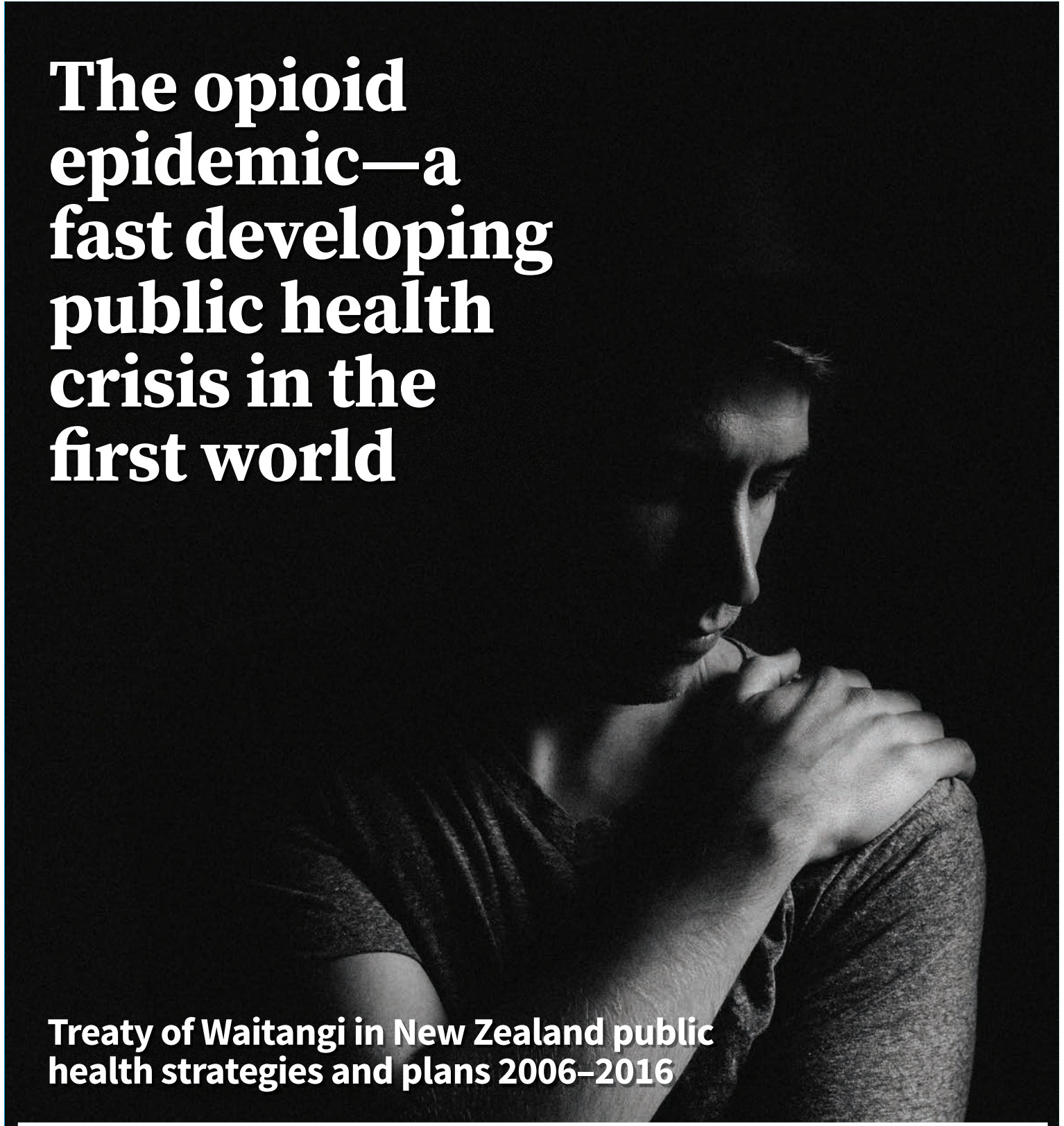


The  
**New Zealand  
Medical Journal**

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## Incidental findings during a surgical procedure—current practice and ethical implications

Rachel McKenzie, Jasper Diong, Jeanne Snelling, Lynley Anderson, André M van Rij

When surgeons carrying out an operation incidentally find an unrelated problem, should they go ahead and treat this too during the same surgery or wait for another time until having discussed it with the patient, and obtaining consent for further surgery if still required? This question was asked of New Zealand surgeons and those in training to see what they thought were the important things to consider and what they would do in different circumstances such as whether it was an emergency, whether the extra surgery could lead to serious complications or if it avoided another operation. The results showed that surgeons vary in what they emphasised but made decisions that reflected a sensible approach. It would be easier to make these decisions if there was a discussion between patient and surgeon beforehand prompted in the surgical consent process.

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## Incidental findings during a surgical procedure—patient and public perspectives

André van Rij, Jamie Thomas, Rachel McKenzie, Jasper Diong, Frank Frizelle, Jeanne Snelling, Lynley Anderson

When surgeons carrying out an operation incidentally find an unrelated problem, should they go ahead and treat this at the same surgery or wait for another time until having discussed it with the patient? This question was asked of patients awaiting surgery, and the public, to see what they thought were the important things to consider and what they would want to be done by their surgeon in different circumstances. These included whether it was an emergency or not, whether the extra surgery could lead to serious complications or if this might avoid another operation. The results showed that patients and public approached the options similarly although patients more often preferred to go on with the treatment of the IF at the same surgery. Both groups considered the opportunity to avoid another operation to be important. Generally, they preferred for surgeons to discuss the possibility of an incidental finding (IF) during the surgical consent process, although some were not so keen as it might confuse the situation. The preferences were very similar to the way surgeons approached an IF in the same situation as described in the previous paper.

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## Treaty of Waitangi in New Zealand public health strategies and plans 2006–2016

Heather Came, Rhonda Cornes, Tim McCreanor

This study examines how public health policy in New Zealand has represented te Tiriti o Waitangi and the Treaty of Waitangi between 2006 to 2016. Twelve of 49 public health strategies and plans reviewed from the Ministry of Health database referred to either treaty text. Crown discourses were categorised as i) rhetoric, ii) aspirational statements, iii) had elements of practical implementation and/or iv) substantive actions. The study confirms public health strategies rarely address Treaty obligations and this silence is inconsistent with legislative requirements to engage with the Treaty and health equity and is likely to inform health-related Waitangi Tribunal claims. Further work needs to be done to strengthen alignment of health policy to fulfil Crown Treaty obligations.

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## Prevalence of hepatitis E virus antibodies and infection in New Zealand blood donors

Joanne Hewitt, David Harte, Michelle Sutherland, Dawn Croucher, Lindsey Fouche, Peter Flanagan, Deborah Williamson

Hepatitis E virus (HEV) can be transmitted by blood transfusion. This study measured the presence of HEV antibodies (evidence of past or present infection) in New Zealand blood donors. This was determined to be 8.1 to 9.7% using two different antibody tests. The rate in New Zealand is similar to that reported in other developed countries. HEV was not found in blood samples from 5,000 donations using a molecular test to detect viral nucleic acid. This indicated no evidence of current HEV infection. This study is the largest to date to assess past and current HEV infection in New Zealand blood donors.

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## Review of acute symptomatic urolithiasis in Auckland

Stephanie Loeff, Manmeet Saluja, Michael Rice

Decreasing incidence of symptomatic stones which could be attributed to a large influx of Asian immigrants. A male aged 40–49 with a past history of stones has the highest chance of stone formation.

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## Disease recurrence following surgery for colorectal cancer: five-year follow-up

Ashok Gunawardene, Brendan Desmond, Ali Shekouh, Peter Larsen, Elizabeth Dennett

In this article, the authors describe the patterns of disease recurrence in patients having curative surgery for colorectal cancer at a hospital in New Zealand over a three-year period. With five years of follow-up data, one in four patients experienced the cancer returning and this is in keeping with data reported in the worldwide literature. Recurrence most commonly occurred within the first two years, and the liver and lungs were the most common sites of recurrence.

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## The American opioid death epidemic—lessons for New Zealand?

Paul L Morrow

There has been an increase in opioid drug deaths world-wide and the US is currently in an epidemic of opioid-related deaths. Although so far New Zealand has not seen a significant rise in opioid drug deaths, there may be a risk. Medical surveillance for an increase of opioid abuse and deaths is warranted to take early action to prevent such an epidemic occurring in New Zealand.

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# The opioid epidemic—a fast developing public health crisis in the first world

Edward A Shipton

**I**n first-world countries, the opioid epidemic is proving to be one of the greatest health challenges of the 21st century. It is generating a current, but fast developing public health crisis in the first world. This opioid epidemic is due to aggressive prescribing practices, widespread opioid misuse, and mounting rates of prescription and illicit opioid overdose-related deaths.<sup>1</sup>

In an article in this journal,<sup>2</sup> Paul Morrow has looked at the epidemic of opioid/opiate drugs deaths in the US. The US consumes 80% or more of all the opioids manufactured in the world each year.<sup>3</sup> He cautions that “the current epidemic of opioid deaths in the US may be a warning to New Zealand.” He proposes “the creation of a rapid reporting system.” In suspected drug overdose deaths, data would be collected from coroners and pathologists, emergency departments and St Johns. This would in turn act as an “early warning system” to trigger a response plan.

Shipton et al have recently shown that the rate of opioid-related deaths in New Zealand has increased by 33% from 2001 to 2012.<sup>4</sup> Opioid analgesic deaths were most likely due to methadone, morphine, codeine and latterly oxycodone prescribed by healthcare professionals.<sup>4</sup> There was a relatively high use of methadone and morphine relative to illicit heroin use (due to island isolation).<sup>4</sup> This study showed the steady annual increases in opioid prescriptions in New Zealand from 2001 to 2012, and the rise in opioid analgesic deaths to be associated with the increases in the numbers of opioid prescriptions.<sup>4</sup>

Regrettably, in the US a second equally serious epidemic has emerged in the context of prescription opioid abuse, that being the use of illicit opioids including heroin and fentanyl.<sup>1</sup> As Morrow states:

“what initially was considered by many to be primarily a problem driven by prescription medication abuse, is shifting to an illicit pattern”. He then goes on to describe the sources of illicit drugs in the US before turning his attention to opioid use mortality rates across the Tasman.

Opioid sales have increased in Australia, although their population-adjusted use is only a quarter to a third of that in the US.<sup>5</sup> Trends in opioid utilisation in Australia from 2006–2015 have recently been published.<sup>6</sup> Number of dispensings, defined daily doses [DDD] or oral morphine equivalents [OMEs] have been combined with a measure of the number of persons dispensed opioids to gain insights into Australian trends in prescribed opioid use. Total opioid use increased according to all metrics, especially OME/1,000 population/day (51% increase) and dispensings/1,000 population (44%).<sup>6</sup> There was a 238% increase in persons dispensed only strong opioids. The use of strong opioids increased according to dispensings/1,000 population (140%), OME/1,000 population/day (80%) and DDD/1,000 pop/day (71% increase).<sup>6</sup> Weaker opioid use remained stable or declined, and the rate of persons accessing weaker opioids decreased by 31%.<sup>6</sup> There are problems with weak opioids as well. In Australia, codeine-related deaths increased from 3.5 per million in 2000 to 8.7 per million in 2009.<sup>7</sup> Severe harms have been described with codeine use, especially from the consumption of high doses of combination products such as codeine/paracetamol and codeine/ibuprofen.<sup>8</sup> In Australia from 1 February 2018, analgesics containing codeine will be available only on prescription.

Morrow then considers deaths in New Zealand attributed to narcotic or psychedelic

drug poisoning and their demographics. In New Zealand in 2016, four of the leading six causes of disability were chronic pain conditions (chronic low back pain, migraine, chronic neck pain and other muscular-skeletal disorders).<sup>9</sup> Opioids are increasingly being prescribed for chronic non-cancer pain, despite limited data on efficacy.<sup>10</sup> Besides the risk of overdose (unintentional or intentional), chronic opioid use can result in tolerance, physical dependence, addiction, opioid-induced hyperalgesia and sexual and endocrine dysfunctions.

During the period 2008–2012 in New Zealand, 179 (55%) deaths resulted from unintentional opioid overdoses.<sup>4</sup> The high number of unintentional overdoses is tragic as these are potentially avoidable.<sup>4</sup> This underlines the need for education of both prescribers and the public alike. Morrow mentions the value in New Zealand of using multidisciplinary pain management education sessions held for primary and secondary care practitioners.

Morrow indicates that already action has been taken regarding opioid prescription patterns and pain management. What is required is a comprehensive strategy to reduce our reliance on prescription opioids, such as prescription drug monitoring programmes.<sup>1</sup>

More specialist pain medicine physicians are needed in New Zealand. They use multimodal therapy (biopsychosocial rehabilitative approach), and can educate

their patients about the risks of opioids and monitor them. In this way they could decrease the risks of opioid therapy.<sup>3</sup> In New Zealand at present there are only three trainee fellowship positions accredited by the Faculty of Pain Medicine. More trainee fellowship positions are desperately needed.

Morrow states that New Zealand “is an island nation with more easily defended borders, at least as far as illicit drug importation may be concerned”. Fentanyl patches became fully funded in New Zealand without special authority from February 2011. The risk of fatality with fentanyl patches arises when given to opioid naïve patients.<sup>11</sup> However, illicit fentanyl can be indistinguishable from prescription fentanyl, and can be ordered over the Internet.

The use of opioid assessment screening tools, random urine testing, opioid treatment agreements and use of universal precautions (making a diagnosis; evaluation of psychological status and addiction risk; treating improvable aetiologies and comorbid psychiatric syndromes) are additional essentials in managing opioid abuse.<sup>12,13</sup>

In this article, Morrow has proposed an “early warning system”, and has reminded the New Zealand medical profession not to become complacent about the dangers of the opioid epidemic spreading here, and to take timely steps (some of which have been discussed here) to prevent this from occurring. For us in the medical profession we should heed his wise advice.

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**Competing interests:**

Nil.

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# Incidental findings during a surgical procedure—current practice and ethical implications

Rachel McKenzie, Jasper Diong, Jeanne Snelling, Lynley Anderson, André M van Rij

## ABSTRACT

**AIM:** Sometimes during an elective surgical procedure, an abnormality is found which is unrelated to the scheduled procedure. In many instances, immediate treatment of this unexpected pathology is in the patient's medical interests, however, specific patient consent has not been obtained. This study investigates current surgical practice when confronted by an incidental finding (IF), as well as surgeons' views on informed consent in this context.

**METHOD:** An online survey was sent to all practicing surgeons and surgical trainees within New Zealand. Respondents were presented with hypothetical scenarios involving IFs and asked to decide whether or not they would proceed with treatment. Opinion was sought on the factors influencing such decisions and the need for a clause within surgical consent documents to prompt discussion about IFs.

**RESULTS:** 151/450 (33.6%) surgeons and trainees responded. Immediate treatment was more likely with IFs of greater clinical significance, lower-risk procedures and where there was prior consent for IF treatment. A proportion of surgeons did not follow these trends. Although a great deal of variation exists in the way that IFs are dealt with in the consent process, the majority of respondents (111/129, 86%) favoured a clause within a consent form that prompts discussion and seeks consent for the treatment of IFs.

**CONCLUSION:** Responses to the IF scenarios were generally consistent with good practice. While variation in decision-making is to be expected, some decisions were concerning. Most surgeons agree that a clause within the consent form should trigger a discussion of IFs during the consent process.

Occasionally during surgery, an additional abnormality is found which is unrelated to the condition for which the procedure is being undertaken. While uncommon, such findings highlight the limitations of pre-operative diagnostics and imaging techniques.<sup>1</sup> A surgical, ethical and legal dilemma arises in cases where it may be medically in the patient's best interests to treat the incidental finding (IF) during the same operation; yet to do so without prior consent would deny patient autonomy. From a legal perspective, to carry out an additional procedure to treat an IF without informed consent may provide grounds for charges of battery or negligence.<sup>2,3</sup> In New Zealand, such treatment may be in breach of The Code of Health and Disability Services

Consumers' Rights. Surgeons may also be subject to disciplinary proceedings.<sup>4</sup> Despite such constraints at least some surgeons are willing to undertake additional procedures under certain circumstances<sup>5,6</sup> and some institutions have used broad consent clauses to cover these events.<sup>7</sup>

Responding to IFs requires an individual surgeon's judgment, which is subject to ethical and legal restraints. This study investigates the perspectives of surgeons and trainee surgeons regarding when it is and is not appropriate to carry out additional procedures for the treatment of IFs, as well as professional opinion regarding current approaches to consent for IF treatment and ways in which this may be improved.

## Method

### The online survey

An online survey constructed with a mixed quantitative and qualitative methodology was sent out to all surgeons and surgeons in training in New Zealand with the agreement of the New Zealand National committee of the Royal Australasian College of Surgeons (RACS) whose office sent our email letter of invitation containing a weblink for an online survey. Respondents remained anonymous to the researchers. The initial invitation was followed four days later by a second reminder email.

The questionnaire used the online survey design programme surveymonkey.com. The survey questions evaluated the circumstances under which respondents would, or would not, carry out an additional procedure at the time the IF is discovered. The scenarios included several key factors that might influence the decision such as the:

- urgency of the need to deal with the IF
- clinical consequence of the IF
- level of increased risk conferred by the additional procedure
- presence or absence of written general consent for additional procedures to deal with IF

Each scenario was followed by the question: “would you or would you not go ahead with the additional procedure in these circumstances?” Respondents were required to record a decision for each proposed scenario before they were able to move on.

Qualitative questions asked respondents to list the factors which would influence their decision making. These open-ended questions both preceded and followed the quantitative questions. Demographic data including the surgeon’s specialty, level of qualification, years of practice or training stage, and other demographic details were noted. Participants were also asked to provide examples of IF in their specialty and their recollection of their institution’s consent form regarding IF. Finally, they were asked their opinion about including a specific clause within surgical consent documents that dealt with IFs. Copies of the anaesthesia and surgical consent docu-

ments from both public and private surgical institutions in New Zealand were obtained to determine the presence and nature of clauses pertaining to IF.

### Data analysis

Those who did not provide a full set of answers within one or more of the survey sections were excluded from the analysis of the data within those particular sections only.

Univariate analysis was undertaken to compare the various factors that affected the treatment decisions using a chi-square test for the categorical data.

Thematic analysis was undertaken for the qualitative data. A template of categories reflecting the themes of the comments given was generated inductively from the text; this was modified or added to throughout the categorisation process to generate a final template containing all of the themes represented within the dataset. The data was then coded and thematic categories were ranked according to the frequency of the appearance of themes within the data. These were corroborated with the surgeon researcher (AvR) to validate these in accordance with contextual knowledge and experience.

This study was granted ethical approval from the University of Otago Human Ethics Committee (Health).

## Results

There were 151 respondents. Of these, 130 (86.1%) provided a complete set of survey answers. The demographic characteristics of the surgeons in this study are shown in Table 1 and were similar to the overall population of New Zealand surgeons.<sup>8</sup> The majority practiced in general surgery, orthopaedic surgery, or otolaryngology. Approximately half had >15 years of surgical experience and 19% were trainee surgeons.

The proportion of surgeons and trainees who would proceed with surgery to deal with an IF increased as the clinical consequence of the finding worsened, and also increased as the additional risk of the added procedure decreased (Figure 1A). In the absence of consent and when the IF had serious consequences for the patient and the operative risk of treatment was low, most surgeons and trainees (91%) indicated

**Table 1:** Demographics of responders.

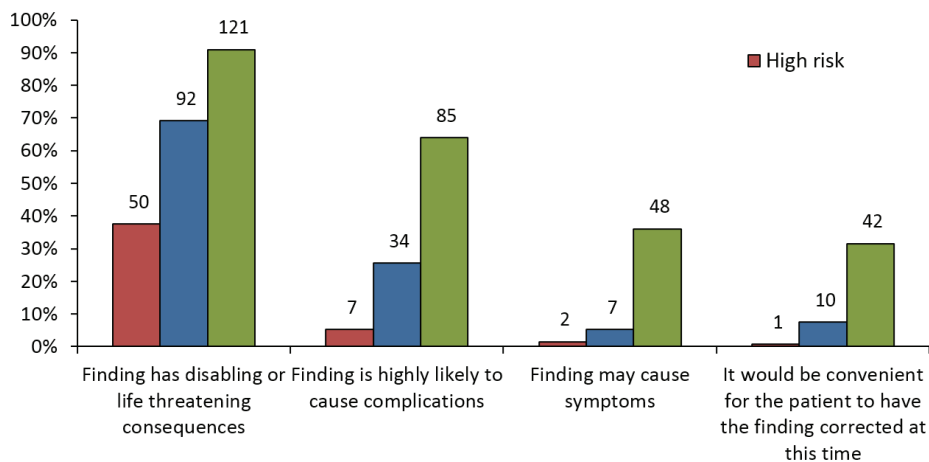
	Demographic	Number (%)
Gender	Male	109 (83.2%)
	Female	22 (16.8%)
Age (yrs)	26-49	78 (59.5%)
	50+	53 (40.5%)
Specialty	General	47 (36.2%)
	Orthopaedic	36 (27.7%)
	Otolaryngology	18 (13.8%)
	Other†	29 (22.3%)
Status	Surgeon trainee	25 (19%)
	Consultant	106 (81%)

†“Other”: Cardiothoracic (4), Neurosurgery (1), Vascular (5), Paediatric (3), Plastic and Reconstructive (9), Urology (7).

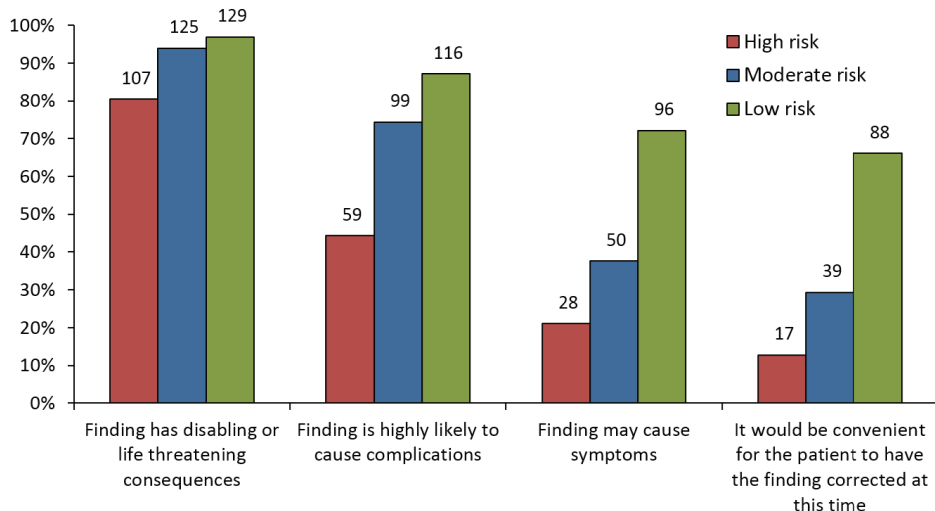
that they would deal with it at that time compared with 38% who would proceed to treat the finding when the additional risk was high. In contrast, fewer surgeons (6%) would choose to proceed if treatment of the IF would be for the convenience of the patient and the surgical risk was moderate, although more (31%) would proceed when this risk was low. The presence of consent for the treatment of an IF dramatically increased the proportion that would proceed regardless of the IF’s severity and additional operative risk ( $p<0.001$ ) (Figure 1B). Of all the decisions made by consultants and trainees, 499/1,596 (31.3%) were in favour of proceeding with the surgery when consent to do so was absent compared to 956/1,596 (60.7%) when consent was present ( $p<0.01$ ).

