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SUMMARIES

Child abuse in Australian camps—whose business, and who should speak out?
Ian Hassall, Scott Metcalfe, Alison Blaiklock
The Australian government has interned asylum seekers including children in camps on Nauru and elsewhere. The Australian Human Rights Commission, medical profession organisations and others have condemned the practice because it is abusive of children. Physical, emotional and sexual abuse and self-harm of children has been reported. Yet Australian law now bars doctors in the camps from speaking out. Doctors in New Zealand, as anywhere, are bound by our ethical code to oppose practices such as the harm to children and others in the camps; and we oppose their doctors being gagged.

After the legalisation of cannabis: the Cannabis Incorporated Society (CIS) regulatory model for recreational cannabis in New Zealand
Chris Wilkins
There is a growing appetite around the world for cannabis law reform, but this desire for change does not need to involve profit-driven commercial markets like we have for alcohol and tobacco. We propose the establishment of not-for-profit Cannabis Incorporated Societies (CIS) who will sell approved cannabis products to members only. CIS will have a number of statutory health objectives including providing information on the health risks of cannabis use, increasing awareness of local drug treatment and counselling services, preventing cannabis use by minors, and minimising cannabis dependency. CIS will only sell approved healthier cannabis products such as edibles or cannabis suitable for vaporising, with a maximum THC level and minimum CBD level. The government will be the sole producer of cannabis products and will only sell to licensed CIS. The tax revenue from these sales will be used to fund drug treatment, counselling and other health services.

New Zealand Health Survey 2012/13: characteristics of medicinal cannabis users
Megan J Pledger, Greg Martin, Jacqueline Cumming
This paper uses the New Zealand Health Survey 2012/13 to estimate the proportion of the New Zealand population aged 15 years and older who report that they use cannabis to treat a medical condition. It compares people who use cannabis for medicinal reasons with people who use cannabis solely for non-medicinal reasons across demographic factors to give an idea of the characteristics of medicinal cannabis users. It looks at what medical conditions medicinal users of cannabis report that they use cannabis to treat, and compares how likely medicinal and non-medicinal users of cannabis report physical harm, and harm to their mental health, from using cannabis.

Influence of law changes affecting synthetic cannabinoid availability and frequency of hospital presentations: 4-year national survey
Paul Glue, Julie Courts, Andrew Gray, Tess Patterson
Synthetic cannabinoids (SC) such as Kronic and K2 are associated with a range of toxicities that often lead to hospital assessment. There were three law changes in New Zealand between 2011 and 2014 that affected availability of these drugs. On each occasion, these led to substantial decreases in hospital presentations associated with SC use.
**Achalasia: a 13-year, single-centre experience comparing endoscopic balloon dilatation and laparoscopic Heller myotomy**

Alexander Huelsen, Ramadan Oumer, Anna Ashcroft, Ross H Roberts, Grant N Coulter, Steven J Kelly, Murray L Barclay

Achalasia is a rare non-curable disorder of the oesophagus causing severe difficulties with swallowing. The two most established long-term treatment options are a surgical intervention (laparoscopic Heller myotomy) and an endoscopic method (balloon dilatation). This study aimed to compare the outcome of both therapies and the risk of serious complications in a single-centre series. Such data may be useful in guiding and supporting decision-making in local practice. The results of this study revealed that both therapies were safe and appeared to be similarly effective treatments for achalasia. Furthermore, the results were also comparable to international outcome and safety data.

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**Outcomes of surgical ablation for atrial fibrillation: a 10-year experience**

Andrew J Borrie, Brecon H Wademan

This audit examined surgical treatment of atrial fibrillation (AF) and the outcomes of this. It covered the last 10 years in Wellington and showed that it has been effective in reducing the re-occurrence of AF and has had a low rate of complications. This compares well to data published internationally.

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**The costs of elective and emergency abdominal aortic aneurysm repair: a comparative single centre study**

Kevin Niall Peek, Manar Khashram, J Elisabeth Wells, Justin A Roake

Over a 3-year period at a tertiary hospital in the South Island, 217 patients presented with a large abdominal aortic aneurysm (AAA) for an arranged repair or with a rupture. On average, repairing a rupture AAA was ~11,000 NZD more expensive than arranged AAA repairs. The costs difference was primarily due to blood products used and when excluding patients that died within 4 days from rupture, the costs difference was ~17,000 NZD. Bearing this in mind, the costs incurred treating rupture AAA can be used to support the case for an AAA national screening program; a well-established and cost-effective program.

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**Clinical utility and outcome analysis of faecal calprotectin in Hawkes Bay District Health Board**

Wayne Bai, Thomas Boswell

IBS (irritable bowel syndrome) is a common condition affecting 10-20% of patients in the Western World and it is reported to be one of the top 10 reasons for general practitioner (GP) visits. To differentiate patients with IBS from inflammatory bowel disease (IBD) patients and also to detect flare of disease in known IBD patients makes up a significant proportion of workload in the gastroenterology outpatients workload. Colonoscopy is the investigation in both these clinical situations, but it is resource intensive and it has its procedural risks. Hence, the use of faecal calprotectin (FCP) to effectively screen for patients with IBS from active IBD patients and to identify those with a flare of disease in known IBD patients is an effective way to reduce demand for colonoscopy. This local study at Hawkes Bay District Health Board (HBDHB) confirms its effectiveness and the results are consistent with international studies.
The diagnostic role of ventilation/perfusion scans versus computed tomography pulmonary angiography in obstetric patients investigated for pulmonary embolism at Wellington Hospital from 2010 to 2012
Sally Easther, Fali Langdana, Dushyant Maharaj, Peter Abels, Richard Beasley, James Entwisle

Pulmonary embolism is a life threatening condition that can prove fatal to pregnant women. It accounts for 10% of all maternal deaths. There is no current consensus in New Zealand regarding investigations of this condition. We propose a simple clinical algorithm that could help streamline the management of this condition in pregnancy.

Pertussis control strategies: A consistent approach for New Zealand. Synopsis of Ministry of Health Workshop, April 2015
Mary Nowlan, Nikki Turner, Tomasz Kiedrzynski, Diana Murfitt, Nina Sawicki

Pertussis, commonly known as whooping cough, is a very serious and highly contagious disease, particularly for infants too young to be immunised. New Zealand experiences pertussis epidemics every 3 to 5 years, during which hundreds of infants are hospitalised who often require intensive care. The Ministry of Health held a workshop in 2015 that reviewed the current pertussis control strategies and immunisation coverage. The workshop concluded that although great improvements continue to be made in immunisation coverage, further work is required to encourage uptake of whooping cough vaccine during pregnancy to protect newborn babies and for infants, especially Māori and the most deprived, to be vaccinated on time.
Child abuse in Australian camps—whose business, and who should speak out?

Ian Hassall, Scott Metcalfe, Alison Blaiklock

As doctors we are often faced with trying to fix damage done to our patients by other people, whether it be car crash survivors, or the multiple victims of the tobacco industry. We might also get involved in stemming the damage at its source through road safety or tobacco control activism. But what if the harm being done is by government? This is the issue faced by Australian doctors concerned for the well-being of children in the Australian prison camps on Nauru and elsewhere.

Conditions in these camps, and the very fact of being interned there for an indeterminate period, are bad for the health and well-being of children. This being so, do you as a loyal citizen of a country with a democratically-elected government accept that this is their business and not yours to question, and is perhaps too complex for you to understand? If you feel strongly enough about it, how is your dissent to be expressed? In an open society it is possible to complain directly to government or to the public through the news and social media in the hope that change can be brought about. Doctors and their organisations have done just this.

Or you can go further and encourage a boycott of medical staffing of the camps, believing that anything less makes you complicit in the government’s ill-treatment of these children. The alternative view is that taking up the medical care of children in the camps might at least mitigate some of the harm, and, despite gagging clauses in contracts and draconian punishments threatened in the law, you can be a witness and whistle-blower in time. Further, by working in the camps you might limit the chances of an even more brutal regimen being imposed by people with fewer scruples than your own.

