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This Issue in the Journal

Mapping the themes of Maori talk about health
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When asked about their understandings of Maori health and their interactions with the health system, a group of urban Maori talked about topics ranging from traditional medicines to rapport building with doctors. Health was seen as holistic, with an emphasis on wairua (spirit) and whanau (family). Explanations for ill-health touched upon various personal, whanau and societal influences. These insights can help clarify potential misunderstandings within healthcare settings and add to knowledge about Maori health.

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B Mackay

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acceptance would be problematic issues. Most knew about nurse practitioners and had experience of working with a nurse in advanced practice, but expressed uncertainty about the role. More education and discussion with Northland GPs is required to reduce uncertainty and confusion over roles and to promote collaboration.

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The re-emergence of iodine deficiency in New Zealand?

Jim Mann and Elizabeth Aitken

Iodine deficiency disorders (IDDs) present throughout the life cycle (Table 1) and represent a major cause of morbidity on a global scale. As recently as 12 years ago, the World Health Organization (WHO) estimated that 1.6 billion people worldwide were at risk of iodine deficiency. The most damaging effect of a deficiency of this trace element is on the developing brain, and at least 20 million were believed to be suffering from impaired mental function. Thus, iodine deficiency is the world's greatest single cause of preventable brain damage and mental retardation. The detrimental effects on mental performance can have profound social consequences and influence national development. Even in the absence of cretinism, iodine deficiency adversely affects growth and development – physical as well as neuropsychological. Goitre, first described and treated with seaweed and other marine products several thousand years BC in China, is the most obvious of the IDDs, and occurs at lesser degrees of iodine deficiency.

Table 1. The spectrum of iodine deficiency disorders throughout the life cycle[1]

Fetus	Abortions Stillbirths Congenital anomalies Increased perinatal mortality Increased infant mortality Neurological cretinism: mental deficiency, deaf mutism, spastic diplegia, squint Myxoedematous cretinism: dwarfism, mental deficiency Psychomotor defects
Neonate	Neonatal goitre Neonatal hypothyroidism
Child and adolescent	Goitre Juvenile hypothyroidism Impaired mental function Retarded physical development
Adult	Goitre with its complications Hypothyroidism Impaired mental function Iodine-induced hyperthyroidism

The iodine content of plant and animal foods reflects the iodine content of the soil, which is typically deficient in parts of the world where iodine has been leached from the soil by high rainfall or glaciation. In these areas, clinical deficiency is especially prevalent when groups or populations exist largely or exclusively on locally sourced foods and have a low intake of marine foods, which are a rich source of iodine. Goitre is typically seen when intake is less than 50 µg iodine/day and cretinism with intakes by the mother of 30 µg or less per day. Usual intakes range between 80–150 µg/day, though some countries (eg, Canada and Japan) have appreciably higher intakes. New

Zealand has a very low level of iodine in the soil in many areas, so not surprisingly goitre was endemic in many parts of the country. In the early years of the last century, surveys suggested that about one third of school children may have had significant thyroid enlargement, with an approximately comparable number having some increase in size of the gland.[2] Iodisation of salt, first implemented in Switzerland in 1920, was introduced in New Zealand in 1924. At first, introduction concentration was too low and little was achieved. However, the concentration was increased in 1938 and remains at a similar level today. This is believed to have contributed to the dramatic reductions in goitre rates. In 1953, surveys of school children suggested that rates had fallen to about 1%. This observation, together with the results of further surveys showing improved iodine status in the 1960s and 1980s, led to reduced attention to iodine deficiency as a health issue in this country.[3–5] Iodised oil by injection, iodine supplements, and iodisation of bread, drinking water, sugar and animal feeds are methods that have also been used successfully in some countries to improve iodine intake.

Interest in iodine deficiency as a possible public health issue was rekindled in 1997 by the publication of a survey of adult blood donors in Dunedin and the Waikato carried out during 1993 and 1994.[6] Iodine status is typically assessed by determining 24-hour urinary iodide excretion, based on the assumption that approximately 90% of iodine intake is excreted in the urine. Information regarding iodine status can be supplemented by measurement of circulating thyroid hormones and thyroid stimulating hormone (an especially useful indicator in neonates), and assessment of goitre rates using simple clinical criteria or thyroid volume by ultrasonography. When excluding subjects taking dietary supplements including iodine, median urinary iodide excretion was 70 µg/day for men and 59 µg/day for women, implying an intake perilously close to the suggested 'critical low intake' (CLI) for adult men and women, 60 µg/day.[7] The CLI is defined as that level below which virtually all people would be at high risk of having an inadequate intake. Below an intake of about 50 µg/day, absolute uptake of iodide falls, the iodine content of the thyroid decreases and risk of goitre increases appreciably. In a later study in Otago adults,[8] although blood concentration of thyroid hormones was normal, when subjects were grouped according to urinary iodine, the low iodine group (46 ± 9 µg/day) had a higher mean thyroid volume than the medium (74 ± 8 µg/day) and high (136 ± 54 µg/day) groups. This suggests that a mean excretion of around 75 µg/day, representing an intake of at least 85 µg/day, is necessary to prevent the consequences of an inadequate iodine intake. Furthermore, using the World Health Organization estimate for iodine deficiency disorders, 5% were at severe risk (median urinary iodide excretion <20 µg/l), 26% were at moderate risk (median excretion 20–49 µg/l), and half were at mild risk (median excretion 50–90 µg/1) of IDD.

Arguably of greater concern were the findings of Skeaff, Thomson and Gibson,[9] published at the end of 2002, relating the iodine status of three hundred 8 to10-year-old school children in Dunedin and Wellington taken in 1996 and 1997. In this study, 3.6% (95% CI: 1.1–6.2) of the children had urinary iodine levels less than 20 µg/l; 31.4% (95% CI: 24.2–38.6) less than 50 µg/l; and 80% (95% CI: 74.1–85.3) less than 100 µg/l, representing severe, moderate and mild IDD respectively. An incidence of goitre greater than 5% is considered endemic, and Skeaff et al found that 11.3% of the children had thyroid volumes greater than the upper limit of normal using 2001 WHO cut-offs by age. Although 83% reported that iodised salt was used in the home, about

one third of the children's caregivers did not use iodised salt in cooking and about half of the children did not use iodised salt at the table. Milk and dairy products were the only potentially good sources of dietary iodine consumed daily, though most consumed red meat, chicken and eggs at least weekly. The New Zealand Children's Nutrition Survey, currently underway, is based on a representative national sample and should help to confirm or refute these findings, but it is noteworthy that successive New Zealand Total Diet Surveys between 1987 and 1998, using modelled (or simulated) diets, have suggested a reduction in iodine intakes in adults and in children.[10] It is important, therefore, to consider possible explanations for the change in intakes, potential clinical relevance, and appropriate public health measures.

Three plausible reasons have been offered to explain a reduction in intakes. First, there has been a decline in the use of iodophors as sanitisers in the dairy industry over the past two decades.[11,12] It is quite conceivable that this 'contaminant' of milking equipment provided a significant source of iodine through intake of milk and dairy products. The use of alternative sanitisers has resulted in reduced intake from this source. A second reason is that people may indeed have heeded the public health advice to reduce discretionary intake of salt, with a concomitant reduction in iodine. However, the findings of Skeaff et al,[9] that iodised salt was not always used in home cooking and at the table, also suggest an element of complacency with regard to the importance of iodine in the New Zealand diet. The third possible factor is that there are more meals eaten away from the home and pre-prepared foods purchased (ie, less food prepared in the home) and salt used in manufacturing is usually non-iodised. The fact that the most obvious clinical consequences of iodine deficiency had all but disappeared may well have led to consumers not ensuring that discretionary salt was always iodised.

The clinical consequences of mild iodine deficiency are uncertain. There is no doubt that measurable functional changes in iodine metabolism occur and risk of goitre increases as average population intakes move downwards towards the CLI; indeed this observation forms the justification for the level set. Even though there is no clear evidence of impaired intellectual function or growth retardation at marginal levels of intake, these observations together with the apparent reduction in intakes warrants some action. This is especially so if the decreasing levels of intake are confirmed by the Children's Nutrition Survey, the first truly national survey of iodine status to be undertaken in New Zealand.

What action should be considered? Iodine supplements are not a good idea as a public health measure. The safe upper limit of intake has been set by various authorities as between 1000 and 2000 µg daily. While adverse effects of a high intake are unlikely when the thyroid gland is healthy, those who habitually have a low intake as well as those with abnormalities of the thyroid gland may respond adversely. People over the age of 40 years with multinodular goitre are at particular risk of iodine-induced hyperthyroidism. Consumption of seaweed and other iodine-containing dietary supplements, such as kelp tablets, may lead to intake beyond the safe upper limit and are therefore not recommended for use in New Zealand. The first and immediate approach is probably to remind health professionals and the public of the importance of this trace element in the human diet and that there is increasing evidence for re-occurrence of iodine deficiency in New Zealand. Milk and low-fat dairy products have traditionally been regarded as good sources and remain important, but with the

reduction in use of iodophors, are not as good a source as they used to be. Eggs, fish and shellfish are good sources of iodine. Foods containing seaweed, such as sushi, are finding their way into the diet of many New Zealanders and are of course excellent dietary sources, even though concentrated seaweed supplements are not recommended. Advice to limit the discretionary intake of salt continues to be an important component of dietary guidelines, and concern over low intakes of iodine should not influence such advice. However, the benefits of always purchasing and using iodised salt for home use should be emphasised. The joint Australia New Zealand Food Standards Code contains Standard 2.10.2 Salt and Salt Products, which includes the composition of iodised salt and iodised reduced sodium mixtures, as shown in Table 2.

Table 2. Iodine content of iodised salt and iodised reduced sodium salt mixtures

Iodised salt must contain potassium iodide or iodate, or sodium iodide or iodate equivalent to no less than 25 mg/kg of iodine; and no more than 65 mg/kg of iodine.
Iodised reduced sodium salt mixtures must contain potassium iodide or iodate, or sodium iodide or iodate equivalent to no less than 25 mg/kg of iodine; and no more than 65 mg/kg of iodine.

In the future, consideration will need to be given to the possibility of mandatory iodisation of one or more staple foods. Of no help to the public health of New Zealanders is the widespread promotion of non-iodised forms of salt by key people such as chefs, in particular those presenting cooking programmes to the nation on television. Where salt is used in food preparation or added to food it should always be iodised salt.

Continued monitoring of the iodine status of the food supply and population is imperative. It is encouraging that work is being undertaken in New Zealand with the commencement of the joint Australia New Zealand review of nutrient reference values, as well as a joint Ministry of Health and New Zealand Food Safety Authority project to address the re-emergence of iodine deficiency in New Zealand. As any change in the fortification of foods with iodine is now managed by Food Standards Australia New Zealand (FSANZ), this issue will be the first significant public health intervention in New Zealand for this agency to manage.

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Strike action by senior medical staff in Timaru – how did this come about?

John Rietveld

Strike action by senior medical staff has never occurred in New Zealand until now. It has been underway in Timaru Hospital since 3 February 2003, in the form of withdrawal of elective services one day a week, progressing through the days of the week over a five-week period.

The decision by senior medical staff to take formal industrial action was not taken lightly, and was preceded by long and heated debates until all alternative avenues of dispute resolution were exhausted.

How did this situation come about?

The collective senior medical staff contract at Timaru Hospital expired on 1 July 2002. Negotiations for a new contract were immediately instigated with the aid of the Executive Director of the ASMS, Ian Powell. Right from the beginning, it was clear the negotiation was going to be difficult, with management dismissing outright the senior medical staff's concerns and also rejection of their new contract offer. A counter offer tabled by Timaru Hospital management was in fact a disguised reduction in salary with no attempt to address the senior medical staff concerns. Over a period of six months, repeated discussions clearly showed that the Timaru Hospital management team was not even prepared to offer a salary increase to cover the inflation rate and they had no intention of changing the status quo on any other issue.

The salary of the senior medical staff at Timaru Hospital is at the lowest end of the national pay range, with the majority of the staff at the lower end of the scale, eg, a staff member with 25+ years' continuous service with Timaru Hospital would be at Step 7 of the 15-step scale. These low remuneration rates have largely come about as the result of the archaic and heavy-handed management approach to contract negotiation over the years and the threat of closure of the Hospital if it exceeded its fiscal budget allocated by the Government.

Associated with this are years of systemic dismissal by hospital management of the concerns and problems of senior staff. More recently, these included issues such as the lack of hospital beds to meet clinical demands, the lack of modern equipment, the onerous nature of the on-call roster, the failure to agree on an updated job size and description, the poor rate of remuneration resulting in retention and recruiting difficulties, and the lack of junior staff support. Previous dialogue with management on these issues had fallen on deaf ears. The senior medical staff felt it was time to make a stand, as these issues had reached a crisis point and could not be dismissed again.

The main issues that needed addressing were:

- **The onerous nature of the on-call roster for senior medical staff.**
  A large number of the medical staff are on call 1:3, or less in specialties with heavy call-back requirements.
- **A failure to reach mutual agreement over job sizing and job descriptions.**
  A large number of senior staff job sizes and descriptions were nearly 10 years out of date and negotiations have failed to result in mutual agreement upon their revision.
- **The lowest pay rates of senior medical staff in the nation.**
  Adequate pay is important to retain staff and recruit new staff. We believe that the South Canterbury DHB has no unique entitlement to underpay its senior medical staff.
- **Lack of registrar cover.**
  There is only one part-time registrar in Timaru for the entire hospital, yet for an equivalent demographic area with the same population, hospital size, and number of senior staff, there would be twelve registrars employed; for this lack of junior staff support we receive minimal to no compensation.

We were able to come to an agreement with management that they would look into employing more staff to address the onerous nature of the rosters in the areas in which the highest call back occurred, namely orthopaedic surgery and general surgery.

Management also made an undertaking to go into formal negotiations on updating job sizing and job descriptions.

Management also agreed to address the pay issue by agreeing to an increase equivalent to our neighbouring DHBs, but would not address the issue of our position at the bottom of the national pay scale.

The lack of registrar cover and junior staff support was not considered to be worth any offer by management, despite our insistence that this was the key issue. Despite multiple requests by senior medical staff for independent arbitration, or for the Board and Board Chairman to become involved, management were not prepared to discuss these options or even contemplate other methods of arbitration. This left us with no choice but to resort to industrial action.

Previous votes of no confidence in hospital management by senior medical staff were of no merit, so this avenue was not pursued. Mass resignation was considered, but it was agreed that industrial action in the form of one-month rolling strikes of all elective services (all acute services would remain unaffected) would be the most effective course of action and the least disruptive to our patients.

Strike action was not entered into lightly and has not been without its toll of the senior staff. On instigation of the strike action, we were overwhelmed by the enormity of the support from the people of South Canterbury. We received full support from the public, the local media, and all of our patients.

Unfortunately, after two weeks of strike action, management remained intransigent, and their new offer was a retrenchment of a previous offer, so drawing us further apart. By now, public support on the doctors' stance was swelling, with independent bodies, including the local chapter of Grey Power, City councillors, and the Mayor of

Timaru, calling for a public meeting to bear pressure on hospital management to resolve the issues and to help clarify the issues for the general public.

The toll of senior staff became evident, with one of our most senior staff members tabling his resignation as the industrial action, which he supported, seemed to make no difference regarding concerns over lack of junior staff support. This increased the public support for the doctors and put pressure on the District Health Board to either get involved or to instigate independent arbitration.

The medical staff also implored the Minister of Health to require the DHB to become involved. We believe as a result of this intervention that headway was again achieved. Informal talks with the Chairman of the Board were instigated within 24 hours of our request to the Minister. This dialogue included instruction by the Chairman to management to improve their offer, resulting in a new offer, which is under consideration and goes some way to addressing issues. It includes a minimal compensation package, while the possibility of the introduction of registrars and more junior staff is being contemplated.

However, whatever the outcome of this latest offer, the net result has been a complete breakdown of any confidence and trust the senior medical staff had in the hospital management team. These wounds will take years to heal.

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Small abdominal aortic aneurysms: exclusion or observation?

Tim Buckenham

The natural history of abdominal aortic aneurysms (AAAs) is to expand, and the risk of rupture is primarily determined by aortic diameter. The relationship between size and rupture describes a parabolic curve, indicating that risk of rupture becomes increasingly probable with increasing diameter. The out-of-hospital mortality of ruptured AAAs is approximately 75%, and of those who arrive at hospital for surgical repair mortality is around 40%. The surgical mortality for elective repair of abdominal aortic aneurysms is approximately 2.5% to 6%, with 5.8% being the all-cause mortality within 30 days as reported by the mixture of vascular and general surgeons contributing data to the UK Small Aneurysm Trial.[1] This figure is probably applicable to the New Zealand situation.

The management of AAAs is to prolong life by preventing rupture, conventionally by surgical exclusion. The mortality burden of surgical repair must be weighed against the risk of rupture. This equation is relatively easy for aneurysms with a maximum antero-posterior diameter in the transverse plane equal to or greater than 55 mm, for which the annual risk of rupture is approximately =10%.[2] For aneurysms measuring 30 mm to 54 mm, there has been considerable conjecture as to the merits of surgical repair and the optimal treatment strategy has been unclear. The management issues relating to aneurysms of this size are commonly encountered, as the prevalence of AAAs in men over 60 is approximately 1.5% to 3%.

The publication of the long-term outcomes of immediate repair compared with surveillance of small AAAs by the UK Small Aneurysm Trial Participants,[3] has clarified the management of AAAs between 30 mm and 54 mm in diameter. In this trial, patients with asymptomatic aneurysms between 30 mm and 54 mm were randomized to early surgery or ultrasound-based surveillance. In the early surgery group, there was an immediate mortality burden related to surgery of 5.8%, but by five years mortality in both groups was equal.[1] However, at nine years there was a small survival advantage for the early surgery group.[3] This was initially thought to be due to increased mortality in the surveillance group as a consequence of the larger aneurysm size in older patients who underwent delayed surgery manifesting itself as an increased perioperative death. This was not apparent when the perioperative mortalities were compared. A major difference between the two groups was in cessation of smoking; in the surgical group the major abdominal operation was a significant impetus to cease smoking, whereas in the surveillance group significantly fewer patients desisted from smoking. Smoking cessation results in a reduction of mortality from cardiovascular causes and this was thought to explain the small difference in total mortality between the two groups.

The results of the UK Small Aneurysm Trial have clarified the options for management of patients with small AAAs, with surveillance being a suitable option and surgery deferred until the aneurysm reaches 55 mm, becomes symptomatic, or

shows rapid expansion. The advantage of the surveillance option is that approximately 25% of patients with AAAs will never require aortic repair, resulting in a considerable reduction in the operative burden. There are, however, a number of issues raised by this study.

First, patients in the operative group described an increase in their perception of wellbeing,[4] and the corollary of that is that patients from the surveillance programme may feel anxious about their aneurysm, many patients perceiving it to be a time bomb. Anxiety may cause a reduction in quality of life, and would be obviated by surgical repair.

Second, surveillance requires a robust protocol to ensure that all patients enrolled are scrupulously followed. Patients who do not attend or have moved to an area that does not offer a surveillance programme are at risk, as their aneurysms may go unmonitored and expansion may be undetected. It would not require many patients lost to follow up resulting in rupture to show a survival advantage for surgery. This is particularly valid in New Zealand, where aortic aneurysm surveillance programmes are inconsistently applied across the country. The role of the general practitioner here is crucial in order to maintain their patients on aortic surveillance in the case of geographic relocation.

Third, it is impossible to individualise risk of aneurysm rupture, and there will always be patients who will rupture whilst on surveillance.

Finally, there are significant issues relating to management of women with AAAs. In the UK Small Aneurysm Trial, the risk of fatal rupture for women was four times that of males although the absolute risk was still low, and it may be that the threshold of 55 mm that has been defined for intervention is too high for women. What the data have allowed is for clinicians to adopt a non-operative management course for men with asymptomatic aortic aneurysms between 30 mm and 54 mm, which should be combined with a robust surveillance programme and encouragement to desist from smoking. This should result in no mortality disadvantage at nine years, but a reduction in the number of surgical repairs. It is less clear whether this advice can be applied to women.

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Mapping the themes of Maori talk about health

Fiona Cram, Linda Smith and Wayne Johnstone

Abstract

Aim This paper reports the findings of a qualitative research project that investigated: how Maori talk about health; Maori health; and Maori experiences of interacting with both mainstream and Maori providers of healthcare.

Methods Twenty eight self-identified Maori were recruited from urban, marae-based healthcare services. Rich descriptions of commonly occurring themes were used to examine participants' experiences, explanations and ideas.

Results Twelve themes provide an overview of how Maori health is conceptualised, the importance of 'traditional' concepts, the experiences of Maori within mainstream healthcare, and Maori health promotion mechanisms.

Conclusions Providing holistic healthcare to Maori in a respectful and collaborative way will provide opportunities for health professionals to have a positive impact on the health of individuals, their whanau and, in turn, their communities, hapu and Iwi.

The present research began with our interest in how Maori health was being talked about, thought about, and experienced by urban Maori. The study was part of a larger study in which Pakeha researchers also interviewed Pakeha general practitioners (GPs) about Maori health.[1]

Descriptions of a Maori view of health are invariably holistic and centred on whanau health and wellbeing rather than the health of the individual.[2–4] Cultural concepts and practices, such as tapu and noa and the ritual of tangi, have been described as key components, as has the use of karakia and processes around food, exercise and illness.[3,5,6] These descriptions have historically been formed by Maori and have, in turn, informed Maori, developing over time as our understanding has grown of what promotes and what undermines good health and wellbeing. For example, a view of Maori health that once encompassed tinana (the physical element), hinengaro (the mental state), wairua (the spirit), and whanau (the immediate and wider family), is now contextualised within te whenua (land providing a sense of identity and belonging), te reo (the language of communication), te ao turoa (environment), and whanaungatanga (extended family).[3,7]

Practices and cultural concepts that are imperative to Maori health and wellbeing have, however, often been undermined by dominant Pakeha views on health.[8] Maori also report perceptions of Pakeha healthcare that are the legacy of past negative interactions between Maori clients and Pakeha health professionals. These perceptions include suspicions about treatment, the reluctance to even engage in an interaction with health professionals, and behaviour referred to in the sociological literature as resistance.[9] Such actions have been interpreted by some as evidence of whakamaa, the notion of culturally appropriate shame or shyness.[10] The actions may also be part of a more general reaction to being treated in a patronising or paternalistic way.[7,11]

The impact of Maori engagement with mainstream health structures on Maori understandings of Maori health can be gauged by how active such perceptions are in everyday talk about health among Maori. The present study was also concerned to discover if any of the concepts embodied in descriptions of Maori health are employed in the talk of Maori informants in discussing Maori health. This will provide a picture of how active these concepts are among Maori in the contemporary setting.

A major feature of the current research was that it was carried out using Kaupapa Maori methods; namely, from the perspective that a Maori world view is both valid and legitimate. Kaupapa Maori is 'by Maori, for Maori' and is inherently about cultural survival and tino rangatiratanga (self-determination).

In this sense, Kaupapa Maori is 'a theory and an analysis of the context of research which involves Maori and of the approaches to research with, by and/or for Maori'.[12] A Kaupapa Maori approach does not exclude the use of a wide range of methods, but rather signals the interrogation of methods in relation to cultural sensitivity, cross-cultural reliability, useful outcomes for Maori, and other such measures. In this context, the use of in-depth interviews enabled us to collect people's views on Maori health at all levels, from personal experience, to community and political perspectives.

Methods

The present study used qualitative methods within a Kaupapa Maori approach. Semi-structured interviews were recorded with 28 Maori (aged 17 to 75 years) in urban Auckland, who were recruited through marae-based health programmes. Marae-based health programmes were selected as a starting point as it was found that Maori using these programmes have experienced something of both Western and Maori health practices. In this way, we would be able to talk to people about the similarities and differences between mainstream and Maori health services.

Interviews with participants followed an open-ended format; the interviewer raising relevant topic areas and encouraging participants to talk rather than pursuing set questions. The topics discussed were:

- What is Maori health?
- Differences between Maori health and the health of the rest of the nation.
- Personal experiences with doctors and other healthcare providers.
- Experiences of family and friends.
- Traditional Maori health practices.

The interviews were transcribed verbatim, checked against the audiotape, and returned to participants for approval before inclusion in the database. Participants were given pseudonyms and identifying markers were masked to preserve confidentiality.

One of our roles as researchers working within a Kaupapa Maori framework is to listen to and document Maori experiences and meanings.[13] As researchers, we carry the responsibility of re-presenting the realities of participants to wider audiences and we take this role very seriously. We therefore use the word 'analysis' cautiously. Our aim is to make space for Maori voices and realities to be heard and considered 'valid'.[14] At the same time, we want to be able to say something, as researchers and analysts, about the society that positions our participants in certain ways. This methodology is described more fully elsewhere (manuscript submitted). We therefore used some of the critical skills we have learnt from discourse analysis to engage with participants' talk.[15]

Results

Twelve recurrent themes arose out of our reading of the transcripts. Rich descriptions that included participants' experiences, explanations, and ideas were then developed for each of these themes. The present findings are the top layer of this analysis. This

overview provides the context in which individual themes can be explored in future papers. Participants have seen and provided feedback on a draft research report that was prepared solely for them.

Maori health Participants answered the question 'What is Maori health?' in a variety of ways. A number of participants talked about the importance of defining health holistically, to encompass more than people's physical health. Participants spoke mainly about the interconnectedness of physical, spiritual and mental health. For some respondents, Maori health was related to specific Maori ways of providing healthcare. Other respondents linked the term 'Maori health' with ill-health. The impact of social and economic wellbeing on health was mentioned and some participants talked specifically about the disparities between Maori and Pakeha health.

Explanations for Maori ill-health In their explanations for the current status of Maori ill-health, participants' views ranged from the examination of what individuals put into their bodies on a daily basis (eg, drugs, overeating) to more social (eg, stress and poverty), and corporate (eg, tobacco company advertising) explanations. These explanations fell into three interrelated categories: individual, whanau and societal. Individual explanations included the things people did that had an impact on their own health and/or the health of others – for example, smoking and drinking. Whanau explanations included occurrences and circumstances that undermined the foundations of the whanau. The whanau was described as being under stress, with people therefore missing out on whanau life (also see below). Societal explanations examined the health system as well as the wider social system and its impact on Maori health. Within this, people's inability to afford healthcare was recognised by many participants.