**Figure 1:** Proportion of decisions in favour of proceeding with the additional procedure according to the levels of lesion severity and additional surgical risk (A) in the absence of consent and (B) with consent to deal with IFs ( $p<0.001$ ). Surgeons  $n=133$ .

**A.**



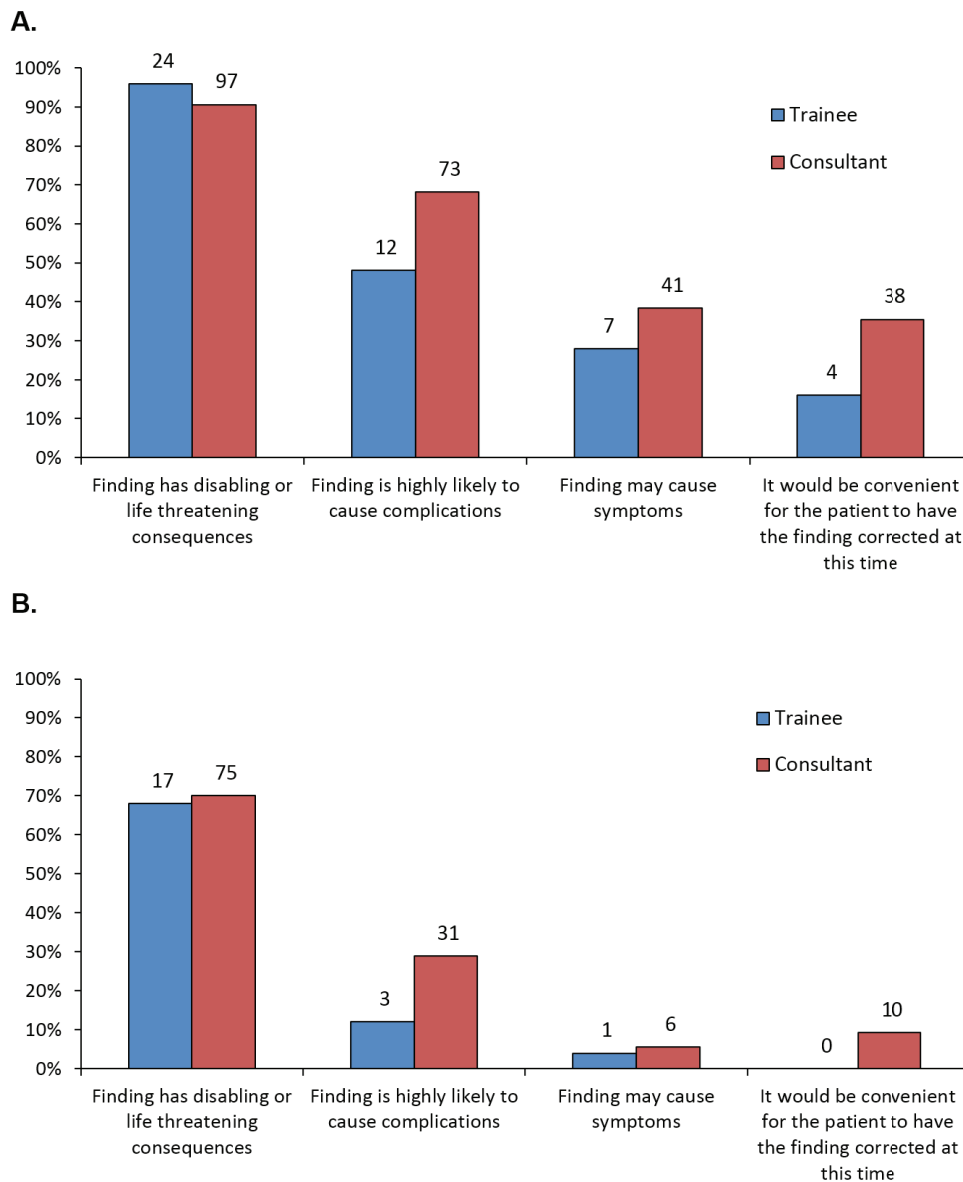
**B.**



When the decision making of consultant surgeons was compared with that of surgical trainees, the proportion of consultants' responses (47%, 152/321) to proceed with the treatment of an IF was significantly greater than that of the trainees (31%, 23/75  $p<0.01$ ) when the IF was non-life threatening, where the additional procedure risk was low, and there was no consent to proceed. This favouring of proceeding was also evident when the operative risk was moderate, 15% (47/321) of consultants vs 5% of trainees (4/75  $p=0.03$ , Figure 2), and when the treatment of the IF was primarily

for patients' convenience despite the absence of consent ( $p=0.02$ ). When consent was present, similar differences were seen with the exception that when the IF was of life-threatening severity or when the procedural risk was moderate-high, decision making by trainees and surgeons was similar. Among the surgeons, regardless of age or experience, responses were similar except for an IF of lesser significance, where older consultants were more prepared to deal with them compared with younger consultants (44%, 66/150 vs 33%, 50/153, respectively;  $p=0.01$ , Table 2).

**Figure 2:** Younger and older consultant surgeons and IF: comparison of decisions to proceed according to lesion severity when additional surgical risk was (A) low or (B) moderate and consent to proceed was absent. Consultants  $n=107$ ; Trainees  $n=25$ .



**Table 2:** Younger and older consultant surgeons and IF: comparison of decisions to proceed according to lesion severity and additional surgical risk when consent present.

	Low risk		Moderate risk		High risk	
	Younger*	Older*	Younger	Older	Younger	Older
Finding has disabling or life-threatening consequences	50 (98%)	48 (96%)	50 (98%)	45 (90%)	43 (84%)	37 (74%)
Finding is highly likely to cause complications	47 (92%)	42 (84%)	41 (80%)	33 (66%)	24 (47%)	23 (46%)
Finding may cause symptoms	40 (78%)	35 (70%)	18 (35%)	23 (46%)	9 (18%)	13 (26%)
It would be convenient for the patient to have the finding corrected at this time	32 (63%)	37 (74%)	13 (25%)	20 (40%)	5 (10%)	9 (18%)

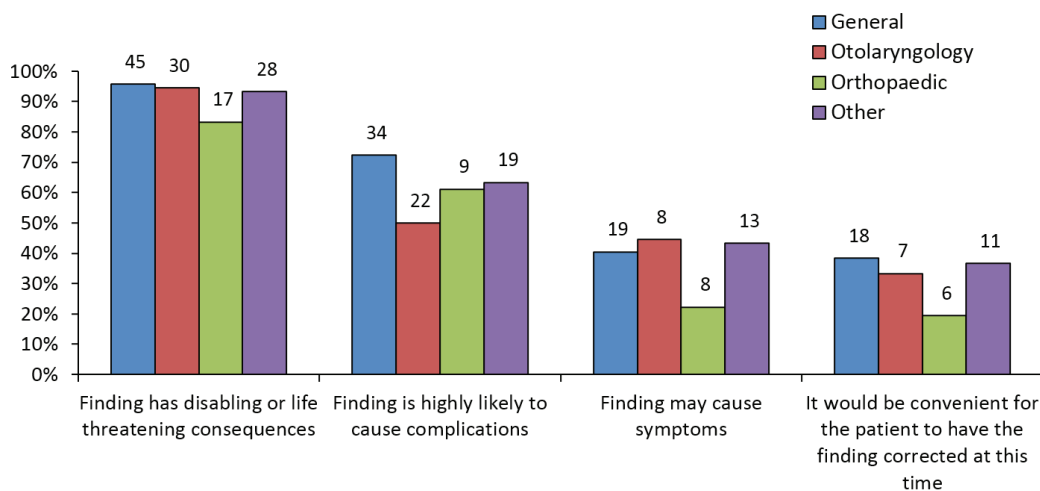
\*Younger surgeons n=51 (32–49 years, experience 1–15 years); Older surgeons n=50 (>50 years, experience >16 years).

Gender comparisons revealed that 83% (364/400) of decisions made by males were in favour of proceeding compared to 73% (159/200) of decisions made by females when the additional operative risk was low with consent to do so ( $p=0.04$ ). Males were more likely to proceed with the additional procedure (72%, 159/220 of decisions) compared to females (57%, 25/44 of decisions) ( $p=0.04$ ) when treatment was either for the patient’s convenience or the avoidance of possible future symptoms.

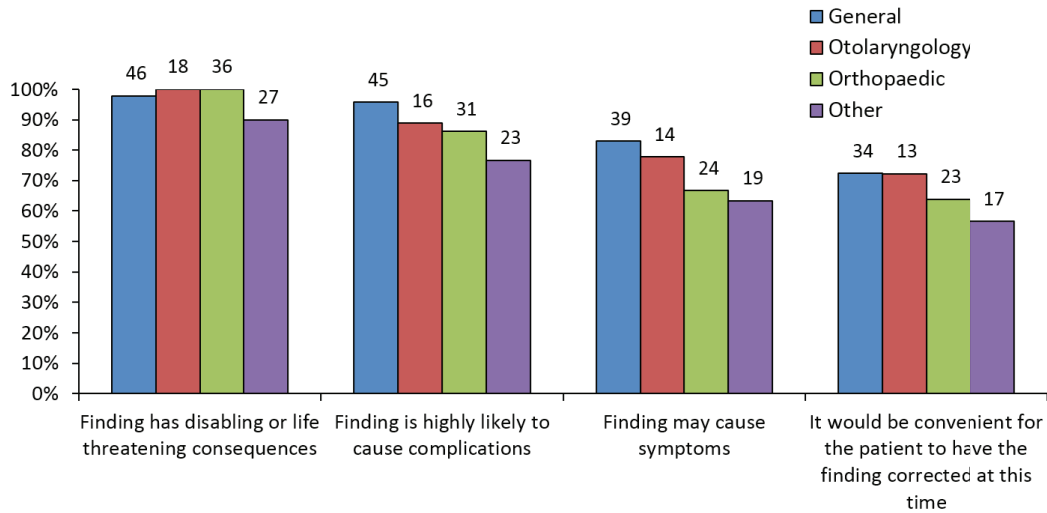
General surgeons and trainees were the most likely of all the specialties to treat an IF, with 562/1,128 decisions (50%) favouring treatment. Orthopaedic surgeons and trainees were the least likely to treat an IF overall, with 372/864 decisions (43%) favouring treatment ( $p=0.01$ ) (Figure 3A). Where consent was present, the general surgeons remained most likely to treat an IF, 164/188 (87%) compared to the ‘other’ surgeons with 86/120 (72%) ( $p=0.01$ ) (Figure 3B).

**Figure 3:** The decisions to proceed with surgery for an IF by surgeons from different specialties according to level of lesion severity when the additional risk of such surgery was low and consent to proceed was (A) absent or (B) present. General surgeons  $n=47$ ; Otolaryngology surgeons  $n=18$ ; Orthopaedic surgeons  $n=36$ ; Other surgeons  $n=30$ .

**A.**



B.

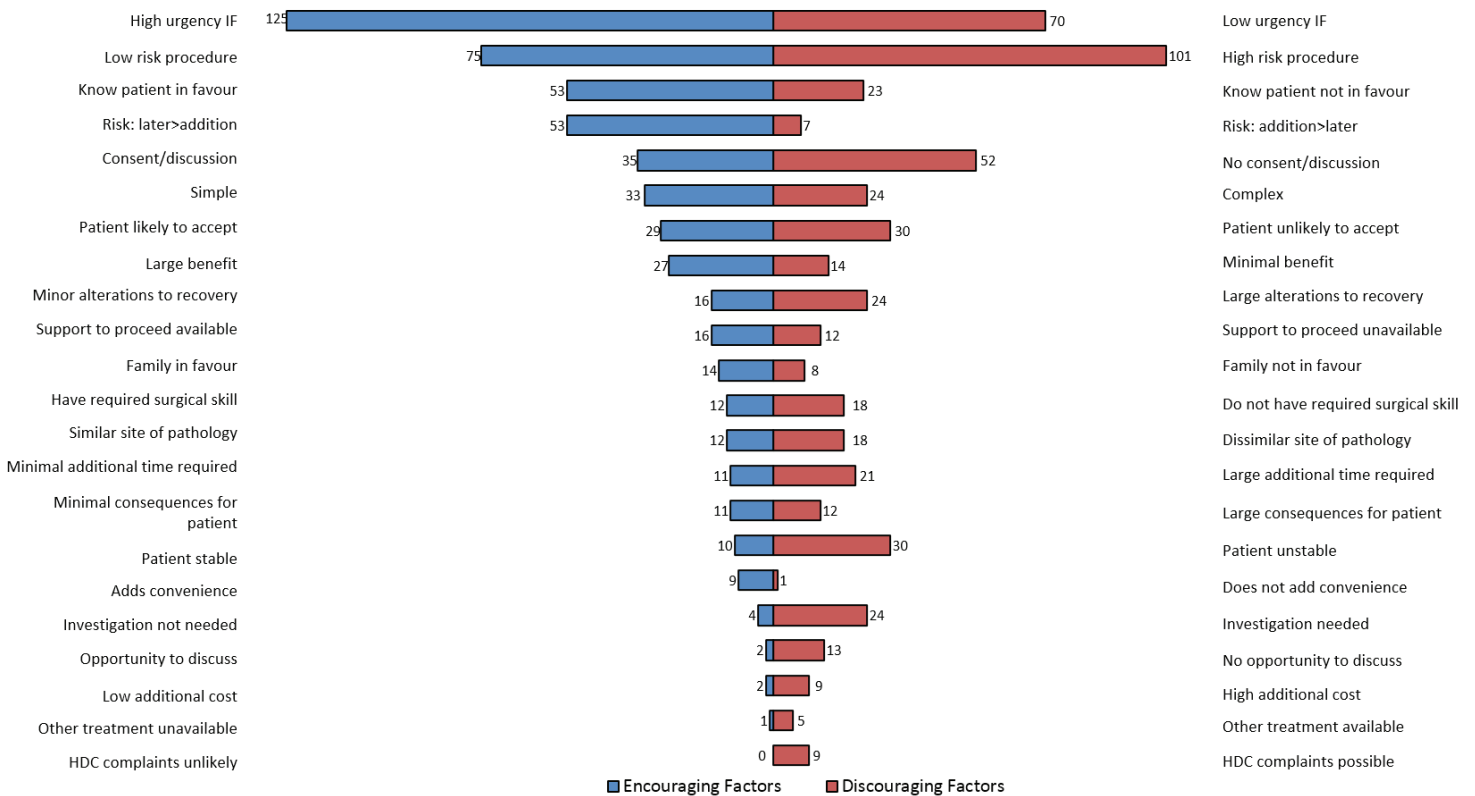


Qualitative comments regarding factors influencing the decision to proceed

Surgeons were asked to identify factors that would influence a decision to perform an additional procedure for an IF. There were a total of 147 statements containing encouraging factors and 145 containing discouraging factors. The relative theme

frequencies are shown in Figure 4. The most dominant factors were: the level of urgency required for treatment, the risk of the additional procedure, the relative risk postponing treatment, the prior knowledge of the patient's wishes and the presence of prior discussion which constituted informed consent. Fear of legal or medical enquiry was an infrequent consideration.

Figure 4: Categories generated from the free-text comments of responders that would encourage or discourage a decision to proceed with an additional procedure generated from 147 statements containing encouraging factors and 145 containing discouraging factors.



### Consent for dealing with an IF

Surgeons were asked whether the consent forms used within their institutions included a section seeking consent for the treatment of unexpected findings at surgery. Approximately half of those working in public hospitals (46.8%, 58/124) believed that there was no such clause present; approximately a third (34.7%, 43/124) believed that such a clause was included, and the remainder were unsure. The situation was similar for private hospitals and did not differ according to the respondents' age, gender, level of experience or sector of the health system.

There were, however, differences in the relative awareness of different specialties. Otolaryngologists were least unsure (16.1%, 5/31) about whether there was a statement to obtain consent for additional procedures to deal with an IF, while orthopaedic surgeons were most unsure (27.1%, 16/59). However, orthopaedic and 'other' surgeons were more confident that their institutions did have such a statement (53.5% and 53.7%, respectively) than otolaryngologists and general surgeons (23.1% and 28.8%, respectively;  $p=0.025$ ).

The majority of surgeons, regardless of specialty, were supportive of the decision to include the clause for IFs (86%, 111/129). Thirty of these added further comments. Eight suggested that such clauses should provide clarification of the circumstances in which this should apply, six emphasised that such clauses would be no substitute for robust discussion about the possibility, while five pointed out that despite this consent, there may be times when the surgeon must be free to make the decision to treat or not treat an IF.

The remainder of surgeons opposed the inclusion of clauses to provide general consent for the treatment of IFs. For eight, such a clause would introduce additional complexity into discussions that are already content-rich, and at a time when a patient's capacity to receive information may be reduced. Four commented that IFs occur too infrequently for such a clause to be justifiable, and it would be more appropriate to add extra discussion where relevant or where there was a great deal of diagnostic uncertainty associated with the original procedure.

### IFs encountered within different surgical disciplines

Surgeons were asked to offer examples of an IF from within their specialty area. Altogether, 58 different types of IF were distinguishable from the 169 examples recorded. These included all specialties, with a wider diversity in the larger surgical specialties. The most common examples were intra-abdominal findings (41.4%) and incidental malignancies (30.2%). The most frequently mentioned specific examples related to the appendix, Meckle's diverticulum (13.6%) and gallstones (8%). Incidental abnormality of the ovary (1.5%) was mentioned surprisingly infrequently. No examples of immediate urgency were given. General surgeons provided the greatest number of examples per surgeon (1.71/surgeon). This suggests that IFs may be a more frequent part of the general surgeon's experience.

## Discussion

This study shows that there is considerable variation in the current practice of surgeons and surgical trainees with regard to the treatment of IFs. A surgeon's decision-making varies with clinical circumstance, gender, level of surgical experience, type of surgical practice and the presence or absence of patient consent.

From a legal perspective, any surgical intervention that is performed competently with a patient's informed consent or alternatively when it is necessary to save the patient's life or to prevent serious harm to health in the absence of consent is consistent with expected ethical, professional and legal standards.<sup>9</sup> Unsurprisingly, participants were more willing to act in these situations. Surgeons are also more inclined to treat IFs when the additional procedure is of lower risk to the patient and broad consent for treatment is present.

It is, however, evident that numbers of surgeons and trainees are prepared to proceed with treatment when the lesion does not require urgent treatment or the risk associated with the additional procedure is significant, even in the absence of specific consent. This is an important finding, and when asked what influenced these choices they emphasised equally what



they consider to be in the best medical interests of the patient and the need to determine patient choice (Figure 4). Such actions, while possibly welcomed by the patient, may not meet legal standards of informed consent; and may, if contested by the patient, result in legal proceedings.

Most surgeons agreed that under certain conditions, when risks are modest and benefits are significant, proceeding immediately is acceptable. However, some surgeons are a little more likely to proceed with treatment of an IF and others less so. Of concern are those few surgeons who would proceed without specific consent, when the risk of doing so is significant and the IF is of low-impact (eg, the treatment is a matter of patient convenience rather than necessity). At the other end, there are a few who would be less likely to proceed with treatment even when the finding is of immediate serious clinical significance and the added risk only modest. While it is plausible that such decisions may be appropriate in rare circumstances, as a general approach they would raise questions about clinical reasoning.

Some variation in surgical decision making should not be unexpected. Some differences may be attributable to age, level of training and experience; others may arise because of changes within the socio-cultural milieu. Only a few decades ago, a doctor's decision making was predominantly paternalistic. Today, there is greater emphasis given to patient autonomy and participation in decision making.<sup>10</sup> Gender differences in clinical decision making are well recognised with males described to be less apprehensive, worrying less, having greater confidence and more likely to take risks.<sup>11</sup> This is consistent with the results of our study where a larger proportion of males consistently favoured treating the IF.

Differences in decision making by surgeons in different specialties, while possibly related to the personal characteristics of the surgeons in a specialty, is likely a reflection of the nature of the surgery, the type and frequency of IFs encountered, and their associated and unique clinical and ethical challenges. General surgeons experience a greater diversity and frequency of IF, which are often potentially more life threatening.

There are other reasons why surgeons might vary in their responses to IF. Although equally guided by the ethical values of beneficence, non-maleficence and respect for autonomy, weighing these values in situations where they conflict can be difficult. Surgeons will differ in their views and the trade-offs they are willing to make. This will translate into differences in practice.

How acceptable is this variation in the practice of surgeons? From an orthodox legal perspective, undertaking non-emergency surgery without consent constitutes negligence and/or battery.<sup>3</sup> A strict interpretation of the law would require IFs that do not pose an immediate threat to life or health be left until express consent is obtained for surgery at a later date. While legally sound, it is not consistent with the good common practice by surgeons and would likely lead to outcomes that would displease many patients. However, individual patient preference may vary widely depending on the nature and implications of a particular surgical procedure. Assumptions about these are hazardous and surgeons should exercise extreme caution if a procedure will have implications for a patient's way of life, reproductive capacity or other functions and lifestyle.<sup>3,12</sup>

This research suggests an apparent disjunction between a strict interpretation of the law and common practice by surgeons and what patients would want to occur. It is a situation that needs some careful consideration and resolution. Ensuring a discussion around the possibility of an IF prior to surgery as part of informed consent would be a step forward. Our review, both nationally and internationally of examples of consent forms used by both public and private providers confirmed the diversity of approaches. Some consent documents take a very generic approach and make the assumption that IF will be raised by the surgeon if it is considered relevant. Some are so specific as to allow no discretion. In this study surgeons were often unaware whether IF were included within the consent forms they used. Despite this there was a clear preference by surgeons to have in place a consent process which incorporates discussion with the patient about the possibility of an IF prior to surgery. This step

dramatically influenced the management of IF and caused a shift towards benefiting the patient by more often providing immediate treatment. We endorse including such a clause in the consent process provided that this does not give inappropriate licence to treat but that it will prompt a meaningful *discussion* and comprehension of the patient's preferences. It is important enough even at the risk of adding to an already content-heavy process.

A limitation of this study is that surgeon participants were constrained to the scenarios given and were unable to incorporate all of the subtleties which may influence decision-making in real life. The expectation of a simple binary (yes/no) decision was additionally constraining and uncomfortable for some. However, we consider this is reflective of the reality in

the operating room, where a decision to either proceed (yes) or not (no) is required within a short timeframe whereas a "maybe" or a "let's go away and think about it" does not apply.

Overall, we have demonstrated that surgeons' responses to an IF at the time of a surgical procedure are generally consistent. Yet these responses not infrequently appear to lie outside the strict interpretation of the law. There is a need to reconcile these perspectives and reduce the ambiguity that exists. There are important ethical and legal factors that must be considered in this context.<sup>3,12</sup> Including a clause relating to IF within a consent form will benefit surgeons and patients. Empirical research into the attitudes and preferences of patients and the general public regarding IF would help.

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#### Competing interests:

Nil.

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# Incidental findings during a surgical procedure—patient and public perspectives

André van Rij, Jamie Thomas, Rachel McKenzie, Jasper Diong, Frank Frizelle, Jeanne Snelling, Lynley Anderson

## ABSTRACT

**AIM:** During a surgical procedure, incidental findings (IF) may be found and often the immediate treatment is in the patient's best interest. Due to the nature of IFs, specific patient consent cannot be obtained under such circumstances. The dilemma is whether the surgeon should proceed or delay until consent is obtained, as there are significant ethical and legal implications. Following an earlier study of surgeons' preferences for IF management, this report investigates patient and public preferences.