Many Australians have spoken out. In 2014, an Australian Human Rights Commission inquiry condemned conditions in the camps.1

“Children are exposed to danger by their close confinement with adults who suffer high levels of mental illness. Thirty percent of adults detained with children have moderate to severe mental illness. The numerous reported incidents of assaults, sexual assaults and self-harm involving children indicate the danger of the detention environment.” (p.30)

A survey of general and community paediatricians reported over 80% of respondents agreed with a statement by the Australian Medical Association that mandatory detention of children constitutes child abuse.2

The Royal Australasian College of Physicians has issued a strong statement that concludes:3

“Held [locked] detention presents an extreme and unacceptable risk to children’s development and mental health, especially for unaccompanied children.”

The Australian government’s response was to introduce a law that forbids doctors and others from reporting publicly on what happens in the camps.4 Reporting child abuse, while mandatory in Australia, became an offence in the camps. In June 2015, Dr John-Paul Sanggaran, and 40 others who had worked in detention centres, sent an open letter to the Australian Prime Minister protesting at the gagging provisions.4,5

On 3 July, 40 senior New Zealand child health workers sent a letter to the Australian Prime Minister and Leader of the
Opposition as follows:6

“We, the undersigned are senior New Zealand paediatricians and child health workers experienced in the care of children and their protection from ill-treatment. We are concerned for the children detained by the Australian Commonwealth Government in the immigration detention centres on Nauru and elsewhere.

The circumstances in which there is no prospect of appeal or release are inevitably detrimental to many of the children's development and mental health because of the impact on them of the depression, anger and desperation of their parents and other adults in the camps. Further, it is the world-wide experience that children in institutional circumstances such as these are unsafe. Some will suffer abuse.

The secrecy provisions in Part 6 of the Australian Border Force Bill 2015 which came into effect on 1 July will exacerbate these effects by severely limiting public oversight of conditions in the camps. In this respect, we support the open letter to yourself of 1 July, 2015 from our Australian colleagues, Dr John-Paul Sanggaran and forty others.

Our plea is that your Government should take steps to mitigate the plight of the children in its custody on Nauru and elsewhere. We respectfully suggest these initial actions:

• Provision for detainees of a realistic hope of resolution through processing as refugees. Without this, children are in the position of hostages in a policy aimed at deterrence which has some of the features of collective punishment, condemned in human rights instruments such as the Geneva Convention.

• Permitting public oversight of the conditions and effects on children of life in the camps through removal of the tight secrecy provisions in the Australian Border Force Bill and provision for independent monitoring and review.”

No reply to this letter has been received.

When doctors speak up, we risk the ire of the authorities. We may attract unwanted attention, not only to ourselves but also to our colleagues. We have to decide carefully if and when it is worth it, or whether ‘behind the scenes' advocacy and negotiation or silent appeasement might be in the best interests of those we serve.

Modern medical, and other health practice, is much more than prescribing pills for individuals. We find ourselves with a wider professional duty to act and speak for patients and populations, current and future, here and elsewhere.7 Doctors' professional roles include not only clinical care and the care of populations within day-to-day practice, but also support for wider movements for social change. This aligns with the long tradition linking medicine with politics and political action (Virchow's “Medicine is a social science, and politics is nothing but medicine at a larger scale”8,9), where having effective public health policies/interventions has often needed some political action.9

As doctors, we are in a strong position to advocate. Health professionals are citizens; as citizens we have no less right to comment than others. We are privileged by our education, access to power, and a professionally compassionate role in society. We can assimilate complex evidence and advocate for health, making us potential leaders.10

The New Zealand Medical Association's landmark 2011 statement on health equity11 mandates doctors to talk about what determines health. The longstanding ethic to “First do no harm” extends, we believe, to speaking out against policies and practices that harm—whether by damaging child health, widening health gaps, escalating climate risk, or ignoring harm. Such ideals are embodied in professional codes and mores. For instance, the NZMA’s Role of the Doctor consensus statement12 and Code of Ethics13 (see Appendix) have doctors as scientists, leaders and public health advocates, with health advocacy a formal role in itself.

Despite opposition,14 doctors need, we believe, to become politically active, to speak out when things are wrong.7,15 If we don’t, divergent views will certainly be promoted within that vacuum—to the detriment of public health and the public good. Doctors have spoken out
before on a range of issues, often against the tide: tobacco; nuclear war; fenoterol; climate change. We have made a real difference—the International Physicians for the Prevention of Nuclear War was even awarded the Nobel Peace Prize—and we must continue.

In the early days of the discovery of child abuse, a common and understandable response of many doctors to the question of whether or not to report to the authorities was that, if they did, they would lose any chance of influencing the family and protecting the child. As we went on to learn that intervention by individual doctors in the clinical setting was ineffective, that position became untenable. It amounted to complicity. Our situation in relation to an abusive government is somewhat similar. We may argue that we are better able to make changes by remaining friends, but in a government that is clearly hell-bent on “stopping the boats” by whatever means at its disposal, this seems unlikely.

Does public “ outing” of the government do any better? There is no guarantee that it will, but the hope is that the majority of Australians are of course decent people and also voters; and that in time these two facts, together with our efforts as a profession and the efforts of others in drawing attention to the plight of asylum seeker children, will end the serious abuse that is taking place in immigration detention. We are reminded of the famous saying of the sage Hillel:\textsuperscript{16}

“If I am not for myself, then who will be for me? And if I am only for myself, then what am I? And if not now, when?”

To which can be added, “And if not me, who?”

Appendix: Some statements by the New Zealand Medical Association on doctors’ roles in public health advocacy

From the NZMA Role of the Doctor consensus statement\textsuperscript{12}


(our emphasis)

Key statements

- Doctors accept their ethical responsibilities to act in the best interests of their patients, \textit{and the population as a whole}, and undertake this in a caring, compassionate, competent, and trustworthy manner.
- Doctors are \textit{advocates for improved population health} and \textit{health equity for all people}.
- Doctors are committed to the spirit and principles of The Treaty of Waitangi, particularly as it relates to the attainment of health equity for Māori.

Doctors as scientists

Doctors have the ability to access, interpret and assimilate new knowledge critically, have strong intellectual skills and grasp of scientific principles, and are capable of effectively managing uncertainty, ambiguity and complexity. They have the capacity to work out solutions from first principles when patterns do not fit, and the ability to work outside guidelines when circumstances demand.

Doctors use scientific tools and techniques, including audit and research, to develop new knowledge.

Doctors as leaders

Doctors have a key role in providing higher level \textit{sector leadership, including in leading and facilitating change}.

Doctors as health advocates

When appropriate, doctors use their influence to advocate for increased resources to improve health outcomes for their patients and populations.
Doctors have a role in the promotion of population health, including ongoing efforts to achieve health equity. Some doctors will take an increased focus on the health of the population through formal roles in health education or promotion, service improvement, public health and/or health advocacy. This commitment is to the health of all New Zealanders, but it exists alongside a professional responsibility for the health of individuals and communities throughout the world.

From the NZMA Code of Ethics
https://www.nzma.org.nz/publications/code-of-ethics
(our emphasis)

Principles
All medical practitioners, including those who may not be engaged directly in clinical practice, will acknowledge and accept the following Principles of Ethical Behaviour:

10. Accept a responsibility to assist in the protection and improvement of the health of the community.

11. Accept a responsibility to advocate for adequate resourcing of medical services and assist in maximising equitable access to them across the community.

Recommendations
Doctors in a just and caring society

68. Doctors should accept a share of the profession’s responsibility toward society in matters relating to the health and safety of the public, health promotion and education, and legislation affecting the health or well being of the community.

69. Doctors have a role in ongoing efforts to achieve health equity. This includes working collaboratively with public health and other colleagues to shape services and programmes that address health inequities and the broader social and environmental factors that influence health and well being.

70. While doctors have a primary responsibility to individual patients, they have a concurrent responsibility to all other patients and the community. Doctors therefore have an ethical responsibility to manage available resources equitably and efficiently. Wherever possible, doctors should use their influence to advocate for appropriate resources to improve health outcomes for their patients and populations.