There were multiple, interrelated layers within each explanation for contemporary Maori health status, and participants found that it was sometimes difficult to establish the root cause of a problem or illness. For example, smoking might be 'caused' by stress but what, in turn, has caused that stress? Some participants were, however, clear that the root cause of Maori ill-health was the disruption of whanau and hapu structures within the historical and contemporary setting of colonisation in this country.

Traditional ways The topic of healing was discussed within the context of traditional Maori approaches and knowledge. These were closely linked to participants' views on Maori health, particularly the holistic, relational nature of Maori health. Traditional healing practices that existed in the past were seen to still exist today, demonstrating the value to Maori of holistic healing practices and the passing down of information from one generation to the next. Participants also talked about healing in terms of both rongoa and wairua (see below).

Rongoa Older participants described their experiences of rongoa (remedies) and other traditional healing practices from when they were younger. In addition, a number of the participants, both young and old, continued to use rongoa and saw this as compatible with the use of Western medicines. Two of the kuia (older women) spoke about their own specialised knowledge of rongoa and sharing this knowledge with others.

Integration Some of the participants talked about using both Maori and Pakeha medicines. These participants had often found Pakeha general practitioners to be very

understanding of their use of rongoa, and some went to great lengths to impart knowledge to their doctor. In such cases, the interchange was usually with a doctor who took time to listen to a patient and was willing to acknowledge other forms of healing (although possibly because they see them as harmless).

Wairua Wairua (spirit) was the most widely mentioned aspect of Maori health. Participants viewed wairua as the key to understanding health and illness as it gives access to the whole person, not just their physical symptoms, allowing healing to take place. This understanding was seen as being fundamental in Maori health practitioners whereas Pakeha practitioners were seen as less likely to understand it, often treating only the symptoms rather than what participants saw as the cause of the problem or illness.

Whanau The whanau was seen by participants as a basic support structure for Maori and therefore an integral part of Maori health and wellbeing. Whanau buffers its members from the wider world, including experiences of illness, treatment and hospitalisation. However, this structure and balance is disrupted in a number of whanau and participants talked about those whanau needing something to believe in. There was also agreement about the importance of input from kuia and koroua (older men) into whanau health and wellbeing.

Interacting with the health system Participants' experience and knowledge of Pakeha doctors was not overly positive. In many cases, either they or a close relative had not received good treatment and sometimes this had resulted in the relative dying. Suspicion and even fear of the health system was therefore often grounded in whanau experience. Participants had found that persistence and assertiveness, often in the face of cultural misunderstandings, were required if good healthcare was to be obtained from existing systems.

Rapport Participants saw rapport as vital to the interaction between a doctor and a patient. Rapport was described as the ability to communicate and included, for example, whether or not information was provided and understood, and whether or not the interaction was friendly. Participants liked Pakeha doctors who took the time to find out about them and their families, who were genuinely interested, and who did not talk down to them. Some participants thought that rapport occurred more with young doctors than old, whereas others thought that the principle of rapport was more 'old school'. Participants felt that rapport was especially important for older patients and those who were shy. However, difficulties in doctor–patient communication could be overcome if patients had support people who could speak on their behalf.

Whakamaa Participants talked about whakamaa as a potential barrier to healthcare; it may prevent people from going to see a doctor or, if they did see a doctor, prevent them from telling the doctor what was wrong with them. This was connected with rapport and the importance of a health practitioner taking time to put patients at ease, as whakamaa will decrease as a relationship is built. Participants also saw the value of personal support for Maori patients to facilitate access and engagement with health services.

Promoting Maori health Participants' suggestions for promoting health among Maori were based on acknowledging peoples' circumstances and needs. For example, health promotion is unlikely to be very successful if people are more concerned about day-to-day difficulties brought about by poverty than they are about their personal

health. This is not to say that health promotion should not also be about trying to ease the burden of poverty. Appropriate health promotion was seen by participants as including the opportunity to:

- talk with and learn from others, including kuia and koroua;
- hear information that is understandable, including visual information; and
- receive support and/or follow up when accessing health services and/or attempting to change behaviour (eg, give up smoking).

Marae-based healthcare delivery The marae provides people with a place to gather, often facilitated by the provision of transport and allowing people to bring their children. Participants thought that this accessibility was also about providing good clinical service and connecting with people at a cultural level. Sometimes both these can be provided by Maori practitioners; at other times a non-Maori practitioner can be 'trained' to be Maori-friendly and Maori involved in the health service can provide the cultural connections for patients. And regardless of whether a health practitioner is Maori or non-Maori, participants again stressed the importance of involving kuia and koroua.

Discussion

The present study examined how Maori health was conceptualised by a group of urban Maori who had knowledge of both mainstream and Maori-provider health services. Participants' conceptions of Maori health and their explanations for poor Maori health demonstrated holistic constructions of Maori health, along with an understanding of the various personal, whanau, and societal influences on health and wellbeing. The findings confirm the ongoing strength of Maori health concepts, as well as highlighting the depth of analysis by Maori of the causes of current Maori ill-health. In addition, the importance that participants put on wairua strongly suggests that they were not merely regurgitating Maori health models that abound in current health policy.

Wairua, generally translated as the 'spirit', is linked to both religious beliefs and relationships with the environment.[3] According to Durie, Maori generally consider wairua to be the essence of Maori health.[3] He describes how this point was made in 1982 by kaumatua Tupana te Hira during the welcome for fieldworkers involved in the Maori Women's Welfare League research project, Rapuora. Te Hira's views were shared by many kaumatua, and were being heard on many marae. Durie argues that 'without a spiritual awareness and a mauri (spirit or vitality, sometimes called the life-force) an individual cannot be healthy and is more prone to illness or misfortune'.[3]

Participants in the present study articulated a similar view when they described healing as occurring at the level of wairua, rather than solely through the treatment of the symptoms of disease. In addition, a disruption of wairua within whanau was linked to the inability of whanau to nurture and support the wellbeing of individual members. Within the urban environment, whanau may experience this disruption because of poverty, unemployment, and/or lack of education.[16]

However, as pointed out by some of the participants in the present study, the root cause of the disruption of wairua needs to be found within the processes used to colonise this country. If, as Durie argues,[3] a lack of access to tribal land is a sign of ill-health for Maori, then a colonisation process that has marginalised Maori from

land must surely be woven through an explanation of poor Maori health status.[17] Likewise, the undermining of a viable Maori economic base sourced from the land must have repercussions for contemporary Maori poverty and ill-health.[18,19]

While the burden of addressing the consequences of colonisation cannot fall solely on the shoulders of health professionals, they need to take into account the context within which they are delivering healthcare to Maori, and the potential barriers to and facilitators of that delivery process. The themes that emerged in the present study articulated participants' experiences and provided insights into the delivery of healthcare to Maori. For example, Pakeha doctors should be mindful that Maori patients may well have a holistic approach to health, with a particular emphasis on wairua. In addition, they should recognise some of the ways in which the health of individuals and whanau is challenged. The challenge of day-to-day survival may well override health concerns for many Maori whanau.[20]

Add to this the cross-cultural nature of many Maori patient/Pakeha doctor interactions and the scene is set for miscommunication and potentially negative experiences for Maori (and possibly also for Pakeha).[21] Maori also carry knowledge of previous negative experiences that they, their whanau, and those in their wider networks have had as a result of such interactions. However, when the participants in the present study found that they were respected in mainstream healthcare services, they were able to relate to and make sense of the communications from their doctor. Rapport was therefore identified as a key facilitator of Maori access to healthcare.

Pakeha doctors, however, may think they are establishing rapport without fully appreciating that rapport is interpreted differently by different cultural groups. This came out strongly in the present research in participants' talk about having to 'train' a Pakeha doctor so that he could work on the marae. Several components of rapport were identified in the present research, including the doctor taking time to listen, communicating in understandable language, taking an interest in whanau health history, and engaging with the patient to deliver a collaborative style of healthcare. These elements not only facilitate healthcare delivery, they signal cultural sensitivity on the part of the health practitioner.

In conclusion, Maori are concerned about their health and do not want to be ill. When Maori find good healthcare service it will undoubtedly provide a pathway to health for both themselves and their whanau.[22]

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Patients' perception of the adequacy of informed consent: a pilot study of elective general surgical patients in Auckland

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Abstract

Aim This study was designed to determine the adequacy of the informed consent process from the patient's perspective and in the light of published standards.

Methods A pre-operative survey questionnaire was filled in during an interview with 77 patients before an elective general surgery operation. Forty two (58%) of the patients also completed a post-operative postal questionnaire.

Results The results show that there is a need for more specific information (including the nature of the planned operation, the alternatives and complications) to be given by the senior doctor undertaking the procedure and before the patient is admitted to hospital.

This study has highlighted the importance of confirming that the patient considers that they understand and are fully satisfied with the information provided, and that they have been able to ask questions without any sense of pressure.

Conclusions In giving voice to our patients' views on the adequacy of the informed consent process, this study has identified where improvements could be made in this important aspect of patient care.

Informed consent has been defined as "the process whereby someone who has the capacity/competence to consent, having been given sufficient information, arrives at a reasoned and unpressured decision as to whether or not to agree to a proposed therapy or procedure".[1] There have been several published statements in New Zealand on information disclosure and consent.[1–3] These statements embody the four imperatives of the informed consent process, namely: 1) the nature of, risks associated with, and alternatives to treatment must be disclosed; 2) the consent giver considers that they understand this information; 3) consent must be given freely by the consent giver; and 4) the consent giver must be competent to give consent.

There have been no New Zealand studies to determine whether informed consent is obtained in a way that meets these imperatives. Further, there have been no studies to determine whether the process of obtaining informed consent meets patient expectation. The aim of this study was to evaluate the adequacy of informed consent in a cohort of elective general surgical patients.

Methods

Permission for this study was obtained from each of the twelve surgeons from the four surgical teams within the Department of General Surgery at Auckland Hospital. Ethical approval was obtained from the North Health Ethics Committee (No. 1004).
Consecutive patients listed for elective general surgery in Auckland Hospital during a six-week period were approached to participate in this study. Verbal consent was obtained after the patient had been given an information sheet and any questions answered. The patients were interviewed before surgery

using a structured survey questionnaire and a similar questionnaire was posted to each patient after discharge from hospital.

Pre-operative survey Patients were interviewed after they were fully admitted to the ward, had been consented for surgery and before they were given any pre-operative medication. The interviews were conducted at the bedside by one interviewer. The interview questions were structured and designed to determine the perceived adequacy of informed consent in three areas: 1) disclosure of information – was there sufficient information given about the proposed operation, its risks and any alternatives to surgery; 2) understanding – did the patient feel they understood the information given; and 3) freedom of choice – did the patient feel free to give or refuse consent. Twenty questions required either a yes or no answer or a short answer, the latter of which were transcribed. Six further questions required the use of a 10-point linear analogue scale to record the answer. It was considered that a cut-off value of 8 or less was significant.

Post-operative questionnaire All patients were sent a similarly structured questionnaire within a week of their discharge, accompanied by a stamped self-addressed envelope. This allowed certain questions to be raised that might have created difficulty if asked by a third party immediately prior to the operation, such as "Did you realize that you could have refused treatment?" The post-operative questionnaire also allowed some questions to be asked that couldn't have been answered before the operation, such as 'Having been through the operation, is there further information that you would have liked?"

Results

Of the 84 patients approached, 79 agreed to participate in this study. Five patients were not interviewed because: they refused to participate in the study (n = 1); they were unable to be interviewed because an interpreter could not be found before surgery (n = 2); or the consent form was only signed once the patient arrived in the operating theatre complex and there was no time for the interview (n = 2). In addition, two patients were excluded from the study because the operation was cancelled after the interview took place. This meant that data from 77 patients (female 51, male 26; median age 52 years, range 19–89 years; European 49, Pacific Island 10, Maori 1, other 17) were available for analysis. There were 42 (58%) patients who responded to the post-operative questionnaire at an average of 10 days (range 1–30) following surgery. The categories of general surgical operations for which consent was obtained are listed in Table 1.

Table 1. The categories of general surgical operations for which informed consent was obtained

Category	Number of patients
Head and neck	14
Breast	12
Upper gastrointestinal	22
Colorectal	25
Other	4

There were 23 (30%) patients who were admitted directly to hospital with an acute problem, did not attend an outpatients clinic, and had their operation on an elective list. Less than half (23/54, 43%) of the remaining patients gave their informed consent prior to admission to hospital, in the outpatients or pre-admission clinic.

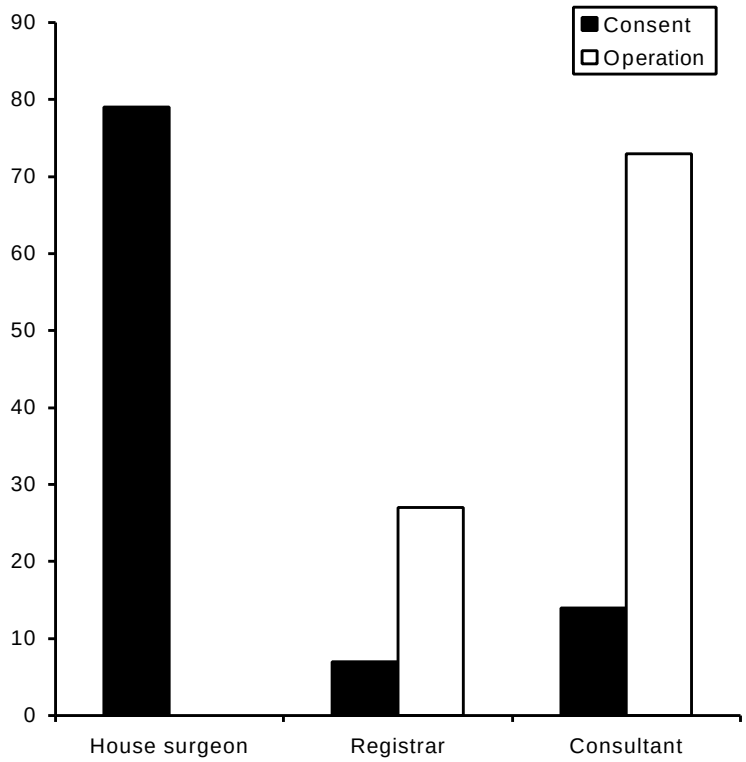
The median interval between the time that written informed consent was obtained and the time of the operation was 6 days with a wide range (1.5 hours to 63 days). Forty

eight (62%) patients gave written consent within 24 hours of surgery. Sixteen (21%) patients gave consent more than one week before the time of surgery, of whom six patients gave consent at more than one month.

The disclosure of information Almost half of the patients (38/77, 49%) received information about their operation in verbal form only, while 37 (48%) patients were given verbal and written information. A further two (3%) patients were shown a video in addition to the verbal and written information.

Information was obtained from multiple sources. The consent form requires the naming of the person who has taken responsibility to ensure that informed consent is obtained, and this was the same person who signed the consent form in almost every case. Overall, the house officer obtained written consent from 79% (61/77) of the patients, the registrar 6% (5/77), and the consultant 14% (11/77). A house surgeon obtained consent from all patients in one team compared with 41% of the patients in another. Figure 1 shows the number of patients consented and the number of operations performed by the house officers, registrars and consultants.

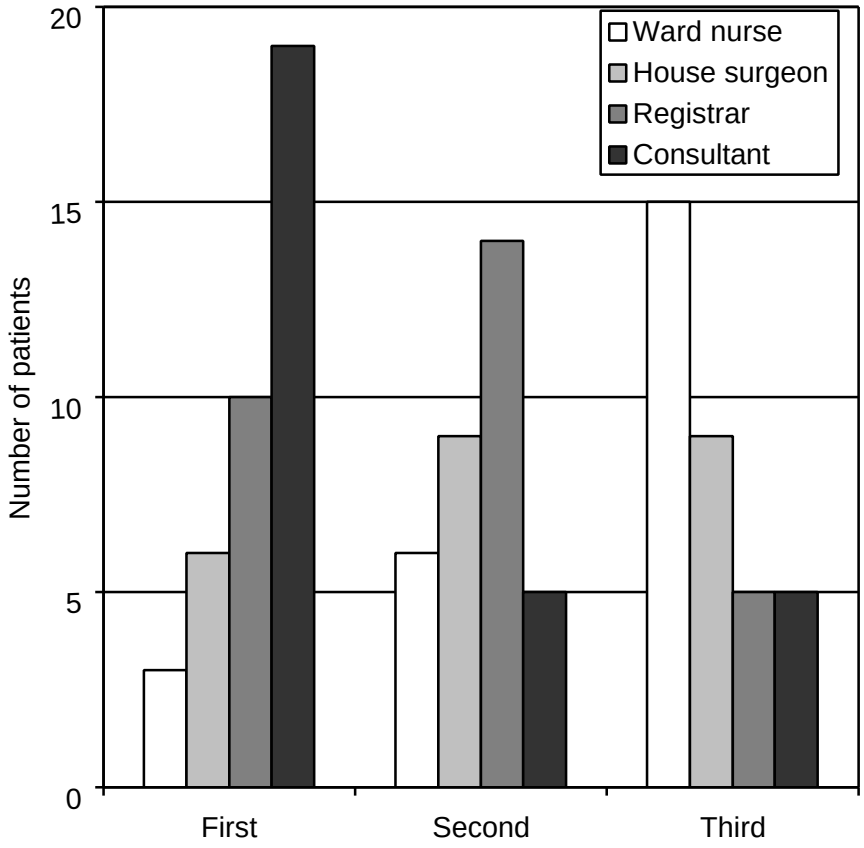
Figure 1. Number of patients consented and operations performed by house surgeons, registrars and consultants



It was of interest that only 34 (44%) patients could name the person who was going to perform their operation and 33 (43%) knew their seniority. The usefulness of the information, as perceived by the patient, was related to the seniority of the person

giving the information (Figure 2). House surgeons were perceived to provide less useful information than the registrars or consultants.

Figure 2. The usefulness of information from four sources, ranked by the patients



Thirty nine (51%) patients were less than "totally satisfied" with the amount of information given before the operation. Only 36 (47%) patients considered that they had received enough information about the risks and complications of the proposed operation. Eighteen (23%) patients did not recall being "told about the risks or dangers of the operation". Thirty seven (48%) patients could not list a single risk of the operation, although 68 (88%) could identify the consequences of not having the operation. Sixty one (79%) patients stated that alternative approaches to treatment had not been discussed.

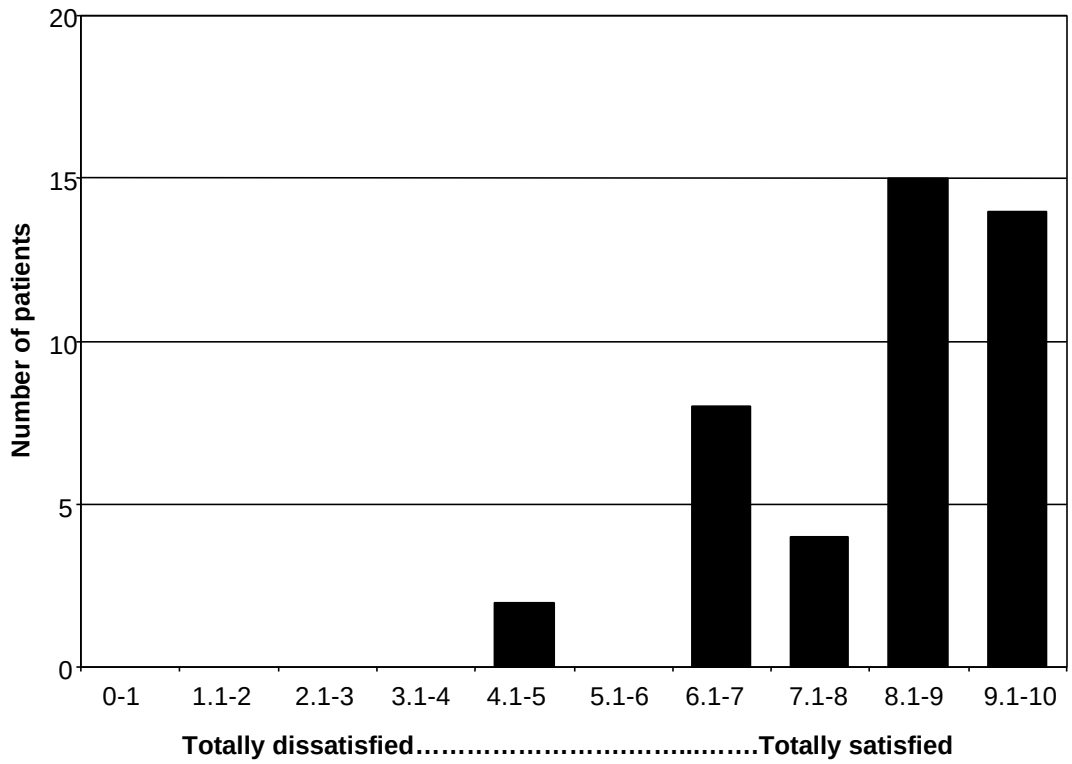
The post-operative survey found that 45% (19/42) of patients were less than totally satisfied with the information that they had been given about the operation, 50% (21/42) with the amount of time spent discussing the operation, and 48% (20/42) with the amount of information received about the operation. The information that patients would have liked before their operation is summarised in Table 2.

Table 2. Specific information patients would have liked to receive before their operation

Information	Number of patients
Complications and risks of operation	13
Recovery time after operation	9
How they would feel after the operation	8
Alternative treatments to operation	8
Likelihood of success of operation	7
Risks of the anaesthetic	6
Nature of the disease	5

The results from the post-operative rating of overall satisfaction with the informed consent process are shown in Figure 3. It can be seen that 69% (29/42) patients were less than totally satisfied.

Figure 3. Overall satisfaction with the informed consent process at the time of the post-operative survey



Understanding the information The language that was used to obtain informed consent was readily understood by all but one of the patients, although the preferred language was English in 63 (81%) patients. Of the remaining 14 patients, 5 were not offered a professional interpreter and 9 had someone available to interpret for them (5 were accompanied by a family member, 3 had a professional interpreter and on 1 occasion a medical student was able to interpret).

Twenty six (34%) patients said they did not understand what the operation itself consisted of. Over one third of the patients (40%) could not name a single complication of the proposed operation. The proportion of patients who considered that they "fully understood" the information provided was 45% (35/77) before the operation, and 43% (18/42) after the operation. In the post-operative survey, 31% (13/42) of patients stated that they would have liked more information about the operation after they had been admitted to hospital.

Giving consent freely The majority of patients felt free to ask questions about the proposed treatment (61/77, 79%) and had enough time to think about having the operation and to discuss it with friends and family (72/77, 94%). The post-operative survey found that 86% (36/42) of patients had enough time to read the consent form before signing it. Some degree of pressure to sign the consent form was experienced by 38 % (16/42) of patients. One third of the patients (14/42, 33%) did not realise that they could change their mind after they had signed the consent form.

The patients before and after surgery rated their overall satisfaction with the process of gaining informed consent. Less than total satisfaction was scored by 38/77 (49%) patients before surgery and 14/42 (33%) patients after surgery.

Discussion

This study has examined patient satisfaction with the way that informed consent is obtained from elective general surgical patients at Auckland Hospital. Three of the four key components of the informed consent process[1–3] have been examined and there is room for improvement in each of them. These are: 1) the actual disclosure of information about the nature of, risks associated with, and alternatives to treatment; 2) whether the consent giver feels they understood the information; and 3) whether consent was given freely. The fourth component regarding the competency of the consent giver was not evaluated in this study. In 1994, the Health and Disability Act established the patient's legal right to informed consent by stating that "no health care procedure shall be carried out without informed consent".[4] Subsequently, a Code of Consumer Rights developed by the Health and Disability Commissioner was given the status of law under the authority of the Act.[4] Of particular relevance to this study are Right 5 (the right to effective communication), Right 6 (the right to be fully informed), and Right 7 (the right to make an informed choice and give informed consent).

In law, there are three different recognised standards for determining the adequacy of information disclosure. The first is the 'professional standard' (also known as the Bolam's test), which is determined by the practice of the majority of the profession. The second is the 'reasonable person' standard (also known as the 'objective standard'), which is determined by what a reasonable or prudent person would require. The third is the 'subjective standard', which is determined by what an individual patient seeks.

In United Kingdom case law, the professional standard is applied most frequently. In North America and Australia, there appears to be a balance between the objective and subjective standards. In New Zealand, the law is less clear.[5] The New Zealand Medical Council considers that the focus of the standard of disclosure should be on

what a reasonable patient would expect rather than on what a reasonable doctor considers appropriate.[3] The guideline states "that information must be conveyed to the patient in such detail and in such a manner, using appropriate language, as to ensure that an informed decision can be made by that particular patient. The necessary standard for the requirement (that is the extent, specificity and mode of offering information) should be what reflects the existing knowledge of the actual patient and practitioner. More generally, it should also reflect what a prudent patient in similar circumstances might expect." The Health and Disability Act (1994) states that "the information needed must be determined both objectively (the information needed by a reasonable consumer) and subjectively (the information needed in that consumer's circumstance)." The present study has evaluated both the objective and subjective standards. It has determined whether individual patients consider that informed consent has been obtained in a manner that meets their standards and it also provides some information about what the profession is currently doing in regards to informed consent.

One of the limitations of this study is that no distinction was made between the person(s) who provided the information during the informed consent process and the person who was the signatory to it. It was clear from this study that the majority of signatories were also the main source of information, and it shown that this is usually the least experienced member of the medical staff, the house officer. The patient considers that the house surgeon provides the least useful information regarding the nature, risks, benefits, and alternatives to treatment. This is in accord with a Scottish study, which showed that the junior doctors gave patients most of the information they had acquired during their stay in hospital.[6] The company policy for the Auckland District Health Board states that the primary responsibility for ensuring that information is imparted lies with the person who is responsible for the procedure.[1] The policy also states that when responsibility for obtaining informed consent is delegated, the patient should be told the reason why the person carrying out the procedure could not personally obtain consent.[1] It was our observation that this was rarely done. Furthermore, the majority of patients did not know the name (56%) or the seniority (57%) of the person who was to perform the operation.

