>. A further 18% (6/34) noted that body surface area (BSA) was part of the eGFR units, whereas the majority (62%, 21/34) made no mention of this aspect. This apparent deficiency is important to identify, as the laboratory-reported eGFR value should be adjusted for the individual patient's BSA when used for drug dosing, especially at the extremes of size.<sup>10</sup>

A BSA of 1.73 m<sup>2</sup> represents an individual with a height and weight of approximately 170 cm and 65 kg, respectively. Thus, using the 'raw' laboratory-reported eGFR value potentially leads to underestimation of renal function and thus under-dosing in the obese patient, and the converse in the underweight patient.

These survey results, of the prescribers in a department that handles a large number of admissions annually, are the first that we are aware of to demonstrate that the laboratory-reported eGFR is more commonly used for drug dosing than the Cockcroft-Gault equation. This reflects the convenience to the clinician of using the former, which is routinely calculated by the laboratory, compared with the latter, which the laboratory does not routinely generate.

Further, we have highlighted the need to inform prescribers that individual patient size should be considered when using the laboratory-reported eGFR values for drug dosing. These results have been presented to the Department, and local prescribing guidelines are being updated to remind prescribers of this aspect of using the laboratory-reported eGFR values.

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## How do adolescents perceive plain packaging?

The New Zealand Government has stated its intention to follow Australia and introduce plain packaging of tobacco products, a policy that would see dissuasive imagery and colours replace the eye-catching and aspirational pack designs that currently advertise smoking to young people.<sup>1-3</sup>

Although the success of Australia's policy will not be evident until medium-term trends in youth smoking initiation can be analysed, emerging evidence suggests two things. First, the tobacco industry's claims about extended transaction times are baseless<sup>4</sup> and, second, plain packaging has so successfully de-normalised smoking that smokers believe the quality of their cigarettes has declined.<sup>5</sup>

These latter findings confirm earlier experimental studies that found smokers perceived progressively plainer packs as less attractive and thought the cigarettes these contained were of lower quality and less likely to taste satisfying.<sup>6-9</sup>

Several studies have documented adults' support for plain packaging;<sup>10-12</sup> however, we know less about how adolescents perceive this measure. As plain packaging's main aim is to reduce smoking initiation and addiction among adolescents, it is timely to explore their support for this policy.

To examine this question, we used data from four years of the ASH Year 10 survey (2009–2012). Conducted annually, these school-based surveys ask 14 and 15 year olds about a variety of current and proposed policy measures. Full details of the survey methodology and sample are provided in Healey et al., 2013.<sup>13</sup>