**METHOD:** A questionnaire presented hypothetical scenarios involving IFs and samples of patients and public respondents reported their preference to proceed with treatment or have their surgeon wait to obtain consent. Opinion was sought regarding factors influencing their decisions and if general surgical consent procedures should cover IFs.

**RESULTS:** A sample of 331 respondents from the general public and 368 elective surgery patients were surveyed. Results showed an overall preference to proceed with treatment in 75.1% of the hypothetical scenarios, which increased with IF severity and decreased with procedural risk. Thematic analysis of open-ended questions revealed a number of factors influencing preferences with avoidance of further surgery being most common. Results showed most respondents preferred for information provided in general consent forms though not all were comfortable about this.

**CONCLUSION:** Patient and public preferences to proceed with treatment in hypothetical scenarios were generally consistent with surgeons' reported practice when faced with IFs. The data suggest that an IF clause in the consenting process could help surgeons make clinical decisions best aligned with individual patients' preferences.

In the course of performing an operation, a surgeon will occasionally discover an abnormality that is completely unrelated to the procedure for which patient consent was obtained.<sup>1,2</sup> These 'incidental findings' (IFs) vary in their nature, severity and consequences. While treating an IF that poses a significant immediate threat to life or limb is justified, indeed required, treating an IF without consulting the patient in any other circumstances is considered contrary to autonomy. Yet in many instances of (non-life threatening) IF, there are potential clinical benefits in dealing with the IF immediately, including avoiding the need for a further operation at a later date. However, performing an additional surgical procedure that is beyond the scope of informed consent could

be considered unlawful.<sup>6-8,9-10</sup> Despite this, the alternative of leaving the IF to discuss its management with the patient may constitute a lost opportunity to benefit the patient. What should the surgeon do in these circumstances? What would the patient want? What is the right balance between seeking to benefit the patient and patient autonomy and legal requirements?<sup>3-5</sup>

In a recent survey of surgeons and surgeons-in-training we found a consensus within the surgical community regarding when treatment of IF is, and is not, believed to be appropriate.<sup>9,10</sup> Significantly, and unsurprisingly, the surgeons preference to treat or wait varies according to the seriousness of the IF, the urgency of that treatment and

the risks associated with performing an additional procedure. However, extending an operation without consent, except in emergency situations, may not comply with current legal and ethical standards. When this happens it can understandably cause significant disquiet for surgeons. Patients may similarly have concerns. Crucially, the viewpoint of patients on the issue of IF has not been systematically investigated. In order to provide some of that perspective, we surveyed samples of both New Zealand healthcare service users and those from the general public, comparing their perspectives regarding the treatment of IFs which may arise during a planned surgery and what they value in this context and what they would expect of their surgeon.

## Methods

### Study sample

Two samples were included in this study. The general public sample was recruited to identify differences between the opinion of patients and public in this healthcare issue. This was done using advertisements displayed in public places such as community notice boards, newspapers and on social media directed at citizens of Christchurch and Dunedin. The general public group were competent adults and potential healthcare users. They were recruited irrespective of demography and previous surgical history. General public participants completed the questionnaire online using a registered product from Survey Monkey. The patient sample was recruited from pre-admission clinics for elective surgery at Dunedin Hospital and Christchurch Hospital. All patients were approached with information about the study by a medical student or clinical nursing staff. The surgical disciplines included general surgery, urology, plastics and reconstructive, otolaryngology, cardiothoracic and vascular surgery. Those involved either completed the questionnaire while at the clinic or were given a form to return at a later date. The study was approved by the Otago University Ethics Committee (Health).

### Questionnaire design

A questionnaire constructed with a mixed quantitative and qualitative methodology was administered to participants. The patients being pre-admitted for surgery were asked to consider the questions as if the situations posed were to arise during their planned surgery, whereas the public

participants were asked to consider the questions as if the situations posed were to arise during an imagined surgery. Participants' preferences were sought regarding the treatment of such a finding without prior discussion versus leaving it to treat at a later time to allow for patient consultation. The survey explored circumstances that might influence the participant's preferences and included several key factors such as the level of risk to the participant's health and the clinical consequence(s) of waiting, versus treating the IF immediately. These scenarios were aligned to those previously presented in our study of surgeons' responses. Following each scenario, participants were asked whether:

I would rather:

- Have treatment ***during the same operation***
- Wait*** for further discussion afterwards

The scenarios were presented in order as shown in Table 1. Additionally, participants were asked open-ended questions exploring how they would prefer this topic to be approached pre-operatively by their surgeon. Relevant demographic information was also collected: age, gender, ethnicity, education, occupational status and previous surgical history—including that of any previous incidental findings. For patients awaiting surgery only, information regarding their planned procedure, anxiety and reason(s) for the procedure were also collected.

**Table 1:** Scenarios presented in the questionnaire. They will be referred to by scenario number in subsequent analyses.

Number	Scenario description
0	General response to IF; no factors specified
1	IF serious; prompt surgery required
2	IF not serious; surgery may be required
3	IF procedure safe; future surgery avoided
4	IF not serious; future surgery avoided
5	IF serious; surgery required; IF procedure may have long-term impact
6	IF serious; surgery required; IF procedure may have serious long-term consequences

## Statistical analysis

Univariate analyses were initially undertaken to compare various demographic groups and their preferences for treatment within the circumstances outlined using chi-square and t test. Thematic analysis was also undertaken for the qualitative data. This involved a combination of both template analysis and qualitative content analysis. A template of categories reflecting themes was generated inductively from the respondents' text and the template was modified as themes emerged throughout the iterative categorisation process until a final template containing all themes represented within the dataset was produced. The data were then coded using this template and the categories were analysed.

All available predictor variables were explored by fixed effects stepwise regression. Population partition (either patient or public) and scenario number (0–6) were put into a logistic fixed effects model to estimate a mean for each level from the data. To model the correlations that exist within these data, including repeated-measures on the same individual grouped by choice framework, cross-classified multilevel mixed effects estimation was applied.<sup>11–14</sup> The questionnaire included six 'proceed or wait' questions and one reference question. Participants were grouped and designated as random effects to allow analysis of the covariance structure introduced by the grouping of the data. Age (as a continuous variable) as well as gender, education, history of surgery, employment and population partition have fixed main effects on these data. Of the subject-level demographics obtained in the questionnaire, all but ethnicity were significant and were included in the model. Introduction of a random slope at the subject-level served to explain over half of the residual variation (55.4%). The partition-level variable anxiety, measured only in the patient sample as they were about to undergo elective surgery, did not significantly improve the fit (not shown). However, fit was improved when the outcome was cross-classified to the participants within the questions in a multi-

level mixed model. The reference groups for the regression included male, no advanced education, no past history of surgery, general public and scenario 0 (overall; no factors considered). All analyses were performed using Stata/IC 13.0 for Mac (Stata Corporation, College Station, TX, USA).

## Results

### Sample characteristics

Data was collected from 368 patients undergoing elective surgery and 331 members of the public from the same regions. The analysis was not restricted to data from questionnaires with complete responses to all questions. A total of 31 respondents (9.4%) in the public sample and four respondents (1.2%) of the patient sample did not answer any demographic questions. Table 2 presents a summary of the characteristics of the participant groups. They were quite distinctive in that the public sample was younger (median: 31 years versus 65 years in the patient sample), had more males (56.8% versus 31.4%;  $p < 0.01$ ), fewer were retired (11.7% versus 48%;  $p < 0.01$ ), and more had university-level education (48% versus 14.7%;  $p < 0.01$ ). The Christchurch and Dunedin patient samples were compared and apart from a small, statistically significant difference in gender distribution with a greater proportion of male respondents in the Dunedin sample (58.4%) than the Christchurch sample (54.5%), there were no statistically significant differences between these two populations (not shown).

In addition to the baseline characteristics that may impact stated preferences to proceed or wait, there were 517 respondents with a past history of surgery (74%) of which 59 (11.4%, 15 patient, 44 public) indicated a past history of IFs (Table 2). Patients' level of anxiety regarding their upcoming procedure and public respondents' level of anxiety for a theoretical procedure were also measured on a 5-point Likert scale (Not anxious, a little, moderately, reasonably, extremely). Patients report less anxiety (median="a little anxious") than general public (median="moderately anxious").

**Table 2:** Sample characteristics. Demographics and p-values for the two-sample t-tests.

Characteristic		Public		Patients		P-values
		N	%	N	%	
Age	Median	31	-	65	-	-
	Range	16–82	-	19–94	-	-
	Inter-quartile range	22–56	-	55–73	-	-
	Unanswered	32	9.6%	10	2.7%	-
Gender	Male	104	31.4%	209	56.8%	p<0.01
	Female	193	58.3%	149	40.5%	
	Unanswered	34	10.3%	10	2.7%	
Ethnicity	NZ European	239	67.9%	329	87.0%	p<0.01
	Māori	10	2.8%	18	4.8%	
	Pacific Is.	6	1.7%	3	0.8%	
	Asian	16	4.5%	2	0.5%	
	Other	50	14.2%	17	4.5%	
	Unanswered	31	8.8%	9	2.4%	
Employment status	Paid employment (full or part time)	172	46.7%	151	39.3%	p<0.01
	Retired	43	11.7%	171	44.5%	
	Providing care for home and family	16	4.3%	8	2.1%	
	Not working due to ill-health	12	3.3%	29	7.6%	
	Not working for other reasons	4	1.1%	9	2.3%	
	Studying	90	24.5%	6	1.6%	
	Unanswered	31	8.4%	10	2.6%	
Highest education	None	4	1.2%	24	6.5%	p<0.01
	Secondary school	85	25.7%	190	51.6%	
	University	159	48.0%	54	14.7%	
	Other tertiary	39	11.8%	56	15.2%	
	Vocational training	5	1.5%	18	4.9%	
	Other	8	2.4%	10	2.7%	
	Unanswered	31	9.4%	15	4.3%	
History of surgery	Yes	189	57.1%	328	89.1%	p<0.01
	No	113	34.1%	30	8.2%	
	Unanswered	29	8.8%	10	2.7%	
	Total	331	-	368	-	

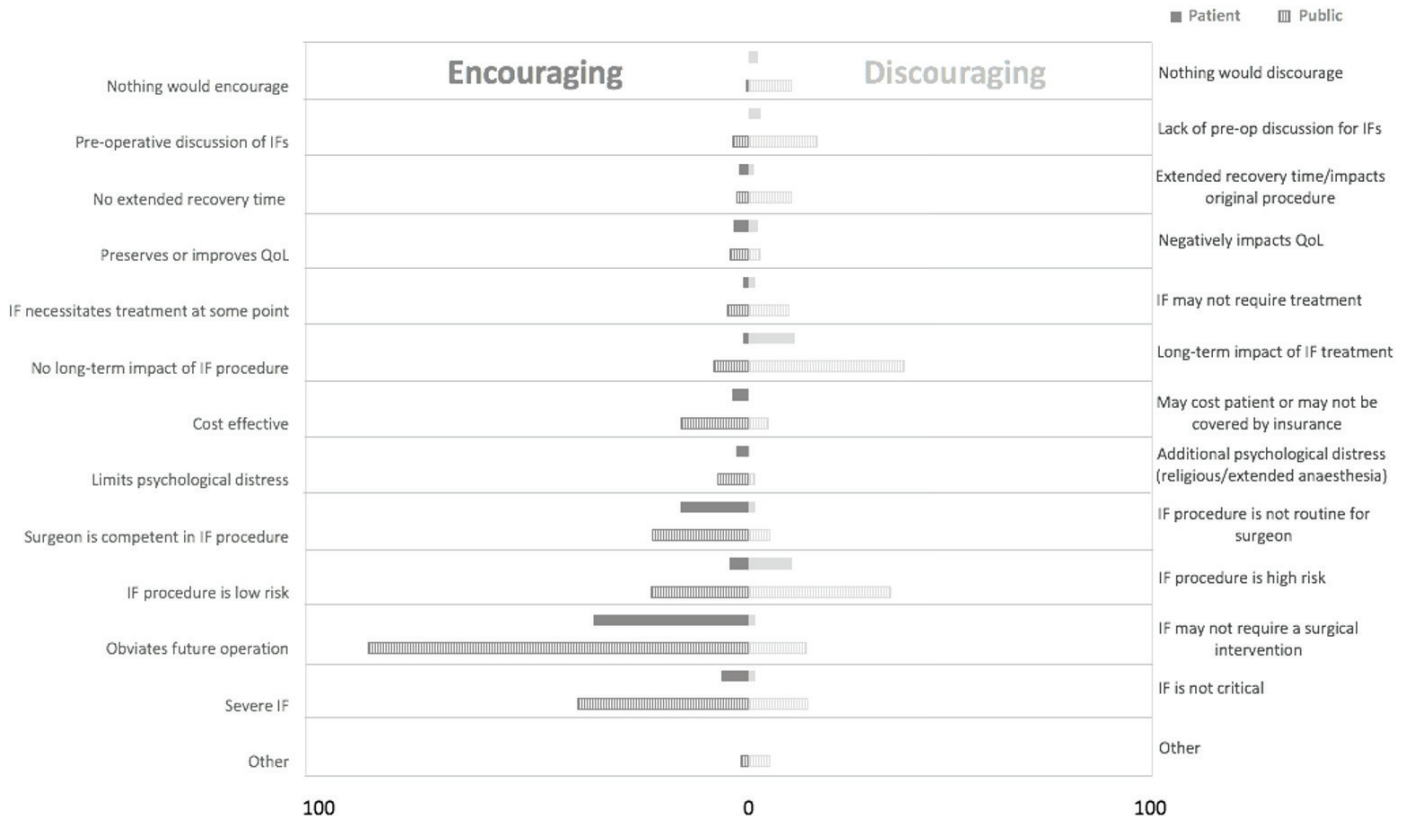
**Main findings**

Initially when unprompted by the scenarios exploring different contexts, 95% of the respondents preferred to have an IF treated without additional consultation. At this *scenario-naïve* point, respondents were also asked in an open-ended format to state the factors that would encourage or discourage their preference to proceed (Figure 1), it emerged that most stated patient and public preferences were similar to the factors subsequently tested in the scenarios: ie, severity of the IF, the risk associated with the IF procedure, long-term consequences of the IF procedure and the likelihood that the IF would eventually require surgery. Several other factors, including the surgeon’s competence, cost-effectiveness and the inclusion of an IF clause in pre-operative discussions were referred to by both the patient and public respondents, but were not explored in the scenarios presented in the questionnaire.

When respondents were subsequently asked to state their preference in the context of different scenarios, there was an overall preference to proceed in 75.1% (81% for patients, and 86.7% for the general public) in

all scenarios. However, the proportion that chose to proceed was scenario-dependent for both the general public and patient samples (Figure 2A). When comparing the proportions for each scenario, a statistically significant greater proportion of patients preferred to proceed with immediate treatment than those in the public sample, except in scenario 2 (IF serious; prompt surgery required) where they were similar. Secondary analyses to examine an age bias, an age matched subset of 316 subjects showed a similar effect except patients and public were more alike when the scenarios associated seriousness with the IF and its outcome (Figure 2B). In these scenarios, if the seriousness of the IF required prompt surgery, the predominant expectation was for the surgeon to proceed (93.1–95.9%). However in the scenario where there was less urgency, but greater risk of longer-term consequences, there was a greater preference to wait and not to proceed (55.4% patients; 80.4% public), especially if these consequences might be serious. In contrast, if the IF was not serious or the surgery was safe and further surgery could be avoided, a large majority (95.7% of the patients, 83.7% of public) preferred the surgeon to proceed.

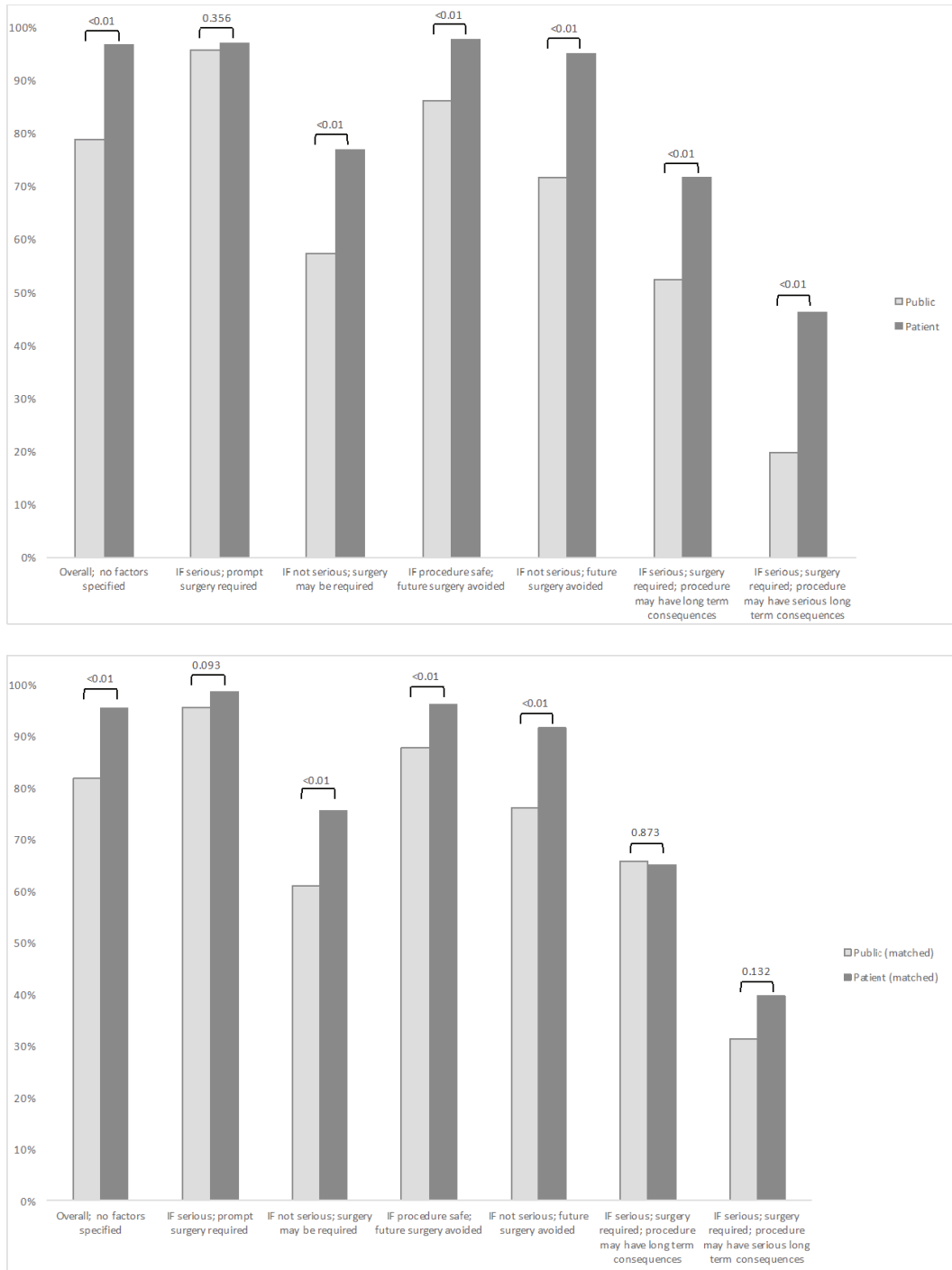
**Figure 1:** Responses to open-ended questions “what would encourage or discourage participants’ choice to proceed during a planned procedure with treatment of a concurrent IF?”.



The relative prevalence of each theme showing the encouraging factors (dark grey, diverging left and discouraging factors (light grey, diverging right) for the patient sample upper bar (solid fill) and the public sample in the lower bar (hash fill).



**Figure 2:** A comparison of the proportion of general public and patient respondents having a preference for the surgeon to proceed with treatment of an IF without prior patient consultation.



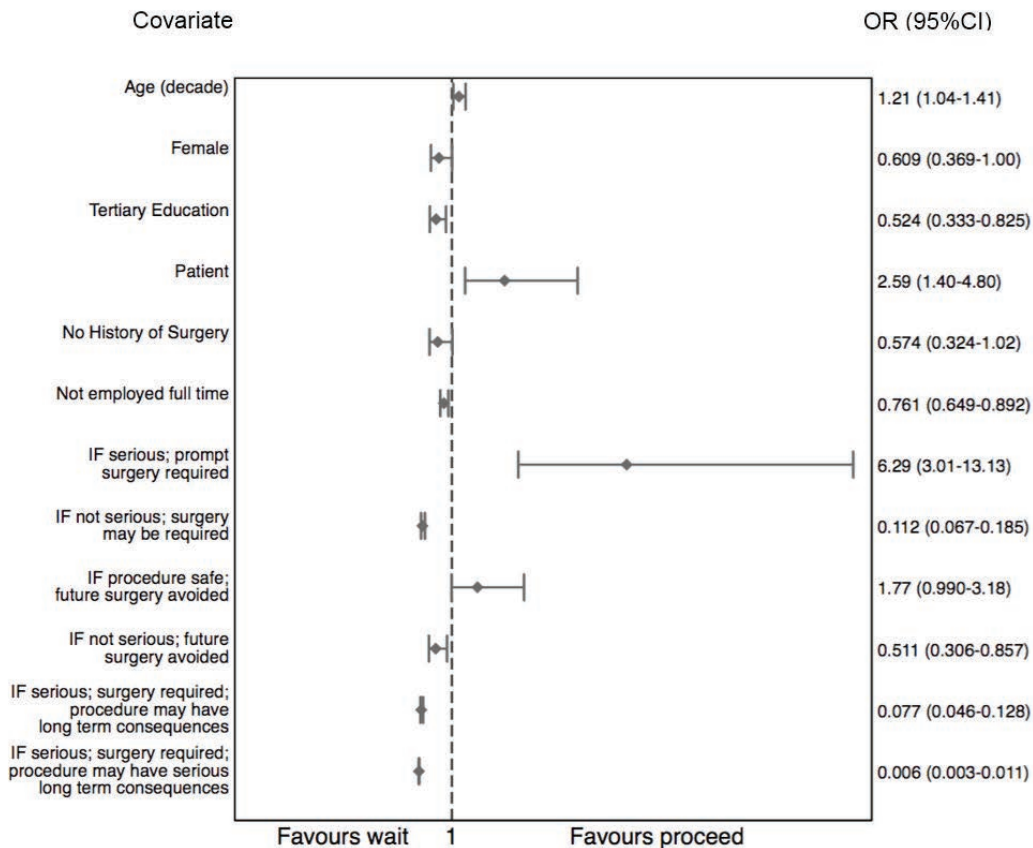
Results are shown for each of the scenarios in the questionnaire. The p-values are for t-tests of the two-tailed null-hypothesis. Panel A describes all respondents (N=699). Panel B is an identical analysis on a subsample of age-matched public and patient samples (N=316; 158 respondents in each sample partition).

Several scenario-independent factors were identified in addition to age and public/patient partition that may impact the preference to proceed or wait. These include gender, level of education, ethnicity, employment status, level of anxiety in patients and prior history of surgery. However; anxiety and ethnicity did not have a significant impact on the choice to proceed or wait. A past experience of an IF, as in 59 of 518 (11.4%) respondents with a past history of surgery, also did not appear to be associated with preference.