In New Zealand, the failure to provide adequate information or to ensure the patient's understanding of the information are grounds for 'medical misadventure' as a result of Accident Compensation Corporation legislation. Legal action would likely involve more than just the health professional who failed to adequately disclose information, but would also include the person to whom the health professional was responsible or by whom they were supervised.

It was Cartwright's view that the onus is on the health provider "to ensure that information, particularly regarding alternatives and diagnosis, is given to the client in an appropriate situation and with sufficient time and in a manner which the client can understand".[5] It was asserted that any difficulty in achieving this was "more likely to be due to the health provider's (doctor's) inability to communicate, than genuine problems with the client's ability to understand".[5] The possibility of alternative treatments was not discussed with over three quarters of the patients in this study and about one quarter of the patients did not consider that they were informed of the specific risks associated with the operation.

It has been previously demonstrated that a higher patient satisfaction rating was obtained when information was given in written form[7] and prior to admission to hospital.[6] In this study, written information was given to fewer than half of the patients. A recent study has shown that patients prefer to receive information verbally, rather than in a written or video format.[8] It has been shown that additional written or verbal information, to reinforce what has already been provided, does not necessarily improve a patient's understanding of the risks and complications of a procedure.[9] The same study demonstrated that the complete disclosure of risks and complications associated with a procedure did not appear to have any benefit over a more simple explanation. It was therefore considered that complete disclosure was not a moral or legal necessity.[9] In this and another study the provision of more information did not appear to increase patient anxiety.[9,10]

This study has demonstrated a significant knowledge deficit on the part of some patients. Half of the patients were not totally satisfied with the level of information provided and one third of the patients did not know of what the operation consisted or of a single complication relating to it. About one third of the patients expressed ongoing concerns about details of the operation, even after informed consent had been obtained. Ensuring that patients have sufficient time to express all of their concerns and ask all their questions will go some way towards addressing this issue.

It appears that the majority of patients in this study gave informed consent in less than ideal circumstances, as they had already been through the admission process and were within 24 hours of surgery. The patients were usually changed out of their own clothing, in bed and in a room with other patients and staff. In these circumstances, it is difficult to conceive how the patients could feel free to refuse surgical treatment, especially if they had been on a waiting list for a long time. Fewer than half of the patients who could have given informed consent in an outpatient setting did so. Patients need to feel completely free to give informed refusal or consent and should not feel dependent, vulnerable or uncomfortable about asking questions or suggesting alternative points of view. One third of the patients in this study did not realise that they could change their mind after they had signed the consent form.

The process of informed consent is complex and continues to evolve. The codification of patient rights and a better understanding of health provider obligations have been important steps forward. These now need to be matched by the development of patient obligations and health provider rights.[5] This would help to bring a balance to this process, moving away from an overemphasis on patient autonomy[11] and towards a partnership between patient and health provider. It is helpful to consider informed consent as a process of shared decision making[12] and to determine the readiness and willingness of a patient to participate in that process. There are still many patients who willingly adopt a passive approach to informed consent, while others seek active participation in all phases of the process.

In conclusion, this study examines the patient's perception of the adequacy of the informed consent process. It has highlighted a number of areas in which improvements could be made. There is the need for more specific information to be given by more senior doctors before admission to hospital. It is important to confirm that the patient understands and is fully satisfied with the information provided and that there has been ample opportunity to ask questions without any sense of pressure.

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Symptom complaints following aerial spraying with biological insecticide Foray 48B

Keith Petrie, Mark Thomas and Elizabeth Broadbent

Abstract

Aim To investigate the effect of aerial *Bacillus thuringiensis* (Foray 48B) spraying on self-reported symptom complaints, health perceptions, and visits to healthcare providers.

Methods Two hundred and ninety two residents within the Ministry of Agriculture and Forestry (MAF) West Auckland spray zone were recruited by a door-to-door survey of homes within the most intensively sprayed area ten weeks prior to the first aerial spraying. Participants completed a symptom checklist and a questionnaire measuring health perceptions. Three months after the start of spraying, 181 (62%) of the original participants responded to a similar postal questionnaire. Symptom reports, health perceptions and visits to healthcare providers were compared between the baseline and the follow-up questionnaire. Rates of symptom complaints in respondents with previously diagnosed asthma, hay fever, or other allergies were compared to those in respondents without these prior health conditions.

Results Symptom complaints increased significantly following the aerial spraying, in particular: sleep problems, dizziness, difficulty concentrating, irritated throat, itchy nose, diarrhoea, stomach discomfort, and gas discomfort. Analyses showed a significant increase in symptoms in those participants with a previous history of hay fever. While overall self-ratings of health decreased following the spraying, most residents saw their health as unaffected by the spray programme, and there was no significant increase in visits to general practitioners or alternative healthcare providers.

Conclusions Aerial spraying with Foray 48B is associated with some adverse health consequences in terms of significant increases in upper airway, gastrointestinal, and neuropsychiatric symptoms, as well as a reduction in overall perception of health in the exposed population.

Following the discovery of the painted apple moth in West Auckland in 1999, an eradication programme was instituted by the Ministry of Agriculture and Forestry (MAF). This programme initially involved ground spraying in the area of the outbreak, and subsequently included aerial spraying in a targeted area of West Auckland starting in January 2002. The spray area included the suburbs of Te Atatu South, Glendene, Kelston, Glen Eden and the Avondale Peninsula, and contained a population of approximately 13 500 residents. The spray programme was expanded later in the year to include other Auckland suburbs, after moths were found outside the initial aerial spray zone.

The spray (Foray 48B) contains spores of *Bacillus thuringiensis kurstaki* (Btk) in a solution derived from the bacterial culture medium. This spray has been used in a

number of similar eradication programmes, including the white-spotted tussock moth programme (Operation Evergreen) in the eastern suburbs of Auckland in 1996. Previous health assessments of the effects of this aerial spray have been based on the monitoring of a variety of health services after the spraying. In the case of Operation Evergreen, this included surveillance of consultation patterns at sentinel general practices and birth outcomes at catchment hospitals two years following spraying. No increased risk of adverse events was detected in the exposed population.[1]

Aerial spray programmes generate a great deal of anxiety in the communities exposed to the spray and there is currently a lack of data on the effect of Foray 48B on symptom complaints and perceptions of health as opposed to its effect on the rates of medically diagnosed illness. In this study, we investigated self-reported symptoms before and after exposure to Foray 48B.

Methods

Participants and procedure The participants were residents within the most intensively sprayed area of the initial MAF aerial spray zone. Participants were recruited by a door-to-door survey of the homes identified by MAF as being within a 100 metre zone along the riparian margins of the Whau River, Wairau Creek and Waikumete Cemetery spray zones. With informed consent and ethics committee approval, residents aged over 18 were invited to participate in a survey of health and symptoms related to the aerial spray programme. Of the 315 residents approached to participate in the study, 292 agreed to participate (refusal rate = 7%). Baseline data were gathered at the end of October 2001, 10 weeks prior to the first spraying by MAF aircraft. At the end of March 2002, after the area had been sprayed on three occasions, study participants were asked to complete a postal questionnaire. Non-respondents were sent two reminder letters.

Questionnaires The baseline questionnaire was completed by participants at their homes in the presence of the research assistant. In this questionnaire, participants provided demographic information and also indicated whether or not they had previously been diagnosed with asthma, hay fever or other allergies. Participants were asked to indicate which, if any, of 25 symptoms they had experienced in the preceding four weeks. This symptom list was derived from the Subjective Health Complaint Scale.[2] This scale has been used previously in a New Zealand population and found to be a highly reliable means of assessing symptom complaints.[3] Participants were also asked to rate their overall health using a seven-point scale from “terrible” to “excellent”, and to state the number of visits they had made to a general practitioner (GP) or alternative healthcare provider during the past three months. The participants’ names and addresses were also collected by the research assistant in order that they could be sent a follow-up questionnaire.

In the follow-up questionnaire, participants were asked to repeat the symptom checklist and the self-rated health item, and to estimate the number of visits they had made to a GP or alternative healthcare provider during the previous three-month period. Participants also indicated whether or not they had changed their medication or taken any new medicines in response to the spraying and if they had discussed concerns related to the spraying with their GP or other doctor. Participants were asked to rate “How much was your health affected by the spray programme in your area?” and, if they had children at home, “How much was your children’s health affected by the spray programme in your area?” Both questions were rated on a five-point scale from “not at all” to “extremely”.

Statistical analysis was carried out using SPSS for Windows statistical software. Differences between the frequency of symptoms and self-rated health reported at baseline and follow up were analysed by comparing subjects who answered both baseline and follow-up questionnaires using paired sample t-tests. Differences in frequency of symptoms reported by participants who gave a history of asthma, hay fever or other allergies and by participants without these conditions were conducted using analysis of variance (ANOVA). Changes in the frequency of visits to GPs and alternative healthcare providers were analysed with non-parametric tests due to the skewed nature of these distributions.

Results

The sample comprised 131 males and 161 females. Participants' ages ranged from 18–79 years, with a mean age of 42.1 years (SD = 15.2). Europeans made up 60.3% of the sample, Maori 7.5%, Pacific Islanders 13.5%, and other ethnic groupings 12%. These demographic characteristics are approximately the same as those identified for the total population of the spray area.[4] In total, 181 (62%) of the initial participants responded to the postal questionnaire. Non-respondents to the follow-up questionnaire were significantly younger (t (87) = 5.20, p = 0.001), and more likely to be non-European (Π^2 = 19.46, p = 001), but did not differ by gender (Π^2 = 0.85, p = 0.36), number of baseline symptoms (t (285) = 0.69, p = 0.49), previous diagnosis of asthma (Π^2 = .71, p = 0.39), hay fever (Π^2 = 0.46, p = 0.49), or rates of other allergies (Π^2 = 0.34, p = 0.56).

Table 1. Percentage of population reporting each symptom at baseline and following spraying

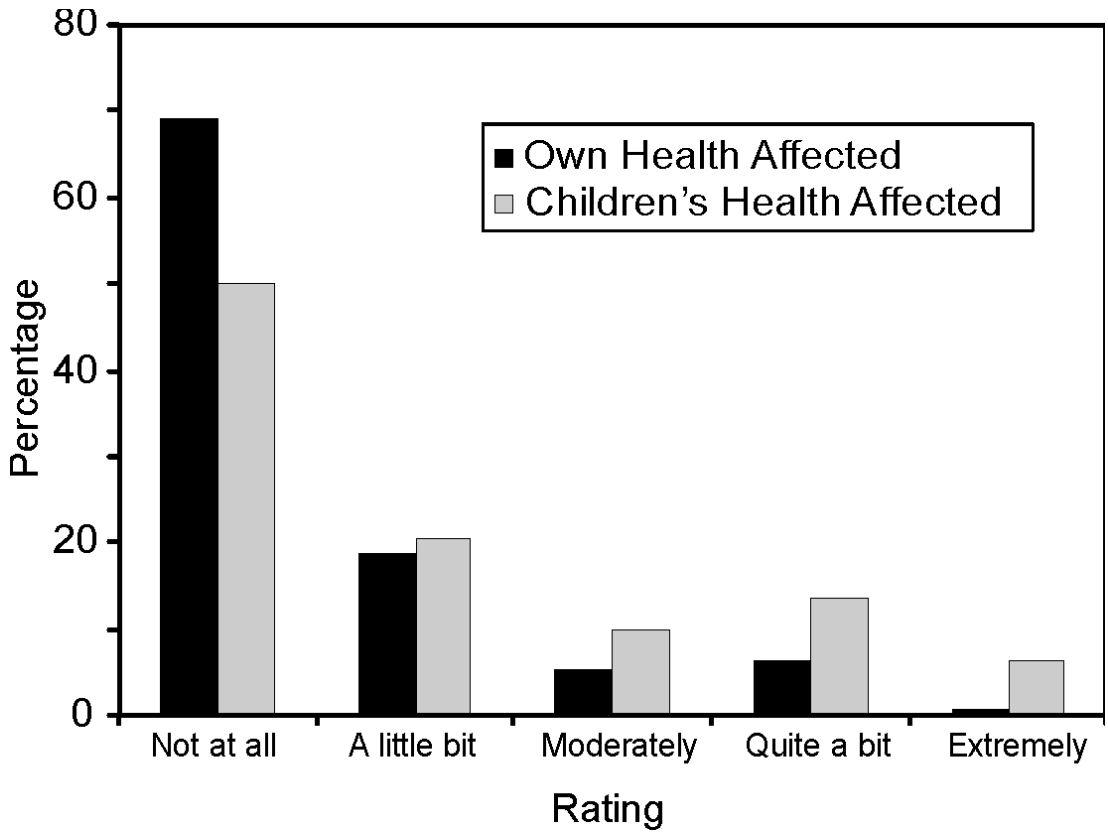
Health problem	Baseline % (n = 292)	After spraying % (n = 181)	Change %	t	p value
Headache	45.5	51.4	13	-1.9	0.06
Back pain	35.9	31.4	-13	1.87	0.06
Coughing	29.1	33.3	14	-1.7	0.10
Cold, flu	28.6	30.1	5	-0.5	0.60
Sleep problems	26.6	36.2	36	-2.2	0.03
Neck pain	23.9	25.0	5	0.15	0.89
Leg pain during physical activity	23.8	19.1	-20	0.9	0.37
Shoulder pain	20.3	23.9	18	-1.1	0.26
Arm pain	17.2	19.0	10	-0.7	0.48
Stomach discomfort	16.6	25.5	54	-2.2	0.03
Irritated throat	16.2	31.9	97	-3.7	0.0001
Itchy nose	16.2	23.2	43	-2.1	0.04
Migraine	12.8	14.8	16	-1.4	0.18
Dizziness	11.0	16.9	54	-2.5	0.01
Wheezing	10.0	13.0	30	-1.6	0.11
Diarrhoea	9.3	16.8	81	-2.2	0.03
Gas discomfort	8.6	16.8	95	-2.3	0.02
Chronic eye irritation	8.3	13.7	65	-1.8	0.07
Eczema	7.9	7.1	-10	0	0.99
Pain in ears	7.9	10.3	30	-0.7	0.49
Chest pain	7.2	8.7	21	-0.7	0.49
Extra heartbeats	6.9	10.3	49	-2	0.05
Constipation	6.2	6.5	5	1	0.32
Difficulty concentrating	5.2	12.5	140	-3.2	0.001
Blurred or double vision	5.2	9.8	88	-1.3	0.20

The data were first analysed to examine differences between reported symptoms at baseline and following the commencement of the spraying programme. Overall, the total number of reported symptoms increased significantly from baseline (mean = 3.90, SD = 3.56) to follow up (mean = 4.78, SD = 4.48), t (156) = -2.99, p = 0.003. As can be seen from Table 1, participants reported increases in a number of symptoms

following the spraying. Significant increases were noted for the following symptom reports: sleep problems, difficulty concentrating, dizziness, irritated throat, itchy nose, diarrhoea, stomach discomfort, gas discomfort, and extra heartbeats.

At the baseline survey, 14.7% of participants reported they had previously been diagnosed with asthma, 24.6% with hay fever, and 19.2% with other allergies. To examine whether participants suffering from these conditions were affected by the spray programme, an analysis of variance was conducted for each of these groups compared to those without the diagnoses, controlling for their symptom scores at baseline. These analyses showed a significant increase in symptoms for participants with a history of hay fever ($F(1147) = 5.30$, $p = 0.02$) compared with those participants not previously diagnosed with hay fever, but no significant increase for participants with a history of asthma ($F(1151) = 2.19$, $p = 0.14$) or other allergies ($F(1139) = 1.53$, $p = 0.22$) when compared with participants without these diagnoses.

Figure 1. Percentage of participants reporting that their own health or their children's health was affected by the MAF spray programme



Participants' self-rated health declined significantly from baseline (mean = 5.40, SD = 1.12) to follow up (mean = 5.08, SD = 1.21) $t(175) = 3.69$, $p = 0.0001$. However, there were no significant increases in the number of visits to the GP (Wilcoxon $Z = -0.94$, $p = 0.35$) or to alternative healthcare providers (Wilcoxon $Z = -0.39$, $p = 0.69$) following the spraying . Overall, 9.2% of participants reported discussing the effects

of the spray with their GP, and 6.5% reported changing their medication because of the spray. Most participants reported that their own and their children's health was not affected by the spray programme, with children's health more likely to be seen as being affected than the participants' own health (see Figure 1).

Discussion

This study found significant changes in the pattern of symptom reports among residents exposed to aerial spraying with Foray 48B. The most notable change was a doubling in the rate of irritated throat following the spraying. Gastrointestinal symptoms also increased significantly following spraying, with increases in stomach and gas discomfort as well as in diarrhoea. Increases in sleep problems, dizziness and concentration difficulties were also noted. Hay fever sufferers were more likely to have increased symptoms following spraying, but no significant increases in symptoms were noted for asthmatics or participants with other allergies. Relatively few subjects considered that the spray programme had produced more than a moderate effect on their health, and there was no increase noted in the rate of consultations with either medical practitioners or alternative healthcare providers.

It was noteworthy that those symptoms that significantly increased in frequency following the aerial spraying, fell into three loose clusters. Sleep problems, difficulty concentrating and dizziness might be considered indicators of a neuropsychiatric response to the spray programme, while irritated throat and itchy nose may reflect local effects on the upper airway, and stomach discomfort, gas discomfort and diarrhoea suggest that there may be effects of the spray on the gastrointestinal system. The factors responsible for these symptom clusters may be different. The neuropsychiatric symptoms may result from sleep disturbance caused by the early morning spraying by low-flying aircraft, as well as increased anxiety in some residents because of the perceived risks of the programme. The upper airway symptoms may result from the local irritant effects of inhaled spray. The gastrointestinal effects may result from preformed endotoxin in the spray or from enterotoxin produced by *B. thuringiensis* replicating in the gut of exposed persons, or may be due to some other mechanism.

Previous work by others suggests that it is not unreasonable to expect that exposure to spray containing *B. thuringiensis* might cause health effects. Commercial sprays such as Foray 48B contain spores of *B. thuringiensis kurstaki*, spore-associated crystals of *B. thuringiensis kurstaki*-derived endotoxin, various volatile chemicals, and residual components of the medium in which the organism was cultivated. Health effects might be due to germination of spores to produce replicating bacilli, direct effects of the pre-formed endotoxin, or irritant or allergic effects of the nutrient or other components of the culture medium. Exposure to sprays containing *B. thuringiensis* commonly leads to human infection with the organism and an associated immune response.[5,6] In one study of farm workers who picked sprayed vegetables, positive skin test responses and IgG and IgE antibody responses to *B. thuringiensis* were common and were correlated with the intensity of exposure to the spray.[6] *B. thuringiensis* is almost indistinguishable from *B. cereus*, a relatively common cause of food poisoning, and produces an enterotoxin which is identical to that produced by *B. cereus*, although at a much lower level.[7] *B. thuringiensis* may have been responsible, at least in part, for an outbreak of gastroenteritis in a Canadian chronic care institution, where it was isolated from spice and from the faeces of four affected

patients, two of whom also had Norwalk virus in their faeces.[8] Thus, there appear to be a number of potential means by which the spray might cause human illness.

Previous research on the health effects of similar spray programmes has not found conclusive evidence of adverse health effects as a result of the spray. These studies have been largely based on monitoring the use of healthcare services,[1,9,10] isolation of *B. thuringiensis* from clinical specimens submitted for culture,[9,10] or specific studies of possible high-risk groups, such as children with asthma.[11] The current study differs from previous approaches by examining changes in symptom complaints in the population before and after being exposed to the spray and is therefore likely to be sensitive to changes in symptoms that are not presented to health services. In fact, individuals only present a very small proportion of physical symptoms to doctors, and the vast majority are managed through restricting activity and self medication.[12] The decision to seek medical care for symptoms is influenced by a wide number of factors, such as the perceived efficacy of medical treatment for the complaint, the presence of pain, level of disability, and economic considerations.[13]

There are a number of limitations of the study, which mean our findings should be interpreted with caution. Although the response rate to the follow-up questionnaire was relatively high for a study of this type, it is likely that people who perceived themselves as being affected by the spray would have been more inclined to respond. Furthermore, we cannot be certain that the changes in self-reported symptoms were a direct result of the spray programme, nor can we exclude the possibility that severe health effects occurred in a very small proportion of the people exposed to the spray. It is also possible that changes in exposure to pollen or other seasonal environmental factors may have contributed to the differences in symptom rates between the two surveys. The main pollen season in Auckland is from October to February, and this may have influenced upper airway symptom reports. However, we would not expect the changes in neuropsychiatric and gastrointestinal symptoms to be related to pollen exposure. Furthermore, the pattern of symptoms (no significant increase in eye irritation, wheezing, coughing) does not support an explanation based on changes in exposure to pollen. The use of a control group without spray exposure in future studies would help to resolve this issue.

While no significant differences in the frequency of visits to GPs or other healthcare providers were evident, it should be noted that the follow-up period may have been too short to pick up such changes in healthcare attendance. It should also be noted that the time period referred to in the initial symptom checklist was made longer in the follow-up questionnaire, in order to ensure all respondents had been exposed to the spray. This may be partly responsible for the overall increase in the number of symptoms found at follow up. However, it does not explain the unequal pattern of symptom changes found following spraying. Bearing in mind these limitations, the results of this study do suggest that aerial spraying with Foray 48B is associated with some adverse health consequences. Further research should focus on the potential effects of the spray on upper airway and gastrointestinal symptoms in populations exposed to it and should investigate the relationship between such symptoms and evidence of *B. thuringiensis* infection.

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General practitioners' perceptions of the nurse practitioner role: an exploratory study

Bev Mackay

Abstract

Aims To explore perceptions of general practitioners (GPs) in the Northland District Health Board (NDHB) regarding the nurse practitioner (NP) role, identifying their knowledge of and perceived problems with that role, and their experience of nurses in advanced practice.

Methods A purposive sample of all 108 GPs in NDHB were surveyed. Fifty replied, representing a response rate of 46.3%.

Results GPs favourably viewed NP functions traditionally associated with nursing, such as health teaching, home visiting, obtaining health histories, and taking part in evaluation of care, but less favourably viewed those functions associated with medicine, such as prescribing, ordering laboratory tests, and physical assessment. While expecting few problems with patient acceptance, the GPs felt that funding and doctors' acceptance would be problematic. Most GPs indicated they have knowledge of the NP role and have experienced working with a nurse in advanced practice, but some uncertainty and lack of knowledge about the NP role was evident.

Conclusions More education and discussion with Northland GPs is needed to ensure they are fully informed about the NP role and its potential positioning in primary healthcare, to reduce uncertainty, minimise role confusion and promote collaboration between GPs and NPs.

This study forms part of a larger research project on forces influencing the development of innovative roles in primary healthcare nursing in the Northland District Health Board (NDHB) of New Zealand. The New Zealand Primary Health Care Strategy sees primary healthcare nursing as crucial to the implementation of the strategy.[1]

The nurse practitioner (NP) role, which originated in the United States (US), is now recognised as an enhanced nursing role working in partnership with clients, rather than just an extended nursing role with delegated medical tasks.[2] A recent systematic review of research comparing nurse practitioners and doctors at first point of contact in primary care, demonstrates a higher level of client satisfaction with care provided by an NP than that provided by a doctor, with no difference in client health outcomes. However, it was found that NPs had longer consultations with clients and it was not possible to carry out an economic analysis of differences in costs.[3] The authors concluded that increasing access to NPs can promote high-quality care and client satisfaction in the primary healthcare context.[3]

General practitioner (GP) attitudes towards advanced roles for primary healthcare nurses appear to be changing. US research found that 49% of physicians were willing to hire an NP and 47% were favourable towards the concept of an NP.[4] A later study

demonstrated that the more knowledgeable a physician is about the NP role, the more receptive the physician is to hiring an NP.[5] Research in the UK shows that GPs are prepared to delegate to practice nurses in an extended role as well as to NPs.[6] However, a US study on the perceptions of physicians towards NPs found that most doctors believe nurses should work under the direct supervision of doctors rather than in an independently collaborative manner.[7] These findings have implications for the introduction of the NP role in New Zealand. The inability of nurses in New Zealand to treat, prescribe and order laboratory and diagnostic tests independently has been identified as a barrier to timely, accessible and cost-effective healthcare.[8] The Ministry of Health proposes that NPs will work in independent practice or in collaborative care delivery models with GPs.[9] As key stakeholders in the delivery of primary healthcare services in Northland, GPs have the potential to influence the development and introduction of NP roles. It is essential that the perceptions and concerns of GPs are identified to highlight areas of potential conflict or misunderstanding. The aim of the research was to explore perceptions of GPs in the NDHB regarding the NP role, and to identify their knowledge of and perceived problems with that role, and their experience of nurses in advanced practice.

Methods

A survey was adapted from the 'Survey of General Practice Physicians' Opinions Concerning the Family Nurse Practitioner' developed by Radke.[10] Questions assessed GPs' perception of role functions, potential problems with utilising an NP, and GPs' source of knowledge of the NP role. As the NP role is only just being introduced to New Zealand, GPs were asked about their experience of nurses who utilise 'advanced knowledge and skills within a specialist scope of practice.' The final questions asked GPs for information on their demographics, organisation and funding, as well as their perception of GP shortage in their community, the potential impact of the NP on enhancing care, and their opinion of working with and employing an NP. In New Zealand, the title Nurse Practitioner is legally protected and can only be used by nurses meeting the requirements of the Nursing Council of New Zealand. GPs were asked to read the following role description of an NP before completing the questionnaire:

'Nurse Practitioners are expert in their field and use advanced knowledge and skills within their specialist scope of practice. Nurse Practitioners are educated through a clinically focused masters degree programme and must meet the competencies set out by the nursing council. These include being able to articulate and advance the scope of their nursing practice, showing expert practice and working collaboratively with other disciplines as well as across settings. Competencies also include demonstration of leadership and consultancy in nursing, active development and influence on policy and nursing practice and demonstration of research activities surrounding nursing practice. Nurse Practitioners may or may not choose to be nurse prescribers (Nursing Council of New Zealand, 2001).'