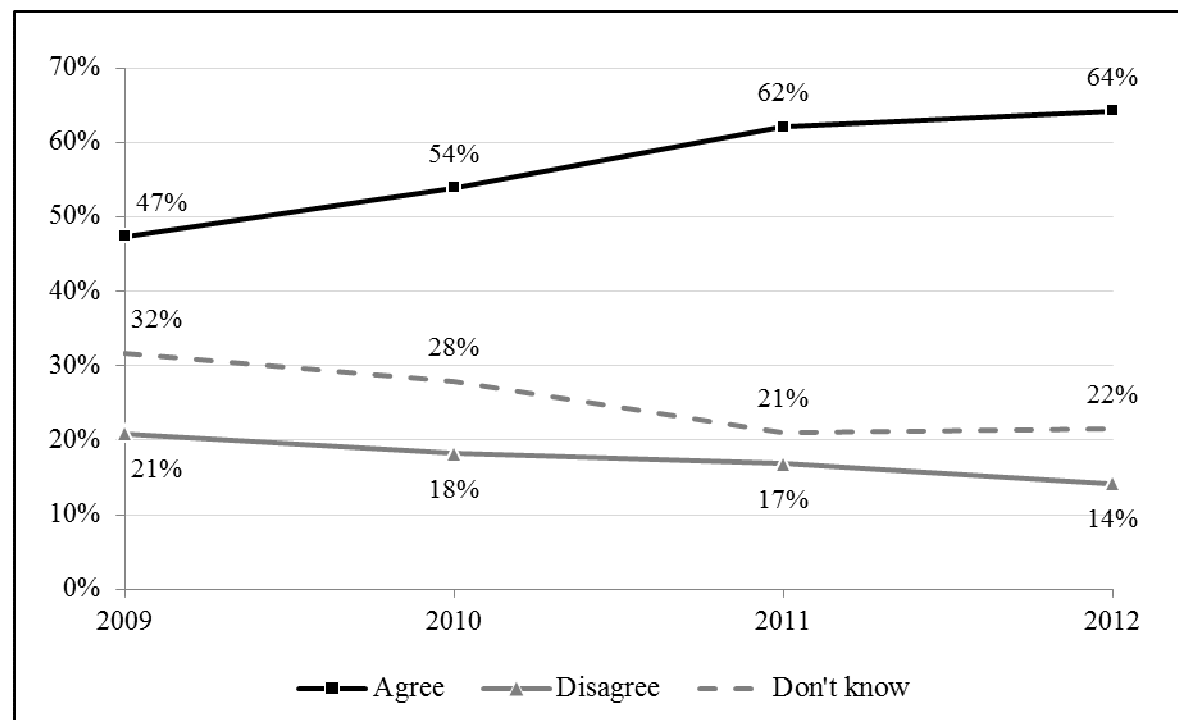
Each year, between 25,000 to 30,000 students complete the ASH survey and, from 2009 onwards, respondents indicated their agreement or disagreement with statements exploring plain packaging. In 2009, the statement tested was: "Tobacco companies should not be allowed to promote cigarettes and tobacco by having different brand names and packaging" and in 2010 it was "Tobacco companies should not be allowed to promote cigarettes and tobacco by having different symbols, phrases, names or colours on the packaging". In 2011 and 2012, the question was "Tobacco companies should not be allowed to promote cigarettes and tobacco with cool looking packs".

The term 'plain packaging' was not specifically used in the ASH surveys because it was not widely known or clearly understood when the statement was first introduced. Since then, the wording has been refined to encompass aspects of plain packaging and to reflect its purpose of recruiting new smokers (using 'cool looking packs').

Agreement with the statements tested suggests adolescents support packaging that removes key design elements designed to promote the smoking experience; i.e., plain packaging.

Figure 1 illustrates how support for plain packaging among 14 and 15 year olds has increased over time.

**Figure 1. Support for plain packaging among 14 and 15 year olds: 2009–2012**



**Note:** Estimates are weighted by ethnicity, and school decile-based socioeconomic status to align with known population parameters. Weighting also standardises the age distribution to account for variations in field timing in different years. The maximum confidence interval across all of the data points presented was  $\pm 1.4\%$ . Confidence intervals were adjusted for clustering at the school level.

Figure 1 shows strong and growing support for removing appealing brand imagery from tobacco packaging. Support for plain packaging has always outweighed opposition and has grown rapidly and significantly over time, from 47% in 2009 to 64% in 2012, while opposition has declined from 21% to 14%; uncertainty has also declined (from 32% to 22%).

By 2012, there was majority support for plain packaging from all demographic groups, as shown in Table 1.

These results provide the first evidence of New Zealand adolescents' support for plain packaging and reveal that this is very similar to that of adults, which was recently estimated at 69% [10].

Furthermore, the most recent dataset (2012) shows majority support among all demographic groups, which suggests adolescents, regardless of their age, gender, ethnicity, or socioeconomic status, recognise and endorse the concept of plain packaging.

Evidence that both adults and adolescents strongly support plain packaging suggests politicians could make more rapid progress in implementing this important public health strategy.