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REFERENCES:


8. Rudolf Virchow (1821-1902): “Medicine is a social science, and politics is nothing else but medicine on a large scale. Medicine, as a social science, as the science of human beings, has the obligation to point out problems and to attempt their theoretical solution: the politician, the practical anthropologist, must find the means for their actual solution. The physicians are the natural attorneys of the poor, and social problems fall to a large extent within their jurisdiction.” Virchow R. Die medizinische Reform, 2. In: Sigerist HE. Medicine and Human Welfare, 1941. Quote available from Medical Anthropology Wiki at: https://medanth.wikispaces.com/Rudolf+C.+Virchow


EDITORIAL

Cannabis in New Zealand: smoking gun or medicalised smokescreen?

Giles Newton-Howes, Sam McBride

Cannabis is an internationally restricted drug, although the level of restriction varies from minimal restraints, as found in countries such as the Netherlands, to a prohibitionist approach, such as occurs at a US federal level and in New Zealand. Ownership of even small amounts of cannabis can lead to criminal conviction, a situation leading to difficulty in clearly understanding cannabis use in New Zealand. Despite the criminal liability associated with cannabis, its use in New Zealand is widespread. The reported annual prevalence of use of 10.2% is high by international standards and cannabis remains the most widely-used illicit drug in New Zealand. The high level of cannabis use indicates a degree of acceptance in society, poorly reflected in New Zealand’s current prohibitionist stance.

Recently there has been increased social pressure to review how cannabis is regulated in New Zealand, with calls for both decriminalisation and medicalisation of cannabis use. In this issue of the New Zealand Medical Journal (NZMJ), two papers explore these differing stances and provide valuable local evidence.

Smoking out the users

One of the significant difficulties in understanding cannabis and its use in New Zealand is the fact it is criminalised, making objective research difficult. Further, this status makes interpretation of the reasons for use for individuals and researchers challenging. Clearly, cannabinoids as a chemical class have novel neurological effects, and current treatments in psychiatry and neurology are far from fully effective at ameliorating symptoms. For this reason, investigating the possibility of cannabinoids as an alternate pharmacotherapy for many possible diagnoses is intuitively sensible. To date, such development has led to one cannabis derivative being brought to market in New Zealand, Naboximols (marketed as Sativex), a spray containing 2.7mg of delta-9-tetrahydracannabinol (THC) and 2.5mg cannabidiol (CBD) for the management of spasticity in multiple sclerosis. It is, however, heavily regulated and expensive, limiting its cost effectiveness.

Juxtaposing this is the clear evidence that cannabinoids are a drug class of abuse, leading to a variety of drug-use disorders. Increased rates of use associated with the availability of medicinal cannabis and more permissive attitudes may increase rates of cannabis-use disorders. Further, cannabis is well-evidenced to increase rates of psychosis and other psychosocial problems. Pledger and colleagues reflect that users of cannabis report use as problematic in this issue of the NZMJ, noting mental health concerns. These factors make identifying the prevalence of cannabis use in New Zealand difficult.

Pledger and colleagues identify a point prevalence of current cannabis use of greater than 11%, with a further greater than 30% of the examined population reporting use, but not in the last year. As they state, these are “admitted use” rates and will be an underreporting of actual use. This suggests two of every five New Zealand adults will report cannabis use if asked, and one in nine report current use. Interestingly, the population of users studied, representative of New Zealand, roughly divide themselves into “medicinal users” and “recreational users”, with rates of “medicinal use” increasing dramatically in middle adulthood. Notably, two thirds of “medicinal users” also endorse recreational
EDITORIAL

use of cannabis. It is much harder to estimate the use of synthetic cannabinoids; however, the paper by Glue and colleagues implies a significant reduction in use related to regulation. These prevalence figures cannot be ignored—it is clear the current prohibitionist approach does little to prevent cannabis use in New Zealand, although the regulatory measures related to synthetic cannabis suggest a harm reduction approaches have some impact.

A smoking gun?

As Pledger and colleagues point out, recently in New Zealand permission was granted for the use of cannabis to treat a medical condition. Alex Renton was admitted to hospital with a neurological condition in 2015. His family successfully advocated for access to cannabis products, a case widely reported and accompanied by considerable support from the public. Since then, media coverage has continued its focus on the use of cannabis in terminal or extreme conditions, often associated with public figures. This portrayal has led to the acceptance of the notion of “medical cannabis”, although this term is poorly defined and often left to the subjective view of the end user to decide upon, as is the case in Pledger’s study in this issue. This is in stark contrast to the use of other controlled drugs, where formal objective criteria are used to identify problematic use and medical use is closely monitored by medical practitioners who prescribe to manage symptoms or conditions. While cases like this are newsworthy, they do not reflect the majority of cases in the literature where cannabis is investigated for medical purposes.

It is notable that the medical evidence to support medicinal use of cannabis is weak. A systematic meta-analysis and review of cannabis and cannabinoid drugs was recently reported in the Journal of the American Medical Association. It concluded that there was moderate-quality evidence to support the use of cannabinoids for treatment of chronic pain and spasticity. There was low-quality evidence to support cannabinoids being useful in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders and Tourette syndrome. The American Academy of Neurology also undertook a systematic review of medical marijuana in selected disorders, concluding that medicinal cannabis showed promise in spasticity, central pain and spasms, and reducing bladder voids associated with multiple sclerosis. There was limited evidence in treating other neurological conditions, including levodopa-induced dyskinesia in patients with Parkinson’s disease, non-chorea-related symptoms of Huntington’s disease, Tourette syndrome, cervical dystonia, and epilepsy. A 2012 Cochrane Review into the use cannabinoids for epilepsy concluded, “No reliable conclusions can be drawn at present regarding the efficacy of cannabinoids as a treatment for epilepsy”. Similarly, a review published in The New England Journal of Medicine investigating cannabinoids in the treatment of epilepsy noted:

"...preclinical and preliminary data from studies in humans suggest that cannabidiol and ∆9THC may be effective in in the treatment of some patients with epilepsy. However, current data from studies in humans is limited and no conclusions can be drawn". Further, the study noted that the role of medical cannabis in epilepsy could follow similar enthusiasms for vitamins and nutritional supplements for which “the science never caught up with the hype”.

Unlike the medical evidence for the use of cannabis, there is good evidence of the harms associate with cannabis use. Population-based studies show increased rates of psychosis associated with cannabis use, and individuals identify mental and physical harms in the Pledger paper found in this issue. There is likely to be carcinogenic effects related to the smoking of cannabis, and there are other weaker reports of physical harms. These reports, although not providing a face to put on the front of a news article, are important and recommend the need for caution in the use of cannabis for a loosely identified “medical reason”. It is notable that despite questions specifically asking “medicinal cannabis” users of the reasons for use, the majority described their reasons as not related to depression, anxiety or pain in the Pledger study.
The smoke screen of “medicinal cannabis”

Bearing in mind the weak evidence of effectiveness of cannabis as a medicine, the lack of regulation compared to other medical products and elsewhere, the uncertainty of active drug dose in botanical cannabis, and the significant risks associated with smoking, the most common mechanism of cannabis use, it is surprising there is the capacity to enable doctors to use botanical cannabis at all as a medicine in New Zealand. This is not to say that cannabinoids may not be valuable for some patients for some symptoms, nor that many of these problems cannot be overcome. There is also evidence in the paper by Glue and colleagues in this issue that legislation has a place in the regulation of cannabinoids and this can lead to a harm reduction approach. Regulation at law has been a common mechanism to manage the population-wide use of psychoactive substances. The success of broad smoking regulation to reduce rates of tobacco smoking is an example of this. The failure to implement the primary recommendations related to alcohol use and the lack of impact in relation to associated harms is the converse. Considering the evidence from the two papers related to cannabis in this issue, the broader literature, insights from regulation (or a lack thereof) of other psychoactive substances and public interest, the time to review the prohibition of cannabis appears appropriate.

On an individual level, the most common conditions for which patients are prescribed cannabis is pain, insomnia and anxiety. Patients are predominantly young and male. There is speculation that patients may use cannabis simply because it makes them feel better.11 The demographic outlined by Pledger and colleagues would mirror these findings. They reinforce the sense that the effects of cannabis across a range of disorders may be a non-specific anxiolytic effect. In many regards the aims of recreational users appear not dissimilar to those seeking cannabis for medical reasons. The increasing rate of identifying use as “medicinal cannabis” with increasing age found by Pledger may reflect changing motivations through the life course. Again, here at an individual level there appears to be a “smokescreen” of medicalisation that may not reflect the reasons for use. The lack of high quality qualitative data limits our understanding in this regard.