To better characterise the impact of these demographics on the outcome (proceed or wait), quantitative data were modelled as the choice to proceed with IF treatment introducing several fixed and random covariates. The final multilevel mixed effects model with the subject-level random effect was highly significant for these data ( $p < 0.0001$ ) compared to ordinary logistic

regression. Neither the addition of interaction terms nor extending the random effects improved the model. Sub-analyses were undertaken to identify the fixed effects of factors, such as IF severity, consequence of treatment, necessity of surgical treatment of IF and convenience. These factors varied across the seven scenarios presented in the questionnaire but the individual contributions of each factor were not resolvable (not shown). Figure 3 shows the fixed main effects of these data in the model and shows that younger members of the public are the most protective of their autonomy while older patients with a history of previous surgery are the least, especially in scenarios where the IF is serious. Figure 3 also shows the relative level of scenario-dependence of public and patient preferences for differing combinations of factors tested in each scenario (severity of IF, procedural risk, convenience, consequences of treatment, consequences of non-treatment.)

**Figure 3:** Forest plot showing the factors that influence the public and patient respondents' preference to proceed or wait.



The plot shows the fixed main effects (age, gender, education, sample partition (patient/public), history of surgery and scenario) of the model expressed as the odds ratio and 95% confidence intervals. The random effects are not shown but were statistically significant ( $p=0.0001$ ).

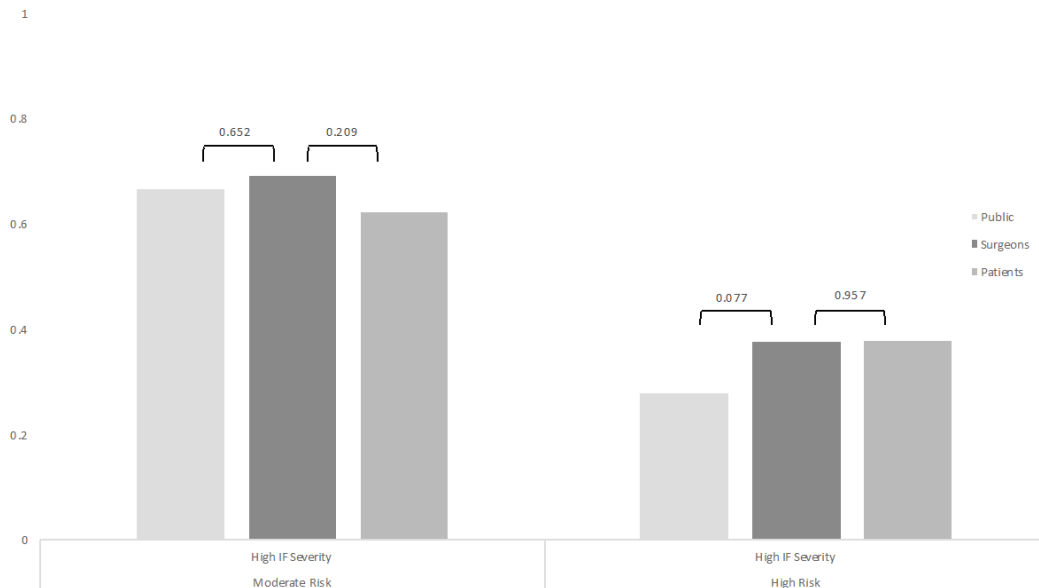
The majority of scenario-primed respondents (in contrast to the earlier scenario-naïve viewpoint) preferred to have the possibility of IFs discussed preoperatively, while a minority but not insignificant number 80/699 (11.4%) who preferred to be informed after surgery. Following on from this, the respondents' opinion of the appropriate IF-related content in pre-operative discussions was then explored in an open-ended format.

The main theme that emerged from this scenario-primed thematic analysis was the desire to be informed beforehand of common IFs and the associated procedures to treat them as well as a cursory discussion of their relative risks. Some respondents indicated a desire to be informed with greater details about risks, impact on quality of life, and outcome in terms of recovery and impact on the original procedure while others desired less information. Secondary themes included the surgeon's competence, cost-effectiveness, inclusion of an IF clause in pre-operative discussions, and the preference to be told nothing about IFs. When respondents offered their reason for wanting to be told nothing or as little as possible, they reported that the additional information on

IFs would lead to undue anxiety, information overload, or confusion. Overall, the public were more responsive in the open questions and had broader expectations of a preoperative process regarding IF.

This survey of patients and public, follows a previous survey of surgeons' preferences to proceed or wait when an IF is found given varying levels of procedural risk and IF severity. The same reticence was identified in surgeon respondents in circumstances where the IF was severe or there were long-term disability implications of IF treatment.<sup>15</sup> While the surgeons' questionnaire and the public/patient questionnaire were designed to be delivered to different groups, the results of both surveys illustrate similar trends across surgeon and public/patient respondents. The tandem questionnaires allow direct comparison of preferences in the cases of differing severity of IFs and risk of IF procedures. The results show that in addition to agreement between public and patient healthcare users, there was also strong agreement between the surgeons and healthcare users with no statistically significant difference between them (Figure 4).

**Figure 4:** The frequency that patient and public respondents chose to proceed with IF treatment compared to the frequency that surgeon respondents chose to proceed in scenarios that were similarly presented across the tandem surveys and which varied procedural risk (moderate or high risk) while holding IF severity constant (high severity).



## Discussion

This is the first study of New Zealand healthcare service users (patients and the general public) stated preferences regarding IFs. The findings illustrate that a high number of respondents generally prefer surgeons to immediately treat an IF when there has been no explicit prior consent for the unforeseen event, especially when the immediate risks of the IF are high and surgery is required. There is also a similar preference when the risk is low and the need for another surgery can be avoided. However, when the unwanted consequences of concurrent IF treatment could be severe or long-term, the contrary preference was expressed: not to treat immediately. Both patient and public samples expressed preferences to proceed based on the severity of the IF and risks of proceeding with treatment. These findings are important because it suggests that most surveyed New Zealand healthcare users prefer concurrent IF treatment when there is a favourable risk-benefit ratio. It is also consistent with the preference for some pre-operative discussion of IF.

This study also sought to obtain an understanding of the extent to which participants value their autonomy and what they would expect of their surgeon in the case of an IF. When it came to IFs, patients were willing to forgo a degree of autonomy when the perceived risk-benefit ratio was low, but communicated a preference to have the possibility of IF included in the surgical consent. Even so, considerable trust in the surgeon was implied in regard to recognising an IF and quantifying the relevant risks, as well as having some cognisance of what might be the patient's preference had a discussion been possible. A small proportion of respondents expressed the desire for reassurance that the surgeon was well trained and competent to deal with the IF.

Furthermore, in qualitative analyses, the themes that emerged from the surveyed New Zealand healthcare users were consistent with themes that emerged from the survey of New Zealand surgeons.<sup>15</sup> The surgeons stated similar values and very closely mirrored the patient and public wishes in their clinical management of IFs. As such, patient, public and surgeon

respondents in New Zealand have similar values and rationales in approaching the management of IFs.

Unfortunately, no studies were found to date regarding healthcare users' preferences of IF management in other locations or populations to offer further guidance. Much of the published literature on the topic of IFs and surgical consent (SC) focuses on prevalence of specific IFs,<sup>16-18</sup> complications of treating IFs,<sup>19</sup> delays in treatment, and pre-empting IFs through more thorough pre-surgical clinical assessments.<sup>20,21</sup> There are also numbers of case reports of non-consensual IF treatment leading to legal action.<sup>22-26</sup> The implications of IF in other areas of healthcare including radiology, oncology and genetic counselling have been explored, but have limited relevance to the immediacy of the surgical context and the unconscious patient.<sup>26-28</sup> Importantly, this study suggests that in general, patient, public and surgeon views are similar regarding the factors relevant to IF and IF decision-making. Since the findings in this study are among the first reporting public and patient preferences regarding this ethically, legally and clinically important issue, the results suggest several ways forward. Firstly, these findings provide an indication of what factors influence a patient's preferences in the decision-making and disclosure processes. This study shows that preferences are influenced by the immediate clinical surgical context of IF severity and procedural risk. Clearly, if there is immediate risk to life or limb, the preference is for immediate treatment. If there is a high likelihood of an adverse outcome associated with the IF or long-term adverse implications from the treatment, patients prefer to participate directly with the surgeon to make the decision; a surgeon who proceeds in such circumstances without consent risks complaint and/or sanctions. However, it also suggests that if the immediate treatment of IF is low risk and another operation is avoided, the majority of patients are more likely to accept concurrent treatment. Generally, in these circumstances, people are happy for their surgeon to take an action by which they would avoid the burden of returning for further surgery. This was evident in the qualitative analysis with reference to avoidance of the added risks

and inconvenience of further surgery as well as added costs or waiting times. This is a reflection also of the knowledge of the health system constraints, limitations on access and long waits that exist for some surgical procedures.

Demographic characteristics of the respondents may also influence an individual's preference to proceed or wait. For example, increased age is associated with a greater preference for a surgeon to proceed, while tertiary education is associated with a reduced preference to proceed. For the surgeon, these findings offer some guidance when confronted with an IF as to the likelihood of a specific patient's preference. However, there is a self-evident note of caution that a patient's demographic does not mean that they will definitely support the expected preference for further immediate IF surgical intervention or not and therefore the surgeon should not rely solely on this. It is unwise to make assumptions based on some demographic characteristic of the patient. While most times the patient will agree with a surgeon's actions, they also may not.

Secondly, the study confirms that the majority of patients and public expect IF to be included in surgical consent. This should be done carefully to avoid overload in the surgical consent process and unnecessary anxiety. This was also the preferred approach of New Zealand surgeons surveyed. In the survey of surgeons, when such consent was obtained, the surgeon's decisions regarding IF were significantly more informed and lead to more interventions for patient benefit.<sup>15</sup> However, the level of detail regarding IF expected by the respondents varied widely from the very detailed and extensive to the much more cursory. Numerous studies of surgical consent have reported that being informed of all risks, both common and rare, were among the top priorities for patients and ranked much higher than being informed of legal rights.<sup>29</sup> Some studies suggest that patients want explicit information about their operation and post-operation recovery as well as direct

involvement in all decision-making along the way<sup>30,31</sup> regardless of their ability to comprehend the complexities and despite reported anxiety. Care should be taken not to make pre-operative discussions too lengthy, dense and difficult for the patient to digest.<sup>32-34</sup> Surgeons are often reported to prefer including less information to make the discussions more comprehensible, but a reasonable middle ground should be achievable.<sup>33-35</sup> Some limitations to this study have been acknowledged and taken into account above. Given the recruitment strategy, there are several characteristic differences between the patient and general public samples. For the general public, there was a larger social media component while the patient sample recruitment was based on contact in the pre-admission clinics. The age disparity between the two populations offers the most likely explanation for corresponding differences in employment status (11.7% retired in the public sample; 44.5% in the patient sample) and education level (48.0% university educated in the public sample and 14.7% in the patient sample). The gender distribution was significantly different with more male respondents from the patient sample (56.8%) than from the general public sample (31.4%). However, the sub-analyses show these are accounted for. This sampling difference has usefully pointed to some differences between the opinion of patients and sampled public in issues of healthcare. In particular, a patient awaiting surgery appears to be more open to additional surgery for an IF, more accepting of greater risk, and more trusting of their surgeon.

This study provides evidence that there is general consistency of opinion among patients and public with that of the surgical community regarding concurrent IF treatments. It confirms that treatment of IF need not just be based on the threat to life and that many times patients are willing to forgo autonomy for the sake of other benefits. The safest way to ensure that the values of the surgeon match with those of the patient with regard to IFs is to include a discussion about this possibility prior to surgery.

**Competing interests:**

Nil.

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# Treaty of Waitangi in New Zealand public health strategies and plans 2006–2016

Heather Came, Rhonda Cornes, Tim McCreanor

## ABSTRACT

**AIM:** This study examines how public health policy in New Zealand has represented the Treaty of Waitangi (the English version) and te Tiriti o Waitangi (the Māori text) between 2006 to 2016.

**METHOD:** A dataset of 49 public health strategies and plans, published between 2006 and 2016, were secured from the New Zealand Ministry of Health database. A thematic analysis using Braun and Clarke's process was undertaken and then the findings were reviewed against the Māori text of te Tiriti.

**RESULTS:** Twelve documents referred to either te Tiriti or the Treaty. Crown discourses were characterised as i) rhetorical, ii aspirational, iii) practical and/or iv) substantive. We present a matrix of Crown health strategy and plan discourses and analyse their relationship to te Tiriti.

**DISCUSSION:** Public health strategies and plans rarely address Treaty of Waitangi or te Tiriti o Waitangi obligations. This silence is inconsistent with legislative requirements to engage with the Treaty and health equity and is likely to inform health-related Waitangi Tribunal claims [WAI 2575]. Further work needs to be done to strengthen alignment of health policy to fulfil Crown obligations under te Tiriti.

The Tiriti o Waitangi (Māori text) and the Treaty of Waitangi (English version) and the understandings that surround them constitute and codify the relationship between Māori and the Crown. Under international law the Māori text of te Tiriti, the text which reaffirms Māori sovereignty—absolute territorial authority—is the sole legitimate version of this founding document of the colonial state.<sup>1</sup> In 2014 the Waitangi Tribunal<sup>2</sup> ruled that Ngāpuhi (and by extension other Māori) did not cede sovereignty by signing te Tiriti, sparking renewed debate about its place in policy. This has been heightened in the health sector with preparations for WAI 2575, the health-related Waitangi Tribunal claims.

The relevance of te Tiriti to health is well-established, particularly in the work of Māori scholars, including Durie,<sup>3</sup> Ramsden,<sup>4</sup> Reid and Robson.<sup>5</sup> This relationship is also established in law through the New Zealand Public Health and Disability Act (NZPHDA)

2000, which requires the health sector to work towards eliminating entrenched health inequities between Māori and other New Zealanders. It expects the sector to engage with Treaty principles of partnership, protection and participation that were developed by the Royal Commission on Social Policy.<sup>6</sup> As public health researchers we are proud that the discipline has led this progressive approach, and eager to see the realisation of its potential and real impact on inequalities.

In this paper we assay the development of policy in public health as an indicator of how the sector has attempted to build from the NZPHDA. We are aware that the community engagement that is vital to public health effectiveness means that it will be among the most sensitive disciplines in the domain of health; few other areas will be more active and progressive in working with te Tiriti.



However, the NZPHDA (and indeed health policy during the period of this study) omits any mention of te Tiriti, referring instead to the Treaty principles and the English text. Nevertheless, Boulton and Simonsen<sup>7</sup> have argued that the inclusion of Treaty clauses in NZPHDA was a significant step towards its incorporation into the administration of the health sector.

Conservative elements of New Zealand society have vigorously opposed legislative protections of Treaty rights. In the health arena, such pressure resulted in senior management within the Ministry of Health, instructing staff to remove all references to the Treaty from health policy. Such incidents confirm that policy remains a contested site of colonial power, and that decolonisation as represented by te Tiriti promises, and the guarantee of Māori sovereignty, remain distant goals. Meanwhile even achievable aims such as the elimination of health disparities between Māori and non-Māori are underserved by this failure of acknowledgement. In this paper, we review how public health policy (from 2006–2016) representations and particularly their failure to engage with te Tiriti and/or the Treaty, have become a roadblock in progress towards health equity.

## Method

Public health policies from 2006 to 2016 were collected from the Ministry of Health's website under publications: strategies and plans. During this time period there were 121 strategies and plans uploaded onto the Ministry's website. In this selection we were guided by Winslow's<sup>9</sup> definition of public health as: "...the science and art of preventing disease, prolonging life and promoting health through the organised efforts of and informed choices of society, organisations, public and private, communities and individuals".

All generic health policy with a focus on treatment, data management, medicines, collation of submissions, progress reports, geographically specific and case studies of organisations were excluded. Workforce planning documents were omitted as they did not cover public health staff. We included strategy and planning documents that were future focused and had a prevention rather than clinical focus. The

selected documents targeted keeping the New Zealand population or a particular ethnic group healthy. The selected documents were then assessed with reference to their level of engagement with te Tiriti and/or the Treaty.

Documents that referred to the Treaty were analysed using Braun and Clarke's well-respected phase method of thematic analysis.<sup>10</sup> First, a search for the term "Waitangi" across the policies was made and one author (RC) familiarised herself with this corpus to get a sense of key ideas, actions and intentions. This was followed by a second reading to generate initial codes and allocate data excerpts to codes. Next, these working divisions were named and shaped into draft themes. These were then reviewed by a second author (HC) to ensure themes reflected the coded extracts. Finally, the team engaged in a collaborative analysis to refine the specifics of each theme and these were mapped into a hierarchy of engagement against te Tiriti articles.

## Results

We found that between 2006 and 2016, 49 public health policy and strategy documents fitted our criteria. None of the documents referred to the Māori text and 37 (75%) contained no reference to the English version.

Table 1 lists the 12 documents that drew upon the Treaty. Five of these documents were specific to Māori, one targeted a particular population group, one was the core health strategy document and the remainder were issue-specific strategies. Those public health policy documents that did not mention the Treaty covered mental health, addiction, disability, child health and Pacific health plans and strategies.

The documents that did discuss the Treaty engaged with it in different ways (see Table 2). There was a rhetorical level where policy named Treaty principles. Others promoted practical actions towards implementing the Treaty. Some offered high-level aspirational statements around health inequities and articulated a commitment to Māori health outcomes. Some policies addressed substantive issues of relationships, Treaty obligations, Māori involvement in decision-making and service delivery.

**Table 1:** Public health policy and/or strategy documents that reference Treaty of Waitangi.

1.	Minister of Health and Associate Minister of Health. (2006). Whakatātaka Tuarua: Māori Health Action Plan 2006–2011. Wellington, New Zealand: Ministry of Health. <sup>11</sup>
2.	Ministry of Health. (2006). Ngā kāwai: Implementing whakatātaka 2002–2005. Wellington, New Zealand: Author. <sup>12</sup>
3.	Thornley L, Waa A, Ball J. (2007). Comprehensive plan to inform the design of a national breastfeeding promotion campaign. Wellington, New Zealand: Ministry of Health. <sup>13</sup>
4.	Ministry of Health. (2008). Te Puāwaiwhero - The second Māori mental health and addiction national strategic framework 2008–2015. Wellington. New Zealand: Author. <sup>14</sup>
5.	National Breastfeeding Committee. (2009). National strategic plan of action for breastfeeding 2008–2012. Wellington, New Zealand: Ministry of Health. <sup>15</sup>
6.	Ministry of Health. (2009). Public health (wellbeing) in New Zealand: Interface with local government. Wellington, New Zealand: Author. <sup>16</sup>
7.	Ministry of Health. (2010). Preventing and minimising gambling harm: Six-year strategic plan 2010/11–2015/16. Wellington, New Zealand: Author. <sup>17</sup>
8.	Ministry of Health. (2012). Whāia te ao mārama: The Māori disability action plan for disability support services 2012 to 2017. Wellington, New Zealand: Author. <sup>18</sup>
9.	Ministry of Health. (2014). The guide to he korowai oranga: Māori health strategy. Wellington, New Zealand: Author. <sup>19</sup>
10.	Associate Minister of Health. (2016). Healthy Ageing Strategy. Wellington: Ministry of Health. Wellington, New Zealand: Ministry of Health. <sup>20</sup>
11.	Ministry of Health. (2016). Strategy to prevent and minimise gambling harm 2016/17 to 2018/19. Wellington, New Zealand: Author. <sup>21</sup>
12.	Ministry of Health. (2016a). New Zealand health strategy: Future direction. Wellington, New Zealand: Author. <sup>22</sup>

**Table 2:** Crown Treaty of Waitangi health policy matrix.

<b>Rhetoric</b>		Treaty principles (see 1,2,4,5,7–12)	
<b>Practical implementation</b>	Monitor, audit and/or review effectiveness (see 1–3,6)	Tikanga and/or Treaty of Waitangi training and/or policy (see 2,5)	Holistic Māori health models (see 2,3)
<b>Aspirational statements</b>		Health inequities, inequalities and/or disparities (see 5,6,11,12)	Improve Māori health outcomes (see 2,4–10)
<b>Substantive</b>	Treaty obligations (see 6)	Treaty partnership and/or relationship (see 5,9–12)	Māori decision-making and service delivery (see 3,4,6,7,8–10)

Note: the numbers here refer to the policy documents named and numbered in Table 1.

## Rhetoric

Most of the policy documents included specific references to the Royal Commission on Social Policy's<sup>6</sup> Treaty principles of partnership, protection and participation. Other Crown-defined treaty principles<sup>23</sup> were not named. These Treaty references were sparse and seemed rhetorical in that there were no actions assigned to them. Some documents provided interpretations of the Treaty principles.

## Practical implementation

Perhaps reflecting a more authentic engagement, some policies included specific actions. The Whakatātaka implementation plan, for example, committed agencies to engage in developing cultural and political competencies through tikanga best practice and Treaty of Waitangi training for staff. Several documents required developing action plans and/or policies about implementing the Treaty and undertaking stocktakes. Two policies mentioned Māori models of health and holistic approaches to health alongside Treaty references. Practical actions around auditing and reviewing activities to monitor their effectiveness in relation to Māori health were identified. The He Ritenga Health Audit Framework<sup>24</sup> was named as a tool in policy documents, as was the Whānau Ora Impact Assessment Tool.<sup>25</sup>

## Aspirational statements

Several policies included aspirational statements around addressing health inequities between Māori and other New Zealanders and made specific commitments around improving Māori health outcomes. One policy explained "Māori have the right to enjoy a health status that is at least the same as that enjoyed by non-Māori".<sup>13</sup> Another notes "The Ministry also intends to identify factors that contribute to gambling harm-related inequities for Māori, and to develop, pilot, evaluate and implement one or more initiatives specifically focused on reducing these inequities".<sup>17</sup>

## Substantive actions

Several policy documents named the strategic, special nature of the relationship between Māori and the Crown and acknowledged the obligations this placed on the Crown. One policy explained "Māori can be seen as having a right to determine the nature of Māori focused breastfeeding

interventions".<sup>13</sup> Another indicated that it provided "... mechanisms for Māori to contribute to decision-making on, and participate in, the delivery of services at all levels of the health and disability sector".<sup>14</sup> Another stated an aim to "... improve Māori health and recognise the Treaty of Waitangi obligations of the Crown".<sup>17</sup> Several policy documents recognised the need for Māori to be involved in decision-making within the health sector and the need for effective service delivery to Māori.

## Discussion

Te Tiriti o Waitangi establishes a partnership that recognises Māori as indigenous people and guarantees their sovereignty.<sup>2</sup> Article One granted the British the right to govern their people, Article Two reaffirmed Māori sovereignty enshrined by He Waka-putanga, Article Three guaranteed Māori the same rights and privileges as British subjects and Article Four, the oral article, recognised the right of religious freedom.

Working within Article One involves sharing power and establishing structural and other mechanisms to ensure Māori representation and involvement in decision-making throughout the health sector.<sup>30</sup> In our analysis of the policy documents, this relates most closely with the domain of substantive action. Health policy more widely has rarely ventured explicitly into this area under a treaty banner. For instance there are only fleeting references in the core health policy documents—He Korowai Oranga<sup>19</sup> and the New Zealand Health Strategy<sup>22</sup> to Māori involvement in decision-making.

Article Two requires that Māori are able to exercise tino rangatiratanga (sovereignty)—being in control of individual and collective destiny. Complimenting this work has been the removal of barriers and obstacles to Māori success, which involves challenging institutional and other forms of racism. This article aligns across the domains of substantive action, aspirational statements and practical implementation. Inclusion of mechanisms such as policy auditing and monitoring are ways of ensuring policy is accountable to Māori for outcomes. Berghan et al<sup>26</sup> argue that Māori providers and/or Māori health promotion have been common expressions of tino rangatiratanga.