**Table 1. Support for plain packaging by demographic characteristics**

Demographic trait	2009 Estimate (95% CI)	2010 Estimate (95% CI)	2011 Estimate (95% CI)	2012 Estimate (95% CI)
<b>Age</b>				
<b>14 years</b>	48.0 (46.7–49.3)	54.9 (53.6–56.2)	63.3 (62.0–64.7)	65.3 (64.1–66.6)
<b>15 years</b>	46.3 (44.8–47.8)	52.1 (50.7–53.5)	59.7 (57.8–61.7)	62.3 (60.5–64.0)
<b>Gender</b>				
<b>Male</b>	49.1 (47.6–50.5)	55.1 (53.6–56.5)	60.8 (59.3–62.4)	62.1 (60.7–63.5)
<b>Female</b>	45.9 (44.4–47.4)	52.7 (51.1–54.2)	63.3 (61.5–65.0)	66.4 (64.8–67.9)
<b>Ethnicity</b>				
<b>NZ European</b>	52.2 (51.0–53.4)	58.8 (57.7–60.0)	68.1 (66.9–69.3)	70.9 (69.8–72.0)
<b>Maori</b>	35.1 (33.2–37.0)	42.2 (40.6–43.8)	49.2 (47.2–51.2)	50.6 (48.8–52.4)
<b>Pacific</b>	42.0 (39.6–44.4)	45.2 (43.0–47.4)	54.2 (51.3–57.0)	54.8 (52.2–57.3)
<b>Asian</b>	52.6 (50.2–55.0)	59.8 (57.3–62.3)	63.7 (61.5–66.0)	67.0 (65.0–69.0)
<b>Other</b>	47.7 (41.4–54.1)	60.0 (54.3–65.7)	68.9 (61.6–76.2)	67.2 (63.9–70.6)
<b>Socioeconomic status</b>				
<b>High</b>	52.2 (50.6–53.8)	58.9 (57.3–60.5)	67.6 (65.7–69.5)	69.5 (68.1–70.9)
<b>Medium</b>	47.0 (45.4–48.5)	54.1 (52.7–55.4)	61.6 (60.2–63.1)	64.3 (62.7–65.8)
<b>Low</b>	38.3 (36.2–40.4)	43.2 (41.0–45.3)	51.3 (48.4–54.2)	52.9 (50.2–55.5)

We call on the New Zealand Government to act now; there is compelling experimental, qualitative and survey evidence that plain packaging will reduce smoking's appeal to young people, and widespread public support for the policy exists.

Deferring the implementation of plain packaging until World Trade Organization and Bilateral Investment Treaty litigation has concluded will simply delay progress towards the 2025 goal of a smokefree New Zealand and condemn more young New Zealanders to the unnecessary suffering caused by smoking.

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## Response to Hadorn et al on increasing recruitment into randomised clinical trials

The proposal by Hadorn and colleagues to increase recruitment into randomised clinical trials by changing the nature of the consent procedures has been criticised by experienced cancer specialists as being both unnecessary and wrong.<sup>1,2</sup>

In support of these criticisms, we think it is worth exploring further the nature of the proposed consent arrangements and the moral problems they entail. Hadorn et al are aware of the controversial moral stance in their proposals and themselves have suggested that patients, ethicists, and clinicians should examine them in detail before implementation is considered. But a number of scholars have already looked closely at ethical problems in theory and practice with post-randomisation consent (PRC). These ethical problems are so serious that we believe they make a cogent case for dropping the proposal without further consideration.

Jackson and colleagues correctly characterise the moral wrong as subordinating the right to consent to treatment to the desire to achieve recruitment targets. “For the doctor sitting with the patient the principles of honesty and respect for autonomy are paramount.”<sup>2</sup> Furthermore, there is a strong argument, not referred to by Hadorn et al, that the lack of candour to patients in the PRC design is the *reason* for any increased recruitment, and thus it tempts clinicians into dishonesty.<sup>3</sup>

The proposal from Hadorn et al is to seek consent from patients who are randomised to the experimental treatment, but not from those randomised to the standard treatment (single randomised consent design). The more patients that refuse the experimental treatment, the more bias is introduced, unlike the conventional design.

Altman et al have explained the nature of the bind that the use of the PRC design puts doctors in: “By definition, they [doctors] should be participating in a trial only if they have substantial uncertainty about which treatment is best, yet they have to give information to patients in the knowledge of the treatment that the patient has already been allocated and also knowing that it is in the interests of the trial for the patient to accept that allocation.”<sup>4</sup> The design provides subtle encouragement to investigators to provide a biased presentation of the relative merits of the treatments.

The other moral problem in the PRC design: of not telling patients who have been randomised to the control (standard treatment) arm that they are in a trial at all, is in our view given insufficient weight by Hadorn et al. They portray the issue as one of using patients’ data without consent and equate it, inappropriately, with the use of routine data in observational studies.