Notwithstanding this, chasing a medicalised access route to cannabis use seems premature in New Zealand. The high prevalence rates and demographic patterns of use found by Pledger identifies a need to change current policy. The regulative successes evidenced by Glue for synthetic cannabis suggests a path forward. While further work is undertaken to consider the most appropriate mechanism to use cannabinoids medically, a social discussion around the decriminalisation of cannabis can occur, without the distraction of “medical cannabis”. This pathway forward recognises the high use of cannabis in New Zealand, the social harms of a prohibitionist legislative approach, the needs for further regulatory development and medical evidence prior to cannabis becoming a prescription drug. This is a public debate the medical profession needs to be actively engaged in, bearing in mind the role of medicine in the public arena.

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REFERENCES:


Outcomes of surgical ablation for atrial fibrillation: a 10-year experience

Andrew J Borrie, Brecon H Wademan

ABSTRACT

AIM: Surgical ablation for atrial fibrillation has been performed at Wellington hospital for 10 years. This audit aims to evaluate the outcomes from surgical intervention for atrial fibrillation and identify variables affecting clinical results.

METHOD: A retrospective audit of clinical outcomes was performed including all patients who had received surgical intervention for atrial fibrillation from 2004 to 2013.

RESULTS: Forty-seven patients who underwent surgical intervention for atrial fibrillation were identified and reviewed. There were no deaths prior to discharge. At 6 months, 81.4% of patients were in sinus rhythm, this dropped to 58.7% at late follow-up (average of 48 months). Procedure type had a statistically significant effect on outcome. Over 288 patient-years of follow-up, 2 strokes and 7 deaths occurred.

CONCLUSIONS: The surgical treatment of atrial arrhythmias in Wellington hospital is a safe and effective management option, although the antiarrhythmic effects do appear to diminish with time. There were lower rates of mortality and stroke long-term than would be expected with simple anticoagulation. It is important that the formal Cox-Maze procedure lesion set is performed to maximise the surgical interventions effectiveness. Atrial size predicts success, and should be considered in patient selection.

ARTICLE

Atrial fibrillation (AF) is the most common clinically-significant cardiac arrhythmia worldwide, and has a prevalence of about 0.5%. With an aging population, and increasing prevalence of risk factors, the number of adults with AF is expected to continue to increase. AF has significant morbidity, in particular the associated increased risk of thromboembolism (by as much as 5 times) and cardiomyopathy, as well as increased mortality.

Rhythm management options include chemical and electrical cardioversion, but with failure rates of up to 60% and 30% respectively, as well as the potential side effects of long-term antiarrhythmic medication. There has been significant proliferation of surgical options.

The Cox-Maze procedure was originally introduced in 1987 as a cut and sew operation, but since then alternate, less invasive modalities have been developed. Radiofrequency, cryosurgical and microwave ablation have largely replaced the time consuming and surgically-challenging cut and sew Cox-Maze procedure. These alternate modalities are promising, but results can vary depending on the surgeon, technique, patient factors (left atrial size, duration and type of AF) and need for concomitant procedures such as mitral valve replacement. Rates of restoration of sinus rhythm at 6 months vary from 40% to 95%.

Surgical ablation procedures have been performed at Wellington hospital since 2004. This audit reports the 10-year experience in this institute and aims to assess the safety and efficacy of these procedures, and to identify factors which determine successful outcomes.

Methods

Patients were identified from searching the Wellington Cardiothoracic unit electronic database using the terms “Maze”,...
“Cox”, “PVI” and “ablation”. Records from 2004 to 2013 were included. Data were gathered on patients from electronic records, PACS system and hard-copy notes in Wellington, as well as notes requested from peripheral hospitals, GPs and peripheral PACS systems able to be accessed from Wellington hospital.

Operative information was collected regarding age, gender, type of atrial fibrillation (divided into paroxysmal (defined as patients intermittently in AF), and persistent (defined as patients continuously in AF), ablation type (full bi-atrial Maze or pulmonary vein isolation (PVI), operative management of the left atrial appendage, duration of AF, left atrial diameter and complications. Key complications were considered to be death, re-operation, pacemaker, DC cardioversion (DCCV), stroke, requiring re-ablation and perioperative MI.

Outcomes were selected based on large international studies to allow easy comparison. Outcomes were recorded at clinic visits or admissions. Primary outcome was sinus rhythm confirmed on ECG by the patient’s primary cardiologist. Secondary outcomes included therapeutic anticoagulation, and number and type of antiarrhythmic drugs (AADs). These outcomes were recorded at discharge, 3 months, 6 months, 12 months and late follow-up. As such, the nearest follow-up to each time point was taken. A further collection of data was also completed examining long-term clinical outcomes of stroke and death.

Analysis was performed on the entire cohort, as well as subgroup analysis on full Maze and PVI, and stratified by left atrial diameter. Differences between outcomes between groups were evaluated using the Chi-squared test.

Results

After review of the database, 47 patients were identified who underwent the Maze procedure. One died within 30 days of procedure leaving 46 with follow up data. The mean patient age at operation was 64 (range 19-79) and 60% were male. 48% of patients were in Paroxysmal AF, the rest in permanent AF (Table 1). Mean left atrial diameter was 51mm (range 35-79mm). Data on duration of pre-op AF was available in very few patients and the accuracy was compromised by incomplete data. AF duration was therefore not analysed.

All ablation procedures were performed concomitantly with another cardiac operation, most commonly mitral valve replacement (MVR) (Table 2). Radiofrequency was used as the method of ablation in all cases. This was completed with the Medtronic Cardioblate® system, utilising both monopolar and bipolar radiofrequency. The bipolar system uses a dose-response algorithm based on tissue impedance to confirm transmurality.

Patients were selected for ablation based on consultant preference and discussion.

---

**Table 1**: AF Classification and ablation type.

<table>
<thead>
<tr>
<th>AF type</th>
<th>Full Maze</th>
<th>PVI</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent</td>
<td>18</td>
<td>6</td>
<td>24</td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>17</td>
<td>6</td>
<td>23</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>12</td>
<td>47</td>
</tr>
</tbody>
</table>

AF, Atrial fibrillation; PVI, Pulmonary vein isolation

**Table 2**: Comcomittant procedures.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>MVR</td>
<td>18</td>
</tr>
<tr>
<td>MVR TVA</td>
<td>4</td>
</tr>
<tr>
<td>MVR CABG</td>
<td>3</td>
</tr>
<tr>
<td>MVR AVR</td>
<td>1</td>
</tr>
<tr>
<td>MVR AVR (redo)</td>
<td>1</td>
</tr>
<tr>
<td>MV repair</td>
<td>6</td>
</tr>
<tr>
<td>MV repair TVA</td>
<td>2</td>
</tr>
<tr>
<td>MV repair CABG</td>
<td>1</td>
</tr>
<tr>
<td>CABG</td>
<td>9</td>
</tr>
<tr>
<td>AVR</td>
<td>1</td>
</tr>
<tr>
<td>Bentalls</td>
<td>1</td>
</tr>
</tbody>
</table>

MVR, Mitral valve replacement; TVA, Tricuspid valve annuloplasty; CABG, Coronary Artery Bypass Grafting; AVR, Aortic valve replacement; MV repair, mitral valve repair
with the patient. Seventeen patients had mechanical valves inserted, and 21 patients had either a biological valve or a valve repair. In 34 patient's operation notes, the left atrial appendage was clearly stated as ligated. Not all patients had data able to be found at all follow-up points. At discharge and late follow-up, data were found on all 46 patients. At 3 months, 6 months and 12 months, 45, 42 and 40 patients had data available respectively.