Content validity was promoted by consulting nurses with experience in research and primary healthcare nursing, a researcher with expertise in developing questionnaires, and a GP. Of the 108 questionnaires posted, 47 of the 50 returned were included in the data analysis. Approval was obtained through the ethics committees of the University of Technology, Sydney, Australia, and Northland Polytechnic, Whangarei, New Zealand. Excel® was used to analyse the data and descriptive statistics used to summarise quantitative data. An approach recommended by Dey was used to carry out content analysis of qualitative data using Microsoft Word®.[11]

Results

The GPs were asked about their perceptions of the functions of the NP role. Responses ranged on a five-point scale from 'highly favourable' to 'highly unfavourable', with a middle category of 'uncertain'. The question on the health teaching role of the NP was rated most favourably with no unfavourable responses. Also rated favourably were making home visits, participating in evaluation of care, and obtaining health histories. Rated least favourably were questions on prescribing

medications under the Nurses Act, ordering routine laboratory tests, and performing a physical examination.

Table 1. GPs' responses to the question, 'Please tick the one response that indicates how you personally feel about the nurse practitioner performing each of the following functions.'

	Role function	Response (%)				
		Highly fav	Fav	Unc	Unfav	Highly unfav
a	Makes the initial assessment of an individual's health–illness status when he or she enters the healthcare system (n=46)	37.0	45.7	8.7	6.5	2.2
b	Prescribes medications with doctor collaboration (n=47)	10.6	48.9	19.1	10.6	10.6
c	Prescribes medications as directed under Section 24 of the Nurses Act 1977 (n=43)	2.3	23.3	48.8	14.0	11.6
d	Evaluates progress of patient with prescribed therapeutic regimen and adjusts medications, treatment or therapy in collaboration with doctor (n=46)	13.0	56.5	13.0	13.0	4.3
e	Provides health teaching to patient and family in order to maintain or promote health, and to prevent illness (n=47)	68.1	29.8	2.1	0	0
f	Performs a physical examination (n=46)	13.0	28.3	26.1	21.7	10.9
g	Recommends plan for healthcare to patient and family based upon clinical findings and in consultation with a doctor (n=47)	17.0	55.3	19.1	8.5	0
h	Makes home visits to do follow-up evaluations of the condition of the patient and their family (n=46)	34.8	56.5	2.2	6.5	0
i	Initiates treatment and therapeutic regimens of commonly occurring, acute health problems of individuals according to standing orders authorised by a doctor (n=47)	21.3	44.7	12.8	17.0	4.3
j	Obtains and records the patient's and family's health history (n=47)	36.2	48.9	10.6	4.3	0
k	Identifies development and behavioural problems of children and adolescents (n=47)	27.7	57.4	12.8	2.1	0
l	Coordinates healthcare of individuals and family referral to other health professionals and/or community agencies (n=47)	28.3	34.8	26.1	8.7	2.2
m	With written guidelines, makes decision regarding when to refer patient to a doctor (n=46)	19.6	47.8	21.7	6.5	4.3
n	Manages routine healthcare of essentially well individuals (n=46)	28.3	52.2	8.7	10.9	0
o	Orders routine laboratory studies as indicated (n=47)	10.6	31.9	25.5	21.3	10.6
p	Manages stabilised, long-term and chronic illness of individuals in all age groups (n=47)	14.9	34.0	29.8	12.8	8.5
q	Participates with doctor in continuous evaluation of the quality and effectiveness of healthcare (n=45)	28.9	60.0	4.4	4.4	2.2
r	Provides counselling regarding the health–illness problems of the individuals and families (n=46)	28.3	54.3	10.9	4.3	2.2
s	Overall, how do you feel about the nurse practitioner concept? (n=46)	23.9	30.4	32.6	8.7	4.3

fav=favourable; unc=uncertain; unfav=unfavourable

The most uncertainty concerned prescribing medications under the Nurses Act. One third of GPs indicated that overall they felt uncertain about the concept of the NP. Table 1 summarises the GP responses to questions on role functions.

The second question asked about the anticipated problems and factors influencing the development of the NP role. An analysis of responses indicates that overall GPs foresee 'some' to 'few' problems with the utilisation of an NP (Table 2). The question relating to patients' acceptance of the NP was viewed most positively. The remaining seven items were rated more negatively. The item the GPs perceived to be most problematic was funding of NP services. Table 2 outlines the GPs' response to potential problems.

Table 2. GP responses to the question, 'Please indicate your perception of the following potential problems in the utilisation of a nurse practitioner. Tick the one response which is most representative of your belief.'

	Potential problems	Response (%)			
		No problems	Very few problems	Some problems	Many problems
a	Patients' acceptance of NP (n=47)	10.6	46.8	40.4	2.1
b	Doctors' acceptance of NP (n=47)	2.1	17.0	55.3	25.5
c	Other nurses' acceptance of NP (n=46)	4.3	34.8	54.3	6.5
d	Quality of service rendered (n=47)	8.5	29.8	44.7	17.0
e	Legal problems (licensure, malpractice, etc) (n=46)	4.3	23.9	41.3	30.4
f	Interference with doctor–patient relationship (n=47)	6.4	31.9	44.7	17.0
g	Availability of funds to cover NP services (n=45)	2.2	8.9	46.7	42.2
h	Demands on doctors' time for supervision of and/or consultation with NP (n=47)	4.3	21.3	63.8	10.6

Other concerns GPs mentioned included confidence in competence, skills and knowledge base, NPs being used as a cheap option by the Government, competition affecting income and workload, increased after-hours workload, fragmentation and duplication of services, confusion over role and professional boundaries, repeat of experience with midwives and nurses not wanting to take on the role and training required.

When asked about their knowledge of the NP role, GPs indicated they have knowledge of and have read about the NP role and most had discussed this with colleagues. The majority had experience of a nurse who 'utilises advanced skills and knowledge within a specialist scope of practice.'

One question concerned demographics, practice settings, organisation structure, capitation, GP shortage, NP service, and willingness to employ or work with an NP. A shortage of GPs in their community was noted by 57%; 70% indicated that the services of an NP would enhance the delivery of healthcare in their community; 64% said they would be willing to employ an NP; and 86% indicated a willingness to work in collaboration with an NP.

One doctor experienced in working with NPs overseas stated, “They allow me to expand my practice and care for more clients…This could be a way for New Zealand and Northland to deal with the shortage of care providers.” Some comments referred to politics or the Government as the key driver of the NP role. It was also apparent that GPs are confused over the proposed role and legal status of the NP. Some GPs indicated that if nurses wanted to be doctors, they should go to medical school.

Discussion

These findings indicate that although the overall perception of GPs regarding the NP role is favourable, there is a degree of concern about some role functions including prescribing, undertaking physical examinations and ordering laboratory tests. These functions could be seen as those traditionally belonging to the domain of the medical profession. GPs felt most favourably towards those functions that have traditionally been part of the nursing role, such as health teaching, home visiting, taking a health history, and evaluating quality and effectiveness of care. The list of role functions included in the questionnaire is not prescriptive or complete. For example, many NPs may elect not to be nurse prescribers. The focus of the NP role will not be on role functions but rather on a scope of practice. NPs will define their own scope of practice according to their area of expertise.[12] If the NP has to carry out those role functions traditionally associated with medicine they will be well prepared to do so, but the emphasis will be on health promotion and disease prevention.[9] The scope of practice will also be developed to meet client needs.[9]

Uncertainty regarding the concept of the NP and concern over legal problems and demands on doctor time indicate some role confusion regarding the NP’s scope of practice and the boundaries between the GP and NP roles. NPs will be legally accountable for their own practice or malpractice. In addition, while it appears that GPs believe that NPs would enhance services, it seems that there is still a problem with doctors’ acceptance of the NP. Comments indicate that this could be due to a perception that NPs will be in competition with doctors or will replace GPs. A concern was expressed about a repeat of the experience with midwives. This is valid in view of the fact that after midwives were enabled to provide independent care and claim reimbursement there was a reduction in the number of GPs providing maternity care.[13] It is estimated that NPs can manage up to 90% of the care currently provided by doctors working in primary care.[14] In this study, 57% of GPs felt there was a GP shortage in their area, therefore it is unlikely that NPs will replace current GPs in Northland. However, the fact remains that NPs can deliver some of the care currently provided by GPs. Clients should be able to access the health professional best able to meet their health needs in the most cost-effective manner.[1]

GPs indicated that funding was the most problematic issue. GPs have traditionally been the lead providers in primary healthcare.[15] Although funding arrangements will change towards capitation for population groups, only 30% of GPs indicated that they receive capitated funds of some sort. This highlights the reliance of GPs on traditional fee-for-service funding systems for part of their income. It is proposed that new captitated funding arrangements will enable the direct funding of nursing and other services through the proposed Primary Health Organisations (PHOs).[1]

The comments and concerns listed by the GPs highlight the stress, uncertainty and confusion they experience in these times of rapid change in the primary healthcare

system. Role confusion and frustration were evident from comments that, "If nurses want to be doctors, they should go to medical school." Professional role boundaries will change and create further uncertainty and challenges to professional identity. Williams found that as role boundaries change, there is increasing uncertainty in professional identity for doctors as well as nurses.[16]

While GPs indicated that they have knowledge of the NP function, incorrect assumptions indicated that more education is required to fully inform GPs about the NP role and how NPs will fit into the context of primary healthcare in the NDHB. Areas in which GPs displayed a requirement for further information were nurse prescribing, legal issues, and funding.

The results of the current study were compared with two US studies that used versions of the same questionnaire. These were an early study of physicians in general practice in Southern California,[4] and a more recent study of primary care physicians in Michigan.[5] Although the results of these exploratory studies cannot be generalised to other populations, there are similarities. The current study indicates that GPs had increased knowledge of the NP role since the time of Radke's original study in 1977.[4] This is not surprising, given that the NP concept has appeared frequently in the international literature over the last 20 years. There were similar responses in GPs' perceptions of the role functions of NPs and potential problems. In the current study and those by Radke[4] and Ivkovich,[5] health teaching was seen as most favourable and doctors' acceptance of NPs problematic. While results cannot be generalised to a larger population of GPs, they indicate that there are doctors' perceptions of the NP that carry over to the present day and the New Zealand setting.

The results of this study indicate that Northland GPs are favourable towards working with NPs and believe NPs can enhance care in the community. GPs as key stakeholders have the ability to positively or negatively influence the support and development of the NP role and models of care delivery. To promote support, it is essential that GPs be fully informed about the NP role and its potential positioning in primary healthcare in order to reduce uncertainty, minimise role confusion, and promote collaboration. The NDHB should explore opportunities to educate GPs about the NP role. Information on the NP role could be taken to GP practices in Northland via a regional version of the roadshow conducted by the Ministry of Health in 2002.[17] The NDHB should also commission research to assess health outcomes as NP models of healthcare delivery are implemented. In addition, doctors who have worked overseas could share their knowledge and positive experiences of working with NPs, defusing any stress and uncertainty regarding this change.

Mutual respect and cooperation is required between doctors and nurses in Northland. NPs are potentially a valuable resource in the provision of primary healthcare. Overseas, medical organisations have fought the introduction of NPs and the perceived threat they present to the medical profession. Australia is currently experiencing this.[18] However, this experience does not need to be repeated in Northland or New Zealand as a whole. Multiple studies have demonstrated that the NP role is one that has much to offer.[3] The government supports the introduction of the NP.[9] Medicine and nursing must move beyond professional lobbying and work together with consumers and other health professionals to develop NP models of care delivery to best meet the needs of their communities.

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The Queenstown Report: proposals for change in the medical disciplinary complaints process

Wayne Cunningham and Murray Tilyard

Receiving a complaint is not a pleasant experience for most doctors. It challenges their practice of medicine, their present and ongoing relationship with their patients, and at times even their sense of self.[1] Society, however, seeks to maintain accountability of the medical profession by, amongst other measures, being able to complain about individual doctors and is unlikely to relinquish this right. There are no published data in the New Zealand literature of doctors' ideas about how a complaints system might be improved, despite doctors having a major stake in the consequences of any proposed change.

In addition to the effect on the individual practitioner of receiving a medical disciplinary complaint ("a complaint"), other issues surrounding the complaints process have an impact on the profession and society. The purpose of a complaints system, the avenues through which a complainant may seek redress, and the standards set and process used in passing judgement on a doctor's practice, are all examples of issues that members of the profession may seek to define and into which they may wish to have input.

This report presents the recommendations of a workshop addressing issues surrounding the complaints process that was held in Queenstown, New Zealand, 13–14 July 2002, under the auspices of the Southlink Health Independent Practitioners Organisation, a body representing 452 general practitioners in the South Island. Thirty five general practitioners attended the workshop. Some senior representatives of New Zealand organisations with a significant stake in the complaints process also attended the workshop, and have had the opportunity to review a previous draft of this report. They were:

- J Adams: Chairman, New Zealand Medical Association
- MAH Baird: President, Medical Council New Zealand
- D Court: Medicolegal advisor, Medical Protection Society
- R Paterson: Health & Disability Commissioner
- G Phipps: Barrister, Medical Protection Society
- P Robinson: Medicolegal advisor, Medical Protection Society
- H Rodenburg: President, Royal New Zealand College of General Practitioners

The way in which New Zealand society approaches the complaints process is currently under review, and this report seeks to present the profession with further material for discussion and debate.

The conference proceedings

The workshop process included small-group work, working-group reports, and facilitated, whole-group plenary sessions.

The first session defined the purpose of a complaints system, presented some recent research findings, and considered what the characteristics of an "idealised" system might be. The second and third sessions defined the most pressing problems of the current system, and sought solutions to them.

Defining the purpose of a complaints system

The workshop identified the complex relationships that link the medical profession (a community of doctors), and society (a community of patients). The maintenance of trust whilst recognising the potential for practice that is less than ideal, and the need for reconciliation and closure between doctors and complainants, were identified as paramount. The workshop identified the purpose of a complaints system as:

- the maintenance of trust between society and the profession, and between doctors and their patients, including accountability;
- acting as a voice for patients and to meet specific patient needs including:
  - explanation,
  - maintenance of safety,
  - maintenance of boundaries,
  - compensation;
- providing the opportunity for reconciliation and closure between doctor and patient in an environment of transparent equity and fairness to both parties;
- maintaining standards of professional practice, including acting as a deterrent against malpractice and corruption.

Recent research into how the complaints system could be improved

Dr Wayne Cunningham presented an overview of preliminary results from his current (unpublished) research into the effect of medical disciplinary complaints on doctors, summarised as follows.

Written answers to the question "How could the disciplinary complaints system be improved in this country?" were received from 453 (out of a total of 598) surveyed doctors in New Zealand. Respondents came from three groups identified from the New Zealand medical register; general practitioners, hospital-based specialists, and general registrants. The responses were thematically analysed, and several key issues emerged:

- Respondents felt that a complaints system is needed, and the current system is in need of improvement.
- Respondents were aware of the tension that exists between the ideal delivery of healthcare and the experienced reality of both doctors and patients. Because complainants may not understand the process and limitations of medicine, they may hold unrealistic expectations that can lead to a complaint. The respondent doctors recognised a relationship between the outcome experienced by the patient rather than actual error, as the determinant of some complaints being laid.
- There was universal recognition of the need for speed in the process and resolution of a complaint.
- Dialogue and mediation between complainant and doctor in the presence of advocates for both parties were seen as desirable, and the complaints process

had to recognise that both patients and doctors had rights and responsibilities. The importance of the complaints process leading to a satisfactory outcome for patients was seen as important, and included the need for rectifying problems that were still being experienced.

- Issues related to the composition of disciplinary bodies were raised by all of the respondent groups. Those sitting in judgement needed to be experienced in the realities of practice in the field in question, and the standards by which a doctor's practice of medicine is judged need to be transparent and realistic.
- The involvement of the media in the process was widely seen as intrusive and contrary to notions of natural justice.
- **The only idea for constructive structural change to the complaints process was the formation of a single complaints body as the point of entry for all complaints.**

The characteristics of such a body as suggested in the last point above are summarised in the following points. It should:

1. Be the point of entry for all complaints;
2. Be capable of rapid response to a complaint;
3. Provide a safe environment for dialogue and mediation between complainants (and their advocates) and doctors (and their advocates);
4. Be based on rights and responsibilities of *both* parties;
5. Be capable of weeding out complaints lacking in substance, or malicious and vexatious complaints;
6. Seek to improve the delivery of healthcare, being able to discriminate between failings attributable to medical (health) systems, error in the practice of medicine, or wrongdoing;
7. Be aware of the limitations of medicine;
8. Consist of members or appointees who are properly trained and funded, appropriately experienced, and whose judgements would be seen as being fair and appropriate:
   - the panel would be appointed, not composed "ad hoc",
   - the panel would be competent in the field in question;
9. Be capable of seeking improved outcome for the patient;
10. Be independent of the influence of the media, offering protection from premature or emotive reporting.

Major problems in the current system and suggested solutions

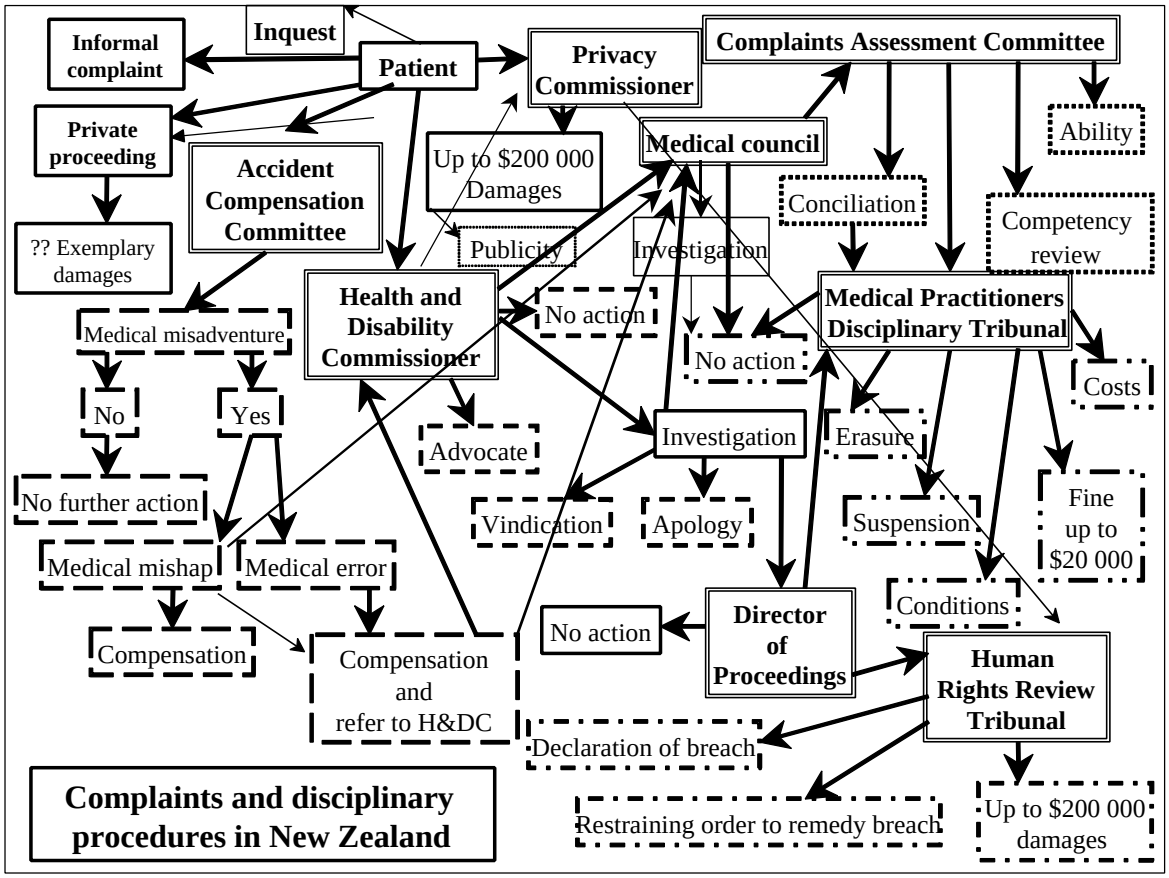
Multiple viewpoints need to be considered to identify the range of problems in a complex system. This workshop asked the key organisations' representatives to present *their* views of the major issues that beset the current complaint system. These were presented, collated and summarised, identifying six problematic issues. These were debated and, where possible, suggested solutions were tabled.

The major problems identified and their suggested solutions (when provided) are as follows.

1) Multiple pathways of complaint

Also expressed as “multiple jeopardy” and “death by 1000 arrows” (Figure 1), the notion of complainants being able to access multiple pathways to complain or otherwise take action against a doctor is problematic (personal communication, Gaeline Phipps, Barrister, Medical Protection Society).

Figure 1. Death by 1000 arrows: the multiple pathways of the current complaints system in New Zealand



Suggested solution Single point of entry into the complaints process. A single complaints body would need to be adequately resourced, and be capable of triaging complaints and allowing low-level resolution between complainant and doctor.

The process would be expected to provide a definite endpoint, and limit the possibility of further complaint. Significant legislative change would be required to create a single point of entry system, but was seen as possible with determination from the profession and political support.

2) The timeliness of the process

The speedy resolution of complaints is important for both doctors and complainants, and entry into any further complaints process has to show just cause. The complaints

process needs to provide sufficient time for both parties to be adequately heard, and have the ability to triage (and remove) unwarranted complaints. The introduction of a Statute of Limitations, with the flexibility to account for the varying nature of complaints, would counter the problem of receiving complaints long after the event.

The process requires closure for both parties, with determination of harm and the potential to improve outcome for the complainant.

3) Appropriate clinical standards and advisors

Determining whether a practitioner's practice is of an appropriate standard is a difficulty encountered by complaints bodies and indemnity insurers. Clinical standards lie along a spectrum from negligence through to best practice, and judgement about practice needs to be based on a realistic standard for the circumstance in question.

Although the medical community (via the representative Colleges) is asked to provide appropriate advisors, the process of appointment may not be transparent, and advice given may be seen as contentious and out of touch with reality.

Suggested solution Review of the process of selection of advisors used by complaints bodies and recommended by Colleges. A pool of appropriately nominated, selected, and funded advisors from all medical fields is needed.

4) The use of expert witnesses

Being an expert witness is difficult at a personal level (for the witness) and at an organisational level (for both defence and prosecuting bodies). The workshop highlighted concerns under the following headings:

Desirable characteristics of the expert witness

The expert witness needs to be transparently appropriate for the role. They need to be knowledgeable of the standards of practice in question, and experienced in the type of practice that is being discussed. They need to be able to communicate their expertise well and be prepared to devote sufficient attention to the details of each case.

Issues facing the expert witness

Being an expert witness is stressful. The witness may find himself or herself judging their colleague's performance in an unfamiliar, adversarial court-based setting. They may lack confidence, and the process is time consuming. These factors contribute to the perception that the most appropriate people for the job are the ones least likely to be available.

Suggested solution Attend to the particular needs of expert witnesses by providing:

- specific training, including the rights of witnesses, how to respond to questioning, and how to provide reports;
- good legal counsel and appropriate access to evidence;
- protection from liability;
- appropriate remuneration, and use of a pool or roster of experts to avoid overuse.

5) Reduction of complaint-related stress

Doctors should recognise complaints as being inevitable and stressful.

Suggested solutions Doctors should:

- have strategies for dealing with the effect of receiving a complaint that are meaningful to them, and they should predetermine the support that they need;
- have a doctor and make use of them;
- have and use their legal/indemnity advice;
- make necessary changes in their practising and personal lives to reduce the risk of a similar complaint in the future.

6) The need for appropriate support systems

Support for doctors in receipt of a complaint needs to be personal and meaningful, and doctors may feel unsupported and alone.

Suggested solutions Create a group of appropriate contact persons. That group would itself have specific needs, including training and funding, and have the capacity to work in privacy and confidentiality. Professional colleges and IPAs are the bodies best placed to create and administer the support group, acknowledging the capacity for individual practices to do this as well.

Conclusions

The negative effect of medical disciplinary complaints on doctors is an issue of importance to both the medical profession and to society at large. Reduced doctor morale and increasingly defensive practice have the potential to erode the delivery of high-quality medical care in this country.

Complaints are inevitable, but the complaints process has the potential to improve the delivery of healthcare to patients. The tension faced by both doctors and society lies in the balance between an (unrealistic) expectation of perfection and the experienced reality of disease, illness, and the practice of medicine.

This workshop sought workable solutions to some of the problems encountered, and the recommendation of this report is that these notions be discussed by practitioners, their Colleges and IPAs, and by indemnity, judicial and disciplinary bodies. Political support will be required for legislative change, and it is the responsibility of all concerned parties to work towards improving the complaints process in a way that benefits all New Zealanders.

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The sorry saga of the statins in New Zealand – pharmacopolitics versus patient care

Evan Begg, Andrew Sidwell, Sharon Gardiner, Gary Nicholls and Russell Scott

In the past five years, the average patient requiring an HMG-CoA reductase inhibitor or 'statin' in New Zealand has suffered at the hands of the Pharmaceutical Management Agency Ltd (PHARMAC) and drug companies. PHARMAC operates in a monopsony (a market with one buyer). With its focus directed on a narrow financial bottom line (the pharmaceutical bill in the short term), it has played reference-pricing dominoes with little consideration for the broader, or long-term concerns of healthcare. The drug companies, rather than making a united stand in favour of best evidence, have competed to outmanoeuvre each other for market share.

In essence, PHARMAC repeatedly changed the reference-priced (subsidised) statin as companies did deals with it. For short-term, narrow-focussed financial reasons, patients were forced to change from simvastatin or pravastatin to fluvastatin, then atorvastatin, and for many, back to simvastatin.

Little consideration was given, by either PHARMAC or the drug companies, to the effects of "switching". There was little consideration of evidence-based medicine. There was little consideration of the relative pharmacological advantages of the individual drugs (adverse effects, drug interactions, etc). There was little consideration of the flow-on costs of this simplistic pricing strategy. As long as short-term savings to the pharmaceutical ledger were apparently being made, PHARMAC could hide behind its oft-quoted crowd pleaser "a saving here will allow more money to be spent there".