The problem is not so much the use of data, as of not telling these patients the truth: which is that their treatment has been decided at random and, in many cases, that their treatment options have been narrowed. It is not true that “nothing has changed” for these patients. They had their treatment decided in the way it was because they were part of a clinical trial. Moreover, as Jackson et al note, there are often several versions of standard care and clinicians would be restricted in the treatment options they could

discuss. A “double randomised consent” design for PRC has been described,<sup>3,4</sup> in which consent is also sought from the control patients. This is clearly better, but also runs into the problems described above for the experimental arm.

The PRC design could only ever be ethical in clinical settings where there is evidence that if patients had been informed of the randomisation they would have been happy to participate. If it were really true, as Hadorn et al claim, that a major reason for lack of recruitment is unwillingness to be allocated to the control arm, they have already claimed that some patients would not be happy being in a standard care arm; thus patients would only be agreeing to standard care because they had not been properly informed.

If equipoise truly holds, and patients truly are reluctant to be randomised to the control arm, this should be met with a more concerted effort to explain the current evidence on risks and benefits of the treatments under comparison rather than withholding information. While all trial participants receive some benefits from being in the trial (such as improved quality of care and having a 50% chance of getting the better treatment – which may not be the new treatment), a large part of their willingness to participate is altruism, that others may benefit from their contribution. This too is a value worth protecting.

The uses of the PRC design outside clinical settings in cluster trials tend not to raise the same moral problems. For example, a trial of screening for colorectal cancer in the UK entailed randomising households to an intervention group, who were offered a screening test, or to a control group, who were not; the control group households were not contacted and only mortality records were accessed.<sup>7</sup> In this case, the trial was not in the context of a doctor-patient relationship, there was no contact with the control group, and there was no temptation to provide biased information. Even so, the ethics of PRC designs in cluster trials have been subject to careful evaluation.

The newly released Ottawa Statement on the ethical design and conduct on cluster randomised trials has proposed strict conditions under which it is appropriate to dispense with consent.<sup>5</sup>

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## The Increase of Cancer in New Zealand (part 3)

*Excerpt published in NZMJ 1913 Dec;12(48):599– and written by P. Clennell Fenwick, M.D., N.Z.; M.B., Lond.; F.R.C.S.E., Christchurch*

(Continued from part 2 at <http://journal.nzma.org.nz/journal/126-1382/5838>)

Dr. Alfred Haviland, in this article on Medical Geography, points out that in England cancer is most prevalent along the lower courses of rivers and least frequent on high ground. This substantiates Dr. Hislop's remarks on the locality of the patients' residences.

Soon after the publication of Dr. Hislop's paper, Dr. Alexander Haig wrote to the Journal calling attention to this report. He said: "With such a large introduction of purins in meat and tea, it is small wonder that rheumatism is universal, and since the men introduce more than the women, and are, moreover, somewhat more exposed to damp, it is not extraordinary that the incidence of cancer is increasing most with men."

In a letter he shows that cancer is most prevalent in the richer quarters of London; thus in St. George's, Hanover Square, the richest parish in England, cancer accounts for one death in eight. In Bethnal Green the proportion is one case in twenty. He ascribes this to the purchasing power of the wealthy, who spend their money on meat, while this luxury is impossible to the poorer classes.

In this country the consumption of meat is very large, and the amount of tea, which is drunk, very often with meat meals, is extraordinary. In support of the suggestion that certain diets are often a factor in the origin of cancer, I would like to quote a very interesting article by Dr. Renner on the spread of cancer among the creoles in Sierra Leone, which appeared in the British Medical Journal in September, 1910. He states that cancer is increasing among the creoles but is rare among the aboriginal tribes of that colony.

He says that the creoles consume a large quantity of meat, which is quite unnecessary in the climate, while the aborigines confine themselves to a grain and vegetable diet, and eat very little flesh, and he points out that the creoles can afford to buy European food and the aboriginals cannot. He also mentions that epithelioma of the lips, tongue and cheek is rare among both creoles and aboriginals, and says that the creoles are not great smokers of clay pipes and have good teeth.

Although the aboriginals of all ages are great smokers of clay pipes their teeth are kept beautifully. He notes a distinct degeneration of the teeth among the creole children, but says that this is not noticeable among the aboriginal children, and ascribes this to the fact that the creole children use European articles of food-sweets, preserves, etc. a diet which is not within the reach of the aboriginal children.