Complications
There was one death after discharge within 30 days of operation. The patient was noted to be severely bradycardic and symptomatic post discharge, but declined further medical treatment and subsequently died from complications related to complete heart block. No instances of stroke or myocardial infarction occurred in the post-operative period. 2.2% and 4.3% required renal dialysis and intra-aortic balloon pump post-op, respectively. 4.3% of patients required re-operation for bleeding. 8.7% required pacemaker insertion, and 17% of patients required DC cardioversion within the first 6 months post procedure. 4.3% of patients developed atrial flutter and required ablation for this. Both patients who developed atrial flutter had PVI only.

Assessment of efficacy
Primary outcome
67.4% of patients were in sinus rhythm at discharge, but rates improved to peak at 81.4% at 6 months (Table 3). The number of patients in sinus rhythm then slowly decreased with time, late follow-up (average of 48 months).

Twenty percent of patients in sinus rhythm at late follow-up had AF at some point during follow-up. Of the patients not in sinus rhythm, the vast majority were in atrial fibrillation, with 2 in atrial flutter and 1 with atrial tachycardia. Sinus rhythm at 6 months or 1 year was moderately predictive of future rhythm. Of the patients in sinus rhythm at 6 months, 87.5% remained in sinus rhythm at 1 year. Of the patients in sinus rhythm at 1 year, 75% remained in sinus rhythm long-term.

Secondary outcomes
Anticoagulation was almost entirely with warfarin, 2 patients were on dabigatran and 1 was changed to enoxaparin as they had malignancy and recurrent embolism. From discharge to 3 month follow-up, anticoagulation rate was unchanged (84.8% to 82.7%), this dropped to 65.1% at 6 months, then gradually increased to 73.9% at late follow-up.

Of the patients in sinus rhythm, many remained on anticoagulation. The rate of anticoagulation of patients in sinus rhythm was 72.7% at 3 months, 57.1% at 6 months, 60.7% at 12 months and 62.9% at late follow-up. When patients with other indications for anticoagulation were excluded, 50% of patients in sinus rhythm at both 12 months and late follow-up remained anticoagulated.

Rhythm stabilising medications were commonly prescribed at discharge, predominantly amiodarone. This dropped rapidly over the first 6 months post-surgery. No patient was on 2 rhythm stabilising medications at any point. Most patients remained on some rate control medications during follow-up, with 50–70% on beta-blockers, 20–30% on digoxin and 2–10% on calcium channel blockers.

Long-term follow-up of stroke and mortality included further data, with a total of 288 patient-years, an average of 6.4 years of follow-up per patient. Two late strokes occurred at 5 and 6 years post-op, a rate of stroke of 0.69% per year. One of these was a fatal ischaemic stroke in a patient with ongoing PAF on unintentionally sub therapeutic warfarin. The other was a clinical possible cerebellar stroke with no changes on CT. It was unclear in either case if the left atrial appendage had been ligated. Seven
Patients had late mortality at an average of 82 months (range 40–105 months). Causes were heart failure, haemorrhage, COPD, two cardiac arrests, and two cases of malignancy.

Logistic regression

This was a small audit not powered to find differences between groups, but data were further examined with logistic regression to look for significant differences between groups in a limited fashion.

A variety of ablation procedures were performed, including Cox-Maze III, Cox-Maze IV, unspecified “Maze”, and simple PVI. Patients who received a Maze had higher success in both short- and long-term restoration of sinus rhythm (Table 4). Patients who underwent PVI—as opposed to a Maze procedure—were significantly more likely to be in AF at 3 months (OR 5.26 (95% CI 1.04–26.66) (p=0.045). At other end points, the difference was non-significant.

Patients were also categorised by left atrial diameter, as it is a known predictor of recurrence of AF. Severity of left atrial dilatation inversely correlated with success rates (Table 6). Further statistical analysis was not performed on this subgroup, as this audit was not powered sufficiently.

**Table 4:** Type of rhythm stabilising medications prescribed.

<table>
<thead>
<tr>
<th></th>
<th>Discharge</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
<th>Most recent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone</td>
<td>56.5%</td>
<td>11.1%</td>
<td>4.7%</td>
<td>13.9%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Sotalol</td>
<td>4.3%</td>
<td>4.4%</td>
<td>0.0%</td>
<td>2.8%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Flecanide</td>
<td>0.0%</td>
<td>2.2%</td>
<td>2.3%</td>
<td>0.0%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Total</td>
<td>60.9%</td>
<td>17.8%</td>
<td>7.0%</td>
<td>16.7%</td>
<td>10.9%</td>
</tr>
</tbody>
</table>

**Table 5:** Primary and secondary outcomes with logistic regression by ablation type.

<table>
<thead>
<tr>
<th></th>
<th>Full maze</th>
<th>PVI</th>
<th>P value</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sinus rhythm at</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharge</td>
<td>20 (65%)</td>
<td>9 (75%)</td>
<td>0.66</td>
<td>0.71</td>
<td>0.15–3.4</td>
</tr>
<tr>
<td>3 months</td>
<td>27 (82%)</td>
<td>6 (50%)</td>
<td>0.04*</td>
<td>5.3</td>
<td>1.1–26</td>
</tr>
<tr>
<td>6 months</td>
<td>27 (87%)</td>
<td>8 (67%)</td>
<td>0.06</td>
<td>6.1</td>
<td>0.88–41</td>
</tr>
<tr>
<td>12 months</td>
<td>22 (73%)</td>
<td>6 (60%)</td>
<td>0.40</td>
<td>2.2</td>
<td>0.36–13</td>
</tr>
<tr>
<td>Late follow-up</td>
<td>22 (64%)</td>
<td>5 (42%)</td>
<td>0.08</td>
<td>3.8</td>
<td>0.82–17</td>
</tr>
<tr>
<td><strong>Anticoagulation at</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharge</td>
<td>30 (88%)</td>
<td>9 (75%)</td>
<td>0.72</td>
<td>0.71</td>
<td>0.11–4.7</td>
</tr>
<tr>
<td>3 months</td>
<td>30 (90%)</td>
<td>7 (58%)</td>
<td>0.06</td>
<td>0.19</td>
<td>0.03–1.1</td>
</tr>
<tr>
<td>6 months</td>
<td>21 (68%)</td>
<td>7 (58%)</td>
<td>0.88</td>
<td>0.88</td>
<td>0.17–4.6</td>
</tr>
<tr>
<td>12 months</td>
<td>20 (67%)</td>
<td>7 (70%)</td>
<td>0.77</td>
<td>1.3</td>
<td>0.20–9.0</td>
</tr>
<tr>
<td>Late follow-up</td>
<td>25 (74%)</td>
<td>3 (75%)</td>
<td>0.71</td>
<td>1.4</td>
<td>0.23–8.8</td>
</tr>
</tbody>
</table>

* significant difference

Discussion

This is the first audit of the outcomes of the surgical ablation of AF in Wellington Hospital, and the results show that it is a safe and efficacious procedure.

The demographics of the patients in our audit were very similar to those described in the literature. Meta-analysis average left atrial diameter and age were 55–58mm and 59–65 years respectively. Frequency of PAF, as opposed to persistent AF, varied widely from 4.3–49%, depending on the selection criteria of the trials involved.

The rate of sinus rhythm across all groups was low at discharge, peaking at 6 months, and then gradually reducing in the long term. This trend is well established in the literature and multiple theories exist that may explain this. Initially, the atrium is oedematous and inflamed, and potentially has a lower refractory period, so macro-entry circuits (and therefore
AF) can occur in smaller areas. This can take 2–3 months to settle back to a normal refractory period. An alternative theory is that it takes 3–6 months for lesions to form complete scar tissue that produces a barrier to electrical impulse. Generally, success rates are not considered accurate until the 6 month mark. Significant heterogeneity in success rates exist. Cox’s results with initial and long-term success rates of 95–99% is unsurpassed and relatively unique. Notably, some papers reporting high rates of success were based on phone surveys of patient-reported AF, and may be under reporting AF recurrence. Several meta-analyses have been published, which our results compare favourably to. Rates of sinus rhythm were: at discharge 67–68%, at 6 months 67–90%, at 1 year 75–84%, and long term 64.4%. Only one other audit of the surgical ablation of AF has been completed in New Zealand. This was at Christchurch hospital and was of a similar size and duration of audit. The ablation was also completed with radiofrequency ablation. It reported rates of sinus rhythm of 15% at 6 months, and 18% at long-term follow-up. Our results show significantly higher efficacy and support the use of surgical ablation of AF in New Zealand.