Let us consider the history of this debacle. The 4S study of simvastatin in secondary prevention provided firm evidence that statins actually save lives in patients with existing ischaemic heart disease. Other studies with pravastatin quickly followed.[1] The WOSCOPS trial showed reduced mortality and morbidity rates with pravastatin in the primary prevention of cardiovascular disease.[2] Both the CARE and LIPID trials, also with pravastatin, showed improved outcomes for secondary prevention of cardiovascular disease.[3,4] Statins became hot property.

PHARMAC rightly realised that the widespread use of statins could result in a financial blow-out. The Pharmacology and Therapeutics Advisory Committee (PTAC) subcommittee of lipid experts concluded that "ideally the statins should be subsidised, based on their ability to modify absolute risk, or reduce total mortality". Simvastatin and pravastatin had the greatest evidence base, and were cheaper per percentage reduction in cholesterol than fluvastatin. Yet PHARMAC stated that "their lipid experts view that there is sufficient evidence that all statins have the same or similar effect". In December 1996, fluvastatin became the reference-priced statin.

On the basis of evidence, the reference-priced drug should have been simvastatin or pravastatin. There were no proven morbidity or mortality data supporting fluvastatin. On the basis of pharmacology, pravastatin had some advantages. It was less lipid

soluble than the other statins, giving it some potential advantages in terms of muscle toxicity and drug interactions.[5] Simvastatin, which is metabolised by CYP3A4, has problems with drug interactions, and also a notable interaction with grapefruit juice. The area under the plasma concentration-time curve of simvastatin can be several times larger when it is taken with grapefruit juice, through inhibition of presystemic metabolism.[6] This interaction does not occur with pravastatin.[7] On the basis of pharmacology, pravastatin was arguably the statin of choice.

But, as already mentioned, fluvastatin became the reference-priced drug. This had the immediate result that doctors were forced to shift the majority of their patients from the statin on which they were stabilised to fluvastatin, or inform them that they would have to pay to remain on their original drug. The use of pravastatin declined, and on 1 June 2002 it was delisted from the Pharmaceutical Schedule (ie, it is no longer funded). No process was put in place to monitor, prospectively, for any adverse effects, and the inevitable extra workload forced on practitioners to facilitate such switching was seen as only a minor problem. PHARMAC expressed pride in the process.[8]

Fortunately, an independent audit occurred. Professor Jim Mann from Dunedin published observational data suggesting that the switch to fluvastatin resulted not only in deterioration in control of lipid concentrations in most patients,[9] but also a significant increase in the frequency of thrombotic vascular events compared to the previous six months of simvastatin therapy ($p < 0.001$).[10] This was not surprising, because fluvastatin, in its suggested dosage range, operates at a lower part of the dose-response curve than the other statins, and the same lowering of lipids in the same number of people could not be expected.[9]

The deficiencies of fluvastatin were so marked that they were quickly perceived, not only by practitioners, but presumably also by PHARMAC, who raced to reference price another, more powerful, statin. The statin chosen was atorvastatin – the most potent, and in the doses selected, the most powerful lipid-lowering agent available at the time. The problem with atorvastatin was that, like fluvastatin, its evidence basis was lacking compared with simvastatin and pravastatin. Pharmacologically, it did not quite have the advantages of pravastatin, but the potential for interactions was quantitatively less than for simvastatin.[7]

The reason atorvastatin was chosen was not actually related to any of the above, but to a cross-subsidisation deal between PHARMAC and Parke-Davis (now Pfizer), distributor of atorvastatin. Parke-Davis was keen to enter the lipid market, and was prepared to discount quinapril, its ACE inhibitor, substantially to get the nod for atorvastatin. As a tickler, Parke-Davis agreed to a ‘capped budget’ for atorvastatin, meaning that if sales increased above a certain point, they (Parke-Davis) would absorb this cost. This is a form of risk-sharing, and serves as an insurance for PHARMAC against cost blow-outs. The deal went through, and quinapril became the reference-priced ACE inhibitor, along with cilazapril. The consequent switching of ACE inhibitors from enalapril, the market leader, to these newer ‘prils’ is another sorry saga, but outside the brief of this article.

Cross-subsidisation deals can make sense in a hard business world, but clearly they render rational discussion difficult or impossible when it comes to determining the cost benefits of an individual drug in the world of medical care.

The effect of the reference pricing of fluvastatin and then atorvastatin was initially predictable. There was a wholesale shift from the evidence-based statins to either of these drugs, and for some patients a double change, through fluvastatin to atorvastatin. With time, however, sales of fluvastatin began to drop off as doctors realised that this drug was not very effective in lowering cholesterol. Atorvastatin sales increased more than expected and surpassed the cap agreed upon by PHARMAC and Parke-Davis.

Meanwhile, Merck Sharp and Dohme (MSD), makers of simvastatin, were able to bring the price of simvastatin (Zocor) down because its patent had expired. This set a new reference price for the group, which PHARMAC grasped with relish. Seeing the possibility that other generics of simvastatin might challenge their market after expiry of patent in January 2002, MSD began long and complicated negotiations with PHARMAC. As a result, a deal was struck in which MSD reduced the price of simvastatin further, with the quid pro quo for PHARMAC being that other generics would not be introduced until at least 2006.

On 1 April (!) 2002, with the price of simvastatin now very low and in response to considerable external pressure, PHARMAC was able to remove the special authority requirements, thereby increasing access to this class of medicines. PHARMAC is to be commended for this. Pfizer's special arrangement with PHARMAC for the pricing of atorvastatin persists until April 2004, at which point this statin will also be reference priced, presumably against simvastatin. To limit the numbers using atorvastatin, and to reduce the cost burden to the company (currently atorvastatin sales exceed its cap by many $millions), the use of this drug remains under 'special authority'. Fluvastatin was deemed unviable for our market by the company that produced it, and was 'delisted' in New Zealand in November 2002 (Lescol) and on 1 February 2003 (Vastin). These moves effectively give the market to simvastatin, with the inevitable new round of switching.

As if this is not complicated enough, MSD now promotes simvastatin under the name Lipex, rather than Zocor. The drug is identical. The name was changed because the price of Zocor in New Zealand had become so low in international terms that comparisons might be made, and there was a risk of parallel importing from New Zealand to other less regulated countries.

Recently, the results of the Heart Protection Study, the largest trial of statin therapy, confirmed the mortality and morbidity benefit of simvastatin in patients at high risk of coronary heart disease.[11] This trial showed benefit regardless of age, gender or baseline cholesterol, and that the drug was well tolerated.

There is still no evidence for either fluvastatin or atorvastatin that is comparable to that for simvastatin or pravastatin in terms of improved clinical outcomes in primary and secondary prevention of cardiovascular heart disease. High doses of both fluvastatin (40 mg twice daily) and atorvastatin (80 mg daily) have been studied in the more specific clinical settings of post angioplasty and post acute coronary syndrome in the FLARE[12], AVERT,[13] and the MIRACL[14] studies. These studies showed some clinical benefits with treatment, but none of them showed clinical benefit in all areas (death, myocardial infarction, intervention rates).

At the end of the day, this saga has been a triumph for the short-term, narrow-focussed financial imperative, and a disaster for the medical practitioner, medical

education, community pharmacists and, most importantly, the patient. Decisions made have flown in the face of evidence-based medicine and conventional teaching of therapeutics. The message imparted is that immediate savings in pharmaceutical spending are the primary concern; long-term savings in the broader health sector, health outcomes, pharmacological principles, teaching principles, practitioner workloads, and good patient care matter less.

It is a tenet in the teaching of therapeutics not to rock the boat. If a drug is working for the patient, make an alteration only with good reason. It often takes a great deal of time and effort to achieve concordance with the patient on what is the right drug for them, at the right dose, and in the right combination with other drugs. Changing from one drug to another in the same class at assumed equivalent doses, should not be undertaken lightly. It is likely to result in therapeutic failure in some patients (through under-dosage), appearance of new side effects in others (through over-dosage, or particular drug idiosyncrasies), and drug interactions with varied effects in others. History abounds with examples of the dangers associated with assuming a 'class effect', eg, the withdrawal of the β-blocker practolol because of serious though rare side effects, various non-steroidals such as benoxaprofen, and the calcium antagonist mibefradil.[15]

Interestingly, PHARMAC pays little heed to its own decision criteria for amendments to the Pharmaceutical Schedule. It is difficult to see how its decisions improved overall budgetary impact, had clinical benefits over risks (unmonitored), or met the needs of Maori and Pacific people, who are particularly prone to cardiovascular disease. The problem with the PHARMAC model is that switching can occur next month, next year, the year after, or whenever a new deal can be struck. Something needs to be done to stem this tide. It is our contention that the incentives under which PHARMAC operate must change, from cost-focussed to health-focussed.

Whether or not the actions of PHARMAC can be considered ethical is open to question. On one hand, the Medical Council of New Zealand states in its Ethical Guidelines for doctors in an environment of competition or resource limitation, "A doctor's primary responsibility is to his or her patient. The responsibility is not only to provide the best care possible within resources available but also to make clear to any patient to whom care of proven effectiveness is being denied by any funder or provider, that what is being provided is not optimal care, by generally agreed standards of medical practice."[16] On the other hand, the Chairman of PTAC argued that "medical professionals tend to weigh too heavily the ethical responsibility they have to the individual patient, but of equal importance is the competing duty of care to the society and the taxpayer".[17]

The history of the health reforms in New Zealand has often been one of silence – silence from those who know things are wrong, but will not say so. We need to be better advocates for our patients. As John Ralston Saul, the Canadian philosopher–author said, "Our primary obligation as citizens is to speak up and disagree."

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Response from PHARMAC: difficult choices

Peter Moodie, Scott Metcalfe and Wayne McNee

We appreciate being given the opportunity to respond to the viewpoint offered by Professor Begg and colleagues.[1] Our perspectives differ, but we do agree on the desirability of open and vigorous debate.

PHARMAC is a Crown entity reporting to the Minister of Health and Parliament, and is responsible for subsidising most prescription medicines sold in New Zealand. It would be hard to imagine a different structure. The model is similar to that used by many other developed countries, including Australia, the United Kingdom, France and Sweden. Other countries that use reference pricing in various forms include Australia, Canada, Germany, Spain, Norway, and Belgium.

PHARMAC's focus must be on health gain and costs versus savings to the health sector as a whole, as we have pointed out elsewhere in this issue of the Journal.[2] We have to be concerned with "opportunity cost", which we define as the health gains that are lost if scarce health funds are spent (squandered?) on less worthwhile services. It is for that reason PHARMAC relies so heavily on its decision criteria and assesses cost effectiveness.

At the time of the decision in 1997 to reference price HMG-CoA inhibitors (statins), PHARMAC was faced with the dilemma that there were fewer than 50 000 patients* eligible in New Zealand for statins (with an uptake of about 12 000), although the National Heart Foundation (NHF) guidelines recommended access to about 186 000. If PHARMAC had widened access to statins at the then price of simvastatin, total spending on statins could have reached nearly $200 million each year. This would have represented 40% of all community pharmaceutical spending and would have meant not funding all the significant new investments PHARMAC has made in other (non-statin) areas and more.[3]

In 1997, the opportunity arose for PHARMAC to widen access by subsidising fluvastatin and reference pricing all available statins to it. For the 12 000 existing patients this meant either a change in medicine or an additional surcharge, but it also offered access for some 112 500 new patients.† When considering this, PHARMAC had to ask how fluvastatin compared to simvastatin, and what the possible risks of reference pricing were. It was recognised that fluvastatin was a drug that had some outcome data[4,5] although no significant mortality data. Although it was acknowledged that the lipid-lowering effect of fluvastatin might not have been equivalent to simvastatin[6] (35% low-density lipoprotein (LDL) reduction with fluvastatin 80 mg/day versus 41% for simvastatin 40 mg/day),[7] the potential to give benefit to many more patients was compelling.

There has been no good evidence of any harm that resulted from the switch from simvastatin to fluvastatin, and certainly no evidence of increased mortality as a result of the application of reference pricing. Although Begg et al quote the observational analysis by Thomas and Mann, who reviewed data in Dunedin,[8] that paper was well

criticised internationally.[9–11] Comparable mortality data were not collected – patients treated on simvastatin before the switch would have had to survive to remain in the cohort, and since no such restriction occurred after switching to fluvastatin, deaths after the switch logically should have been excluded. Because it was an uncontrolled before-and-after study, potential bias was introduced by the unmasking of clinicians who admitted and then assessed patients, and of the evaluators who extracted and assessed the data. Additionally, the data before the switch were obtained from the hospital computer system (not fully reliable), whereas the data after the switch appeared to have been collected systematically and with care. In addition, that analysis tabulated but failed to comment on a key possible reason behind the reported increase in cholesterol concentrations: the possible subtherapeutic dosing of patients with the substituted drug (fluvastatin).[11,12]

At the time of the 1997 decision to reference price, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) had commented that there was then little evidence for or against a statin class effect.[7] However, CCOHTA considered that since cholesterol reduction had been associated with a reduction in coronary events, it could legitimately be assumed, until proven otherwise, that because all statins decreased LDL levels and increased high-density lipoprotein (HDL), all would produce a decrease in coronary events. This statement came with the caution that lipid level was a surrogate outcome, and that surrogate outcomes should be regarded in light of their limitations. CCOHTA concluded that there was no clear evidence that one approach was better than the other.

For class effects, it has been commented that there exists in evidence-based medicine a continuum between those who are prepared to assert a class effect after a single clinical trial and others who believe that drug use must be restricted to only those drugs proven in mortality-based studies and at doses used in clinical trials and for similar populations. Where one stands on this continuum is probably a matter of individual clinical judgment. However, it seems sensible that if three or more compounds are beneficial in clinical studies, have very similar pharmacological characteristics, and have similar multiple surrogate endpoint data, a class effect may well exist for other drugs that show similar properties across the range of surrogate endpoints. A balance has to be struck between the requirement for absolute proof for each compound in mortality studies ("at substantial ethical cost")[13] and the inhibition of innovation by a different form of monopolistic marketing lock-in. Multiple drug options stimulate price competition, can reduce healthcare costs and increase access for patients to possibly superior compounds before absolute proof of their efficacy becomes available. "Evidence-based medicine is a difficult concept to practise and each physician needs to think carefully about how they stand on the issue with each drug."[13]

PHARMAC has accepted that the implementation of reference pricing of statins did not go perfectly.[14] PHARMAC subsequently fully funded simvastatin for patients who met defined criteria by January 1998, and atorvastatin later that year. However, fluvastatin is still widely used around the world, and randomised evidence has shown that it too can produce health outcomes equivalent to other statins in terms of one-year cardiac events in hyperlipidaemic patients with symptomatic coronary heart disease (CHD).[4] Subsequent publication of FLARE concluded fluvastatin treatment in patients with average cholesterol levels undergoing their first successful percutaneous

coronary interventions significantly reduces the risk of major adverse cardiac events.[15]

Begg et al have not criticised the seemingly inappropriate very high ongoing uptake of atorvastatin, despite what they say is lack of clinical evidence of superiority (along with fluvastatin) over simvastatin. If atorvastatin does not have the hard clinical outcomes evidence then, to be consistent, simvastatin and pravastatin should have been used ahead of atorvastatin too.

What price should we all pay for atorvastatin, when simvastatin is largely as effective at reducing LDL/HDL ratios for the few patients needing very high doses?[16,17] Recent HealthPAC data (for October 2002) indicate there are some 46 417 patients using atorvastatin at a nominal cost of $23.1 million each year (excluding rebates). Simvastatin at equivalent doses would cost some $17.8 million. Special authority data have shown that less than 1% of patients with pre-existing CHD had total cholesterol levels of 10 mmol/l and over – maybe 1600 patients.[‡] In fact, 20% of atorvastatin patients are currently using very high doses at greater than 40 mg/day – some 9202 patients. (Further details can be found at http://www.pharmac.govt.nz/pdf/AppendixToDifficultChoices.pdf)

Simplistically, even at high doses of atorvastatin for patients at highest risk (here, patients with total cholesterol >7.5 mmol/l with pre-existing CHD), we would need to treat perhaps 49 patients with atorvastatin for five years to prevent one more CHD event than if we were to use simvastatin, for what is a much more expensive agent. At $52 100 per quality-adjusted year of life (QALY) gained[§] this compares poorly with other options. Arguably, resources have been ostensibly squandered through patients using atorvastatin when simvastatin was both as effective and was cheaper at equivalent doses.

PHARMAC was able to remove special authority requirements (hence widen access) in April 2002 because of a favourable price agreed with Merck Sharp and Dohme (making simvastatin much more cost effective)[18] – not in response to "considerable external pressure". Access increased to potentially around 300 000 people, up from 180 000. This compares with the fewer than 50 000 people eligible for statin treatment before the 1997 changes, potentially "saving" in just three months to June 2002 an estimated 37 extra "statistical lives" and freeing up a nominal $531 000[¦] to the health sector.[2] Statins have not always been favourably priced, which was the main contributor to the "delays" in widening access criteria.[3]

It is tempting to advocate solely for the patient sitting in front of you and not for others. We think this approach is unacceptable when resources are limited and we have to make choices. If prescribing overly expensive treatments leads to other patients missing out altogether, then we have to reconsider the ethical issues. Under these circumstances, we stand firmly by the comments made by the Chairman of PTAC (Dr John Hedley), and note that the Medical Council of New Zealand's position includes principle 6 that "Doctors must not waste money allocated to health care or misuse resources that are at their command."[19]

For PHARMAC, the patient is not just the individual person with disease or disability. It is the whole New Zealand population that may benefit from pharmaceutical treatment. Different "patients", but the same duty of care met in different ways. What happens for those patients who do not have the advantages of well-organised effective

clinical advocates? Or who are comparatively less well organised? Who advocates for the silent or less media-genic patients, those unseen, and people with health needs not even yet identified as patients? We note that, despite being particularly affected by cardiovascular disease, Maori and Pacific peoples have had much lower rates of statin use than NZ Europeans (see Table 1).

Table 1. Cumulative statin approvals until March 2000

Ethnic group	Number of patients	% of all patients	% of patients of known ethnicity	Crude rate per 1000 population aged 35+	RR vs European
European	40 605	57	77	38.4	1.00
NZ Maori	2118	3	4	14.8	0.39
Pacific Island	669	1	1	13.7	0.36
Other	9521	13	18	26.0	0.68
Not stated or (blank)	17 976	25	n/a		
Total	**70 889**	**100**			
Total, where ethnicity identifiable	**52 913**		**100**	**32.8**	**0.85**

Source: analysis of HBL data supplied to PHARMAC 5 June 2000

If PHARMAC uses commercial processes to achieve fair prices for medicines, it is because it is dealing with commercial multi-national companies. Switching between medicines is not ideal. But nor is it ideal for large numbers of people to miss out on beneficial medicines because they cost too much, when cost-effective alternatives are available.

These events occurred in 1997, since when many other medicines have been funded and PHARMAC has made changes. We appreciate Begg et al raising this issue openly and hope this debate will inform and enhance the work of prescribers and policy-makers alike.

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Conflicts of interest: Scott Metcalfe is externally contracted to work with PHARMAC for public health advice.

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Endnotes:

[*] 1991 SA criteria (NHF groups A1:1-2,A2 with total cholesterol (TC) >7.0 mmol/l, other A and B-E TC >9.0 mmol/l) applied to [age/sex/Framingham CHD risk/total cholesterol and total:HDL cholesterol ratio] prevalence rates derived from 1993/94 Fletcher Challenge-University of Auckland Heart and Health Study (FCUAHHS) (unpublished prevalence data supplied by Rod Jackson and Roy Lay Yee, University of Auckland), applied to age/sex-specific intercensal estimates for NZ population.

† 124 500 patients estimated eligible under proposed 1997 SA criteria, minus 11 960 patient-month equivalent usage of all statins. Number eligible calculated from 1997 SA criteria (NHF groups A1:1,A1:3-4,A2,A3 with total cholesterol (TC) >6.0 mmol/l, A1:2 TC >5.5, B-E TC>9.0 mmol/l) applied to FCUAHHS [age/sex/Framingham CHD risk/total cholesterol and total:HDL cholesterol ratio] prevalence rates and age/sex-specific intercensal estimates for NZ population.

‡ Based on 190 200 patients estimated from FCUAHHS [age/sex/CHD status] prevalence, applied to age/sex-specific intercensal estimates for NZ population; and HealthPAC special authority data for statins, where of 26 045 approvals patients were identified as being in group A1:1 and where total cholesterol (TC) was stated, and 216 had TC of 10 mmol/l or more (0.83%).

§ $52 069 based on nominal atorvastatin price of $1.30/day versus simvastatin $0.45/day, using the same model as for simvastatin (http://www.pharmac.govt.nz/pdf/statin02CUA.pdf) with 54% improvement in LDL/HDL with atorvastatin versus 49% with simvastatin[16] (RR 1.09). After taking into account the effects of prevented CHD and stroke events on life expectancy and quality of life, the model suggests patients using atorvastatin might save 0.0200 extra QALYs for every five years' treatment beyond what they might have saved using simvastatin. This equals treating 50 patients for five years to gain one extra QALY. Includes 4% offsets from potential savings to DHBs through fewer cardiovascular events because of the small surrogate advantages of atorvastatin over simvastatin. QALYs and costs discounted at 10%.

¦ 357.9 QALYs for 70 073 extra person-months treated, based on discounted cost/QALYs of $2111/QALY for simvastatin (http://www.pharmac.govt.nz/pdf/statin02CUA.pdf, >10% five-year cardiovascular risk excluding pre-existing CHD) and $7690 for atorvastatin (as for simvastatin, but atorvastatin price), hence volume-weighted discounted offsets at 37% of pharmaceutical spending. Net extra costs and patient-year equivalents are above that predicted from simvastatin and atorvastatin individual trends for the pervious 12 months, hence total gain in QALYS, discounting both costs and QALYS at 10%. The $531 152 nominal potential "savings: to the health sector are hospitalisation and other DHB costs averted by preventing cardiovascular events, permitting those funds to be used to treat other health needs.
Total QALYs can translate to "statistical lives saved", where each saved life is equivalent to living a full quality of life for 36.4 remaining years expected for the average New Zealand citizen, which with discounting has a present value of 9.7 years (10% discount rate); no. 'statistical lives saved' = no. total discounted QALYs/9.7. Hence, the above 358 QALYs translate to 36.9 'statistical lives saved'.

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PHARMAC measures savings elsewhere to the health sector

Scott Metcalfe, Sean Dougherty, Matthew Brougham and Peter Moodie

There has been ongoing debate in the New Zealand Medical Journal regarding PHARMAC's subsidisation (or lack thereof) of prescription medicines in New Zealand.[1–6] We believe such opinions deserve a response, and believe that PHARMAC (the Pharmaceutical Management Agency of New Zealand) does systematically assess the cost-effectiveness of new proposals in ways designed to limit bias and help decision-making – where cost-effectiveness is but one criterion.

How cost-effectiveness affects the decisions PHARMAC makes

PHARMAC's core objective, as laid down by the New Zealand Public Health and Disability Act 2000, is "to secure for eligible people in need of pharmaceuticals, the *best health outcomes* that are reasonably achievable from pharmaceutical treatment and from *within the amount of funding provided*" (our italics).

The normal decision-making process for a new medicine listing on the Pharmaceutical Schedule* (endnotes can be found after references at the end of this article) takes into account clinical benefit, pharmacoeconomic analysis and affordability. The usual steps include: clinical evaluation of efficacy relative to existing medicines; cost-benefit analysis; prioritisation against other new medicines; assessment against budget allocation; assessment against established criteria; consultation with the wider health sector; and final decision by the PHARMAC Board.

To support this process and meet its statutory obligations (maximising health gain within budget constraints), PHARMAC has a number of established structures, policies and procedures:

1) Formal decision criteria

PHARMAC has nine explicit published decision criteria as part of its formal Operating Policies and Procedures (OPPs),[7] described in Table 1. The PHARMAC Board uses these decision criteria each time it makes a decision. Cost-effectiveness is just one of these criteria.

2) Clinical evaluation by PTAC

The clinical evaluation role is carried out by the Pharmacology and Therapeutics Advisory Committee (PTAC). PTAC is an independent expert advisory committee to PHARMAC and is involved in PHARMAC's decision-making process. PTAC and its subcommittees provide independent and objective advice to PHARMAC, and comprise medical practitioners with broad general experience and a particular interest in medicines and their therapeutic indications. PTAC has a generalist focus, but increasingly it takes advice from known experts in their field, often via its subcommittees. PTAC members are practising clinicians, appointed by the Director-General of Health, who are specialists in their own areas and are usually drawn from the areas of general medicine, general practice, paediatrics and clinical pharmacology.

PTAC follows established processes,[8] and makes recommendations either for the attachment of high, medium, or low priorities to proposals, or that a proposal be declined or be referred back to suppliers for further information.

Table 1. PHARMAC decision criteria

No.	Criterion
1	The health needs of all eligible people within New Zealand
2	The particular health needs of Maori and Pacific peoples
3	The availability and suitability of existing medicines, therapeutic medical devices and related products
4	The clinical benefits and risks of drugs
5	The cost-effectiveness of meeting health needs by funding drugs rather than using other publicly funded health and disability support services
6	The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule
7	The direct cost to health service users
8	The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere
9	Such other criteria as PHARMAC thinks fit; PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account

PTAC uses the same decision criteria as PHARMAC when it evaluates medicines. Any recommendation by PTAC may ultimately vary from PHARMAC's view, in part because PTAC reviews Pharmaceutical Schedule applications at a different stage in the assessment process to PHARMAC; PHARMAC may have a wider range of relevant information when making decisions. Consequently, PHARMAC may attach a different listing priority or make a decision that differs from PTAC's recommendations.

One criticism of PTAC has been that its processes have not been completely transparent. However, the problem for PTAC and PHARMAC has been one of commercial sensitivity. Pharmaceutical companies have often insisted that their applications remain confidential, for both commercial reasons and to avoid any adverse public comment about their medicines. Indeed, there have been times when disclosure of PTAC minutes has been resisted by a company and they have been released only as the result of an Official Information Act request.