## **Tobacco control in the United Kingdom**

This irate *Lancet* editorial was spurred by a WHO report that stated that 2.3 billion people were reached by at least one measure to reduce tobacco use, including warning labels, advertising bans, or high taxes.

Lack of similar actions in the UK are annoying to the editorialist who goes on to say that 'New Zealand's ambitious plan to reduce smoking prevalence to less than 5% by 2025 and Australia's introduction of standardised packaging, which was targeted by cynical legal opposition, have set benchmarks in tobacco control'.

Furthermore, by contrast, 'the UK Government's decision to pause the consultation about the introduction of standardised packaging (citing sparse data, economic grounds, and fears of rises in illicit trade) is a disgrace'.

And finally a recommendation that the UK should join Australia and New Zealand in the fight against tobacco.

Lancet 2013;382:182.

## **Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital**

Specialist units have been proposed to improve outcomes and experience for people with cognitive impairment admitted to hospital and to reduce health and social services resource use. This report concerns a randomised trial to test this issue. 600 patients aged over 65 years who were identified as "confused" on admission to hospital participated.

The patients were randomised to be admitted to a specialist medical and mental health unit or a standard hospital ward. The primary outcomes measured were days spent at home (or in the same care home) in the 90 days after randomisation, patients' experience by direct observation, and satisfaction of family carers with care by telephone interview.

The authors conclude that days spent at home, health status, and service use were no different between settings, but the experience of patients and satisfaction of family carers were improved in the specialist setting. On the down side, inpatient falls were more frequent on the specialist unit (27% vs 18%).

BMJ 2013;347:f4132.

## **Treatment of knee osteoarthritis associated with a meniscal tear**

The proposition evaluated in this study is whether arthroscopic partial meniscectomy for symptomatic patients with a meniscal tear and knee osteoarthritis results in better functional outcomes than nonoperative therapy.

This randomised trial involved 351 symptomatic patients 45 years of age or older with a meniscal tear and evidence of mild-to-moderate osteoarthritis on imaging.

The patients were randomised to surgery followed by postoperative physical therapy or a physical therapy regimen. Physical function testing was evaluated in the patients at 6 and 12 months. The researchers found no significant differences between the study groups in functional improvement at follow-up.

The frequency of adverse events did not differ between the groups. Thirty percent of the patients in the physical therapy group elected to have surgery within 6 months.

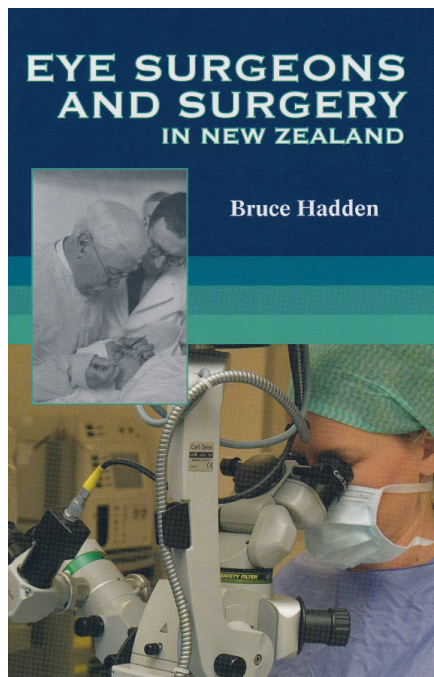
N Engl J Med 2013;368:1675–84.



## Eye surgeons and surgery in New Zealand

Bruce Hadden. Published by Wairau Press, [Random House](#), 2012. ISBN 9781927158036.  
Contains 305 pages.

Bruce Hadden's *Eye surgeons and surgery in New Zealand* (Wairau Press, Random House)—a history of eye surgery in New Zealand—was an unexpected pleasure for me to read. (I acquired a copy of the book as Bruce was posting another off at the local Post Office to the current president of the Royal Australia and New Zealand College of Ophthalmologists.)



The spectrum of development of the speciality is relevant to all specialities. In 17 chapters and just over 300 pages, acknowledgement is made of the talents and tenacity of those who contributed to ophthalmology. Their careers seem to have a common thread—a clarity of vision, and perspicacity, without obvious perspiration, that we all wish to have more of. Their successes are stunning.