Article Three is about embracing ethical decision-making that reduces health inequities and addresses the wider determinants of health.<sup>26</sup> This most closely aligns with aspirational statements and practical application. Of the policy documents that included treaty references this was a major focus of their Treaty responsiveness.

Working with Article Four involves normalising wairuatanga, te reo me ono tikanga (Māori language and cultural protocols).<sup>26</sup> There is little in the policy documents that addressed this element beyond parts of practical application that recognised holistic models of health.

## Conclusion

This study shows that health policy substantively ignores Māori rights as laid down in te Tiriti, in that 75% of our sample is silent in this regard. This marginalisation can be viewed as a breach of the

governments te Tiriti obligations and is likely to inform [WAI 2575] health-related Waitangi Tribunal claims. Where there have been efforts at engagement with te Tiriti as a foundational policy framework, we see weak, fragmented work that relates piecemeal to some articles and no comprehensive whole of te Tiriti response. Little is happening in terms of kāwanatanga and tino rangatiratanga, there is some engagement with օritetanga and limited progress in relation to wairuatanga. Although one can look at te Tiriti in its component parts, it is more useful to look at it as one coherent framework. It seems logical that a multi-level systems approach including strong engagement with kāwanatanga responsibilities and tino rangatiratanga would strengthen Māori health outcomes. Further work is needed to strengthen alignment of health policy to Crown obligations under te Tiriti.

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### Competing interests:

Dr Came reports being co-chair of STIR: Stop Institutional Racism—this is a nationwide network of activist scholars and public health practitioners committed to eliminating institutional racism in the health sector.

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# Prevalence of hepatitis E virus antibodies and infection in New Zealand blood donors

Joanne Hewitt, David Harte, Michelle Sutherland, Dawn Croucher, Lindsey Fouche, Peter Flanagan, Deborah Williamson

## ABSTRACT

**AIM:** Blood transfusion is one route of transmission of hepatitis E virus (HEV). The aim of this study was to assess both the prevalence of HEV antibodies and HEV infection in New Zealand blood donors.

**METHOD:** To determine HEV seroprevalence, donor plasma samples (n=1,013) were tested for HEV antibodies using two commercially available ELISA kits, the Wantai HEV IgG ELISA and the MP Diagnostics HEV ELISA 4.0. To assess the prevalence of HEV infection, pooled plasma samples from individual plasma donors (n=5,000) were tested for HEV RNA using RT-qPCR. Samples that tested HEV antibody positive or gave an equivocal result with either ELISA were also tested for HEV RNA.

**RESULTS:** The HEV seroprevalence in New Zealand blood donors was 9.7% using the Wantai HEV IgG ELISA and 8.1% using the MP Diagnostics HEV ELISA 4.0. The presence of HEV antibodies was significantly and positively correlated with increasing donor age. HEV RNA was not detected in any of the samples tested, indicating no evidence of current infection.

**CONCLUSION:** This study, the largest to date to assess HEV seroprevalence in New Zealand, provides valuable baseline information on HEV seroprevalence and infection in New Zealand blood donors. The seroprevalence rate in New Zealand is similar to that reported in other developed countries.

Hepatitis E virus (HEV) infection is a common cause of acute hepatitis in developing countries, where faecal-oral transmission via faecally contaminated water is the most common transmission route.<sup>1</sup> Hepatitis E cases identified in developed countries are commonly associated with travel to developing countries where the virus is endemic. However, there are increasing reports of autochthonous (locally acquired) cases of HEV infection in developed countries. These cases are usually associated with HEV genotype 3 (Europe, America) or 4 (Asia).<sup>1,2</sup> The transmission route(s) for HEV in developed countries are not well understood, but there is good evidence to show that zoonotic transmission from pigs and foodborne transmission from undercooked pig and deer meats are important.<sup>3-5</sup> The majority of HEV infections in humans are asymptomatic.<sup>1</sup> One potentially important route of HEV transmission is transfusion of blood components.<sup>6,7</sup> However, the contribution of such

transmission to overall HEV disease burden is unclear.<sup>8</sup> There have been several recent HEV seroprevalence studies of blood donors, with a broad range in reported seropositivity. For example, Cleland et al reported an HEV seroprevalence of 4.7% in 1,559 Scottish blood donors in 2012,<sup>9</sup> Slot et al observed a seroprevalence of 26.7% in 5,239 Dutch blood donors in 2011 and 2012,<sup>10</sup> and Lucarelli et al reported a 49% seroprevalence rate in 313 blood donors in central Italy in 2014.<sup>11</sup> Several studies have attempted to determine the presence of HEV viraemia in blood donors, and therefore the more immediate risk to blood and blood product recipients.<sup>12-14</sup> This risk has prompted some countries, including Ireland and the UK, to introduce routine testing of donated blood for HEV RNA to prevent transmission by transfusion. Other countries are considering its implementation either selectively (eg, intended for high-risk patients) or nationwide.<sup>15</sup>

There are no recent data on HEV seroprevalence among the New Zealand population and no published data on HEV viraemia in New Zealand blood donors. One previous New Zealand study of 265 blood donors published in 2007 observed an HEV IgG seropositivity rate of 4.2%, although limited information on donor characteristics was available.<sup>16</sup> Accordingly, the aims of this study were: (i) to determine the contemporary seroprevalence of HEV in New Zealand blood donors, and (ii) to assess the prevalence of HEV infection (as measured by HEV RNA detection) in New Zealand blood donors.

## Methods

Plasma samples collected by the New Zealand Blood Service (NZBS) between 11 November 2014 and 10 March 2015 were used for the seroprevalence study. The sampling strategy was based on the New Zealand population census 2006 distribution with target sample numbers calculated from each of five New Zealand regions (classified as Northern, Auckland, Midland, Central and Southern) covering urban and rural areas and three age groups (<30 years, 30–59 years and >60 years). For each of the donors participating in this study, data on age, sex and region of residence were collected. For statistical analysis, age groups were classified as: 16–30 years, 31–45 years, 46–60 years and >60 years of age.

Previous studies have reported differences in the relative specificity and sensitivity of the ELISA kits used for HEV IgG detection.<sup>17</sup> To allow comparison with other studies that have used various ELISA assays, two different ELISA kits were used to test each donor plasma sample. These were the Wantai HEV IgG ELISA (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, Beijing, China) and the MP Diagnostics HEV ELISA 4.0 (MP Biomedicals Asia Pacific, Singapore). According to the manufacturer's kit insert, the Wantai HEV IgG ELISA detects HEV IgG only, while the MP Diagnostics HEV

ELISA 4.0 detects total (IgG, IgM and IgA) HEV antibody. Testing and calculations (ie, sample to cut-off ratio and determination of equivocal results) were in accordance with the manufacturer's instructions. Samples that tested HEV seropositive by either kit were subsequently tested for the presence of HEV RNA using the method described below.

To assess the prevalence of HEV infection, pooled plasma samples were prepared from individual plasma donations collected by the NZBS between 26 June and 8 October 2015. Between eight and 12 plasma aliquots from individual donations were pooled. Pooled samples were tested for HEV RNA using a commercially available real-time reverse transcription (RT)-qPCR assay (RealStar® HEV RT-PCR Kit 1.0, Altona Diagnostics, Hamburg, Germany) according to the manufacturer's instructions. The analytical sensitivity of RealStar® HEV RT-PCR Kit is 0.31 International Units (IU)/µl as reported by Altona Diagnostics.

Statistical analysis was performed using Graphpad Prism (GraphPad Software Inc., San Diego, CA) and R.<sup>18</sup> The binomial 95% confidence interval (CI) was determined for seroprevalence rates. The Pearson's Chi-squared test ( $\chi^2$ ) was used to determine the significance of any observed differences in the seroprevalence rates for different demographic subgroups. A P value of  $\leq 0.05$  was considered significant.

## Results

In total, 1,013 plasma samples were tested for HEV antibodies. The Wantai HEV IgG ELISA gave a positive result in 98/1,013 samples (9.7%, 95% CI 7.9–11.7%). The MP Diagnostics HEV ELISA 4.0 gave a positive result in 82/1,013 samples (8.1%, 95% CI 6.5–10.0%) (Table 1). The difference between the kits was not statistically significant ( $p < 0.05$ ). A total of 79 (7.8%, 95% CI 6.2–9.6%) samples tested positive using both ELISA assays.

**Table 1:** Comparison of HEV antibody test results using Wantai and MP Diagnostics HEV ELISA kits.

		MP Diagnostics (HEV IgG, IgM, IgA)			
		Positive	Equivocal	Negative	Total
Wantai (HEV IgG)	Positive	79 (7.8%)	0 (0%)	19 (1.9%)	<b>98 (9.7%)</b>
	Equivocal	0 (0%)	0 (0%)	2 (0.2%)	2 (0.2%)
	Negative	3 (0.3%)	0 (0%)	910 (89.8%)	913 (90.1%)
	Total	<b>82 (8.1%)</b>	0 (0%)	931 (91.9%)	1,013

Of the 1,013 samples tested, 103 gave a positive or an equivocal result for HEV antibodies with either ELISA kit. Discordant results were obtained for 24/1,013 (2.4%) samples. Of the 98 Wantai HEV IgG positive samples, 19 were negative using the MP Diagnostics ELISA kit (that detects HEV IgG, IgM and IgA), whereas, of the 82 MP Diagnostics HEV antibody-positive samples, three were negative using the Wantai HEV IgG ELISA. Two samples gave an equivocal result using the Wantai HEV IgG ELISA but were negative using the MP Diagnostics HEV ELISA.

No significant difference in the seroprevalence rate between males and females, or by geographic region was observed. However,

there was a significant association between seropositivity and age, with the lowest (3%, 95% CI 1.5–5.5%) and highest (18.0%, 95% CI 12.6–24.6%) seroprevalence rates in the 16–30 year and over 60 year age groups respectively using the Wantai HEV IgG ELISA (Table 2).

A total of 625 pooled plasma samples prepared from 5,000 individual donors were tested for HEV RNA. HEV RNA was not detected in any of the pooled samples. HEV RNA was not detected in any of the 103 individual samples that tested HEV antibody positive or that gave an equivocal result with either ELISA kit.

**Table 2:** HEV seroprevalence by sex, age group and New Zealand region using Wantai and MP Diagnostics ELISA kits.

	Samples tested	Wantai			MP Diagnostics		
		Positive	% positive (95% CI)	P value	Positive	% positive (95% CI)	P value
<b>Overall</b>	1,013	98	9.7 (7.9–11.7)		82	8.1 (6.5–10.0)	
<b>Sex</b>				0.428 <sup>a</sup>			0.475 <sup>b</sup>
Male	483	43	8.9 (6.5–11.8)		36	7.5 (5.3–10.2)	
Female	530	55	10.4 (7.9–13.3)		46	8.7 (6.4–11.4)	
<b>Age group</b>				<0.01 <sup>c</sup>			<0.01 <sup>d</sup>
16–30	331	10	3.0 (1.5–5.5)		9	2.7 (1.3–5.1)	
31–45	206	12	5.8 (3.0–10.0)		13	6.3 (3.4–10.6)	
46–60	304	45	14.8 (11.1–19.3)		36	11.8 (8.4–16.2)	
61+	172	31	18.0 (12.6–24.6)		24	14 (9.2–20.1)	
<b>Region</b>				0.073 <sup>e</sup>			0.129 <sup>f</sup>
Northern <sup>g</sup>	152	20	13.2 (8.2–19.6)		15	9.9 (5.6–15.8)	
Auckland <sup>h</sup>	215	17	7.9 (4.7–12.4)		16	7.4 (4.3–11.8)	
Midland <sup>i</sup>	233	29	12.5 (8.5–17.4)		24	10.3 (6.7–14.9)	
Central <sup>j</sup>	167	17	10.2 (6.0–15.8)		16	9.6 (5.6–15.1)	
Southern <sup>k</sup>	246	15	6.1 (3.5–9.9)		11	4.5 (2.2–7.9)	

<sup>a</sup> $\chi^2 = 0.629$ , degrees of freedom (d.f.)=1; <sup>b</sup> $\chi^2 = 0.510$ , d.f.=1; <sup>c</sup> $\chi^2 = 43.13$ , d.f.=3; <sup>d</sup> $\chi^2 = 27.413$ , d.f.=3; <sup>e</sup> $\chi^2 = 8.579$ , d.f.=4; <sup>f</sup> $\chi^2 = 7.126$ , d.f.=4.

<sup>g</sup>Northernland and Waitemata District Health Boards (DHBs).

<sup>h</sup>Auckland and Counties Manukau DHBs.

<sup>i</sup>Waikato, Lakes, Bay of Plenty, Tairāwhiti, Taranaki and Hawke’s Bay DHBs.

<sup>j</sup>Whanganui, MidCentral, Hutt Valley, Capital & Coast and Wairarapa DHBs.

<sup>k</sup>All South Island (Nelson Marlborough, West Coast, Canterbury, South Canterbury and Southern DHBs).



## Discussion

This study reports on the HEV seroprevalence rate and presence of HEV RNA in New Zealand blood donors, 2014–2015. The seroprevalence rates of 9.7% and 8.1%, as determined by the Wantai and MP Diagnostics ELISA kits respectively, are similar to results from some developed countries where the HEV seroprevalence rates were determined in blood donors using either of these ELISA kits. These include England/northern Wales (10%),<sup>19</sup> Ireland (5.3%),<sup>20</sup> Australia (6%)<sup>21</sup> and US (7.7%).<sup>12</sup> This compares to countries with HEV seroprevalence of >10% to ≤20% among blood donors, such as Austria (13.6%),<sup>22</sup> Denmark (10.7%)<sup>23</sup> and Norway (14%).<sup>24</sup> Higher seroprevalence rates (>20%) reported for blood donors include The Netherlands (26.7%),<sup>10</sup> France (22.4%)<sup>25</sup> and China (21.1%).<sup>26</sup>

Differences in specificities and sensitivities of HEV ELISAs have previously been reported.<sup>17,27</sup> Overall, higher seroprevalence rates are reported for studies that use the Wantai HEV IgG ELISA. In an Australian study, 194 plasma samples that tested positive and 200 samples that tested negative using the Wantai HEV IgG ELISA were subsequently tested using three MP Diagnostics HEV ELISA kits (ie, IgG only, IgM only and total [IgM, IgG, IgA]).<sup>28</sup> That study demonstrated poor agreement between the assays but found a higher concordance between the Wantai and MP Diagnostics HEV total antibody kits (both used in our study).<sup>28</sup> A meta-analysis of 73 published HEV IgG seroprevalence studies from Europe showed significantly higher seroprevalence rates across all cohorts in studies using the Wantai IgG ELISA assay.<sup>29</sup> The reason for this is unclear, and while it is possible that the Wantai assay may be overly sensitive (less specific), this ELISA is widely used (hence useful for comparisons) and considered one of the best performing HEV IgG ELISA kits available.<sup>29–31</sup>

Our study measured a higher seroprevalence than detected in an earlier New Zealand study of blood donors (11/265, 4.2%) which also used the HEV IgG Wantai ELISA.<sup>16</sup> It cannot be confirmed whether this is a true increase in seroprevalence among blood donors. The difference may be a result of differences between the study populations

(age, sex and geographical distributions, eg, the earlier study only obtained samples from Auckland) and the sample numbers (265 vs 1,013).

As reported in other studies, age was shown to be a significant risk factor for previous HEV exposure, with seropositivity increasing significantly with age.<sup>24–26</sup> A higher seroprevalence in older persons is indicative of an age-related cohort effect due not only from a cumulative exposure throughout life but increased infection pressure in the past.<sup>32,33</sup>

In our study, we found no significant difference between seropositivity among males and females. This is in agreement with Hartl et al (2016) who, from a meta-analysis of 45 European studies on HEV seroprevalence, showed no significant difference in prevalence between genders.<sup>29</sup> However, some studies have observed a significantly higher HEV IgG prevalence in males than in females. For example, Zhuang et al demonstrated a significantly higher HEV IgG seropositivity in male (25.3%) than female (17.7%) blood donors in China.<sup>34</sup> The reason for this observation is unclear but may reflect different exposure risks between genders in different populations (eg, occupational or food preparation/consumption practices).

The lack of detection of HEV RNA in our study was not unexpected considering the low prevalence rates of HEV RNA in blood donors from other HEV-sporadic countries and the number of specimens tested (n=5,000). Examples of reported rates include 0.007% (1:15,000, Australia and Scotland), between 0.04–0.01% (1:3,000–1:10,000, England, Ireland, Austria and US) and 0.08% (1:1,300, Germany and The Netherlands).<sup>9,12–14,20,22</sup>

Information on potential risk factors for HEV exposure such as overseas travel (eg, travel to HEV endemic areas), occupation (eg, abattoir work, animal handling) and food consumption habits (eg, consumption of undercooked meats or pork) were not available for donors in our study. Several overseas studies have demonstrated the presence of HEV RNA in the food chain, most notably in pork products and an association between HEV seropositivity and exposure to pigs.<sup>35,36</sup> HEV IgG has been

detected in 20/22 (91%) of New Zealand pig herds.<sup>37</sup> It is plausible that for a proportion of New Zealand blood donors, HEV acquisition is autochthonous rather than overseas-acquired. As most cases of HEV infection are asymptomatic, with risk factors unclear, identification of HEV viraemic blood donors via additional questions on the current New Zealand Blood Service Donor Health Questionnaire is not feasible.

Any future studies (eg, a case-control study of HEV exposure risk) should attempt to identify specific risk factors for HEV exposure, particularly those related to transfusion and food consumption. A larger sample size would provide a better test of any regional differences in seroprevalence and a more accurate measure of HEV infection in the blood donor population.

#### Competing interests:

Dr Flanagan reports grants from Grifols, from null, outside the submitted work.

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# Review of acute symptomatic urolithiasis in Auckland

Stephanie Loeff, Manmeet Saluja, Michael Rice

## ABSTRACT

**AIM:** To evaluate the incidence of acute symptomatic urolithiasis in the Auckland region. Associated epidemiological factors and stone characteristics were also studied and compared to previous research conducted in order to analyse trends.

**METHOD:** All patients that presented acutely with symptomatic urolithiasis to the Auckland District Health Board (AHDB) between July 2014 and June 2015 were studied. Clinical data was obtained from medical records and population data was based on estimates provided by the Ministry of Health. Two-tailed tests and the Pearson Chi-Square tests were used for analysis.

**RESULTS:** Overall, 1,125 patients (1,328 events) presented with an incidence of 85 per 100,000 per year, which was lower than that reported in 2006. The highest incidence was found among the Middle Eastern ethnic subgroup (0.130 %), followed by Māori (0.102%), Asian (0.087%), European (0.084%) and Pacific (0.041%) ethnicity. Males were more likely to be affected than females. Urolithiasis was most common in the fifth decade of life (25%). Forty-seven percent of the study population presented with multiple stones and 64% had recurrent urolithiasis or were 'high risk' stone formers. Distal ureteric stones <5mm were the most common (27%). Urine cultures were positive in 16% of cases. Seven hundred and thirty-nine (57%) were managed with medical management and ureteroscopy was most commonly performed for those who needed surgical intervention.

**CONCLUSIONS:** The overall incidence of urolithiasis has decreased compared to previous research conducted in Auckland. This deviation could be attributed to the large influx of Asian immigrants observed in this period of time. A caucasian male, between 40–49 years, with a calculus <5mm in the distal ureter with a history of a previous urolithiasis has the highest chance to present with renal colic.

Acute urolithiasis can be an extremely disabling condition and represents a substantial proportion of everyday urology practice. The incidence of urolithiasis has increased both within New Zealand and globally over the last few decades.<sup>1–3</sup> In the US, incidence rates are as high as 10.6% in men and 7.1% in women.<sup>3</sup> This rising trend could partially be attributed to changing lifestyle factors, as diseases such as obesity, diabetes and metabolic syndrome are on the rise and are related with stone formation.<sup>4–6</sup> Naturally, morbidity and healthcare costs attributable to acute kidney stone disease is further increasing. Henceforward, the focus on prevention is becoming more important.

Auckland has an estimated population of approximately 1.5 million people<sup>7</sup> with

a variable ethnicity. The majority of the population is Caucasian (59%), followed by Asian (23%), Polynesian (15%), Māori (11%) and a smaller Middle Eastern (2%) population. Patient demographics were studied to evaluate which patient groups are most likely affected. Stone characteristics, current management and prevention strategies were analysed with the prospect of improving future practice.

This review is related to an existing line of research performed in the Auckland City Hospital, which adopted the same inclusion criteria. Subsequently, the incidence rate was compared with previous numbers, in order to monitor a potential rise in incidence. We hypothesised that the overall incidence of acute urolithiasis had increased compared to 2006.<sup>3</sup>

## Methods

All patients that presented acutely to the Auckland District Health Board (ADHB) between July 2014 and June 2015 with symptomatic and radiologically diagnosed urolithiasis were retrospectively reviewed. Patients could have their first encounter or a recurrent presentation within the study period with a new stone. Clinical data was obtained from medical records after the study was ethically approved. Stones were mostly diagnosed with a non-contrast CTKidney, ureter, bladder (KUB) as per hospital protocol, however an ultrasound KUB was preferentially used in younger women. Population data was based on estimates provided by the Ministry of Health and Statistics as the national census was last updated in June 2013.

Statistical Analysis Software programme (SAS) was used for analysis and comparisons were made by means of two-tailed tests and Pearson Chi-Square test. ROKS (recurrence of kidney stone) nomogram was used to predict the risk of a second kidney stone episode recurrent. The scores are based on the predictive power developed following a large historic cohort study, whereby potential risk factors for recurrence in first-time stone formers were identified.<sup>8</sup> The rates were subsequently calculated by using the QMXD calculator, which has been implemented for the nomogram (<http://qxmd.com/calculate/roks-recurrence-of-kidney-stone-2014>).

## Results

### Incidence and demographics

A total of 1,328 new presentations of acute urolithiasis were identified among 1,125 patients. Nine hundred and seventy-two (86%) patients had a singular presentation. The remaining 153 (14%) patients had recurrent presentation(s) within the study period (Figure 1).

The incidence rate calculated by means of the estimated population data was 85 per 100,000 (0.085%). Although the number of events has increased compared to 2006, the overall incidence has decreased from 0.132%.<sup>1</sup>

Mean age of presentation was 48.9 years for men and 46.1 years for women. Since 2006, the 60–69 age group showed a significant increase in incidence, while the other age groups showed a decrease (Figure 2). Males (68%) were more likely to be affected than females (32%), and remained similar to the proportions in 2006.

From the ethnic subgroups, caucasians predominated and constituted 57% of the study population for both 2006 and 2014. The Asian population showed a significant increase in incidence, whereas the Pacific Island group has had a significant decrease in incidence (Table 1). The Middle Eastern population continued to have the highest overall incidence of acute urolithiasis.