Following consultation, PHARMAC decided that from 1 July 2002 the minutes of PTAC meetings would be made publicly available. Once the record of a PTAC or PTAC subcommittee meeting is finalised (including review by PTAC), minutes are published on PHARMAC's web site, although PHARMAC may withhold any elements on the grounds of commercial sensitivity (guided by the principles and withholding grounds of the Official Information Act 1982).[8]

3) Systematic derivation of clinical data

PHARMAC uses cost-utility analysis, which is a form of cost-effectiveness that measures costs per quality-adjusted life year (QALY) gained. (An explanation of QALYs and how to measure them can be found on PHARMAC's website: http://www.pharmac.govt.nz/pdf/QALYExplanation.pdf) PHARMAC attempts to

conduct these analyses rigorously, with extensive data searches and analysis, peer review, consultation and sensitivity analyses.

Critical to the measurement of cost-effectiveness is the medicine's relative efficacy and side effects. In conjunction with PTAC processes, PHARMAC has systems to systematically identify and synthesise relevant clinical inputs.[9] Development of these systems happened in line with ongoing international concerns about the quality of clinical components of economic analyses,[10] and is similar to international jurisdictions.[11,12,13] PHARMAC's systems include: explicitly defining indications for treatment; defining the comparator medicines or regimes/protocols; defining disease-severity groups; explicitly stating literature search strategies; defining both explicit outcome measures and eligibility criteria for source data; assessing quality of evidence, including structured critical appraisal and place in hierarchy of evidence; assessing missing data and possible publication bias; using additional clinical opinion and clinical contacts; and review processes. The degree of rigour applied to the process relates to the level of detail required (see section 4 below).

Again, depending on the level of detail required, data used in effectiveness and cost-utility analyses are classified according to a hierarchy of evidence, using the Scottish Intercollegiate Guidelines Network (SIGN) grading system.[14,15] Clinical trials used in analyses, and guidelines used when developing access criteria, are critically appraised in a structured manner, in line with standard practice (http://www.nzgg.org.nz/tools.cfm) and using tools such as the GATE checklists developed by EPIQ (Effective Practice, Informatics & Quality Improvement) at the University of Auckland and the AGREE Tool for Critical Appraisal of Guidelines (http://www.agreecollaboration.org).

PTAC, its subcommittees, and external reviewers are used to review the clinical aspects of analyses for major investment proposals, and these analyses are then adjusted as needed.

PHARMAC expects industry to provide all relevant evidence, and will seek out evidence independently, but does also consider all evidence supplied to it. PHARMAC does accept research that is funded by the pharmaceutical industry, if remaining wary of the potential influence that funding sources might have on either the design, operation, reporting or interpretation of any clinical trial, as a possible source of bias (in common with standard international practice).[16] The funding for many clinical trials comes from pharmaceutical companies; were PHARMAC to dismiss all such funded evidence out of hand, then it would be unable to perform many evaluations at all. In short, we use this evidence, but are aware of the potential for bias.[17–23]

4) Policies and processes for economic analyses

PHARMAC also has explicit policies for assessing the comparative costs and benefits of new medicines, set out in its Prescription for Pharmacoeconomic Analysis.[24] These policies include: estimating costs not only to the Pharmaceutical Schedule, but also to other areas of the health sector, including direct costs to patients; estimating improvements in QALY gains; discounting both costs and QALY gains according to PHARMAC's current rate (10%); and using univariate and multivariate sensitivity analyses.

PHARMAC undertakes four levels of economic analysis: very rapid, preliminary, indicative, and detailed. These levels are described in Table 2. In a pragmatic public policy/purchasing environment with finite analytical capacity, there are inevitable trade-offs between precision and timeliness. The level (extent and depth) of economic analysis varies according to individual policy issues, availability of analyst resources at the time, the defensibility of any recommendations derived from the results, and the extent of information available for analysis.

Table 2. Levels of economic analysis undertaken by PHARMAC

Type	Description
Detailed	Includes a detailed and systematic identification and synthesis of effectiveness, quality of life, and cost data. Requires on average 3–6 months of full-time analyst input. Reviewed internally (PTAC for clinical assumptions, PHARMAC) and externally.
Indicative	An interim assessment using some opportunistic data, but more detailed than a preliminary analysis. These typically require 4–6 weeks of full-time analyst input. Typically reviewed internally (PTAC for clinical assumptions, PHARMAC).
Preliminary	A rapid assessment largely using opportunistic data. Likely to take 1–2 weeks' analyst input
Very Rapid	A very rapid assessment using opportunistic data, usually involving 1–2 days' full-time analyst input. Includes supplier analyses that have not yet been evaluated by PHARMAC staff.

At a minimum, less detailed analyses are explicitly described as such, permitting audiences to informally assess the robustness of analysis and the sourcing of component clinical data and assumptions. At last count, PHARMAC had completed 73 economic analyses since 1996, varying in extent and depth according to individual policy issues and analyst resource availability (16 detailed, 30 indicative, 17 preliminary, and 10 very rapid).[†]

As used to be the case with PTAC minutes, the results and component assumptions of economic analyses have not generally been widely disseminated. Commercial sensitivity is even more of an issue here, because the price offered by suppliers is so pivotal to the analyses. Further, analyses are sometimes used to estimate fair prices, using a range of notional cost/QALY values, as part of PHARMAC's negotiations with suppliers – information that is very sensitive to the supplier. Hence, explicit publication of full analyses can be problematic, apart from when such publication is no longer commercially relevant.

That said, key examples of analyses of particular interest (and that are no longer commercially sensitive) can be found on PHARMAC's web site (http://www.pharmac.govt.nz) on the resources page (pharmacoeconomics and pharmacoepidemiology) (http://www.pharmac.govt.nz/economic_analysis.asp). PHARMAC will continue to be judicious about which analyses are published in this manner.

PHARMAC reports to Parliament each year a summary of both numbers of patients receiving medicines specifically funded by new decisions in that year, and the extent of population health gains (QALY gains) expected from those investments that year.[25–29] This information is publicly available and can be found on the PHARMAC

web site publications page (http://www.pharmac.govt.nz/annual_report.asp). Data for the four years July 1998 to June 2002 can be seen in Table 3.

Table 3. Results of economic analyses and expected population health gains reported by PHARMAC's annual reports to Parliament: QALYs gained in year of decision, from key PHARMAC funding decisions from 1998/1999 to 2001/2002 (where information available)

Investment decision, where indicative cost/QALY estimates available*	No. patients in FY	Gross cost to schedule in FY ($)	Possible net costs to health sector in FY, discounted ($)	Dis-counted net health sector $/QALY in FY ($)	Net present value of total QALYs gained in FY[†]
1998/1999					
Listing of anastrozole for oncology treatment	50	15 000	13 500	8500	1.6
Listing of letrozole for breast cancer	50	15 000	15 000	8500	1.8
Listing of atypical antipsychotics for schizophrenia[‡]	5900	22 500 000	4 920 563	43 138	114.1
Listing of dorzolamide for glaucoma	200	391 000	391 000	4638	84.3
Extending access to statin drugs	2500	1 900 000	1 320 902	6559	201.4
Listing of tacrolimus for liver transplant	10	75 000			
Listing of tacrolimus for renal transplant	10	75 000	3750	2500	1.5
Listing of tolcapone for parkinsonism	270	600 000	258 000	10 084	25.6
Listing of ursodeoxycholic acid for liver disease	300	357 500			
Listing of azithromycin for chlamydia	2000	25 000			
Price increase of ceredase for Gaucher's disease	150	152 000			
Extension of access to cyclosporin for atopic dermatitis	2500	182 000			
Listing of insulin lispro for diabetes patients	60	2 000			
Listing of new HIV/ AIDS drugs nelfinavir and nevirapine		-400 000			
1999/2000					
Listing of alendronate for severe osteoporosis	341	98 333	88 418	3545	25.0
Listing of beta-interferon for multiple sclerosis	156	250 000	139 253	80 700	1.7
Listing of lamivudine for chronic Hepatitis B infection	72	11 400	3300	1500	1.2
Extending olanzapine for schizophrenia to new cases	87	172 132	91 585	27 467	0.9
Access for olanzapine for schizophrenia[§]	2282	4 494 352	-479 250	-5748	57.2
Listing of latanoprost for glaucoma	502	153 750			
2000/2001					
Listing of topiramate for epilepsy (refractory)	284	320 209	320 209	18 500	17.3
Listing of gabapentin for refractory epilepsy	42	35 870	35 870	15 000	2.4
Listing of eformoterol for asthma symptom control	2117	265 891	205 402	40 000	5.1
Listing of quetiapine for schizophrenia	208	108 419	-182 775	74 995	-2.4
Extending access to alendronate for osteoporosis to 1+# (BMD<-3.0)	502	464 246	421 457	12 426	33.9
Listing of brimonidine for refractory glaucoma	800	287 462			
Listing of abacavir for HIV/AIDS	28	48 334			
Listing of efavirenz for HIV/AIDS	79	134 465			

2001/2002					
Extending access to tranexamic acid for heavy menstrual bleeding	888	81 201	81 201 64 879	2185 141 991	37.2 0.5
Extending access to beta interferon for multiple sclerosis	122	106 469	426 976	771	553.7
Extending access to statins for cardiovascular risk (dyslipidaemia)	31 097	1 423 492	892 339	2495	357.6
Listing of leflunomide for rheumatoid arthritis	380	147 257			
Listing of budesonide with eformoterol for asthma	1237	547 927			
Extending access to Monogen for special food	13	4482			
Extending access to alendronate for severe osteoporosis	770	59			
Listing of erythropoetin beta for anaemia	205	102 184			
Listing of carvedilol for hypertension/heart failure	253	27 691			
Listing of Cosopt (combination dorzolamide & timolol) for glaucoma (refractory)	895	50 866			
Extending access to dorzolamide for glaucoma (refractory)	363	13 026			
Extending access to Timoptol XE & Timpilo for glaucoma	450	-2022			
Extending access to latanoprost for glaucoma (refractory)	641	41 385			
Listing of coal tar with salicylic acid and sulphur for	191	2067			
Extending access to quetiapine for schizophrenia	-322	-27 264			
Extending access to ranitidine for [ ]	2254	5336			
Extending access to losartan for [ ]	182	5381			
Total for investments during the FY of decision, where data available	**47 558**	**33 475 270**	**8 751 858**	**8946**	**978.3**

*indicative estimates, where the extent and depth of analysis varies according to individual policy issues and analyst resource availability (ranging from very rapid to detailed assessments); all analyses comply with PHARMAC's policies for pharmacoeconomic analyses, http://www.pharmac.govt.nz/download/pfpa.pdf

†total QALY gains in patient users over time horizon during the financial year decided, at net present value (discounting at 10%)

‡risperidone, clozapine and olanzapine

§existing patients refractory or intolerant to risperidone

PHARMAC measures 'savings' elsewhere to the health sector

There still seems to be a perception by some that PHARMAC considers only direct pharmaceutical costs when evaluating new proposals. This is incorrect. As many direct health costs as possible are included in analyses. These extend beyond just medicine costs, to include potential costs and savings (ie, costs averted) in hospitalisations and other health and disability support services, and direct costs to patients. PHARMAC consulted widely, including with the pharmaceutical industry, on this and other issues in 1999, prior to releasing the 'Prescription for Pharmacoeconomics'.[24]

For instance, the information displayed in Table 3 allows calculation of the extent of potential savings to the rest of the health sector, as a proportion of pharmaceutical spending, seen in various analyses (columns 'Possible net costs to the health sector in FY, discounted' and 'Gross cost to schedule in FY'). For instance, potential 'savings' elsewhere might have accounted for 53% of pharmaceutical spending on four key medicines newly funded or extended during 2001/02 (tranexamic acid for heavy menstrual bleeding, leflunomide for rheumatoid arthritis, statins for dyslipidaemia, beta interferon for multiple sclerosis. We intend to more fully describe such potential savings in forthcoming publications.

Given the wide consultation that PHARMAC took before deciding which costs to include in its analyses,[24] it is disappointing to keep hearing claims otherwise.

Some have suggested that "global socioeconomic costs" should be included in such evaluations.[1] PHARMAC does not include such costs, primarily because trying to quantify these figures is typically fraught, and because they can bias against certain groups. Attempts to determine the full financial implications of disease burden can produce awkward results. For example, extrapolating a recent analysis of the burden of asthma[30] to all disability-adjusted life years (DALYs) lost in New Zealand[31] would cause predicted costs to the New Zealand economy of $563 billion each year.‡ The magnitude of this figure seems overwhelming, especially when compared with the New Zealand Gross Domestic Product for 2001/02 of $120 billion.[32] The extent of the economic costs of any particular disease, although still important, can be overestimated by such methods, at the expense of other health priorities for which such analysis has yet to be undertaken. Including indirect costs, such as loss of earnings, may prejudice decisions against issues affecting the young, elderly, and other low-income groups.

Concluding remarks

One of the comments arising from the Journal's anonymous review of this viewpoint article was that it read more like an advertorial justifying PHARMAC'S current practices. As evidenced by the volume of comment in the Journal,[1–6] there is confusion about how PHARMAC undertakes assessments of new medicines. The descriptive and subjective view provided here simply aims to address some of the criticisms voiced in others' viewpoint articles.

PHARMAC was specifically set up to provide medicines from within the funding provided. This is set in legislation, and critics must realise that any increase in the total budget must come from somewhere, be it the health sector itself, other areas of government spending, or an increase in taxation. Contrary to the view that New Zealand is "going it alone", similar debates are occurring in all developed countries, including Australia, Canada, Great Britain and the USA.

If the overall budget constraint is accepted as binding, then how that budget is allocated becomes critical. It is tempting to try to find one "magic number" that will prioritise all medicines. However, any decision will be a compromise based on accessibility, relevance to the population need, effectiveness, equity, social acceptability, efficiency,[33] and level of risk and uncertainty. Many of these can only be assessed subjectively.

It is also tempting to reduce the prioritisation debate to a battle between an uncaring regulator and pressure groups (clinical, patient support groups, or suppliers). However, PHARMAC consciously seeks out the views of, and tries to work together with, the health sector to improve its decision-making processes and improve health outcomes. While PHARMAC works hard to include the views of all affected groups, it also has to work in a commercial environment, as evidenced by litigation by the pharmaceutical industry. Most of all, it is our job to worry about the health opportunities forgone from making the wrong decision.

To quote Arthur Schopenhauer, "In a constrained environment…there will be both winners and losers." There will always be a tension between those who look at the

individual and those who look at the whole of society, just as there will be a tension between those who wish to maximize profit and those charged to manage cost. For those who lose, it may be helpful to know that at least the process was fair.

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Conflicts of interest: Dr Scott Metcalfe is externally contracted to work with PHARMAC for public health advice.

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Endnotes:

* Note that the process described in this paper relates to PHARMAC's assessment of community-dispensed pharmaceuticals listed on the Pharmaceutical Schedule. However, PHARMAC also has recently established a process to assess new hospital pharmaceuticals under the National Hospital Pharmaceutical Strategy. This process involves concurrent (or as near as possible) assessments by PHARMAC of pharmaceuticals assessed by DHB hospitals. Note however that national assessment by PHARMAC does not oblige DHB hospitals to fund or not fund a new pharmaceutical. The key objectives of the process are to introduce cost-utility analysis into assessments, promote dialogue and build confidence in a system aimed at ultimately achieving national consistency of access (and also reduce duplication of work). As such, the process for hospital pharmaceuticals differs in form and intent from that described in this paper for community pharmaceuticals. Further details of the New Hospital Pharmaceutical Assessment Process (and the National Hospital Pharmaceutical Strategy) are available on PHARMAC's web site at http://www.pharmac.govt.nz/hospital_strategy.asp and http://www.pharmac.govt.nz/pdf/nhps.pdf

† This figure underestimates the number of very rapid analyses, including (but not confined to) rapid assessments for Exceptional Circumstances.

‡ The 18,800 DALYS lost from asthma accounted for around 3.3% of DALYs lost in New Zealand in 1996, out of 563,000 total DALYs lost. Applying the ARFNZ report's $100,000 statistical value for a life year to these 563,000 total DALYs lost suggests that overall DALY losses cost New Zealand some $563 billion per annum.

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Takayasu's arteritis and ulcerative colitis

Richard Gearry, Peter Carne and Frank Frizelle

The association between ulcerative colitis (UC) and Takayasu's arteritis (TA) has been well described in patients of Asian ethnicity. We present a Caucasian patient with TA who underwent restorative proctocolectomy with ileal pouch–anal anastomosis (IPAA).

Case report

A 42-year-old female with TA was referred for colectomy after developing side effects from corticosteroid therapy for inflammatory bowel disease. In 1991, she presented with pyrexia. Subsequent investigations revealed angiographic abnormalities consistent with TA. Symptoms resolved with introduction of corticosteroids. She had also previously undergone an aortic valve replacement for mixed aortic valvular disease and was anticoagulated.

On subsequent reduction of her corticosteroid dose she developed symptoms of proctitis. Colonoscopy with histopathology confirmed ulcerative colitis (UC). Corticosteroids were continued for treatment of the colitis but could not be withdrawn because of ongoing symptoms. Introduction of azathioprine was unsuccessful due to drug allergy, so the patient was referred for restorative proctocolectomy. Pre-operative magnetic resonance angiography revealed total occlusion of her coeliac axis and inferior mesenteric artery, with all abdominal viscera supplied by the superior mesenteric artery.

A restorative proctocolectomy with (stapled) IPAA and defunctioning loop ileostomy was performed. Histopathology confirmed the diagnosis of UC. At the time of surgery, she was taking 30 mg/day of prednisone. Anticoagulation was withheld for the surgery. Her initial post-operative course was uncomplicated and she was discharged on day 7 post-operatively. On day 18 post-operatively, she re-presented with fever. An abdominal computed tomogram revealed a pelvic collection; this was drained percutaneously and antibiotics commenced. She was subsequently discharged well with a drain *in situ*.

When last seen (three months after surgery), the patient was well, the drain had been removed, and she was awaiting a contrast study of her pouch prior to ileostomy closure.

Discussion

While rare, there are case reports of UC associated with TA.[1–6] Most of these patients are Japanese.[1,2,4,7–9] Reports of surgery for these patients are even less common.[10]

Nakayama reported on two patients with known TA requiring surgery, one undergoing a proctocolectomy and end ileostomy, the other having a three-stage operation for total proctocolectomy.[10] We believe our patient is the first report of a non-Asian patient with both TA and UC undergoing a proctocolectomy with IPAA.

Technically, the surgery was no different from that in other patients with UC, though the presence of significant collateral vessels was noted. A tension-free, well vascularised anastomosis was constructed. The combination of anticoagulant therapy and corticosteroid therapy probably contributed to the subsequent pelvic sepsis experienced by our patient.

The relationship between TA and UC is not entirely clear. TA is an autoimmune disease in the family of collagen vascular diseases. It may be that the diseases share a similar pathophysiology,[1,7,8,11,12] or that TA is an extraintestinal manifestation of UC.[6]

It has been suggested that genetic susceptibility to both UC and TA is mediated through major histocompatibility complex genes.[10] In particular, HLA-Bw52 (84.2%), -DR2 (68.4%), and -A24 (47.3%) haplotypes are over-represented in both inflammatory conditions in nineteen Japanese patients.[10] In our patient of Caucasian ethnicity, HLA analysis revealed HLA-A24xx, *3201; B*1302/3/8, 44xx; DRB1*0701/3-5, *1201/6-8. Therefore, only HLA-A24 was also found in our patient. The other HLA haplotypes found in Japanese patients with TA and UC were not identified in our patient, suggesting that these may relate to ethnicity rather than a disease association. Additionally, it is common for Japanese and, to a lesser extent, Caucasian populations to be positive for A24.

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CHRONIC URETHRAL DISCHARGE.

[By P. Clennell Fenwick, M.B. Lond., F.R.C.S.E., F.R.G.S., Surgeon to Wanganui Hospital.]

The urethral canal, owing to its inaccessibility to local treatment, is peculiarly liable to chronic disease. When one reflects that the constantly recurring flow of urine sweeps away all applications to the mucous membrane, and that in addition the urine itself is often abnormal and consequently irritating to the diseased surface, the chronicity of urethral troubles is not a matter of wonder.

Ricord's definition of Hades must have appealed to many practitioners: "Gentlemen, if I am to go to the bad place I know what my punishment will be. I shall have a lot of fellows standing round me with their lamentations, their importunities, and their prayers to make them well." There is no doubt that an obstinate urethral discharge, inducing as it always does increasing mental depression, is one of the most tedious diseases to treat.

I have quite recently had two cases in which no arguments could convince the patients that they were cured, and it was only by the drastic logic of circumcision that they were persuaded back to mental and urethral health. I quote these cases to show to what a great extent suggestion aggravates symptoms.

Case 1.—A young healthy man sent to me from the South Island. Had gonorrhœa "several years ago." Was treated and apparently cured. On examining his prepuce one day he noticed several white ulcers surrounding the "collar of the glans" when the prepuce was turned back. To obtain a cure he visited a large number of chemists and several doctors. For the last few months he had on advice packed his prepuce with lint soaked in black wash. I examined the glans and prepuce with a magnifying-glass in a strong light. It was absolutely healthy. The patient accepted my statement with pity for my ignorance, and pointed out five imaginary ulcers. I told him I could cure them by cutting them away, and he gladly accepted the offer. I circumcised him very thoroughly and touched the frenum with caustic. When his bandages were removed he looked for his ulcers, and when he found that the whole foreskin lately occupied by his imaginary ulcers had been removed he joyfully admitted himself cured, and my last news of him is that the ulcers have not returned. I believe this case would have ended in chronic melancholia, and it certainly taught me not to waste time persuading a man determined to be diseased that he was deceiving himself.

Case 2.—A very strong, healthy young man consulted me for a chronic discharge of white matter from his urethra. Some years previously he had gonorrhœa, which was cured by injections. After a short period of health he noticed a white thick paste exuding from his penis. I examined the canal, which was perfectly healthy, and after much questioning I found that the white matter did not come from the meatus but from behind the glans—in fact, it was smegma liquefied by urine caught in a sac formed by a tight prepuce. This patient told me he had "spent a fortune" at chemists', and had been most depressed and worried for many months. He has had no return of his symptoms.

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The long locum: health propaganda in New Zealand

Derek Dow

Abstract

Health Department folklore since the 1950s has attributed the rise of health education in New Zealand almost entirely to the efforts of one man, 'Radio Doctor' Harold Turbott. The historical evidence reveals, however, a more extensive commitment by the Health Department, dating back to its foundation in 1900. This paper examines the evolution of health education in New Zealand and concludes that Turbott's role in its development has been overstated, largely at his own instigation.

In the last months of the nineteenth century, the wife of an Auckland painter and carpenter gave birth to a son who would become one of the best-known voices in New Zealand. Dr Harold Bertram Turbott's broadcasts as the 'Radio Doctor' spanned more than four decades. Several generations have abiding memories of growing up with the doctor's avuncular tones from his weekly Saturday morning broadcasts. Indeed, one Auckland GP resisted a colleague's entreaties to attend continuing medical education courses by boasting that he kept himself up to date by listening to the Radio Doctor! (Personal communication, Dr JR Richards, who was not the GP in question!) These talks covered public health and medical topics but not surgical. Copies were sent to every public health nurse as background for their own talks to local audiences and many also appeared in the departmental magazine *Health*, which began publication in 1948.

Outliving one's contemporaries is one of the most effective ways of fostering a particular version of events. In Turbott's case this reached its apogee in April 1984, when he was interviewed for a *Spectrum* documentary entitled 'The long locum' – a reference to a broadcasting career that began as a temporary measure during World War 2.

The introduction to the *Spectrum* interview stated that Turbott broadcast his first health talk in 1943, after Prime Minister Peter Fraser sacked the Controller of the New Zealand Commercial Broadcasting Service, the controversial Colin Scrimgeour. Fraser phoned Turbott to ask him to take over 'Uncle Scrim's' daily three-minute talks on health. Turbott confirmed this during the *Spectrum* interview, and repeated the claim in his unpublished autobiography, which noted that the format of his talks changed to a weekly seven-minute broadcast in 1946 and that he maintained this pattern with only one six-month interruption until 1984.[1]

Turbott's involvement in health education, of which his radio work was the most visible outcome, has given rise to one of the most pervasive mythologies in the history of the Department of Health, as it was known until 1993. The seeds of the myth were sown more than thirty years before the *Spectrum* programme, and were strongly rooted.

Addressing a conference of medical officers of health in 1953, Turbott described how he persuaded Health Minister Arnold Nordmeyer in 1943 to fund health education, in

the face of opposition from Director-General of Health Dr Michael Watt.[2] Turbott's summary dismissal of Watt stemmed in part from resentment at his failure to succeed him. Watt had retired in 1947, and Turbott confidently expected to take over in 1950 when Watt's stop-gap successor, Dr Thomas Ritchie, also retired. Instead, the position went to Dr John Cairney, a hospital medical superintendent who had never previously worked in the Department. Many other senior officers retired in the early 1950s, leaving few in a position by 1953 to challenge Turbott's interpretation of events.

Turbott's account of the origins of health education was endorsed in 1960, the year after he finally became Director-General. Writing in the *International Journal of Health Education*, Dr Derek Taylor claimed that 'The story of health education in New Zealand goes back to 1927 when a young medical officer of health began an active health education programme in his district', before concluding that 'We have made steady progress since the early struggles of that young medical officer of health over 30 years ago.'[3] Taylor was hardly an impartial observer. He had followed in Turbott's footsteps as Medical Officer of Health for Gisborne and was installed by him as the first Director of Health Education in 1957. In his unpublished autobiography, Turbott wrote that Taylor's appointment signified that 'my long struggle had achieved its end'.

The myth that health education had been added to the public health agenda as the result of a personal crusade by Turbott was now firmly established, but departmental and other records reveal a very different story. Educating the public through the print media had been part of the Department's agenda from its foundation in 1900. The prime mover behind its early media campaigns was the country's first Chief Health Officer, Dr James Mason, who was no stranger to writing for a general audience. On 30 June 1888, shortly after qualifying in Medicine, he contributed an article entitled 'My First Operation' to his Scottish hometown paper, the *Arbroath Guide*.