Just like the New Zealand Government was the first to buy a plane from Boeing in 1917, Bruce describes new milestones, technology and techniques in ophthalmology, whose advantages were decreed by common sense, that were assiduously taken on board by New Zealanders. Kiwi ingenuity operated long before the collaboration and clear sightedness of randomised controlled trial data.

It almost seems a breath-taking account of the establishment and exponential development of ophthalmology. As a history of ophthalmology it is interesting, because it shows a variety of personalities and interests from the pioneering to the present, characteristics we most want in New Zealanders. It takes us from the first medical practitioner who arrived in New Zealand in 1833, Dr Hocken in 1862 and Dr Thomas Philson in 1845 whose legacies we have in the form of two libraries. The first medical practitioner recorded to have any interest in eyes was Sir David Monro (1842), of 'impeccable medical lineage' (his great great grandfather was the founder of Edinburgh Medical School and both his great grandfather and grandfather were demonstrators in anatomy there).

Ophthalmology owes its birth to Henry Lindo Ferguson (1858–1948) a foundation member of the Ophthalmological Society of Great Britain, and was involved with the founding of the Royal Australasian College of Surgeons.

Sir Randal Elliott (1922–2010), Editor of the *New Zealand Medical Journal* and Chairman of the New Zealand Medical Association, was an ophthalmic surgeon in Wellington, but also 'his influence extended far beyond the eye into the wider fields

of general medical practice, community affairs, road safety, search and rescue, the Order of St John and service in the South Pacific and South East Asia.

Hylton Le Grice returned to New Zealand in 1967 after being senior registrar at Moorfields having ‘worked with Pierse in the design of the first British Keeler operating microscope’ (p 99) gaining large operating experience and assisting with distinguished clients. He served the speciality uniquely with providing lectures to medical students for 14 years single-handed. He served the community as Chairman of Southern Cross, Director of Montana Wines, Director of Metlifecare Ltd, and Chairman of the New Zealand Symphony Orchestra, awarded the OBE in 1995 and CNZM in 2010.

Travel enabled Dorothy Potter (1922–2009) to admire and be influenced by Professor Ida Mann, the first woman to become a professor of ophthalmology in Britain and to become a professor at Oxford University in any subject. Dr Potter served Masterton as a medical ophthalmologist and became the first woman president of the OSNZ in 1984.

Those provincial were by no means ‘provincial’. Dr Geoffrey Orbell (1909–2007), an ophthalmologist, who served Invercargill and Southland, is perhaps best known for his momentous discovery of the flightless takahe in the Murchison Mountains in November 1948 (they had not been seen since 1898). It was more than ‘good luck,’ (p. 132) since he had been fascinated by it ever since his father showed him a stuffed one in the Otago Museum. They were rewarded by seeing the birds, photographing them on the shores of Lake Despair and seeing the sensational report featured in the *Illustrated London News* and *National Geographic*.

Formalisation procedures dominate the latter half of the book, the formation of RANZCO, of which the author, Bruce Hadden was elected the first New Zealand president in 2002. Included is reference to the ‘*annus horribilis*’ of 1998 for the ophthalmologists—the Commerce Commission’s case against them. The book provides much evidence of what can inspire jealousy. It is apparent that ophthalmologists have high standards. One was prepared to say of a peripheral eye clinic, and quoted on the front page of a newspaper, ‘as undoubtedly the worst facility in the country with no sight (*sic*) of improvement’ p. 134.

The remainder of the book focuses on developments and institutions rather than individuals, which includes an account of New Zealand ophthalmologists in the Pacific and (VOSO) – Volunteer Ophthalmic Services Overseas Charitable Trust. Their work is extensive. Professor Charles McGhee arrived in 1999 to take Ophthalmology into the 21<sup>st</sup> Century. Academic development occurred exponentially which includes The W. and B. Hadden Chair in Ophthalmology and Translational Vision Research.

This book is an interesting read not least for the talent, flair, laser-like precision, perspicacity some of which is too hyperpixillated, not showing the true perspiration involved of the ophthalmologists. It is a lovely read that no matter what our speciality captivates and inspires. The excellent quality photographs could have been enhanced by an additional photography of Paul Rosser’s ‘brass plaque’—illustrating all these qualities—the number plate of his car reads ‘Eyelid’.

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