A substantial large group of 720 cases (56%) were either recurrent or ‘high risk’

**Figure 1:** Number of patients presenting with acute renal colic events within the study period.

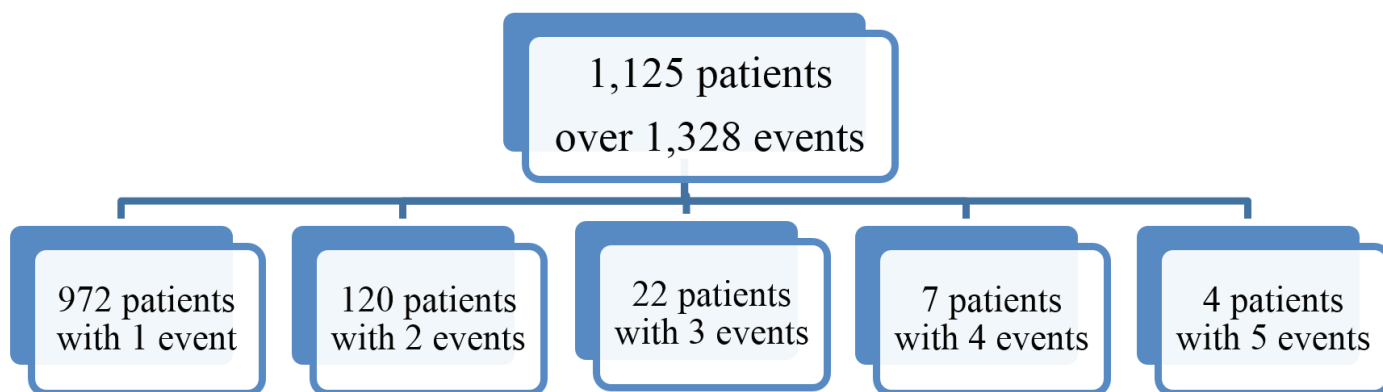


Figure 2: Age distribution of patients in 2006 and 2014.

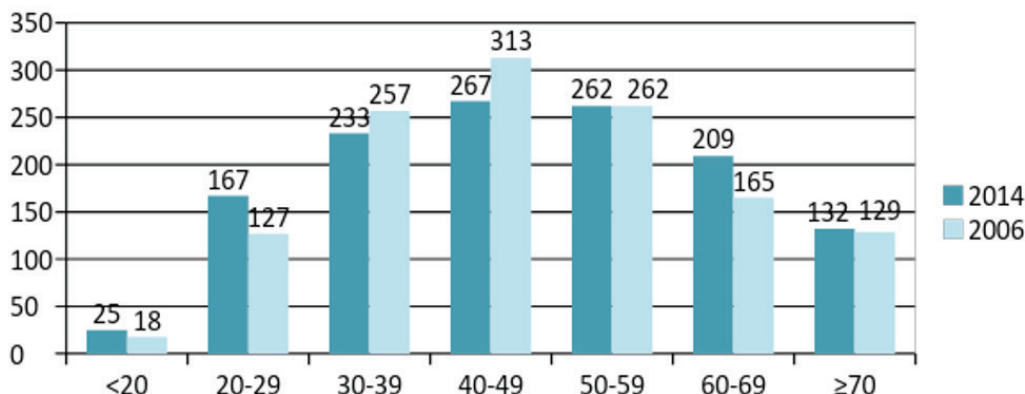


Table 1: Incidence and distribution of nephrolithiasis by ethnicity in 2006 and 2014.

	Distribution of nephrolithiasis by ethnicity				
	Asian	European	Māori	Middle Eastern	Pacific
2014	304 (24%)	741 (57%)	119 (9%)	29 (2%)	94 (7%)
2006	204 (16%)	719 (57%)	109 (9%)	27 (2%)	142 (11%)
P-value	<0.0002	0.739	0.585	0.842	0.0006
	Incidence of nephrolithiasis by ethnicity				
	Asian	European	Māori	Middle Eastern	Pacific
2014	0.087%	0.084%	0.102%	0.103%	0.041%
2006	0.076%	0.137%	0.093%	0.255%	0.125%

stone formers as defined by the EAU guidelines.<sup>9</sup> As many as 46% reported having a previous episode of renal colic(s) in their lifetime. For the majority of this group (77%), a singular previous episode was reported. (Table 2). Metabolic syndrome was recorded as the most common morbidity associated with ‘high risk’ patients (Table 3). From the ROKS nomogram, it was estimated that recurrence risk in the first-time symptomatic stone former was 7% at two years, 14% at five years and 23% at 10 years.

Table 2: Recurrent stone formers.

Previous episodes	Cases
0	693 (54%)
1	455 (35%)
2	84 (7%)
3	28 (2%)
>3	26 (2%)

### Stone characteristics

Seventy-four percent of stones smaller than 5mm were found in the distal ureter or recently passed into the bladder. As expected, distal stones were smaller and proximal stones tended to be larger (Table 4). Of the cases presented, 47% had multiple stones, this mostly involved small non-obstructing, intra-renal stones.

### Management of urolithiasis

Seven hundred and thirty-nine cases (57%) were managed conservatively without further treatment or intervention being required. An additional 70 cases failed conservative management and needed elective surgery. Smaller and more distal stones were more likely to be managed conservatively (Table 5). A total of 622 surgeries were performed with ureteroscopy accounting for the majority (81%). ESWL (9%) and PCNL (3%) were less commonly performed. Three (0.5%) nephrectomies were performed due to xanthogranulomatous pyelonephritis.

**Table 3:** Factors associated with increased risk.

High-risk stone formers	Cases
Early onset	18
Familial stone formation	32
Struvite/uric acid containing stones*	43
Metabolic syndrome (BMI >30)	99
Gout	53
Hyperparathyroidism	1
Hypercalcaemia	1
Crohn	1
Cystics fibrosis	2
Cystinuria	1
Horseshoe kidney	3
Solitary kidney	5
Xanthogranulomatous pyelonephritis	4
Medullary sponge kidney	12
Renal tubular acidosis	1
Sjorgen syndrome	1
Spina bifida	1

\* Stones which constituted some struvite or uric acid of the total composition were also included.

### Metabolic work up

Table 6 shows the performed metabolic work-up. The investigations recommended by the EAU were hereby set as a standard. Basic serum and urine analysis were performed in most patients; however, serum calcium and phosphate levels were measured in only half the cases. Two hundred and three (15%) cases had a urinary tract infection diagnosed on microscopy. Gram negative organisms constituted the most common growth.

Thirty-six percent of patients who had surgery had stone analysis compared to 7% with conservative management. Calculi analysis yielded 42% of calcium oxalate, 33% of calcium oxalate-phosphate and 11% of predominant uric acid components (Figure 3).

Overall, 24-hour urine analysis and dietician review was performed poorly for high-risk and recurrent stone formers during the study period, however some of the recurrent stone formers may have had metabolic workup performed previously (Table 6).

**Table 4:** Stone position by size and location.

Location symptomatic stone				
Size stone in mm	Distal	Proximal	Total	
<5	299 (74%)	48 (12%)	56 (14%)	403
5-10	240 (43%)	104 (19%)	208 (38%)	552
10-15	23 (19%)	15 (12%)	83 (69%)	121
≥15	15 (28%)	3 (5%)	36 (67%)	54

**Table 5:** Management by stone size.

Size in mm	<5	5-10	10-15	≥15
Conservative management	334 (83%)	245 (44%)	18 (15%)	15 (27%)
Intervention; surgical/ ESWL	69 (17%)	307 (56%)	103 (85%)	40 (73%)
Total	403	552	121	55

(Chi-square = 293,323<sup>a</sup> p<0.001, 8 df).

Figure 3: Stone composition.

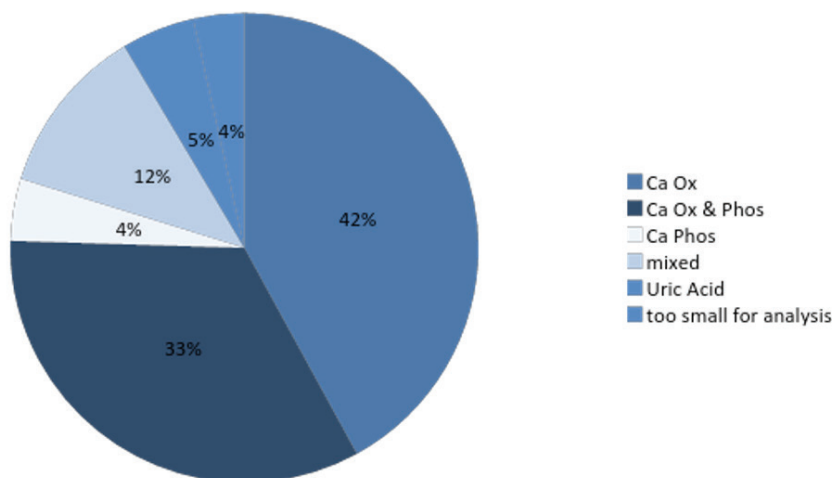


Table 6: Overview of completed metabolic work-up.

	Urology	ED	Other
<b>Cases</b>	<b>827 (64%)</b>	<b>382 (29%)</b>	<b>86 (7%)</b>
Operative	530 (64%)	0	25 (29%)
Non-operative	296 (36%)	382 (100%)	61 (71%)
<b>Stone analysis</b>	<b>228 (28%)</b>	<b>22 (6%)</b>	<b>8 (9%)</b>
Operative	192 (84%)	0	5 (63%)*
Non-operative	36 (16%)	22 (100%)**	3 (38%)
<b>Basic analysis—blood</b>			
Sodium	816 (99%)	379 (99%)	84 (98%)
Potassium	816 (99%)	379 (99%)	84 (98%)
Creatinine	816 (99%)	379 (99%)	84 (98%)
Calcium	498 (60%)	211 (55%)	45 (52%)
Uric Acid	446 (54%)	202 (53%)	29 (34%)
<b>Basic analysis—urine</b>			
Erythrocytes	806 (97%)	377 (99%)	84 (98%)
Leukocytes	806 (97%)	377 (99%)	84 (98%)
Nitrate	806 (97%)	377 (99%)	84 (98%)
Proteins	806 (97%)	377 (99%)	84 (98%)
pH	806 (97%)	377 (99%)	84 (98%)
Culture	718 (87%)	349 (91%)	80 (93%)
<b>High risk and recurrence</b>	<b>499 (60%)</b>	<b>177 (46%)</b>	<b>44 (51%)</b>
<b>24 hr urine</b>	<b>77 (15%)</b>	<b>14 (8%)**</b>	<b>16 (36%)**</b>
<b>Seen by dietician</b>	<b>22 (4%)</b>	<b>5 (3%)**</b>	<b>5 (11%)</b>

\*These surgeries were performed by the urology department but were discharged from different wards due to coexistent health issues.

\*\*Stone analysis and 24 hr urine performed by the urology/renal department after referral.



## Discussion

According to this study, acute kidney stone disease has decreased in incidence for the Auckland region compared 0,132% in 2006 to 0,085. It must be stated that in this period, Auckland has had an 11% population growth from 1,373,000 (2006) to 1,526,900 (2014).

During the same period of time, there has been a major influx in the Asian population with an increase of 30% in their population (268,700 in 2006 to 348,900 in 2013).<sup>7</sup> The lower incidence of urolithiasis in the Asian population could therefore account for the overall decrease in the incidence of urolithiasis. This is an important finding of this study as it suggests that mass migration influences the incidence of acute nephrolithiasis. There is no other literature that discusses this phenomenon and further hypothesis generating could be considered.

Almost two-thirds of patients were identified as high-risk or recurrent stone formers. Even within a year, more than 10% of patients had a recurrent presentation with another stone. This demonstrates the large burden of stone disease in our population and emphasises the need of prevention. Both basic and 24-hour metabolic analysis was inadequately performed. Both are fundamental prior to medical/dietary follow-up and are considered standard of care.<sup>9</sup>

These trends are also seen elsewhere in the world; a large series showed a prevalence of metabolic workup in high-risk patients in only 7.4%.<sup>12</sup> Dietician referrals were also infrequent even though these patients may benefit from a personalised dietary plan.<sup>10</sup> Henceforward, our department has set a more targeted focus on prevention management by means of a dedicated renal team. To achieve this goal, an adequate metabolic evaluation beforehand is now being routinely performed for high-risk patients. Patient education, medical management and dietician input are now being offered and implemented in our stone clinic.

Although more than half of the cases were managed conservatively, primary ureteroscopy was used in the majority of

surgical treatments. Auckland is unique, as the acute services can accommodate an after-hours laser service with availability of theatre and medical expertise. However, there is enormous stress on elective services if primary ureteroscopy is not possible. As such, alternative surgical options such as ESWL, which has similar efficacy in proximal stones, could be better utilised in the future.<sup>13</sup>

There are a few limitations to the study. All symptomatic stones referred to the ADHB were incorporated. This study is based on public hospital-statistics, therefore presentations at general practices or private hospitals were not included. The true incidence of acute urolithiasis in Auckland is likely to be higher than quoted in our study. Furthermore, there may have been changes in patient flows regarding public versus private health. However, since there is very limited data available on this matter, no conclusions can be drawn. Patients' BMI and family history were grossly under-reported in patient records and no major conclusions could be drawn regarding these two variables.

Aetiological factors which may contribute to the formation of nephrolithiasis, such as geographical location, water hardness,<sup>11</sup> have not been taken into account as these variables were the same for both datasets. Previous research conducted in Auckland has shown that there are clear seasonal variations on the incidence of stone disease, as with higher temperatures and increased sun hours correspond with a higher incidence. These components are not accounted as confounding factors in this present study.

A strength of this study is that there were no exclusion criteria; all people presenting to the ADHB with renal colic were included. Moreover, almost without exception all the cases had received imaging. Furthermore, the same inclusion criteria applied for the previous Auckland urolithiasis research conducted, which was also performed in the public-hospital setting. Therefore, the comparisons made between the two study populations and the conclusions drawn ought to be legitimate for the ADHB hospitals and gives a clear insight on the epidemiological trend of this disease.

## Conclusion

Although the number of cases presenting with acute urolithiasis in Auckland has increased, there is an overall decrease in incidence. This deviation is attributed to the large influx of Asian immigrants observed in this period. A Caucasian male between 40–49 years with a calculus <5mm in the

lower urinary tract has the highest chance of presenting with a renal colic. Metabolic workup and dietary management of these patients needs to be improved. Further prospective studies are needed once prevention strategies are implemented to monitor a reduction of recurrent symptomatic urolithiasis events in our population.

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### Competing interests:

Nil.

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# Disease recurrence following surgery for colorectal cancer: five-year follow-up

Ashok Gunawardene, Brendan Desmond, Ali Shekouh, Peter Larsen, Elizabeth Dennett

## ABSTRACT

**AIM:** To describe the patterns of recurrence in a contemporaneous cohort of patients undergoing surgery with curative intent for colorectal adenocarcinoma at a New Zealand hospital with five-year follow-up.

**METHODS:** Patients with colorectal cancer undergoing potentially curative surgery between January 2010 and December 2012 were followed up for a median of 61 months with three-monthly CEA (carcinoembryonic antigen), a colonoscopy after one year and yearly computed tomography scans of the chest, abdomen and pelvis for the first three years.

**RESULTS:** Overall, 59/237 (24.9%) of patients experienced disease recurrence, the most common sites being the liver, followed by the lung and local recurrence. Recurrence rates did not differ significantly between colon and rectal cancer and ranged from 5.1% in stage I to 60% in stage IV. Seventy-three percent of all recurrences were observed within the first 24 months post-operatively.

**CONCLUSION:** While New Zealand outcomes in colorectal cancer have historically compared unfavourably against international standards, the outcomes observed in this cohort are encouraging and may reflect advances in care, including multidisciplinary team discussion, increased use of adjuvant therapy, surgical subspecialisation and protocolled surveillance and follow-up.

The New Zealand Ministry of Health has reported colorectal cancer (CRC) as the third most common cancer after prostate and breast, comprising almost 14% of all those registered in 2012, and as the second leading cause of cancer-related death behind only lung.<sup>1</sup> Furthermore, data collated by the International Agency for Research on Cancer (IARC) has placed New Zealand as having one of the highest incidence rates of colorectal cancer in the world.<sup>2</sup>

Historically, outcomes of CRC in New Zealand have compared unfavourably to international standards with five-year mortality rates around 40%.<sup>3,4</sup> While the issue of timely diagnosis will be addressed by the much-anticipated national screening programme, there is a need to re-evaluate oncological outcomes in the context of other recent advances in colorectal cancer

management. These include routine multidisciplinary team discussion, surgical sub-specialisation, increased utility of neo-adjuvant and adjuvant therapies and protocolled follow-up and surveillance.

While prior cohort studies have reported on mortality in detail, they have not reported on recurrence rates. This study was conducted to examine more contemporary mortality rates in a New Zealand cohort, and to provide data on recurrence rates.

## Methods

Patients with newly diagnosed adenocarcinoma of the colon or rectum between January 2010 and December 2012 at a single tertiary hospital were included in the study. Consecutive patients undergoing curative intent surgery during this time-frame were

included provided their follow-up was also at the host institution and patients with a prior history of colorectal malignancy were excluded. Patients with stage IV disease at presentation were included in the study if they had no residual disease following their definitive treatment. This study complies with regulations for audit at the host institution and meets the New Zealand definition of observation research.

A standardised protocol for post-operative follow-up and surveillance was used during the study period and involved three- to six-monthly surgical outpatient visits and yearly computed tomography (CT) scan of the chest, abdomen and pelvis for the first three years. A complete colonoscopy was performed within a year of surgery if one had not been completed pre-operatively with a repeat colonoscopy after three years. Yearly outpatient appointments were scheduled between years three to five and three-monthly serum carcinoembryonic antigen (CEA) was checked for all five years. Surgery for rectal cancer was typically carried out by three colorectal surgeons and colon cancers by general and colorectal surgeons at the hospital.

Time-to-recurrence was calculated from the date of surgery to either histological confirmation or clinical-radiological evidence of loco-regional or distant disease recurrence on review at a multidisciplinary meeting, where the date of meeting was taken as the end-point. Patients that were alive and without evidence of disease recurrence on 1 November 2016 were censored. The site of primary cancer was taken from the operation note and disease stage based on classification in accordance with the American Joint Committee on Cancer (AJCC) Seventh edition.<sup>5</sup>

Statistical analysis was performed using IBM SPSS Statistics Version 24.0. Categorical variables were compared between groups using Chi squared or Fischer's exact tests. Kaplan-Meier curves were plotted to evaluate time-to-recurrence and the log-rank test performed to compare groups by stage. Univariate and multivariate survival analyses were performed using Cox proportional hazards model including variables with  $p < 0.1$  on univariate analysis into a multivariate model optimised through the backward step-wise elimination method. The null hypothesis was rejected when  $p$  values were equal to or below 0.05.

## Results

Two hundred and thirty-seven patients were included in the study, including 116 males and 121 females with a median age of 71 years (range 32 to 91 years). Two hundred and nine (88.2%) were of European, 10 (4.2%) of Māori and nine (3.8%) patients were of Pacific Island ethnicity. Fifty-nine (24.9%) cancers were rectal, 21 (8.9%) recto-sigmoid and the remaining 157 (66.2%) colonic. Thirty-six (15.2%) patients required an emergency operation, which was most commonly due to obstruction (Table 1).

The operations performed for primary colorectal cancer were, right hemicolectomy or extended right hemicolectomy ( $n=97$ ); transverse colectomy ( $n=3$ ); left hemicolectomy ( $n=9$ ); anterior resection ( $n=81$ ); Hartmann's procedure ( $n=15$ ); abdominal perineal resection (APR) ( $n=20$ ); subtotal colectomy ( $n=11$ ); proctocolectomy ( $n=2$ ); transanal excision ( $n=1$ ).

**Table 1:** Site, stage and presentation of patients in the cohort.

	<b>Patients N=237 (%)</b>
<b>Age</b>	71 (range 32-91)
<b>Gender M:F</b>	116:121
<b>Comorbidities</b>	
0	156 (65.8)
1	63 (26.6)
2+	18 (7.6)
<b>Site</b>	
Rectum	59 (24.9)
Recto-sigmoid	21 (8.9)
Colon	157 (66.2)
<b>Stage</b>	
I	39 (16.5)
II	90 (38.0)
III	98 (41.4)
IV	10 (4.2)
<b>Presentation</b>	
Emergency, all	36 (15.2)
Obstruction	26 (11.0)
Perforation	10 (4.2)

Figure 1: Sites of recurrences.

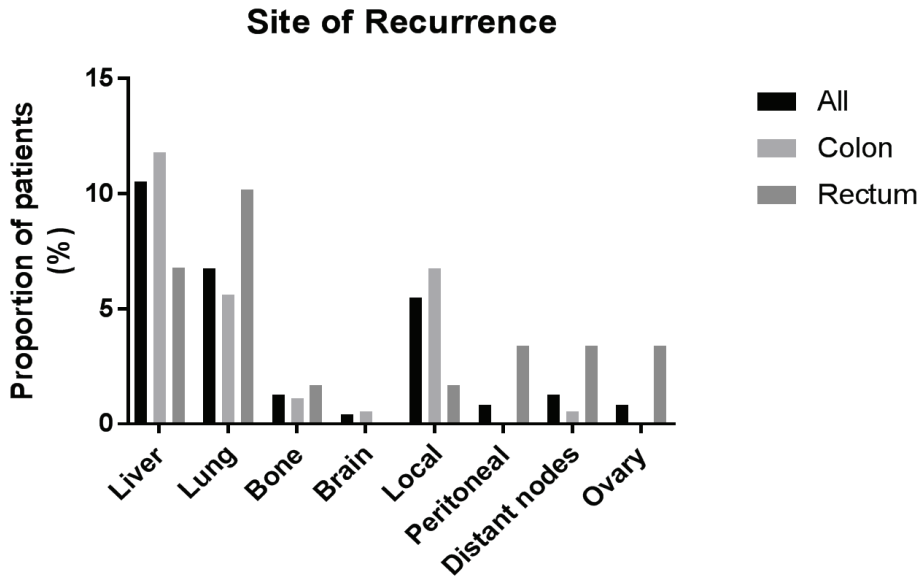
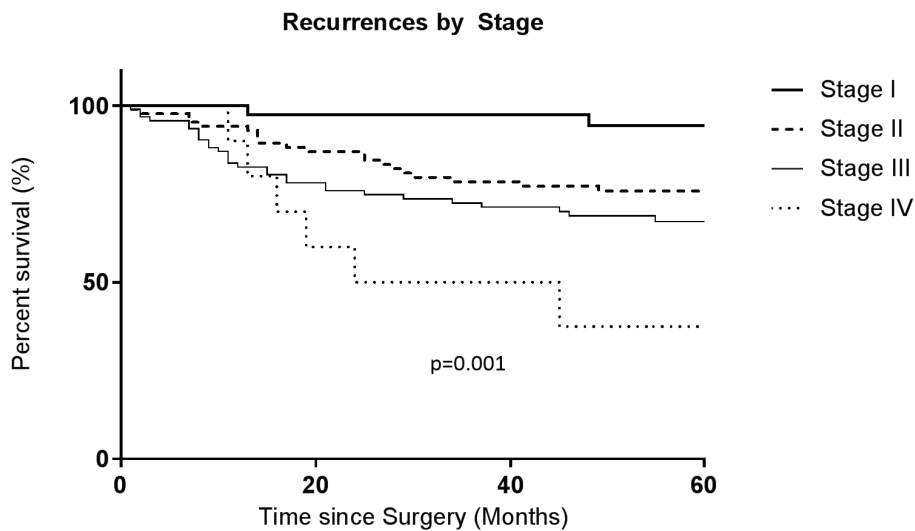


Table 2: Recurrences by stage and site of primary.

Stage recurrence site	Colon	Rectum	Total
Stage I	21	18	39
Local	0 (0)	0 (0)	0 (0)
Distant	0 (0)	2 (11.1)	2 (5.1)
Stage II	73	17	90
Local	8 (10.9)	1 (5.9)	9 (10.0)
Distant	7 (9.59)	4 (23.5)	11 (12.2)
Stage III	77	21	98
Local	6 (7.8)	0 (0)	6 (6.1)
Distant	21 (27.3)	4 (22.2)	25 (25.5)
Stage IV	7	3	10
Local	0 (0)	0 (0)	0 (0)
Distant	5 (71.4)	1 (33.3)	6 (60.0)

Figure 2: Kaplan-Meier Curves for time-to-recurrence by stage.