A rate of stroke of 0.69% per year in post-ablation patients compared favourably to patients anticoagulated with either warfarin (1.66–2.2%) or novel oral anticoagulants (1.53–1.7%). Comparison is somewhat complicated, as many patients remained anticoagulated post ablation. Left atrial appendage ligation was not documented in both patients who experienced stroke. This is consistent with research indicating ligation of the left atrial appendage is key in preventing stroke. Higher rates of anticoagulation were present in our study compared to others. International rates of freedom from anticoagulation post ablation varied from 30–59%, depending on concomitant procedure. Other centres have been more proactive in stopping anticoagulation for all patients in sinus rhythm at 3 months. In our series in patients with other indications for anticoagulation excluded half of patients in sinus rhythm remained on warfarin. Presumably this represents concern regarding recurrent or undetected AF. This may not be unreasonable given the variability in rhythm demonstrated. In previous meta-analyses of trials examining valve surgery alone vs valve surgery plus surgical ablation, there was no significant difference in stroke risk. The risk of requiring pacemaker insertion in large meta-analysis varied from 4.3 to 7.7%, comparable to our rate of 8.7%. Reoperation for bleeding was also reported at a similar rate of 4.4%. Rarer complications, such as in-hospital death and stroke, are reported at rates of 2–8% and 1.6–5%, respectively, in other studies. This audit did not have sufficient numbers to fully

Table 6: Primary and secondary outcomes by atrial size.

<table>
<thead>
<tr>
<th>Atrial size</th>
<th>≤50mm</th>
<th>50–61mm</th>
<th>≥61mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus rhythm at Discharge</td>
<td>13 (68%)</td>
<td>8 (67%)</td>
<td>4 (67%)</td>
</tr>
<tr>
<td>3 months</td>
<td>16 (80%)</td>
<td>7 (54%)</td>
<td>4 (67%)</td>
</tr>
<tr>
<td>6 months</td>
<td>17 (89%)</td>
<td>9 (75%)</td>
<td>4 (67%)</td>
</tr>
<tr>
<td>12 months</td>
<td>15 (88%)</td>
<td>6 (50%)</td>
<td>2 (40%)</td>
</tr>
<tr>
<td>Late follow-up</td>
<td>11 (55%)</td>
<td>9 (69%)</td>
<td>2 (29%)</td>
</tr>
<tr>
<td>Anticoagulation at Discharge</td>
<td>16 (80%)</td>
<td>12 (92%)</td>
<td>6 (86%)</td>
</tr>
<tr>
<td>3 months</td>
<td>15 (75%)</td>
<td>12 (92%)</td>
<td>5 (83%)</td>
</tr>
<tr>
<td>6 months</td>
<td>9 (47%)</td>
<td>11 (92%)</td>
<td>4 (77%)</td>
</tr>
<tr>
<td>12 months</td>
<td>10 (59%)</td>
<td>10 (83%)</td>
<td>5 (100%)</td>
</tr>
<tr>
<td>Late follow-up</td>
<td>14 (70%)</td>
<td>11 (85%)</td>
<td>7 (100%)</td>
</tr>
</tbody>
</table>
examine rarer complications, however the absence of these complications in our series is reassuring. Notably, in meta-analysis of studies comparing cardiac surgery with and without ablation, rates of complications, including pacemaker and stroke, were not significantly different.\textsuperscript{13,22}

Some studies have shown that adding ablation to valve surgery resulted in higher survival rate, greater freedom from stroke and cardiac events.\textsuperscript{6}

Maze procedure was only superior to PVI at 3 months, not at other end points. Further research could be useful in this area including patient subgroups, such as AF duration or AF type, which could affect outcome. An enlarged left atrium is a significant risk factor for recurrent AF in the literature,\textsuperscript{6,15} but this audit was not powered to investigate this. Left atrial size should be considered in patient selection. Long duration of AF pre-ablation is also well established as a risk factor, and together these factors imply the importance of early referral and intervention.\textsuperscript{15,21}

This audit reported a high rate of freedom from antiarrhythmic drugs. Rates of freedom from AAD have been reported to vary from 35–83%.\textsuperscript{23,26} In some studies it is unclear how medications were classified. Amiodarone was given by protocol for 3 months for patients with post-operative AF. The increase in prescription at 12 months possibly relates to patients relapsing into AF and a further attempt at rhythm control.

Limitations

This audit was limited by its small size; despite 10 years of data being collected, only 46 patients receiving an ablation procedure were identified. This significantly limited the ability of this audit to examine rarer complications. This was also a highly varied group with multiple different techniques and concomitant procedures, although this does reflect the nature of ablation procedures. The patient group was selected based on consultant preference which limits the generalisability of results. Assessment of outcomes was retrospective, and also based on a single ECG, which could introduce false negatives.

Conclusion

In Wellington Hospital, the surgical ablation of AF has produced comparable results to international standards, and has exceeded previously published success rates in New Zealand. It also has demonstrated a good safety profile. We have identified the importance of performing a formal Cox-Maze lesion set as opposed to pulmonary vein isolation for improved results. Atrial size is also an important factor in success rates and should be considered in patient selection. There were lower rates of mortality and stroke long-term than would be expected with simple anticoagulation. This audit supports the Maze procedure’s continued use and provides a benchmark for future comparison, both within Wellington and to other centres.

Competing interests:
Nil

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REFERENCES:

1. Fuster V, Ryden LE, Cannon DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: A report of the American college of cardiology/American heart association task force on practice guidelines and the European society of cardiology committee for practice guidelines (writing committee to revise the 2001 guidelines for the management of patients with atrial fibrillation); Developed in collaboration with the European heart rhythm association and the heart rhythm society. Circulation. 2006;114:e257-354


12. Sie H, Beukema W, Elvan A, Misier A. Long-Term Results of Irrigated Radiofrequency Modified Maze Procedure in 200 Patients With Concomitant Cardiac Surgery: Six Years Experience


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New Zealand Health Survey 2012/13: characteristics of medicinal cannabis users

Megan J Pledger, Greg Martin, Jacqueline Cumming

ABSTRACT

AIM: To explore the characteristics of medicinal and non-medicinal cannabis users, and the conditions that were treated with cannabis.

METHODS: The data comes from the New Zealand Health Survey 2012/2013, which sampled 13,009 people, aged 15+ years, living in private or non-private dwellings in New Zealand. Participants self-reported cannabis use and were put into groups: 1) non-users; 2) ex-users; 3) last year users—non-medicinal; 4) last-year users—medicinal. Prevalence was reported for the major demographic subgroups; sex, age and ethnicity. Regression models were then used to find associations between demographic characteristics and cannabis use for groups 3 and 4.

RESULTS/CONCLUSIONS: About five percent (4.6%, 95% CI 4.1–5.1) of those aged 15+ report using cannabis medicinally. This use was associated with being male, younger, less well-educated and relatively poor. While Māori have the highest prevalence of medicinal use, European NZ/Others make up 67.9% (95% CI 62.7–72.6) of medicinal users. Reported medicinal use was associated with reported conditions that were typically hard to manage: pain, anxiety/nerves and depression. Medicinal users were more likely to report chronic pain and pain interfering, moderately or more, with housework and other work.

It is currently illegal to cultivate, possess, supply and use cannabis through the Misuse of Drugs Act 1975. However, the Minister of Health is able to approve the medical use of the cannabis plant, although in practice, the decision has been delegated to the Associate Health Minister Hon Peter Dunne. In 2015, the first application was approved for the use of cannabis oil for a case of “status epilepticus”. In the context of this application, Hon Peter Dunne said that this should not be seen as a “significant change in policy”.

In 2010, consent was given for use of the cannabis medicine, Sativex, in New Zealand. This medicine is an extract of the cannabis plant and is a standardised product with known levels of psychoactive content—unlike illicit cannabis, which can vary greatly in potency. Sativex is available on application to the Ministry of Health by the patient, the patient’s GP and specialist. Sativex is not fully funded by PHARMAC, and is relatively expensive compared to illicit cannabis. As of January 27 2016, 104 applications to prescribe Sativex had been approved in New Zealand. In the same month, a patient who had recurring seizures that her specialist said could lead to coma and death had the medicine fully funded.