Mason was a gifted communicator, even within the potentially dull pages of his annual reports. The first of these was described in 1901 by one of his old Glasgow medical teachers as being reminiscent of the work of Joseph Addison or Charles Lamb, two of the greatest essayists in the English language.[4] New Zealand commentators echoed this sentiment. An *Evening Post* editorial of 29 September 1904 on his fourth report commented favourably on Mason's technical knowledge, enthusiasm and bright literary style.

Mason was keen from the outset to convey the public health message as widely as possible. From 1900 until 1905 he acted as editor of the *New Zealand Medical Journal*, a role that provided him with a further outlet for health propaganda. In April 1904, he included several graphic photographs of smallpox victims with his account of a recent outbreak. There was no adverse response to these shock tactics. Five months later, Mason incorporated some of the same illustrations into his annual report, prompting sharp criticism in parliament.[5] What was acceptable in a medical journal, it seemed, was not regarded as suitable for a predominantly lay readership.

From the time of his arrival in the colony, Mason had been eager to include Maori in the health education programme. In August 1895, he wrote to the Premier, Richard Seddon, offering to devise simple guidelines for sanitation in Maori kainga, presumably unaware of the earlier publication of James Pope's *Health for the Maori*, one of the colony's first public health pamphlets.[6] As Chief Health Officer, Mason

encouraged Maori Health Officer Dr Maui Pomare to publish pamphlets in Maori on smallpox (1902) and infant welfare (1909). The latter paralleled the efforts of Plunket Society founder Dr Truby King, whose writings on the subject were also sponsored by the Department.

The Department's commitment to health education survived Mason's dismissal in 1909. Dr Doris Gordon, later to become a fearless advocate for improved maternal and infant health, recalled in her autobiography how one of the major concerns of senior departmental officials in 1917 was to evaluate what had been written for the press, in order to allay public anxiety about health issues.[7] The following year's great influenza epidemic gave ample opportunity to test the effectiveness or otherwise of these endeavours.

Initially, such efforts were restricted to print media. In 1925, the Department published *New Zealand: A Healthy Country: Striking Facts and Records*. This 48-page booklet comprised reprints of ten articles from the *Evening Post*. They dealt with core public health and preventive medicine topics, such as maternal welfare, school children, pure food, the dental health of children, and Maori health. The opening sentence noted it was 'important in the public interest periodically to review the activities of a Department like the Health Department in an effort to determine if its progress has been satisfactory and if that progress is still tending in the right direction'.

The institution in 1925 of the country's first national radio broadcasting system allowed for an extension of health propaganda. The Division of Dental Hygiene was the first of the Department's branches to grasp the new medium, with a series of broadcasts in 1926, the year before Harold Turbott's recruitment as a district health officer. Yet the Department was slow to make full use of the opportunities afforded by radio. In the late 1920s, the emphasis remained on spreading the health gospel by means of the written word. This involved the widespread distribution of posters to heavily used venues such as railways stations, and exhibitions at locations such as Agricultural and Pastoral shows and annual health weeks. Staff lectured to a variety of unspecified audiences but the annual reports contain no mention of broadcasts at this time.

A new era in health education began with the retirement in 1930 of Dr Thomas Valintine, who had headed the Department for the previous 21 years. Dr Michael Watt, about whom Turbott was later so dismissive, took over as Director-General of Health. From the early 1930s, Watt's annual reports contain acknowledgements to the Radio Broadcasting Board for its courtesy in transmitting talks on health education. By the middle of the decade, departmental representatives were delivering weekly health discourses, supplemented by a separate series of radio addresses by school medical officers. Officials also undertook one-off assignments, such as a 1932 broadcast by Miss Janet Moore of the Department's recently established Postgraduate School for Nurses on nursing as a career for young girls.

Watt regarded these broadcasts as an important part of the health agenda. When the executive council of the New Zealand Obstetrical Society discussed the 'Suggested Education of Public by Suitable Broadcasting Addresses' in 1935, they were heartened by a letter from Watt stating he was in thorough agreement with the proposal.[8]

Even before this date, health authorities had been willing to endorse appropriate messages. In February 1931, for example, the *NZMJ* published the text of a 1YA broadcast by Dr James Hardie Neil, a well-known Auckland doctor, on behalf of the Auckland Cancer Committee. Soon afterwards, the Department's annual report noted that cancer publicity was continuing and stressed the importance and effectiveness of health education in preventing illness.

By 1932, concerns were being expressed about the potential misuse of the airwaves. In June, the council of the New Zealand Branch of the British Medical Association resolved that any radio broadcast of a medical nature should be submitted to the Health Department by the Broadcasting Board before transmission. Council minutes contain several references to this issue over the next year or so, but it was not until 1936 that the root cause of this concern became clear.[9,10]

In September 1936, the BMA council expelled Dr Ulric Williams for gross breaches of its ethical rules. His transgressions included contradicting scientific orthodoxy and he was also accused of advertising, by permitting his photograph to appear alongside one of his articles in the *Radio Record*. Williams also broadcast regularly on health topics. In March 1938, the BMA wrote to Health Minister Peter Fraser about Williams' misleading observations regarding the supposed causes of poliomyelitis, asking Fraser to ensure that public statements, especially on infectious diseases, should conform with official statements made by departmental officials.[11,12]

The Department's response was heavily influenced by Dr Watt's research trip to America and Europe later that year. In a report dated June 1939, he concluded that health education in New Zealand did not receive the attention it merited, and proposed the appointment of someone with journalistic training to supply copy for press and radio, prepare exhibits, and revise the Department's growing collection of educational pamphlets.

During his visit to London, Watt had attended a national conference on nutrition in April 1939. His report made no mention of this but it did note that many health departments in the USA employed special officers trained in dietetics, who disseminated information through lectures, radio talks, and pamphlets.[13] Watt, for whatever reason, failed to press home the point by referring to events closer to home; on 22 April 1939 the *Journal of the American Medical Association* reported that the Queensland health authorities had sponsored a series of dramatised broadcasts on nutrition.

New Zealand's response to this trend kicked off in September 1939, with the first of eight radio talks on nutrition by Dr Elizabeth Bryson. Although no longer connected with the Health Department, Bryson had been a school medical officer from 1915 until 1918. She was also prominent in the League of Mothers, founded in 1926 by Lady Alice Fergusson (wife of the Governor-General) to promote the Christian upbringing of children.[14]

In 1939, the Health Department broke new ground with the appointment of Dr Muriel Bell, one of the country's few recognised medical scientists, as its Nutrition Officer. One of her first tasks was to edit *Good Nutrition: Principles and Menus*. Based on a League of Nations initiative, this was intended to 'check false dietary habits, oust faddism and give food its normal significance'. The publication was a joint endeavour

by the Otago Medical School, the Health Department, and the recently formed Medical Research Council chaired by Director-General Watt.

Bell quickly became a household name thanks to her contributions to *The Listener*, another government venture launched in 1939. The magazine's 'Advice on Health' column was published alternately under the names of Muriel Bell and of Harold Turbott, who was promoted to the position of Director of School Hygiene in 1940. For a country caught up in the rigours of war, Bell's nutritional counsel was an important part of the overall propaganda effort. In pursuit of this end she worked closely with the redoubtable Maude Basham, whose first morning programme for the New Zealand Broadcasting Service had gone to air on 30 October 1936. Bell provided the expert explanation for using certain foodstuffs while 'Aunt Daisy', as she was better known, followed up both on air and in *The Listener* with recipes to make Bell's recommendations more palatable.[15]

Turbott's *Listener* columns, in contrast, were more wide-ranging. Many depended on advice tendered by other departmental specialists and reworked by Eric Marris, the journalist recruited as a result of Watt's 1939 report. In 1941, the Department was given the opportunity to extend its efforts to the spoken medium. The chance was too good to pass up. By this time, 86% of all households possessed radio licences, almost a six-fold increase from the 60 000 or so recorded listeners a decade earlier.

The initial series of Health Department broadcasts in the second half of 1941 were labelled 'Health in the Home'. Nurses were urged to tune in, and were asked to encourage lay people to do likewise. With Aunt Daisy already in situ and covering similar territory, Muriel Bell was probably never a contender for the role of presenter. Harold Turbott, with his wider remit, was the logical choice.

I have not trawled through *The Listener*'s back files in detail, but a perusal of Health Department records reveals that these broadcasts continued in some form or another during 1942. Cabinet subsequently approved a national health education plan on 7 May 1943, following discussions with Dr Watt. The programme included increased use of radio and presumably confirmed Turbott's role as the voice of the Department.

Turbott made the most of his opportunities. He enjoyed even greater longevity as a broadcaster than Aunt Daisy, partly because he started earlier in life. She enlightened the nation for more than a quarter of a century until shortly before her death in July 1963, aged 84. He remained on air until 1984, by which time he too was in his 85th year.

Turbott unquestionably made a major contribution to broadcasting, for which he received the Mobil radio award in 1987. However, claims that he had to mount a personal crusade to overcome opposition from within his own Department bear the hallmark of an unrepentant self-publicist. The seeds of the Health Department's health education policy were sown much earlier and nourished by senior staff such as Dr Watt, whose contribution Turbott repeatedly failed to acknowledge.

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The painted apple moth

The painted apple moth destroys plants by eating their leaves and is a serious threat to New Zealand's gardens, crops, forests and native bush. MAF estimates that if the moth is not eradicated it could cost the country $350 million over the next twenty years. The moth may also be a health risk to some people who are allergic to its hairs. Aerial spraying is the most reliable way to reach moth larvae in the upper tree canopy and is a key part of MAF's campaign to eradicate the moth.

Larva of the painted apple moth

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Nursing home patients given ‘inappropriate’ tranquillisers

More than 80% of elderly people prescribed strong tranquillisers in a sample of British nursing homes were given them with no proper medical justification, according to research published last weekend.

The neuroleptic drugs – administered to quieten patients with what staff call “behavioural problems” – were likely to make their dementias worse and risk making them break their hips or other limbs in falls, say the doctors who conducted the study.

The Alzheimer’s Society said that the finding was true of old people in homes across Britain and could apply to up to 100,000 of the 500,000 in residential care. The report was “a nail in the coffin” for indiscriminate prescribing, said the society’s chief executive, Harry Cayton. The Liberal Democrats’ spokesman for older people, Paul Burstow, said that they were the victims of “a chemical cosh”. Nursing homes, short of trained staff, were turning to chemical cocktails to make patients easy to manage.

The research by five doctors at London teaching hospitals was published in the journal Age And Ageing. The study of nearly 1,000 patients over 65 found that drugs were given to just under 25% of all patients. But medical notes showed the prescriptions were not “appropriate therapy” for 82.8% of those who received them. More than half the prescriptions had not been reviewed for six months.

Guardian Weekly, 13–19 February 2003

Canadian high court rejects OncoMouse

Canadian researchers don’t have to worry about paying licensing fees for the use of transgenic animals. The nation’s top court ruled last week that higher life forms aren’t patentable.

In a 5–4 decision, the Supreme Court of Canada ended Harvard University’s 17-year quest to obtain Canadian patent protection for its OncoMouse, ruling that the cancer-prone rodent can’t be owned. The court said that OncoMouse, developed by Philip Leder of Harvard Medical School in Boston, isn’t an invention under an 1869 Canadian law that protects “any new and useful art, process, machine, manufacture or composition of matter.”

Writing for the narrow majority, Justice Michael Bastarache made a philosophical argument for the court’s ruling, which stands in contrast to patents granted by 17 nations, including France, Germany, Japan, and the United Kingdom. “A complex life form such as a mouse or a chimpanzee cannot easily be characterised as ‘something made by the hands of man,’ ” he wrote. Nor is OncoMouse a “composition of matter,” he added. “Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic matter of which they are composed,” Bastarache noted. “A person whose genetic makeup is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist

absent the injection of the oncogene into the fertilized egg cell; it simply would not be predisposed to cancer."

Science 2002;298:2112–3

Lack of new drugs is reaching crisis point

The number of new drugs approved in the United States last year fell to half the annual average over the past five years. The miserable tally of new drug approvals in 2002 – at the time of writing, just 15 new molecular entities had passed FDA review – well down even on the depressingly low average for the last five years – 31 a year, shows just how rare an event success can be in the drug discovery world. And with new drug application numbers down worldwide, concern is beginning to spread beyond the borders of the pharmaceutical industry.

Faced with sparsely populated pipelines, companies are beginning to shift research budgets towards more aggressive marketing of existing products. These are worrying times.

The process of turning ideas into drugs is acknowledged as being the hardest skill to teach new recruits to the drug discovery business. Selecting research targets for new drugs takes place in an environment that is strongly influenced by financial considerations.

Most so called blockbuster drugs were not forecast to be big sellers. The initial sales forecast for tamoxifen was a modest £100 000 ($160 000; €150 000).

BMJ 2003;326:119

'Protato' to feed India's poor

Generically modified potatoes will play a key part in an ambitious 15-year plan to combat malnutrition among India's poorest children. Anti-poverty campaigners have greeted the "protato" with cautious support.

The three-pronged attack on childhood mortality would aim to provide children with clean water, better food and vaccines. "Zero child mortality in underprivileged children would be the goal," says Govindarajan Padmanaban, a biochemist at the Indian Institute of Science in Bangalore.

Formulated in collaboration with charities, scientists, government institutes and industry, the anti-hunger plan is under consideration by the Indian government. Meanwhile, the protein-rich GM potatoes are in the final stages of testing, prior to being submitted for approval.

Padmanaban, who outlined the plan at a conference at the Royal Society in London last month, hopes Western-based environmental groups and charities will not demonise the project in the same way as they did AstraZeneca's "golden rice", a strain modified to make more vitamin A. "The requirements of developing countries are very different from those of rich countries," he says. "I think it would be morally indefensible to oppose it."

Asis Datta's team at the Jawaharlal Nehru University in New Delhi added the *AmA1* gene to potatoes, with the result that they make a third more protein than usual, including substantial amounts of the essential amino acids lysine and methionine. *AmA1* is a gene from the amaranth plant, a crop long grown by native South Americans and now available in some Western health food stores.

New Scientist, 4 January 2003

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The influence of consumption of A1 b-casein on heart disease and Type 1 diabetes – the authors reply

We would like to respond to Jeremy Hill's letter published in the previous issue of the Journal (http://www.nzma.org.nz/journal/116-1169/346/).

Ischaemic heart disease (IHD)

As Hill notes, we found that A1 ß-casein correlated significantly with IHD mortality.[1] This, we now find, also applies to non-fatal IHD, at least in males. For 13 WHO MONICA (Monitoring trends and determinants in cardiovascular disease) study countries (all healthcare affluent, and including New Zealand), we had sufficient data to test for correlation.[2] A1 ß-casein per capita in the 1985 food supply correlated significantly with the non-fatal, fatal, and total IHD events rates for 35 to 64-year-old males 4–9 years later. This was not true for females, nor for serum cholesterol, smoking, or body mass index in males.

Tobacco consumption was not correlated with IHD mortality at population level – heavy smokers' risk is only 20% higher, and so most smoker IHD deaths occur among moderate or light smokers.[3] As the consumption per smoker varied greatly between countries,[4] reduction in consumption may not reap a proportionate reduction in IHD mortality.

Type 1 diabetes (DM-1)

In children, besides consumption of cow milk, likely factors include genetic predisposition, impaired gut immunity, and enterovirus infection.[5] Higher levels of ß-casein antibodies have been found in DM-1,[6] specifically against A1 ß-casein.[7] The quantity of cow milk consumed during childhood has been associated with DM-1;[8] and infants in a high risk group for DM-1 and exposed to cow milk formula had increased auto-antibodies against bovine and human insulin.[9]

Inclusion of cheese per capita (mostly eaten by adults) did weaken the association between milk per capita and childhood DM-1 in our study. Child cheese consumption may vary more from adult cheese consumption internationally than child milk consumption varies from adult milk consumption. Also, choice of cow breeds, manufacturing processes, and market share of different brands, long storage before sale, and wastage, may affect national A1 ß-casein per capita in cheeses differently from milk.

As we stated, the temporal decline in per capita (mainly adult) milk supply cannot explain the rise in child DM-1 incidence, but what might explain the rise are the trends in child A1 ß-casein consumption in response to the greater range of pre-cooked foods and yoghurts now available.

Hill refers to an animal feeding trial in diabetes-prone rodents,[10] a trial designed to determine whether DM-1 incidence differed between diets supplemented with A1 and A2 ß-casein respectively. In the (BB) rats there was a difference, but not in the (NOD) mice. The latter finding was at variance with earlier findings.[11] That rodent chow

containing no milk protein had the highest DM-1 incidence in both species is interesting, but young humans consume milk not chow. Further animal research alone will never be sufficient to provide the basis for public policy.[12]

A1, B and C variants of ß-casein are similar in that all have histidine at position 67 of the molecule, instead of the proline present in the A2 variant. In the case of A1, this is the sole difference, whereas there are further differences in the B and C variants. This may be why A1 but not B and C variants are correlated with DM-1. The B and C variants are in any event usually very minor components, and estimates of their prevalence are not available for some countries. Elliott was author of both of the studies that show this '+B and +C' difference. Our study includes more countries, all surveyed during the same six-year period.

We need more and better data in the public domain, aided perhaps by the International Dairy Federation or Fonterra itself, monitoring and publishing A1 ß-casein content in milk and other foods, by brand, country, and year.

The correlations we have described are far from conclusive, but cannot be ignored. They merit further research on the milk-drinking habits of those with and without IHD; and similarly for DM-1.

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A1 b-casein milk and Type 1 diabetes: causal relationship probed in animal models

Laugesen and Elliott's epidemiological analysis (http://www.nzma.org.nz/journal/116-1168/295/) suggests a correlation between regional A1 ß-casein cow milk consumption and ischaemic heart disease or Type 1 diabetes. Correlations were not significant for the A2 variant of ß-casein. The result of their analysis with respect to Type 1 diabetes is similar to a previous report of a high correlation between milk protein consumption and diabetes incidence across various countries.[1] Unfortunately, food disappearance data are notoriously unreliable, representing disappearance of foods on a country basis, and therefore only provide a rough approximation of food consumption by individuals. The data do not necessarily reflect either the type or amount of food consumed by individuals at risk for various chronic diseases. The only way to begin to associate any environmental exposure such as diet with development of chronic disease is to follow a cohort of individuals prospectively and monitor food intake (plus other exposures) and biomarkers of health, disease and/or disease outcome. Therefore, because randomised trials of A1 versus A2 ß-casein-based diets in children have not been conducted, an assessment of a possible causal relationship between diet and disease must presently rely on feeding studies in animals.

We were involved in several such studies including a trial of A1 versus A2 ß-casein initiated by Professor Robert Elliott and in part supported by Dr Jeremy Hill of the New Zealand Dairy Research Institute (now Fonterra Research Centre). Our experience from these studies can be summarised thus: cow milk proteins or whole milk preparations only modestly promote the development of immune-mediated insulin dependent Type 1-like diabetes in mice or rats genetically predisposed to develop such disease (NOD mice, BB rats). Partial protection from diabetes development was seen if hypoallergenic diets with amino acids from hydrolysed proteins were fed.[2] For this reason, intervention studies in infants at risk are currently being conducted, comparing conventional and hypoallergenic infant formula (http://www.trigr.org/).

Diets entirely devoid of milk but containing other protein were also found to promote diabetes development in animals, and the most diabetes-promoting diet contained no milk products and was mainly wheat based (37%).[2,3] The comparison of A1 versus A2 ß-casein-based diets in NOD mice did not demonstrate different risks for the two diets. The latter study is the only published trial with blinding of the investigators with regard to the type of diets fed to the different groups.[2] This study did not confirm earlier findings of a higher diabetes risk for A1 versus A2 ß-casein diets in NOD mice.[4] The blinded animal trial also included BB rats. Here, one of two comparisons showed a significantly higher diabetes incidence ($p < 0.05$) for the A1 ß-casein-containing diet. The other comparison showed a trend towards the opposite effect.

A more recent, second, 'blinded' comparison of A1 versus A2 ß-casein milk-based diets again failed to confirm an increased 'diabetogenicity' of A1 ß-casein milk in

NOD mice. Rather, the highest diabetes incidence was observed for an A2 ß-casein milk-based diet. A protective effect of A2 ß-casein milk-based diets was also not observed in the BB rat model (manuscript in preparation).

Hence, the experience from two well accepted animal models of Type 1 diabetes fails to demonstrate a consistently higher diabetes-promoting potential of A1 as compared to A2 ß-casein milk. As judged from feeding studies in animals, avoidance of A1 ß-casein milk consumption may not decrease the risk of Type 1 diabetes.[5] In fact, A2 ß-casein milk led to a very high diabetes rate in one experiment mentioned above. Furthermore, several studies reported on substantial diabetes rates after feeding soybean or wheat protein to NOD mice and/or BB rats.[6] In conclusion, many protein-based diets promote the development of Type 1 diabetes-like disease in genetically predisposed animals, and these include A1 ß-casein deficient milk.

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Setting the record straight: A1 ß-casein, heart disease and diabetes

In the January issue of the NZ Medical Journal you published an article concerning A1 ß-casein and its apparent associated health risks (http://www.nzma.org.nz/journal/116-1168/295/).[1] The article states that McLachlan's work, now licensed to A2 Corporation, took place as a result of viewing an inter-country correlation of A1 and B ß-casein consumption versus Type 1 diabetes (IDDM) by Elliott and Hill.[2] This comment is incorrect. However, the history of this association may be of general interest to your readers.

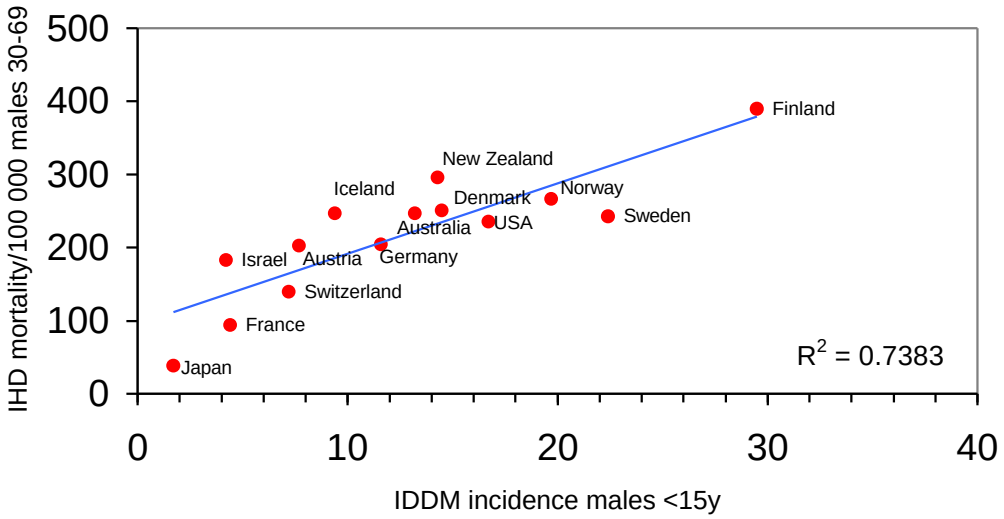
A correlation between consumption of cows' milk and IDDM was first proposed in 1984 by Elliott and Martin.[3] Robinson, one of the early exponents of this position, associated consumption of bovine serum albumin, present in cows' milk, and a peptide fragment derived from it called ABBOS, with the initiation of the autoimmune process leading to IDDM.[4] After an enthusiastic initial reception, this proposal fell from favour. Elliott's 1994 research programme, which McLachlan reviewed for the NZ Child Health Foundation, sought to show that NOD mice developed diabetes when fed a Pregestimil-based diet containing added A1 ß-casein, but not when fed A2 ß-casein.[5] However, in earlier research, Elliott using NOD mice,[6] and Scott using BB rats,[7] had found that increased concentrations of casein in the diet reduced the incidence of IDDM. This led Scott to conclude that casein diets were "protective" against IDDM rather than causal as was being suggested by Elliott.

What struck McLachlan was the remarkable similarity between IDDM incidence rates and ischaemic heart disease (IHD) mortality data that he had encountered in work to commercialise a process to manufacture low-cholesterol or cholesterol-free foodstuffs.[8] This observation is illustrated in the following plot of IDDM incidence in 0 to 14-year-old males[9,10] versus population standardised heart disease mortality data for 30 to 69-year-old males[11] (Figure 1).

Considering IDDM is thought to be a disease of immune stimulation and IHD is a disease associated with immune compromisation, the parallels are remarkable. This similarity raises questions with respect to commonality of the source of damage, as well as the time of primary damage. However, to confound the issue, IDDM is increasing at 1–2% per annum in many countries, while IHD mortality, but not necessarily incidence, is declining in most of the countries in Figure 1.

Milk proteins had been proposed as potential sources of heart disease prior to any suggestion of a link to IDDM. Annand demonstrated that deaths from heart disease increased dramatically after the introduction of pasteurised milk in many English communities.[12] Seely[13] and Segall[14] found, in inter-country comparisons of food component consumption and heart disease, that milk protein consumption gave the highest correlation with disease mortality. Diets containing casein were also observed to be atherogenic in animal studies when compared with vegetable proteins such as soy.[15]

Figure 1. IHD death rate 1985 (males aged 30– 69) vs IDDM incidence (males aged <15)



Contrary to the assertion of Laugesen and Elliott, no inter-country data on individual milk protein consumption existed when McLachlan began gathering data on individual milk protein consumption and heart disease. He observed that whilst relative milk protein frequencies may vary between animals, in bulk milk there is a remarkable consistency between breeds and between countries. This knowledge and data on the genotype, or phenotype, of the animals allowed him to calculate from the national herd breed data for each country the amount of each of the major milk proteins consumed. This had not been done before.