Of the 10 patients with stage IV disease at presentation, one had an oophorectomy for an ovarian metastasis at the time of initial surgery. The remaining nine had surgery for synchronous metastases following an interval (range 98–215 days) after the initial surgery. Six patients underwent segmental liver resection, two hemi-hepatectomy and one open excision of a lingular mass of the lung.

The median follow-up duration was 61 months (46–81 months) and overall survival rate was 68.6%. In total, 59 (24.9%) patients developed disease recurrence at a median time of 14.0 months. The annual recurrence rates were 10.5% for year one, 7.6% for year two, 3.8% in year three, 2.1% in year four and 0.8% for year five and greater. The median time to local recurrence was 12.5 months (IQR 8.5–26.0) with a similar time for distant recurrence at 14.0 months (IQR 8.0–25.0).

Of 59 patients with rectal cancer, 39 (66.1%) underwent neo-adjuvant therapy. Fifteen (25.4%) of these received short-course radiotherapy and 24 (40.7%) long-course chemo-radiation. Seventy-seven (32.5%) patients of the full cohort received adjuvant chemotherapy: 2.6% for stage I, 18.2% for stage II, 72.7% for stage III and 100% for stage IV.

The most common site of disease recurrence was the liver (n=25) followed by the lung (n=16) and local (n=15) recurrence in colorectal cancer patients combined (Figure 1). The overall recurrence rate was 26.4% for colon and 20.3% for rectal cancer (p=0.35); liver recurrences occurred in 11.8% of colon and 6.8% of rectal cancers (p=0.28); lung recurrences in 5.6% of colon and 10.2% of rectal cancers (p=0.23) and local recurrence occurred in 7.9% of colon cancer and 1.7% of rectal cancer (p=0.09). Recurrences are summarised by stage in Table 2.

In Figure 2, Kaplan-Meier curves reveal recurrences to increase significantly by advancing disease stage (p=0.001). The recurrence rates by stage are 5.1% in stage I, 22.2% in stage II, 31.6% in stage III and 60% in stage IV. On univariate analysis, stage, emergency presentation, histological grade, lymphovascular invasion and perineural invasion were associated with recurrence although following multivariate analysis only disease stage was found to be independently predictive (Table 3).

Recurrences were detected as a result of CEA testing in 24 patients (40.7%), clinical symptoms or signs in 16 patients (27.1%) and routine imaging in 19 patients (32.2%).

**Table 3:** Univariate and multivariate analysis: time-to-recurrence.

	Univariate analysis		Multivariate analysis	
	HR (95% confidence interval)	p value	HR (95% confidence interval)	p value
<b>Stage</b>				
I				
II	4.88 (1.14–20.87)	0.033	4.70 (1.10–20.12)	<b>0.04</b>
III	7.76 (1.76–30.8)	<b>0.006</b>	6.90 (1.64–29.03)	<b>0.008</b>
IV	15.01 (3.02–74.52)	<b>0.001</b>	12.40 (2.45–62.76)	<b>0.002</b>
<b>Emergency</b>	1.84 (1.002–3.36)	<b>0.049</b>	-	
<b>Colonic site</b>	1.48 (0.79–2.79)	0.23	-	
<b>High grade</b>	2.11 (1.17–3.79)	<b>0.013</b>	-	
<b>Lymph vascular invasion</b>	1.79 (1.06–3.02)	<b>0.03</b>	-	
<b>Perineural invasion</b>	2.41 (1.32–4.12)	<b>0.004</b>	1.82 (0.98–3.39)	0.06

## Discussion

In this study we found a recurrence rate of 24.9% at five years, with a median time to recurrence of 14 months and mortality rate of 31.4%; these findings are comparable to the modern international literature.<sup>6–18</sup> Recurrence most commonly occurred in the liver, followed by lung, with a local recurrence rate of 6.3%. Recurrence was strongly linked to disease stage.

Twenty-five out of 59 (42.4%) recurrences were observed in the first year following surgery and 43/59 (72.9%) within the first two years, with annual recurrence rates decreasing sharply thereafter. That the majority of recurrences occur within the first two years post-operatively is reflected in several guidelines, which recommend increased frequency of follow-up clinic appointments within the first two to three years, such as those of the American Cancer Society, National Comprehensive Cancer Network and European Society for Medical Oncology.<sup>19–21</sup> Studies with longer formal follow-up programmes have demonstrated low recurrence rates beyond five years also and this includes Seo et al's study of 4,023 patients that revealed 36 (0.9%) recurrences occurred beyond five years.<sup>17</sup>

Our results are consistent with others in demonstrating the liver as the most common site of disease recurrence for rectal and colonic primaries combined.<sup>9,11,12,14,22,23</sup> Recurrences in the lung were relatively more common for rectal primaries compared with colonic, occurring in 10.2% and 5.6% respectively, although this difference was not statistically significant ( $p=0.23$ ). This pattern is frequently attributed to systemic venous drainage of rectal cancers via the pelvic veins.<sup>24</sup> Although much less common, we found other sites of disease recurrence to include bone, brain, distant lymph nodes, peritoneum and ovary. While we did not observe any recurrences in the spleen, this has also been reported previously, albeit infrequently.<sup>25</sup>

We found recurrence rates to range from 5.1% to 60% in stages I to IV and multivariate analysis identified disease stage as a strong independent predictor of recurrence, with a greater than four-fold increase for stage II, six-fold for stage III and 12-fold for stage IV when compared to stage I (Table

2). Pathological features including histological grade, lymphovascular invasion and perineural invasion were not identified as independent predictors of time-to-recurrence in this study, perhaps due to a relatively small sample, as these tumour characteristics have been shown elsewhere to independently predict poor prognosis and are considered high-risk features of stage II CRC when selecting patients for adjuvant chemotherapy.<sup>19–21</sup>

Routine post-operative surveillance is carried out with the aim of earlier detection of disease recurrence and with it to maximise the chance of curative treatment and improve survival. While it was beyond the remit of this study to evaluate the treatment and survival in patients subsequent to the development of recurrence, five-year survival rates of 40% have been reported following surgery for metastatic recurrence involving the liver with similar outcomes being reported for the lung.<sup>26</sup> In our series, CEA measurement lead to more detection than CT surveillance and overall 73% of recurrences were detected by these surveillance investigations.

The all-cause mortality rate in this cohort of 31.4% compares favourably to rates of approximately 40% reported historically in New Zealand and suggests a continuing trend of improving outcome.<sup>3,18,27</sup> Data from the SEER database reveals a five-year mortality of 35.1%, although this is not limited to patients undergoing surgery with curative intent.<sup>28</sup>

The proportion of patients receiving adjuvant therapy in this cohort, 32.5%, falls short of the 40% reported by Buchwald et al, who have demonstrated a steady increase in the use of adjuvant therapy at their tertiary centre between 1993 to 2009.<sup>29</sup> The proportion of stage III colon cancer patients receiving adjuvant chemotherapy was 58.4% in this cohort, which is very similar to 59% reported in the PIPER project report. Likewise, 34.7% of patients with non-metastatic rectal cancer in this cohort compared with 36% in the PIPER project report received adjuvant chemotherapy.<sup>30</sup> For rectal cancer, 66.1% of patients received some form of neo-adjuvant therapy, which falls between the national average of 52% reported in the PIPER project report and 82% achieved in the 2009 cohort reported

by Buchwald et al.<sup>29,30</sup> While the figures presented in this cohort are in concordance with the national average, there is still room for improvement in this regard.

We report a very low rate of local recurrence following rectal cancer surgery of 1.7%, which compares well against modern international studies, where rates of 2.4–10% are frequently reported.<sup>15</sup> Rectal cancer surgery at the unit is performed exclusively by surgeons with subspecialist training and may go towards explaining the low local recurrence rates and indeed the one case of local recurrence was in a patient that needed an APR and declined surgery for 15 months. This also reflects a large improvement from rates in excess of 20% reported in the literature prior to the introduction of total mesorectal excision, adjuvant therapies, multidisciplinary team discussion and surgical subspecialisation.<sup>27,31</sup>

The authors acknowledge that the current study has limitations. An assessment of compliance with post-operative follow-up protocol, including completion of follow-up,

would be useful in order to evaluate the risk of bias, which is inherent in retrospective studies. Additionally, the outcomes presented here are those of a single hospital and may not be representative of New Zealand in general and, as shown in the PIPER project report, variations in practice and outcomes do exist across the country.

The outcomes reported in this study are encouraging and may reflect advances in colorectal cancer care, including the multidisciplinary team model, increasing use of adjuvant therapy, surgical specialisation and protocolled surveillance and follow-up.

## Conclusion

While New Zealand outcomes in colorectal cancer have historically compared unfavourably against international standards, the outcomes observed in this cohort reflect improvement. However, ongoing quality improvement to further reduce mortality and recurrence remains an important health priority for this group of patients.

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### Competing interests:

Dr Gunawardene reports grants from Wellington Surgical Research Trust, Phil & Teds, outside the submitted work. Dr Larsen reports grants from Wellington Medical Research Foundation, Lotteries Health Research, University of Otago Research Grant, outside the submitted work.

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# The American opioid death epidemic—lessons for New Zealand?

Paul L Morrow

## ABSTRACT

The US is currently in the grips of an epidemic of opioid drug deaths. The pattern has shifted from prescription opioids to illicit fentanyl in most recent years. In New Zealand there has been concern about prescription opioid drugs, although we have not seen the rapid increase in mortality that has been observed in the US. It is not clear whether we will follow the American pattern, but there may be lessons we can learn from the American experience and develop appropriate surveillance for this potentially significant public health problem.

For anyone who follows the US media or watches the American medical scene, it is not news that America is currently in the grips of an unprecedented epidemic of deaths due to opioid drugs. Recently, the US surgeon general released an extensive report on the problem of drug and alcohol addiction in the US,<sup>1</sup> and the National League of Cities/National Association of Counties issued a joint report calling for action.<sup>2</sup> The issue receives frequent coverage in major national newspapers such as the Washington Post and New York Times, and is the subject of innumerable investigations and stories in local print and electronic media. By 2015 the number of fatal overdoses in the US had quadrupled over 1999 rates, with 63.1% (33,091 of a total 52,404) of drug deaths involving opioids.<sup>3</sup> Although official 2016 data is not yet available, the New York Times estimates that there will likely be a 19% increase over 2015 figures, based on a review of local medical examiner and health department data from across the country.<sup>4</sup>

CDC data shows that overdoses involving commonly prescribed natural and semisynthetic opioids and methadone paralleled the general rise in opioid deaths from 2000 to 2010, when a resurgence of heroin was associated with an increase in the slope of the rise of opioid overdoses. This was followed by another increase in the slope

associated with the appearance of synthetic opioids, notably fentanyl and its analogues in 2013.<sup>5</sup> Although it can be difficult to determine the source of the drugs in fatal overdoses, it would appear that fentanyl and its analogues are coming largely from non-pharmaceutical sources used to cut or substitute for heroin, or in the illicit manufacture of pharmaceutical 'look-alikes' sold on the street.<sup>4,6,7</sup> Thus, what initially was considered by many to be primarily a problem driven by prescription medication abuse, is shifting to an 'illicit' pattern, although it is difficult, if not impossible, to disentangle the two. Prescription drug look-alikes sold on the street tend to blur that distinction, and the nature of opioid addiction is such that dependent individuals may switch from prescription to illicit sources depending upon ease of access, which may account for the re-emergence of heroin. Furthermore, the pattern of the opioid drug death epidemic has not been uniform across the US, with certain states hit harder than others, some of which may be accounted for by differing sources of drug. Indeed, heroin use has been shown to follow market source patterns, such as the black tar variety seen in San Francisco versus the powdered form in Philadelphia.<sup>8</sup> The latter may be more easily cut with powdered fentanyl, accounting for some of the drug

mortality differences seen in the two cities.<sup>4</sup> The epidemic of opioid/opiate drugs deaths in the US has been greatest in the eastern northern and southern states parallel to and along the Appalachian mountain chain.<sup>9</sup> In Cuyahoga County (greater Cleveland), Ohio, one of the hardest hit states, drug deaths climbed from 250 in 2006 to 370 in 2015 mostly due to heroin on a background of other opioids (predominantly oxycodone with recent addition of fentanyl).<sup>10</sup> Deaths occurred predominantly in males (71%, county population 47.6%) and in the 30–44 and 45–60 age groups (35% and 36% respectively). Fifty-five percent (55%) were suburban (non-urban). Highest attained level of education was high school diploma or less in 70%. Seventy-five percent (75%) were white (64% of county population).

Opioids are of course available worldwide. In a 2015 study, Martins et al<sup>11</sup> suggest that “[t]here has been a substantial increase in drug overdose incidence and prevalence in several countries worldwide over the past decade, contributing to both increased costs and mortality”. Opioid use more than doubled worldwide between 2001–03 and 2011–13, but in an uneven distribution with Canada, Northern Europe and Australia showing similar patterns to that in the US,<sup>12</sup> indicating that patterns of prescription opioid utilisation in these parts of world are similar to those seen in the US during the early stages of the American opioid death epidemic.

It is not entirely clear whether mortality trends in Australasia will necessarily follow the same pattern as in America. According to coronial data, there were 4,102 opioid-related deaths in Australia between 2007 and 2011, about 500 to 600 per annum with a peak of 685 in 2009. In this series, heroin was most frequently reported, with methadone and oxycodone second and third.<sup>13</sup> Tse<sup>14</sup> at the Department of Forensic Medicine, Newcastle, NSW, reported on 81 fentanyl-related deaths between 2010 and 2014. During this period he observed a steady annual increase from one case in 2010 to 38 cases in 2014, mirroring an increase in volume of fentanyl prescriptions in Australia over the same period. A significant majority (79%) of the Newcastle cases injected fentanyl extracted from a patch, suggesting that illicit use was following national prescribing patterns.

In New Zealand it has been estimated that there were 9,142 chronic opioid drug users in 2010 of whom half were not receiving opioid substitution therapy.<sup>15</sup> Based on data from the 2012/2013 New Zealand Health Survey, McFadden<sup>16</sup> estimated that approximately 29,200 persons used opioid or sedative drugs in New Zealand. Between 2009 and 2013, the years for which most recent data are available from Ministry of Health Statistics, there were 200 deaths in New Zealand attributed to narcotic or psychedelic drug poisoning, either of accidental (181 cases) or undetermined (19 cases) intent. Presumably, most of these are opioid related. Between 35 and 47 deaths were reported each year with the peak in 2012 and nadir in 2010.<sup>17</sup> No unequivocal trend was apparent. Among the 200 deaths, 124 (62%) were male, 155 (77.5%) were New Zealand European and 42 (21%) were Māori. Peak age group was in the 40’s (28.5%), followed by the 50’s (25%) and 30’s (24.5%).

As noted, the initial phases of the American rise in opioid deaths appeared to be associated with increased use of prescription opioids and methadone, over a longstanding baseline of illicit drug mortality. Therefore, it was generally held that a significant contributory factor was physician opioid prescribing practice, especially for chronic non-cancer pain. It was considered that this led both to the creation of opioid dependence and addiction, as well as to increasing the availability of prescription medications that might be diverted to the illicit market. Consequently, efforts to change prescribing patterns were initiated. In Staten Island, New York, for example, intensive public health measures including targeted educational programmes for general practitioners and emergency room providers on appropriate guidelines for effective pain management, and opioid prescription appeared to lower mortality.<sup>18</sup> Likewise, an opioid utilisation programme instituted by Massachusetts Blue Cross Blue Shield insurance programme was shown to be effective in reducing opioid prescriptions.<sup>19</sup> Here in New Zealand there have been similar efforts. For example, a campaign at Capital and Coast District Health Board demonstrated a 24% overall decrease in prescriptions for oxycodone. As part of this programme the largest

oxycodone primary care prescribers were identified, and a pharmacist facilitator specifically supported their practices. The programme included campaign posters, education forums and peer review groups. Multidisciplinary pain management education sessions were held for primary health providers. A similar programme was run for secondary care practitioners.<sup>20</sup> Thus, the significance of physician prescribing patterns and appropriate management of pain has been recognised.

Another aspect of the drug death epidemic in the US that may be of relevance to New Zealand is the resurgence of heroin and other illicit opioids in response to changing physician prescribing practices. Acceleration in the US mortality rate since 2013 has been particularly associated with the appearance of the illicit synthetic opioids fentanyl and its analogues,<sup>5</sup> which significantly increase the lethality of illicit drug preparations.<sup>7</sup> In Cuyahoga County, for example, a 64% increase in total overdose deaths from 2015 to 2016 was associated with a 324% increase in fentanyl.<sup>10</sup> This latter phenomenon has not been apparent in New Zealand so far, although drug mortality data over the past two or three years are not yet available. Unless anecdotal observations and reporting by emergency departments or forensic pathologists who perform the autopsies in overdose cases are made, we may not know we have a trend until it is well underway.

The medical practice environments may be similar in the US and New Zealand, at least in terms of pain management and opioid prescription patterns, but patterns of illicit drug distribution may be quite different. The US shares a long land border with Mexico, a major source of US heroin and over which illicit drugs may be easily imported despite best law enforcement efforts. Reportedly, the primary source of illicit fentanyl in the US is manufactured in China and ordered over the Internet or imported through Canada,<sup>7</sup> which shares an even longer and less closely guarded border than that with Mexico. New Zealand, on the other hand, is an island nation with more easily defended borders, at least as far as illicit drug importation may be concerned. Furthermore, law enforcement measures and techniques may differ between the two nations. Thus, it is not clear whether New Zealand will inevitably follow the American pattern.

On the other hand, there is illicit use of opioid drugs in New Zealand, and opioid deaths are seen. Opioid drug misuse appears to be increasing worldwide, and therefore New Zealand is at risk for an opioid drug death epidemic, whether on the American scale or not. A particular challenge in regard to this is data: how will we know, and how soon will we know, if such an epidemic is developing? Will we miss an opportunity to take early action?

In New Zealand, drug overdose deaths fall under the jurisdiction of the coroner, who ultimately reports cause of death to Births Deaths and Marriages, a process that takes several years from time of death to published statistics. Thus, there are not yet publicly available statistics on opioid overdose deaths for 2014, 2015 or 2016, the same period in which the illicit fentanyl component of the American drug epidemic made its appearance. Individual coroners and pathologists and their consulting toxicology laboratory (ESR) may become aware of an emerging problem, but there is no formal mechanism other than the coronial inquest channel to report their suspicions. In the US, local Medical Examiners and Coroners (ME/C) may provide data to various authorities, and have begun to coordinate with groups responsible for aspects of this public health threat, and at least one model online reporting system has been proposed.<sup>21</sup> Coordination with the state prescription drug monitoring programme has proven useful in Virginia,<sup>22</sup> and in Maryland ME/C data linked to GPS data has been used to coordinate local response to an outbreak of fentanyl-related deaths.<sup>23</sup> The creation of a rapid reporting system, including data from coroners and pathologists, emergency departments and St Johns, on suspected drug overdose deaths in New Zealand might serve as an “early warning” system in order to coordinate a response plan to a developing opioid death epidemic.

In summary, the current epidemic of opioid deaths in the US may be a warning to New Zealand. Although we are not currently experiencing the same rate of opioid deaths as in the US, there are deaths due to opioid drugs. Some of the factors in the American epidemic, such as physician prescribing patterns and the clinical management of pain, are relevant, while others, such as the flood of illicit fentanyl, are not currently

in play. Already action has been taken regarding opioid prescription patterns and pain management. On the other hand, our death reporting system may be inadequate to warn us in a timely fashion of a sudden rise in opioid deaths, or of the introduction

of new deadly illicit opioids into our illicit drug use scene. It would behoove the New Zealand medical profession to take a leadership role in surveillance of this potentially significant public health problem.

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**Competing interests:**

Nil.

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# A buzz in the ear!

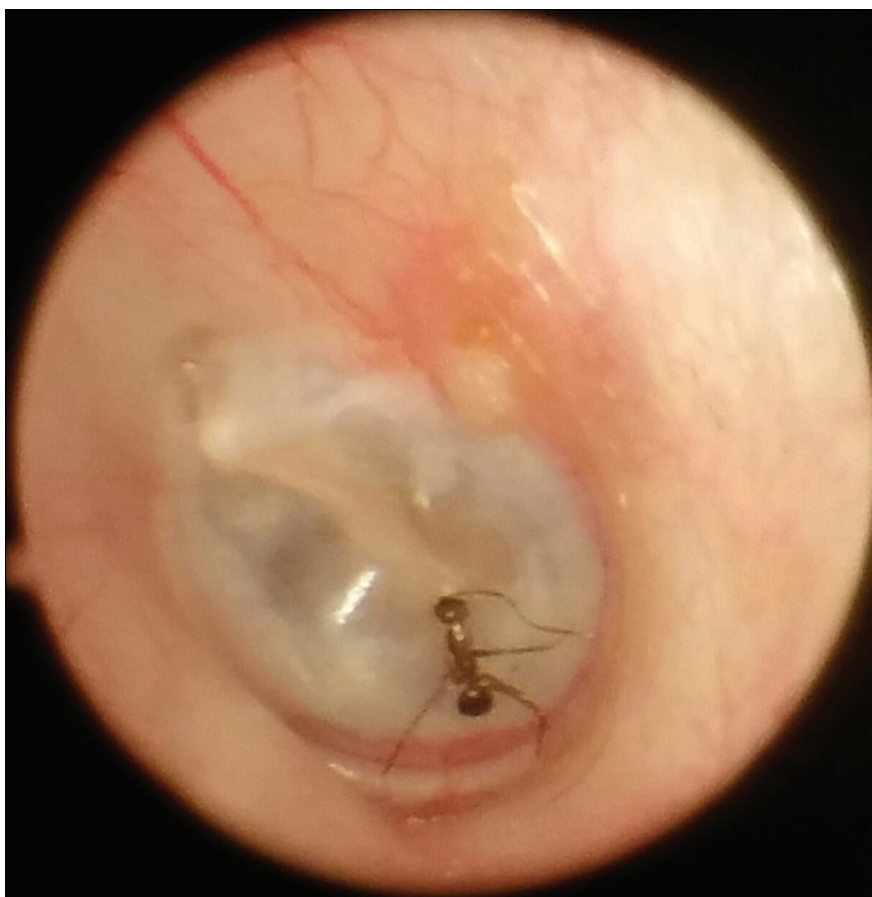
Satvinder Singh Bakshi

**A** 23 year-old girl presented with complaints of a crawling sensation in the ear for three hours. She had been sleeping on the floor when suddenly she felt an insect enter her ear followed by a crawling sensation. On examination a live ant was seen over the tympanic membrane (Figure 1). The ant was removed by irrigating the ear with warm saline. The tympanic membrane was intact and the patient had no further complaints. The most common ear foreign bodies include beads, plastic toys, pebbles and insects. The external auditory canal narrows at the bony cartilaginous junction. Foreign bodies can become impacted at this point, increasing the difficulty of removal. Most cases may be asymptomatic, especially in children, and the foreign body may be detected incidentally. Other patients may present with pain, irritation, hearing loss or a sense of ear fullness.

The removal of the foreign body depends on the size and nature of foreign body and the experience of the physician. Options for removal include water irrigation, forceps removal and suction catheters. Live insects can be killed rapidly by instilling alcohol, 2% lidocaine, betadine paint and diluted hydrogen peroxide or mineral oil into the ear canal, however this is to be avoided in patients with perforation of tympanic membrane. Adequate visualisation, appropriate equipment, a cooperative patient and a skilled physician are the keys to successful foreign body removal.