As cannabis use is illegal, it is difficult to get information about who is using cannabis medicinally and for what reasons. In 2003, the Green Party of New Zealand randomly surveyed general practitioners and selected hospital specialists about their views on medicinal cannabis. The results showed that 20% of these doctors knew they had patients who were using cannabis medicinally. They also showed that 32% of doctors would consider prescribing medicinal cannabis products if they were legally allowed and 10% of doctors had patients they felt could benefit from cannabis.

In 2006, the Green Party of New Zealand introduced the Misuse of Drugs (Medicinal Cannabis) Amendment Bill, but it was defeated in a conscience vote in 2009. However, other countries have legalised...
medicinal cannabis use, eg, Israel in 1996,\(^9\) Canada in 2001,\(^{10}\) and The Netherlands in 2003.\(^{11}\) In the US, medicinal cannabis use is illegal at the Federal level, but medicinal use of cannabis is currently legal in 23 states.\(^{12}\) In Canada and The Netherlands, the government supplies cannabis to users directly or through registered suppliers, allowing them to control quality and supply, whereas in the US, medical cannabis users have to grow or find their own supply, leading to a free market in cannabis.\(^{10,11,13}\) In California, where medicinal cannabis was legalised in 1996 through a citizen’s initiative, any debilitating condition can be treated with cannabis if a physician recommends it.\(^{12}\) This has led to recreational users being able to access medicinal cannabis through misleading their doctor about their health, or with their doctor’s cooperation.\(^{13}\)

Given the defeat of the Green Party’s bill, legalisation of medicinal cannabis is unlikely to happen in New Zealand in the foreseeable future. This leaves practitioners with little information about who uses cannabis medicinally, and why. The aim of this study was to explore the characteristics of medicinal cannabis users using representative national survey data.

**Methods**

Confidentialised, unit record data from the 2012/2013 New Zealand Health Survey were supplied by the Ministry of Health (MoH) with administration through Statistics New Zealand.\(^{14}\) The adult data set contains 13,009 respondents, aged 15 years and above, who were living in a private or non-private dwellings, and were from the New Zealand usually resident population. Non-private dwellings include such things as aged care accommodation and student hostels. However, people in hospitals, prisons, dementia units or those in hospital-level care accommodation were excluded, as well as people in meshblocks with sparse populations, and New Zealand’s off-shore islands.

The survey used a complex method of sampling that included the means of oversampling Māori, Asian and Pacific people, but the survey has been weighted to produce a representative sample. Estimates produced by these weights form unbiased estimates of population values. The data set also includes a set of 100 replicate weights which create 100 further estimates. The variance of these estimates around the unbiased estimate gives the sampling variance. For the purpose of this paper, SUDAAN was used to do these calculations.\(^{15}\)

Results can suffer from bias when the number of respondents that contribute to an estimate are too few, or an estimate may have little meaning if it has large sampling variation. The relative sampling error (RSE) is monitored to check if an estimate has these problems. The MoH advises that estimates with a RSE of 30%–50% should be used with caution, and estimates with RSE over 50% should be considered too unreliable for most practical purposes.\(^{14}\) In this article, estimates with RSE between 30% and 50% are marked with an asterisk, estimates over 50% are marked with a double asterisk, and estimates that rely on few respondents will be suppressed, eg, an estimate of 6.4% with a RSE of 45% will be marked as 6.4*%.

The New Zealand Health Surveys consist of a core questionnaire and rotating modules. In the core questionnaire, survey respondents were asked if they had used cannabis in the last 12 months for recreational or non-medical purposes, or to “get high”. In the 2012/13 survey, the tobacco, alcohol and drug use modules were also included, which asked questions about use of those products. Questions used from this module include: lifetime use of cannabis; cannabis use in the last 12 months; and whether cannabis was used in the last 12 months to intentionally treat a range of medical conditions—pain, nausea, depression, anxiety/nerves, other, or none of these. These questions were used to assign people to a category of cannabis use:

1) **non-users**—respondents who had never used cannabis;
2) **ex-users**—respondents who had used cannabis but had not done so in the last year;
3) **last year users: non-medicinal**—respondents who had used cannabis in the last year, but who had not intentionally used it to treat a medical condition;
4) **last year users: medicinal**—respondents who had used cannabis in the last year, and had intentionally used it to treat a medical condition.
Table 1: Questions and answers used to classify cannabis users.

<table>
<thead>
<tr>
<th>Main Module</th>
<th>Alcohol and Drug Module</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the last 12 months, have you used any of the following drugs for recreational or non-medical purposes, or to get high? (Cannabis option)</td>
<td>Have you ever tried cannabis?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Have you used cannabis in the last 12 months?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refused</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Don’t Know</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refused</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Don’t Know</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refused</td>
<td></td>
</tr>
<tr>
<td>Don’t Know</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Don’t Know</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refused</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Don’t Know</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refused</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Don’t Know</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Main Module**
  - In the last 12 months, have you used any of the following drugs for recreational or non-medical purposes, or to get high? (Cannabis option)

- **Alcohol and Drug Module**
  - Have you ever tried cannabis?
  - Have you used cannabis in the last 12 months?
  - In the past 12 months, did you intentionally use cannabis to treat pain or any of the following medical conditions?

- **Notes:** 1. All identical classifications are similarly coloured. 2. Non-italicised, bolded classifications are classifications where data is consistent and not missing; italicised classifications are either contradictory or have missing data. The following rules were used to define an italicised classification in this order: a) use information from drug module questions only; b) use additional information from main module question if data is missing from drug module questions; and c) any unresolved classification has data for the missing question to be treated as if they answered “No”.
Table 2: Count of Classifications by the rules applied.

<table>
<thead>
<tr>
<th>Rule</th>
<th>Non-Users</th>
<th>Ex-Users</th>
<th>Last Year Use non-Medicinal</th>
<th>Last Year Use Medicinal</th>
<th>Total</th>
<th>Cumulative % classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Rule</td>
<td>7,379</td>
<td>3,924</td>
<td>587</td>
<td>648</td>
<td>12,538</td>
<td>96.4</td>
</tr>
<tr>
<td>Rule a</td>
<td>42</td>
<td>129</td>
<td>153</td>
<td>0</td>
<td>324</td>
<td>98.9</td>
</tr>
<tr>
<td>Rule b</td>
<td>0</td>
<td>15</td>
<td>12</td>
<td>6</td>
<td>33</td>
<td>99.1</td>
</tr>
<tr>
<td>Rule c</td>
<td>94</td>
<td>3</td>
<td>17</td>
<td>0</td>
<td>114</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>7,515</td>
<td>4,071</td>
<td>769</td>
<td>654</td>
<td>13,009</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Prevalence of cannabis use across major demographic variables.