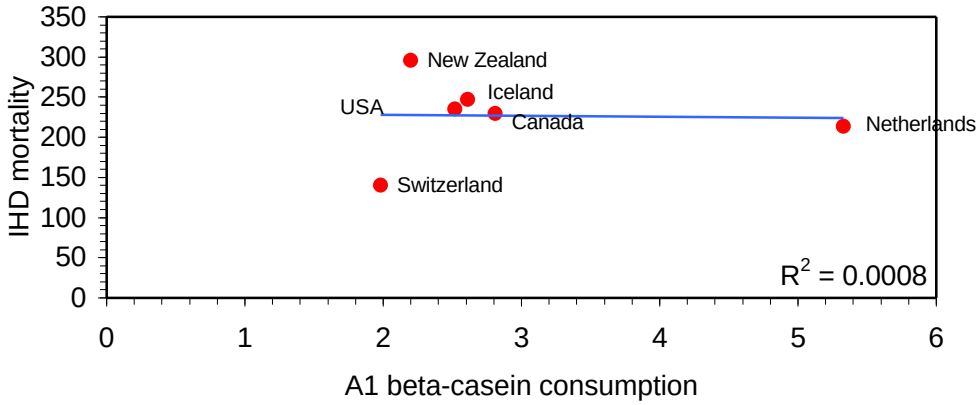
The primary work in this respect was completed in 1995, and the outcome is included in the patent application made that year.[16] This analysis showed a very strong correlation between A1 ß-casein consumption and IHD. However, it did not show a stronger relationship with A1 + B as reported later by Elliott and Hill for IDDM, and showed no significant relationship with any of the other major proteins in milk: ß-lactoglobulins A and B; a-caseins A, B or C; ß-caseins A1, A2, A3, B or C; or ?-casein A and B.

In the meantime, Elliott and Hill, from a more detailed knowledge of the ß-casein amino acid structures, proposed that one fragment of the A1 ß-casein molecule, later refined to casomorphin-7, was their candidate molecule for IDDM damage.[17] This theory required B ß-casein to be as damaging as A.

When McLachlan's findings were presented to the NZ Dairy Board, their milk scientists rejected the analyses on various grounds, including those that a number of sets of data were from PhD theses and had not been subject to peer review, and that the number of animals measured in some breeds were too small to allow accurate phenotype data to be calculated. In the end, the NZ Dairy Research Institute report set

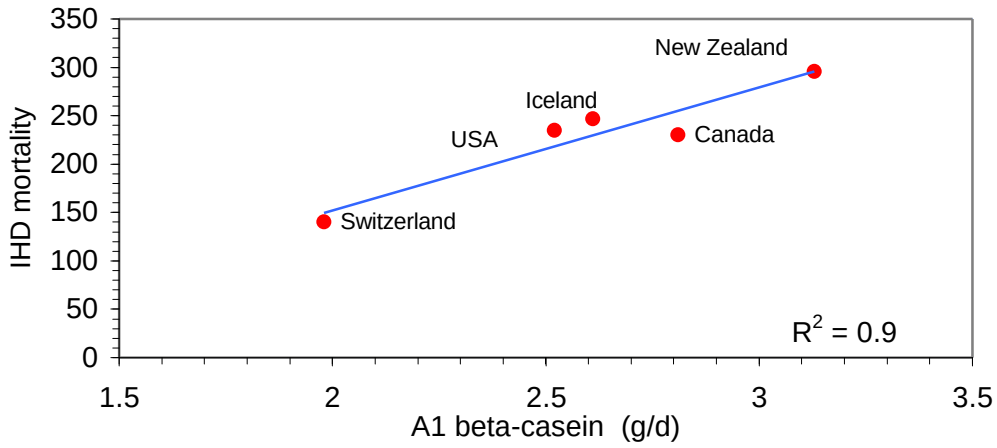
out the following graph and concluded that the McLachlan data was not supported (Figure 2).[18]

Figure 2. IHD mortality vs A1 ß-casein consumption (NZDRI data)



McLachlan had on independent expert advice rejected the Netherlands data on several grounds to do with the analytical procedure used. In subsequent publications, other NZDRI scientists, including Elliott and Hill, rejected them based on uncertainty as to the milk composition because the Netherlands imports and exports so much dairy protein. The other major point of difference concerned the composition of the New Zealand dairy herd. NZDRI based their calculations on the national co-op herd, whereas McLachlan based his calculations on the New Zealand town milk supply herd for the period under consideration, which was recorded as being 95% Friesian[19] and which provided the drinking milk consumed by New Zealanders until the mid 1990s.

Figure 3. New Zealand Dairy Research Institute data re-plotted with New Zealand town milk supply, excluding Netherlands



When the correct NZ herd composition is used, the NZDRI phenotype data give a value for A1 ß-casein consumption of 3.13 g/d per person. The NZDRI data have been re-plotted including this value and excluding the Netherlands (Figure 3). One can see that, contrary to the NZDRI conclusion, the data fit is excellent, supporting the McLachlan findings.

Corran McLachlan
Chief Executive

Felix Olsson
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A letter of thanks to volunteer health professionals deployed to East Timor

In December 2002, the international community saw the downscaling of troops from East Timor. It marked the end of three years' effort to provide a safe and stable environment for the newly established country of East Timor.

The New Zealand Defence Force had a significant role in this multinational effort to provide stability. New Zealand troops were in the isolated south-western corner of East Timor, bordering West Timor. Due to this remote location, the New Zealand Forward Surgical Team (FST) was deployed in support of the Battalion for 20 months, at which time the role was handed over to another United Nations agency.

The FST provided continual surgical and medical support to the thousand United Nations troops in the region, and emergency support to the local population of 40 000. Their work is detailed in a paper published in the October 2002 issue of *Military Medicine*.

This tented surgical and medical facility was sustained not only by military medical personnel but also by civilian volunteers. These were health professionals ranging from specialist nurses, radiographers, and laboratory scientists, to anaesthetists and surgeons, who volunteered their time to assist the New Zealand Defence Force in this peacekeeping zone.

Their families, colleagues and Health Boards (in particular Waikato and Otago) all helped and supported their initiative to work with the FST.

We wish to acknowledge and thank all those people directly and indirectly involved. The mission was a great success and they can all take pride in the part they played.

Lieutenant Colonel Andrew Dunn
Director of Army Health Services.

Colonel Anne Campbell
Senior Medical Officer Joint Forces

Brigadier David Le Page
Director General of Defence Medical Services
New Zealand Defence Force

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Palliative home care and cost savings: encouraging results from Italy

Patients with incurable cancer inescapably need medical and psychosocial aids. Palliative care is required to ensure they have the best quality of life possible and is also of great importance to those who prefer to spend their last days at home.[1] However, home assistance for terminally ill patients is an overwhelming challenge for health and social resources.[2]

The Division of Oncology of Santa Maria Goretti Hospital has an admission rate of approximately 550 cancer patients each year and accommodates about 13 terminally ill patients each month (range 9–17). Considering the high number of advanced cancer patients expected each year, a home care service was planned. The home service, called Servizio di Assistenza Oncologica Domiciliare (SAOD), was financed by grants from the Italian League against Cancer, Latina Section. The team consisted of six professionals – four full-time trained oncologists and two qualified professional nurses with additional skills in cancer nursing – from our Division of Oncology. In addition, the service provided a telephone hotline operated daily between 8am and 2pm. Given their crucial role in advanced cancer management, general practitioners also took part in the project, providing primary care.[3]

Home palliative care was available for patients whose remaining life span was two months or less, as estimated by clinicians. During a period of 20 months, the SAOD took care of 256 patients (140 males, 116 females), with a median age of 66 years (range 8–92 years). Thirty eight cancer patients were still alive when the SAOD was interrupted. The SAOD provided 15 379 home care days with a median duration of domiciliary assistance of 60 days per patient. The total number of home care interventions made by oncologists and professional nurses, over a period of 20 months, was 2308 and 2520, respectively. Oncologists and professional nurses made 4 and 4.5 visits per day on average, respectively. Each patient was seen at home by an oncologist on average every 6.6 days, and by a professional nurse, on average, every 6 days, for a total of 19 interventions (9 by the oncologist, 10 by the nurse) over a period of 60 days. In addition, the patients received a minimum of one home visit per week by their district general practitioner. The SAOD visits are listed in Table 1.

Blood transfusions and pleural-peritoneal drainages were performed by the oncologist. Only 17% of patients died in the hospital. Our home death rate (83%) equalled that reported by De Conno (86%)[4] and exceeded those presented by Jordhoy (25%)[1] and Hinton (29%).[5] Our rehospitalisation rate (9.4%) was lower than those shown by Hughes (14.8%) and Cummings (10.3%), and higher than those exhibited by McCorkle (8.4%) and Zimmer (6.8%).[6]

Table 1. Baseline characteristics, palliative care interventions and cost analysis of the SAOD home care service for advanced cancer patients

Patients characteristics	**n (256)**
Age (years)	
Mean	66
Range	8–92
Gender	
Male	140
Female	116
Disease characteristics	**%**
Lung	24.5
Colorectal	12.8
Breast	11.7
Stomach	7.4
Head and neck	5.0
Pancreas	2.7
Ovarian	2.7
Occult	6.6
Other	23.0
Mean disease duration	**Months (range)**
Non small cell lung cancer	4.7 (1–19)
Small cell lung cancer	2.6 (1–6)
Colorectal cancer	5.3 (2–17)
Gastric cancer	3.5 (1–10)
Unknown primary cancer	3.8 (1–8)
Home care programme	
Days of domiciliary assistance	15 379
Days of in-hospital readmission	1459
Rehospitalisation rate	9.4%
Mean days of domiciliary assistance per patient	60
Patients died at home	83 %
Patients died in hospital	17 %
Interventions	**n**
Physician visits per day	4.0
Nurse visits per day	4.5
Urinary catheterisations	84.0
Blood sample collections	71.0
Blood transfusions	53.0
Intravenous therapies	98.0
Medications	36.0
Pleural-peritoneal drainages	22.0
Cost analysis per patient per day	**€**
Home care team	7.4
Specialist consultant	0.5
Nursing	3.8
Drugs	12.8
Supplies	1.5
Medical examinations	4.5
General practitioner	5.0
TOTAL	**35.5**

The cost associated with running the programme averaged out at €35.5 per patient per day. This amount covered not only the costs of the support and coordination team (€7.4), but also the costs of drugs and supplies (€12.8 and €1.5), nursing (€3.8),

medical examinations (€4.5), specialist consultations (€0.5), and general practice fees (€5.0). Strikingly, according to the Italian Ministry of Public Health annual expense report, the cost of each in-hospital admission is close to €310 per patient per day. The SAOD costs for managing incurable cancer patients at home were about nine times lower than those for in-hospital care. Several authors investigated the economic burden of various home care projects and reported a home/hospital expenses ratio of 1:3.[7] This remarkable resource-saving project achieved a ratio of 1:9, which has never been reported. However, it must be noted that the SAOD's daily expenses were derived from the average of the global costs needed for each visit provided during the 20 months of home assistance.

In summary, it appears that by transferring palliative care to the home setting, a cost-effective alternative is available for the Italian healthcare system. However, further research is needed before drawing any firm conclusions.

We acknowledge Pasquale Cagnazzo, Giuseppina Carreca, and Milvia Salimbeni for their contribution in planning and organising the home care service and the participating general practitioners in Latina District who made this experience possible. This study was supported by grants from the Italian League against Cancer, Latina Section. We are grateful to doctor Antonio Di Poce for his advice on economic evaluation.

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Diabetes and deprivation: a small area study in Te Tairawhiti

Diabetes is a disease that can disable, maim and kill. Its impact on individuals and their whanau should never be underestimated. Diabetes is the ninth leading cause of years of life lost (YLL) in NZ (accounting for over 6500 YLL in 1996).[1] Of more concern, however, from both a financial and quality of life perspective, is the impact of diabetes on years of life disabled (YLD). In 1996, diabetes was the third and fourth leading cause of YLD among males and females respectively in NZ, accounting for a total of 14 684 YLD.[1]

The impact of Type 2 (NIDDM) diabetes has been described as reaching epidemic proportions throughout the world.[2] It has been suggested that the burden of 'diabetes mellitus is becoming unsustainable'.[3] This international trend has not left NZ untouched, and disquiet over the prevalence of diabetes here is long standing.[4] Current concern over the threat of NIDDM has been fuelled by the increasing prevalence of obesity in NZ.[5]

Although diabetes is recognised as a major public health problem in NZ, it is an issue of particular importance in Tairawhiti given the increased risk among groups such as older Europeans and Maori,[6] and its association with deprivation.[7] Poverty-related issues associated with diabetes include factors such as treatment and diagnostic costs, as well as increased dietary costs.[6]

Discharge data for the financial years 1996-1999 citing diabetes mellitus (ICD code 250) in any of the first five diagnosis columns, relating to residents of Tairawhiti, were accessed from NZHIS. Age-standardised hospital discharge rates were calculated for both the Maori and Pakeha/NZ European ethnic groups (based on the total district population). Deprivation in this analysis was measured using the raw values of an area-based measure called NZDep96.

Analysis revealed that Maori hospital discharge rates citing diabetes are substantially higher than those for the Pakeha population. The age-standardised hospital discharge rate citing diabetes per 1000, per year, among Pakeha was 8.63, while among Maori the rate was 23.70. Area-based (ecological) analysis of the 22 Census Area Units in Tairawhiti revealed a significant relationship between deprivation and the Pakeha discharge rate for diabetes mellitus ($r = 0.432$, $p < 0.05$). Surprisingly, however, no such significant relationship was found for Maori.

It is important to note that under-diagnosis of diabetes is a significant and variable problem, and that hospital discharge summaries universally under-record diabetes.[6,7] This analysis highlights the need for significant further work. Future initiatives should establish alliances with primary care providers to examine and tackle this issue.[8]

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Medical discipline – conduct unbecoming

Charge: The Director of Proceedings charged Professor Francis Antony Frizelle with conduct unbecoming a medical practitioner and that conduct reflected adversely on his fitness to practise medicine.

The charge particularised the allegations against Professor Frizelle as follows:

1. He failed to communicate with his patient in a sensitive and respectful manner.
2. He removed a seton from his patient without first obtaining her informed consent to that procedure.
3. He failed to offer his patient pain relief when he knew or ought to have known she was experiencing significant pain.
4. Having removed a seton from his patient he failed to adequately explain to her:
   (a) that he had done so; and/or
   (b) the consequences or care following removal.

Background: The patient was first referred to Professor Frizelle in 1996, and he diagnosed that she had Crohn's disease. After this diagnosis the patient was seen by Professor Frizelle and other doctors on a number of occasions between 1996 and 1999.

On 25 June 1999 Professor Frizelle performed a procedure on the patient under general anaesthetic. On this occasion Professor Frizelle inserted a seton – a drainage tube which is inserted to assist with the treatment of a fistula with sepsis. The seton was sutured into place with a slip knot. The technique employed by Professor Frizelle when inserting the seton required the suture to be slowly tightened over a period of time allowing the seton to slowly cut through the sphincter muscle. The tightening of the seton suture was carried out uneventfully on 19 July and 30 August 1999.

On 2 September 1999 the patient telephoned Professor Frizelle's Registrar and advised she was in significant discomfort as a result of the tightening of the suture on 30 August. The patient contacted the Registrar again on 3 September. Her pain was such she could hardly walk. It was arranged the patient would attend Christchurch Hospital the following morning to see the Registrar.

The patient explained to the Registrar that the seton was very painful. She asked him to be gentle. The Registrar then examined the patient and attempted to cut the suture with a scalpel. This caused the patient considerable pain and she cried out. The Registrar stopped his efforts to enable the patient to take some codeine. A few minutes later the Registrar made another attempt to cut the suture. The process was so painful the patient screamed. It was accepted that the patient was in such pain that she "grabbed a cord on the wall, was crying with pain, and felt she was going to vomit". At this stage the Registrar stopped the procedure and asked a nurse to get some morphine which he proposed to administer intravenously. He also called for nitrous oxide.

Soon after the nurse left Professor Frizelle entered the room. He asked if he could examine the suture. The patient asked Professor Frizelle to be gentle with her.

When Professor Frizelle examined the patient he pulled on the suture which caused the patient to scream with pain. He told the patient to stop screaming. The patient said he was blunt and unsympathetic.

Professor Frizelle then asked the Registrar to get some scissors, as he said that administering a local anaesthetic would hurt as much as cutting the suture. Professor Frizelle then told the patient to raise her buttocks. He provided no further explanation of what he was going to do, or what options were available. He did not offer the patient any pain relief.

Professor Frizelle then proceeded to remove the seton. The patient had assumed the suture was going to be loosened. She did not appreciate the seton had been removed until the following day when she took a shower.

The process of removing the seton caused the patient considerable pain and anguish. Subsequently the patient requested a transfer of her care to another surgeon.

Professor Frizelle explained that when he saw the patient she was screaming at the top of her voice. He said the patient was distressed and that rapid action was necessary. He believed the seton was the cause of the patient's pain and accordingly he thought it appropriate to remove the seton as quickly as possible.

Professor Frizelle accepted he did not explain matters in any detail and that he may have been brisk and firm with the patient. He thought he had made it clear he intended to remove the seton. He also accepted he had been annoyed with the Registrar for seeing the patient without his knowledge and that his displeasure with the Registrar may have been conveyed to the patient.

Professor Frizelle accepted he had acted inappropriately. He wrote a letter of apology on 3 May 2000 and again apologised to the patient at the hearing before the Tribunal.

Professor Frizelle has accepted most of the factual evidence upon which the charge was based. However, he contested the suggestion that his acts and omissions amounted to conduct unbecoming a medical practitioner.

Finding: The Tribunal found Professor Frizelle guilty of conduct unbecoming a medical practitioner and that conduct reflected adversely on his fitness to practise medicine.

When considering the first particular the Tribunal was unanimously of the view that Professor Frizelle's lack of sensitivity and respect for the patient on this occasion met the threshold of conduct unbecoming a medical practitioner and that his conduct reflected adversely on his fitness to practise medicine.

Professor Frizelle's explanation for failing to communicate in an appropriate and sensitive manner with the patient was that he wanted to move with "haste" to address the patient's situation. The Tribunal accepted Professor Frizelle's motives were genuine but also recorded that the situation which Professor Frizelle encountered was not an emergency. The patient was clearly in considerable pain and the situation required a calm and sensitive approach.

When considering the second particular the Tribunal was satisfied that Professor Frizelle elected to remove the seton without providing the patient with an explanation as to:

- What he was proposing to do;
- What options were available; and
- What the likely consequences of his treatment were.

The Tribunal was in no doubt that an ordinary patient, in the patient's circumstances would expect to be told that it was the doctor's intention to remove the seton, as opposed to cut or release pressure on the suture holding the seton in place. An ordinary patient would expect to be told the options available and what the consequences were of removing the seton.

In addition to failing to inform the patient in accordance with the standard expected of a reasonable patient, Professor Frizelle failed to take account of the patient's personal circumstances and desire to understand what was happening. The Tribunal considered the fact the patient was unaware the seton had been removed until the following day highlighted the inadequacy of Professor Frizelle's explanations to the patient.

The Tribunal was of the view Professor Frizelle failed to:

- Properly inform the patient of his proposed method of treatment, the consequences of that treatment and the options available; and
- Obtain the patient's consent to the removal of the seton.

The Tribunal was satisfied Professor Frizelle's failures as alleged in the second particular constituted conduct unbecoming a medical practitioner and reflected adversely on his fitness to practise medicine.

When considering the third particular the Tribunal was satisfied Professor Frizelle knew the patient was in considerable pain. At the time he removed the seton Professor Frizelle did not know his Registrar had called for morphine which he intended to administer intravenously. The Registrar had also called for nitrous oxide. The circumstances Professor Frizelle faced necessitated he not remove the seton without providing the patient with the option of sedation or strong analgesia. The Tribunal was of the view Professor Frizelle's acknowledged shortcomings constituted conduct unbecoming a medical practitioner which reflected adversely on his fitness to practise medicine.

When considering the fourth particular the Tribunal was left in no doubt Professor Frizelle failed to communicate to the patient he had removed the seton and the consequences of his having removed the seton. The Tribunal was of the view that Professor Frizelle's conduct as alleged in this particular constituted conduct unbecoming a medical practitioner which reflected adversely on his fitness to practise medicine.

Penalty: The Tribunal ordered Professor Frizelle be censured, fined $4000 and pay costs of $9483.13.

The Tribunal recorded that under normal circumstances Professor Frizelle could expect a fine in the vicinity of $7000–$10 000 in relation to the findings made against him. However, in this instance the Tribunal discounted the fine it would normally

impose due to its concern that the events in question occurred more than three years before the hearing. In addition, Professor Frizelle had on two occasions proffered a full apology to the complainant, and also he had a cooperative approach to the hearing of the charge against him.

The Tribunal further ordered publication of its orders in the New Zealand Medical Journal.

The full decisions relating to the case can be found on the Tribunal web site at www.mpdt.org.nz Reference No: 02/94D.

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Patrick Philip Eric Savage

Dr Patrick Savage MBE, ED, MB, ChB(NZ), DPM (Eng), DPM (RCP & SI), FRANZCP, COP Psychology III (Auck) died in Auckland on 21 November 2002 after a brief illness. He was born in Nowgong, Central India on 5 February 1918, the eldest child of Colonel and Mrs Philip Savage. His father was a medical officer in the Indian Medical Service and at the time Nowgong was a Turkish Prisoner of War Camp.

Patrick commenced his education at the Lawrence Royal Military School, Sanawar and then after the family migrated to New Zealand in 1932 continued at Kings College, Auckland (1932–1935). From 1935 he studied at Otago University and graduated MB ChB in 1942.

He then worked as a house surgeon in Wellington Hospital. In 1944 he married Margot Jerram, who was a medical student in the same year. After graduation, she practised as a GP virtually continuously until shortly before her death in 1993.

In 1945, Patrick enlisted in the NZEF and served as a medical officer in Italy, returning as a captain in 1946. He had joined the Otago University Medical Company (OUMC) as a student, and so he continued to serve on in the Territorial Army (TF) after his return to New Zealand. His army connection was always a very important part of his life and he was a familiar figure at TF camps until his retirement from the army in 1980 as a lieutenant colonel.

On his return from overseas, he practised as a GP in Ohakune/Raetihi until 1948. In 1951, he took up an appointment at the then Avondale Mental Hospital and started his career in Psychiatry. In 1955, he went to London to continue his studies, gaining a DPM RCP and RCS (Ireland) and DPM RCP and RCS (England) in 1956. He later gained a membership of the RANZCP in 1963, and was appointed a Fellow in 1986.

On his return to New Zealand in 1956, he took up an appointment at Sunnyside Hospital near Christchurch, then in 1963 moved to Lake Alice.

In 1965, Patrick was appointed Superintendent of Oakley Hospital and continued on as Superintendent of the Forensic Unit after the general psychiatric section was split off as a separate Carrington Hospital. He remained there until his retirement in 1983. He was well known as a leading forensic psychiatrist throughout New Zealand, and in the latter part of his professional life practised almost exclusively in that field.

His professional life was not without controversy. He was a man of strong principles and he pursued these to the utmost if he felt that they were in the best interests of his

patients. He opposed the government policy of closing down mental hospitals and releasing psychiatric patients into the community without adequate provisions for their care. These views made him unpopular with some sections of Government. He was also Superintendent of Oakley during a period of industrial unrest and was instrumental in having the army called in to assist with patient care. This made him unpopular with the union, although he was always very concerned for the needs of his staff as well as for his patients.

He was the final surviving member of a small group who in 1967 established the Oakley Mental Health Research Foundation to mark the centenary of Oakley Hospital's first 100 years of service to the people of Auckland. He gathered together a number of prominent citizens who became the initial founders. The Trustees then set out to raise a fund for mental health research. The appeal was the first ever made for mental health research in New Zealand and it is significant that he was still intensely interested in the work of the Foundation until his death, and was present at the meeting on 31 October 2002 just before his death.

Patrick was a committed Anglican and was involved with the Selwyn Society, which opposed certain modern trends in the Anglican Church. He was a very reserved person, who had a great respect for people and was blessed with a wonderful family life. His main non-professional interest was trout fishing, which was usually conducted from the family holiday home on the edge of Lake Rotorua.

He had an extremely happy married life with Margot, who was a real support to him during his professional career until she died in 1993. They had four children, Jill, Philippa, Christopher and Debbie, and he is survived by all of them plus four grandchildren.

In 1995, he married Daphne Sarney who was also a tremendous support and made his last years very happy. He was a true gentleman and was much respected by all who knew him well.

We are grateful to Dr Brian J Linehan for this obituary

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Patient drug facts 2003

Published by Facts & Comparisons 2002. ISBN 1-57439-160-7. Contains 1904 pages. Price US$19.95

This book is published by Facts and Comparisons, St. Louis, Missouri, USA and the editorial advisory panel is a group of pharmacists and physicians from centres in the USA. The book comprises monographs of over 6500 generic and brand-name drugs, including both prescription and non-prescription drugs. The monographs have been compiled from the Facts and Comparisons electronic database, the web site for which is www.drugfacts.com.

It is not really clear whether the book has been written primarily for patients or for health professionals, but it is stated that the book is for health professionals to use with their patients to help provide them with drug information.

Pros

- The drug monographs are concise, usually 2–3 pages long each.
- The book is very well indexed, and drug monographs can be found quickly and easily.
- The list of drugs appears to very comprehensive, although there are some unusual omissions, as described below.

Cons

- The book is American, and some trade names and drug names will not be recognised or used in New Zealand.
- In the monographs, there is a section entitled ‘Use with caution in the following situations’. There is no explanation of what ‘use with caution’ means, and no explanation for why these situations are problematic.
- There are lists of interacting drugs, but no description of the type of interaction or the need for dose adjustment up or down.
- Side effects are presented in a long list with no indication as to their relative frequency and therefore no way of knowing how to put them into perspective.
- Not all important drug monographs are included; for example, many new monoclonal drugs are included but there are no monographs for intravenous gentamicin or tobramycin.
- There is little in the way of information for dose individualisation, such as dose per body weight, age, or renal function, and little pharmacokinetic data to enable these calculations.

In summary, the book provides some useful information on a very large number of drugs and is easy and quick to use, but does lack some information to give perspective

on side effects and to help with individualised dosing. At the same time, it is too technical for most patients to use.

Murray Barclay
Clinical Pharmacologist
Christchurch Hospital