Multiple foreign bodies are common, especially in small children and mentally challenged adults. Therefore all other orifices of the head should be inspected in these patients.

**Figure 1:** Endoscopic view of the external auditory canal showing the ant over the tympanic membrane.





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**Competing interests:**

Nil.

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# Gaming: a 21<sup>st</sup> century variant of seated immobility thromboembolism

Irene Braithwaite, Philippa Shirtcliffe, Richard Jurevics, Richard Beasley

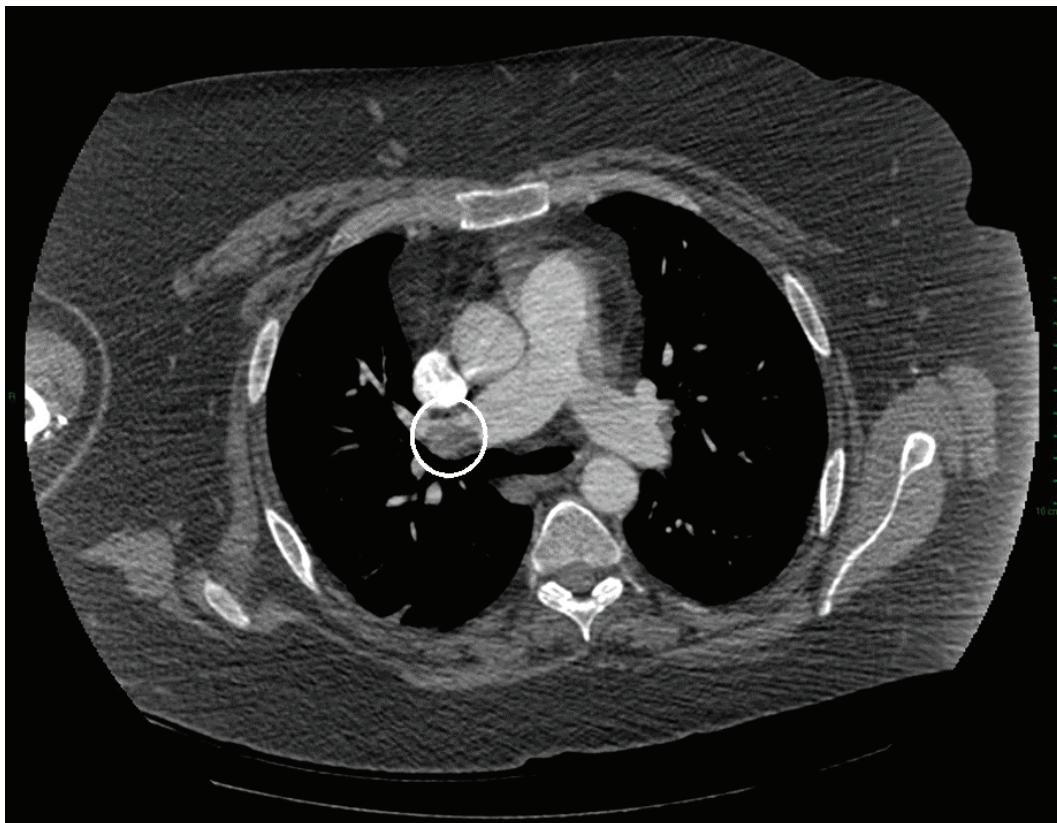
**R**ecognition of prolonged seated immobility as a risk factor for venous thromboembolism (VTE) has important clinical implications, as this may lead to a diagnosis of provoked rather than idiopathic venous VTE. We describe the case of a man who developed VTE after prolonged online computer gaming.

## Case report

A 44-year-old man presented to hospital with a two-week history of progressive left leg swelling and discomfort. Five days before presentation, he developed increasing breathlessness and right pleuritic chest pain. He

was referred after a community ultrasound showed an extensive left femoral vein thrombosis. On examination his weight was 156 kg, heart rate 90 beats per minute, oxygen saturation 95% on room air, BP 127/78, chest was clear to auscultation and his left leg was markedly swollen. There was no right heart strain on the ECG, the hs-troponin T was <5ng/L (N=0 to 13) and pro-BNP 16pmol/L (N=0 to 34). A CTPA showed a near-completely occlusive thrombus at the bifurcation of the right main pulmonary artery, extending into the lobar artery and segmental arteries in the right upper lobe (Figure 1) and right subpleural pulmonary infarction.

**Figure 1:** CTPA, axial image, shows near-completely occlusive thrombus (circled) at the bifurcation of the right main pulmonary.



With respect to possible causes of the VTE, there was no personal or family history of this, and no recent surgery, illness or long-distance travel. A thrombophilia screen completed on cessation of warfarin was negative. He smoked 20 cigarettes per day and had a BMI of 48.4kg/m<sup>2</sup> despite previous gastric bypass surgery. Medications included escitalopram 20mg and amitriptyline 300mg nocte for depression. Specific questioning identified that his office-based work involved sitting for up to five hours at a time for most of his eight to 12 hour shifts. His main hobby was online gaming and three days prior to the onset of symptoms he was 'online' continuously for a 36-hour period, sitting for up to 12 hours at a desk without getting up. The longest period he had ever done this was 44 hours continuously. He also enjoyed "binge watching" television, eg, a box set of 24 episodes in one sitting, while in a Lay-Z-boy chair. While recognising the multi-factorial causation of VTE, we considered that the main risk factor was his repeated episodes of prolonged seated immobility.

He was treated for a provoked VTE, with a six-month course of warfarin with initial bridging low molecular weight heparin. Following this he was prescribed aspirin. He was advised about smoking cessation, weight loss and to avoid prolonged seated immobility (eg, setting a timer for one hour periods at work, avoiding prolonged TV watching sessions). At follow up, he had reduced his gaming sessions to 24 hours. Four years later he has not re-presented with VTE.

## Discussion

The role of prolonged seated immobility as a risk factor for VTE was first recognised in 1940 with a report of people

developing fatal pulmonary embolism following prolonged periods of sitting in deck chairs in air-raid shelters during the London blitz in World War II.<sup>1</sup> The role of prolonged seated immobility associated with long-distance air and car travel was then recognised.<sup>2</sup> Subsequently, prolonged seated immobility working at a computer was recognised as an important risk factor for VTE,<sup>3,4</sup> (also called 'e-thrombosis'<sup>5</sup>) and now gaming has been recognised as the latest variant of the sedentary 21<sup>st</sup> century lifestyle which increases the risk of VTE.<sup>6-10</sup> This case further demonstrates the extraordinarily long periods a person may sit without getting up,<sup>6,7</sup> and also the different work and recreational situations in which prolonged seated immobility may occur in an individual.

We do acknowledge the multi-causal nature of venous thrombosis and that there were a number of risk factors in this man. While the mechanism is unclear, there is a recognised association between antidepressant use and increased risk of VTE.<sup>11</sup> Obesity is also a moderate risk factor for VTE<sup>12</sup> and it is well recognised that it can interact with other risk factors in VTE development and recurrence.<sup>13</sup> Thus this case also highlights the fact that VTE is a disease that often involves more than one risk factor.

We propose that the term seated immobility thromboembolism (SIT) is used to encompass all cases of VTE in which prolonged seated immobility is a provoking factor. We suggest that recognition of SIT may lead to a diagnosis of provoked rather than idiopathic VTE, which would influence the duration of anticoagulant therapy<sup>14</sup> and recommendations for lifestyle changes to reduce the risk of recurrence.

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### Competing interests:

Dr Braithwaite reports grants from Health Research Council of New Zealand, grants from Health Research Council of New Zealand, from null, during the conduct of the study. Dr Beasley reports grants from Health Research Council of NZ outside the submitted work.

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# Playground drinking fountains in 17 local government areas: survey methods and results

George Thomson, Nick Wilson

## ABSTRACT

Appropriate public access to water is an increasing concern, and to further explore field observation methods for assessing such access, we aimed to survey drinking fountains in playgrounds across many local government areas. We systematically collected data (including photographs) of drinking fountains in randomly selected public playgrounds in 17 local government areas (TLAs) in New Zealand. The time for playground surveys was always less than 15 minutes. We found only one of the 17 TLAs had working drinking fountains in all the playgrounds sampled, and 11 working fountains in all 54 playgrounds (20%). Three had metal discolouration within 1cm of the nozzle. The systematic observation method was relatively quick, making it suitable for local officials and health promoters.

The supply of drinking water is a civic and public health issue, due to the need to re-normalise water use and protect against heatwave effects.<sup>1</sup> Advocates and policymakers need accurate information on the prevalence, distribution and quality of water supplies accessible by the public, so as to better plan, maintain and advocate for them. Outdoor field observation can provide objective data on the presence and functionality of assets and infrastructure.<sup>2</sup>

While there is a literature on drinking water availability and standards in schools<sup>4,3</sup> there is less on the prevalence of drinking fountains in urban public places.<sup>4-6</sup> We found two objective evaluations of the availability of fountains in non-school (public) locations; a 2013 study of parks in a North Carolina city<sup>7</sup> and a previous 2014 New Zealand study in one city.<sup>8</sup> Neither study reported on the time taken to access an area.

We aimed to survey fountains in playgrounds across a larger number of local government areas, so as to better determine their distribution and functionality, and

to further develop the methods used. Our methodological aims included simplicity of data collection, methods that could be used with a minimum of training, the ability to check the data, testing the method across many jurisdictions and a short field data collection time per site.

## Methods

The study involved systematic outdoor field observation by solo observers. We used a convenience sample of 17 contiguous Territorial Local Authorities (TLAs) in the lower North Island of New Zealand (see Table 1). Within each TLA a random selection of playgrounds was made from a denominator list generated from information from TLA websites or by identifying playgrounds from Google Maps. We sampled either 10% of the playgrounds or two per TLA, whichever figure was higher. Field observations were conducted between December 2016 and May 2017 by observers who walked around the perimeter of each playground area, surveying the area within 100 metres of the play equipment.

Each fountain found was photographed for each of the following aspects:

- From a distance (20–30m) and from between 5–10m, to provide locational and other context to the fountain.
- Close up to show any features such as side taps or attached basins for facilitating drinking by pet dogs.
- A close photograph (side-on and level with the drinking nozzle) of the water stream to allow assessment of the water flow.
- A close photograph of the nozzle where the water leaves the fountain—to assess for discolouration (eg, from biofilm).

- A photo of the playground or park name, or a nearby street name.

All of the taps were tested. Notes were taken on any features of the fountains or their context that might affect the fountains' usage.

## Results

All playground surveys took less than 15 minutes to conduct per site. The analysis of photographs and notes for the features of interest and other relevant aspects of fountain context and design (see Figure 1), took approximately 10 minutes per fountain.

**Figure 1:** Poorly maintained fountain with grass growing in the drainage sink.



Figure 2: Example of fountain with side tap.



Only 20% (11) of the 54 playgrounds had a working drinking fountain within 100 metres of the playground equipment. Two other playgrounds had non-functioning fountains, although one of these had a side tap working. Eight of the TLAs sampled (47%) had working fountains in only some (9/33) of the playgrounds sampled, and another eight TLAs had *none* in the playgrounds sampled (Table 1).

Of the 11 working fountains, nine (82%) had side taps for filling water bottles or bowls (Figure 2). The water stream in Figure

1 was the most marginal for drinking. The working fountains appeared to be well maintained, albeit with the exception of grass growing out of one (Figures 1 and 2). Three fountains had discolouration on the metal surround (eg, from biofilm) within 1cm of the nozzle of the fountain (Figure 3).

Fountains varied in the type of nozzle surround used (Figures 2 and 3). The nature and extent of such surrounds appeared to affect the ability to clean around the nozzle, to allow sunlight exposure and to increase the likelihood of discolouration.

**Figure 3:** Example of discolouration (probably from biofilm) around a drinking fountain nozzle.**Table 1:** Results for the 17 local government areas in the lower North Island of New Zealand.

Local government area (CC: City Council; DC: District Council)	Playgrounds with or without working drinking fountains within 100m of playground equipment		Total (N)
	No fountain (N)	Working fountain present (N)	
Carterton DC	1	1	2
Central Hawkes Bay DC	1	1	2
Gisborne DC	2	0	2
Hastings DC	2	1	3
Horowhenua DC	2	0	2
Kapiti Coast DC	0	2	2
Lower Hutt CC	6	0	6
Manawatu DC	1	1	2
Masterton DC	1	1	2
Napier CC	2	0	2
Palmerston North CC	4	1	5
Porirua CC	3	1	4
South Wairarapa DC	2	0	2
Tararua DC	2	0	2
Upper Hutt CC	3	0	3
Wairoa DC	2	0	2
Wellington CC	9	2	11
<b>Total</b>	<b>43</b>	<b>11</b>	<b>54</b>



## Discussion

While access to sites across a number of jurisdictions can take time and resources, within jurisdictions this method could be a simple and easy way for local health promoters and local government workers to assess fountains (and other health-related assets such as signage). Such inspections could be part of a parks and playground audit.<sup>9</sup> Photographs provide data that can be checked and interpreted by multiple observers.

There appears to be a need in New Zealand (as in other countries) for the systematic requirement and provision of drinking water in public places.<sup>10</sup> Civic authorities need strong procedures in place for the monitoring, maintenance, repair and replacement of drinking fountains and the water provided, reinforced by required national standards.<sup>11</sup>

Further research could use similar methods to examine the presence, quality and operation of more drinking fountains per jurisdiction, across larger numbers of local government areas and larger cities, and to compare drinking water access between countries. While children's playgrounds seem a relative priority area for the presence of drinking fountains, other relatively high

priority sites for such research include parks with sports fields, public squares and popular beach locations.

The limitations to this research include the lack of testing to see if Google Street View (GSV) could supplement or replace the field data collection. While GSV is increasingly being used for field research in the built environment,<sup>12</sup> our preliminary work<sup>13</sup> found it of limited value with this type of fountain (and so we did not evaluate it formally in this study). The utility of GSV was limited because some fountains were located relatively deep in parks and away from roads. But when the 'footpath view' function of GSV is more widely available in such parks, then this tool could be studied more formally for this purpose.

Further limitations include the lack of research into the types of people who use fountains, the nature of fountain use, the causes of the nozzle surround discolouration and the microbiological quality of the water. Further research could look at possible algal growth and degradation of the nozzle metal components as possible causes of the observed discolouration.

**Further information** on the methods and results from this study is available in an online report (<http://www.otago.ac.nz/wellington/otago660055.pdf>).

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**Competing interests:**

Nil.

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# Reply to Dr Bendavid's letter: mesh hernia repair is not perfect but it is currently the best treatment available

Steven Kelly

**D**r Bendavid's letter<sup>1</sup> implies that no hernias should be repaired with mesh. He hasn't defined in his statements the difference between ventral and groin hernia. I agree that if a hernia can be repaired reliably without mesh then they should be. The best example of this is a small ventral hernia such as umbilical hernia, which can be sutured with success. However, the case for mesh in the repair of medium to large ventral abdominal wall hernia (fascial defects larger than 3cm) is very strong. The suture repair of these is almost futile without the use of tissue reinforcement.

Dr Bendavid's claim that the Shouldice open inguinal hernia repair is superior to mesh repair is not supported by the best available level 1 evidence in the literature. In 2012, the Cochrane collaboration published a systematic review of 16 randomised control trials with a total of 2,566 hernias comparing Shouldice repair to other mesh and non-mesh inguinal hernia repair. They found that the Odds ratio for Shouldice hernia recurrence was 3.8 compared to mesh repair. Importantly there was no difference between the techniques in chronic pain, complications and hospital stay.<sup>2</sup> Only one of the 16 studies were performed in a specialised hernia centre. The rest were performed by general surgeons who performed many different operations, which included hernia repair. This situation most closely represents the real-world environment.

So why are the Shouldice clinic reported results better than the randomised control trials? There are two main explanations. Firstly, the results may be better because

the surgeons are specialist hernia surgeons as compared to the real-world environment of general surgeons. The other explanation may be case series publication bias. It is well known that randomised control trials are the best form of unbiased evidence.

In regard to the surgical removal of hernia mesh for complications, this should be performed by an expert herniologists of which there are a number in New Zealand.<sup>3</sup> Although this surgery is difficult and complex, the results in many cases are successful.

Dr Bendavid claims that there are 120,000 people in the US each year who develop chronic pain after mesh inguinal hernia repair. Given the results of the randomised control trials there would be an equivalent number of patients with chronic pain even if the operations had been performed with Shouldice technique. The Shouldice technique is a four-layer darn of stainless steel wire. This conceptually is a stainless-steel mesh that is formed in situ. This would explain why there is no difference in chronic pain with the randomised trials.

It is an unfortunate fact that chronic pain develops post-operatively in 10–50% of patients after many common operations. These operations include mastectomy, cardiac surgery, hysterectomy, joint replacement, back surgery and even after minor surgery.<sup>4</sup>

To progress hernia surgery in the future and improve patient outcomes we need more high-quality randomised control trials with a focus on patient-centred outcomes. Relying on case series and anecdote will not progress surgery.

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**Competing interests:**

Nil.

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## Romosozumab or alendronate for fracture prevention in women with osteoporosis

Romosozumab is a monoclonal antibody that binds to and inhibits sclerostin, increases bone formation and decreases bone resorption.

Over 4,000 postmenopausal women with osteoporosis and a high risk of fracture were enrolled in this study. They were randomly assigned in a 1:1 ratio to receive monthly subcutaneous romosozumab (210mg) or weekly oral alendronate (70mg) in a blinded fashion for 12 months, followed by open-label alendronate in both groups. The primary end points were the incidence of vertebral and non-vertebral fractures at 24 months. The researchers report a 48% lower risk of new vertebral fractures and a 19% lower risk of non-vertebral fractures in those receiving the combined treatments. Adverse effects were balanced between the two groups.

It was concluded that in postmenopausal women with osteoporosis who were at high risk for fracture, romosozumab treatment for 12 months followed by alendronate resulted in a significantly lower risk of fracture than alendronate alone.

*N Engl J Med* 2017; 377:1417–27

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## Effect of azithromycin on asthma exacerbations and quality of life in adults with persistent uncontrolled asthma

Adults with uncontrolled persistent asthma despite maintenance treatment require additional therapy. Since macrolide antibiotics can be used to treat persistent asthma, these researchers aimed to assess the efficacy and safety of oral azithromycin as add-on therapy in patients with uncontrolled persistent asthma on medium-to-high dose inhaled corticosteroids plus a long-acting bronchodilator.

Four hundred and twenty appropriate patients were randomised to receive 500mg of azithromycin or placebo three times per week for 48 weeks. Those in the azithromycin cohort were reported to have improved quality of life and fewer asthma exacerbations. They also had fewer respiratory infections. The treatment was well tolerated.

The study was noted in an editorial with interest. These commentators suggest that a future trial using a non-antibiotic macrolide would be warranted.

*Lancet* 2017; 390:659–68 & 629–630

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## Benzodiazepines and risk of all-cause mortality in adults

What is the risk of all-cause mortality associated with benzodiazepine initiation in adults?

This question is reviewed in this retrospective cohort study. The researchers examined data concerning patients who were treated with benzodiazepines and those who were not so treated. The study involved over 1.25 million patients between 2004 and 2013.

This study found either no increase or at most a minor increase in risk of all-cause mortality associated with benzodiazepine initiation. If a detrimental effect exists, it is likely to be much smaller than previously reported and to have uncertain clinical relevance.

*BMJ* 2017; 358:j2941

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# Tuberculosis and Public Health

February 1918



Returned servicemen with tuberculosis, on the Repatriation Department's farm at Tauherenikau, Wairarapa. Making New Zealand :Negatives and prints from the Making New Zealand Centennial collection. Ref: PAColl-8550-30. Alexander Turnbull Library, Wellington, New Zealand. /records/22786277

Until recently statistics had shown that cancer was increasing in New Zealand and tuberculosis diminishing, but as the result of the war mainly, the unpleasant fact is now revealed that tuberculosis is again in the ascendant. The official figures for 1916 are 850, and 1,521 for the year 1917, the increase being largely due to cases among returned soldiers. Up to 31<sup>st</sup> January of this year 15,623 soldiers had returned to New Zealand. The number of phthisis cases among these men, including cases which had developed after the arrival of the men in New Zealand, was 593, and of these 492 had developed the disease before return to this country, and the others—that is, about 20 per cent.—had contracted it apparently after arrival. Forty-two deaths

had occurred up to the date mentioned. The belief that once prevailed that native-born New Zealanders are not so liable to phthisis as persons born in the United Kingdom cannot be upheld. It is true that the death-rate from tuberculosis in England and Wales is 1.34, and for New Zealand .76; but, on the other hand of 544 persons certified as having died from phthisis in New Zealand in 1914, 341 were born in New Zealand, and 92 were born elsewhere but had lived in this country for fifteen years or more. It is not surprising that the hardships of war should give rise to an increase of tuberculosis, and we should also expect an increased incidence among returned soldiers as compared with the civilian population.

The matter is one for the action of the Health Department, and it will not permit of delay. It also concerns very much the medical profession, whose business likewise it is to see that phthisical soldiers do not become a menace to the rest of the population. These soldiers deserve, and will get, the best treatment that is available. The Minister of Public Health announces that one or more sanatoria are to be built. We hope they will be erected in the cheap, simple, and efficient style that has been found satisfactory in other countries. The consensus of opinion is that consumptive sanatoria have by no means fulfilled the high hopes that they once inspired, and that they are a greater benefit to the community at large than to the patients.

In the general scheme of coping with consumption, housing is of first importance, and it is a painful thought that here in this new land slum conditions are present in the larger towns, and nothing very perceptible is done to abate the evil. We are geographically more favourably situated than most parts of Europe. Invercargill is in about the same latitude in the south as Lausanne is in the north; similarly, Wellington corresponds to Barcelona, and Christchurch to Marseilles. New Zealand has one of the lowest, if not the very lowest death-rate in the world, being slightly above 9 per 1,000. The rates for other countries are: United States 13.6, England 14, Scotland 15.5, Germany 15, France 19.6, Ceylon 32, and Australia 10.5.

Our pride in this, however, should be limited by consideration of the fact that our birth-rate is much below what it should be, and that the death-rate in the garden cities in England is only 6 per 1,000. This latter fact shows what could be done by a proper

system of town-planning in New Zealand. How much time is given to town-planning and kindred subjects in our Parliament by the noisy cits and sleepy squires who make our laws? In a recent pamphlet the Chief Justice has shown how advantages that our country may well be called the Fortunate Isles. He writes: "Without physical strength we can do nothing, and yet what are we doing as citizens of this great nation to build up our physical strength and our public health?" We have done something, but a great deal more is required.

Smokeless cities in New Zealand should be easily possible by transmitting the great water-power of the country into electricity. "In America they are making hard concrete roads far quicker than we make them, far more lasting, more efficient, and at a great saving in expense." The abolition of slums and these other questions are of primary importance in the prevention of tuberculosis and other diseases, and they come well within the province of the medical profession. With questions of morality we are told now by many of our leaders that we have no concern, and if that be so we are no better than veterinarians, and no doctor should consider that page of the New Zealand Official Year Book for 1915, where it is shown that out of a total number in 1915 of 3,870 legitimate first births within one year after marriage, 2,023 of these births were the fruit of marriages of a duration less than nine months, and during the same year there were 1,137 illegitimate births in addition. In face of these figures all we have to do, according to the medical authorities who say we have no concern with morality, is to bury our heads, ostrich-like, in the sand.

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