<table>
<thead>
<tr>
<th></th>
<th>Non-Users</th>
<th>ex-Users</th>
<th>Last Year Users: non-Medicinal</th>
<th>Last Year Users: Medicinal</th>
<th>p-value for difference between group 3 and 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statistic</td>
<td>95% CI</td>
<td>Statistic</td>
<td>95% CI</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>58.7</td>
<td>57.7–59.8</td>
<td>30.2</td>
<td>29.3–31.2</td>
<td>6.5</td>
</tr>
<tr>
<td>Sex (row %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>62.3</td>
<td>60.8–63.8</td>
<td>29.8</td>
<td>28.4–31.2</td>
<td>4.5</td>
</tr>
<tr>
<td>Male</td>
<td>54.9</td>
<td>53.4–56.4</td>
<td>30.7</td>
<td>29.2–32.2</td>
<td>8.5</td>
</tr>
<tr>
<td>Age Mean</td>
<td>48.9</td>
<td>48.5–49.2</td>
<td>42.1</td>
<td>41.6–42.6</td>
<td>30.7</td>
</tr>
<tr>
<td>Age Group (row %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15–24</td>
<td>56.6</td>
<td>53.8–59.4</td>
<td>19.9</td>
<td>17.7–22.2</td>
<td>14.7</td>
</tr>
<tr>
<td>25–34</td>
<td>43.4</td>
<td>40.3–46.5</td>
<td>38.7</td>
<td>35.7–41.7</td>
<td>10.4</td>
</tr>
<tr>
<td>35–44</td>
<td>46.0</td>
<td>42.9–49.1</td>
<td>43.3</td>
<td>40.1–46.5</td>
<td>6.5</td>
</tr>
<tr>
<td>45–54</td>
<td>49.9</td>
<td>47.4–52.5</td>
<td>41.6</td>
<td>39.1–44.2</td>
<td>4.3</td>
</tr>
<tr>
<td>55+</td>
<td>79.3</td>
<td>77.8–80.6</td>
<td>18.8</td>
<td>17.4–20.2</td>
<td>0.9</td>
</tr>
<tr>
<td>Ethnicity (row %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Māori</td>
<td>36.3</td>
<td>33.6–39.0</td>
<td>39.1</td>
<td>36.6–41.6</td>
<td>14.5</td>
</tr>
<tr>
<td>Pacific people</td>
<td>68.2</td>
<td>63.3–72.7</td>
<td>24.7</td>
<td>20.6–29.4</td>
<td>4.9 *</td>
</tr>
<tr>
<td>Asian</td>
<td>91.1</td>
<td>88.5–93.1</td>
<td>6.3</td>
<td>4.8–8.2</td>
<td>-</td>
</tr>
<tr>
<td>European/Other</td>
<td>57.0</td>
<td>55.7–58.3</td>
<td>32.8</td>
<td>31.6–34.1</td>
<td>5.8</td>
</tr>
</tbody>
</table>

Notes: 1 - an estimate with RSE between 30% and 50% will be marked with an asterisk, estimates with RSE over 50% will be marked with a double asterisk and estimates that rely on a few respondents will be suppressed.
Not all respondents could be assigned to a category, either because they had answered “don’t know”, or refused to answer a particular question, or because their answer to the question from the core module disagreed with their answer to the questions in the drug use module. Whenever an assignment could not be made directly from the data, the following rules were used to make a classification, and they were done in this order:

a) only use information from drug use module questions;
b) use additional information from main module question if data is missing from drug module questions;
c) any unresolved classification has data for the missing question to be treated as if they answered “No”.

The classifications are outlined in Table 1. Table 2 shows the number of people classified into each group according to these rules.

While people who answered “don’t know” may be ambiguous as to their classification (eg, they could not remember if they had used cannabis 11 or 13 months ago, or didn’t know if a herbal remedy contained cannabis), those people who refused were more likely to be respondents who ought to have answered “yes”, but were reluctant to do so; for example, they did not want to admit to a criminal offense. However, since respondents could also lie about use, the categories can be described as “admitted use” rather than “actual use”, and therefore are an undercount of “actual use”. The size of the groups get smaller when moving from classification 1 to 4 so that putting a respondent in a category with more respondents, rather than a category with fewer (eg, non-user, rather than ex-user), means they make a lesser contribution to the results.

The data were analysed, and proportions, means and their 95% confidence intervals appear in the tables for all four groups, and are commented on in the results section. It is well known that cannabis users and non-cannabis users have different characteristics, however, little is known about the differences between medicinal and non-medicinal users of cannabis, so their responses were modelled, compared, and tested using p-values. If the responses were continuous, they were analysed using regression methods. If the responses were from a question with two or more options, they were analysed using multinomial logistic regression with a generalised logit link. In both cases, as there was only one class variable, the proportions or means presented in the tables were equivalent to the conditional marginal means outputted by these regression analyses. The difference between the conditional marginal means for groups 3 and 4 were tested, and the associated p-value appears in the tables. As age, sex and ethnicity are known to be associated with cannabis use, the models were re-run with these factors as confounders to see if that changed the interpretation of the differences; if so, this is mentioned.

Results

Prevalence in major demographic factors

Overall, 58.7% (57.7–59.8) of respondents were non-users, 30.2% (29.3–31.2) had used cannabis, but had not done so in the last year, while 6.5% (5.9–7.1) had used cannabis in the last year, but not medicinally, and 4.6% (4.1–5.1) had used it medicinally in the last year (see Table 3). Of the people using cannabis medicinally, 68.6% (61.5–75.0) had also used it recreationally, or for non-medicinal purposes, or to “get high” in the last year.

Sex

Non-users were more likely to be female than male (54.5% (53.5–55.4) vs 45.5% (44.6–46.5), respectively), ex-users were more evenly split (male 50.8% (48.8–52.4), female 49.4% (47.7–51.2)), and last year users were more likely to be male, whether medicinal users (62.9% (57.9–67.6)) or non-medicinal users (63.9% (59.6–67.9)). Of the people using cannabis for medicinal purposes only, 61.0% (51.7–69.7) were male.

Age

Nine percent (8.8% (7.3–10.6)) of 15–24-year-olds said they used cannabis for medicinal reasons, and 14.7% (12.6–17.0) had used it non-medicinally. This age group had the largest proportion of both types of users. They were also the group with the second largest proportion of respondents who have never used cannabis (56.6% (53.8-59.4)), behind the oldest age group, 55+ years, with 79.3% (77.8–80.6). The
### Table 4: Demographic information about Cannabis users and non-users.

<table>
<thead>
<tr>
<th></th>
<th>Non-Users</th>
<th>ex-Users</th>
<th>Last Year Users: non-Medicinal</th>
<th>Last Year Users: Medicinal</th>
<th>p-value for difference between group 3 and 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statistic</td>
<td>95% CI</td>
<td>Statistic</td>
<td>95% CI</td>
<td>Statistic</td>
</tr>
<tr>
<td><strong>School Qualifications (col %)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>27.1</td>
<td>25.6–28.8</td>
<td>21.3</td>
<td>19.7–23.0</td>
<td>24.9</td>
</tr>
<tr>
<td>Year 11/ Form 5</td>
<td>17.7</td>
<td>16.5–18.9</td>
<td>20.3</td>
<td>18.6–22.0</td>
<td>21.5</td>
</tr>
<tr>
<td>Year 12/ Form 6</td>
<td>16.2</td>
<td>14.9–17.6</td>
<td>23.4</td>
<td>21.5–25.4</td>
<td>21.8</td>
</tr>
<tr>
<td>Year 13/ Form 7</td>
<td>17.0</td>
<td>15.7–18.4</td>
<td>26.0</td>
<td>23.8–28.2</td>
<td>27.4</td>
</tr>
<tr>
<td>Non-NZ qualification</td>
<td>22.0</td>
<td>20.6–23.5</td>
<td>9.1</td>
<td>7.6–10.8</td>
<td>4.4</td>
</tr>
<tr>
<td><strong>New Zealand Deprivation Index 2006 (col %)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deciles 1 &amp; 2 (least deprived)</td>
<td>21.1</td>
<td>20.0–22.3</td>
<td>21.7</td>
<td>20.1–23.5</td>
<td>11.3 *</td>
</tr>
<tr>
<td>Deciles 3 &amp; 4</td>
<td>21.5</td>
<td>20.3–22.8</td>
<td>20.3</td>
<td>18.7–22.1</td>
<td>19.6</td>
</tr>
<tr>
<td>Deciles 5 &amp; 6</td>
<td>20.1</td>
<td>19.0–21.2</td>
<td>19.9</td>
<td>18.5–21.4</td>
<td>23.5</td>
</tr>
<tr>
<td>Deciles 7 &amp; 8</td>
<td>19.9</td>
<td>19.0–20.8</td>
<td>19.9</td>
<td>18.8–21.0</td>
<td>21.8</td>
</tr>
<tr>
<td>Deciles 9 &amp; 10 (most deprived)</td>
<td>17.4</td>
<td>16.5–18.3</td>
<td>18.2</td>
<td>16.9–19.5</td>
<td>23.7</td>
</tr>
<tr>
<td><strong>Household</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No of adults (mean)</td>
<td>2.5</td>
<td>2.5–2.6</td>
<td>2.4</td>
<td>2.4–2.5</td>
<td>2.9</td>
</tr>
<tr>
<td>No of children (mean)</td>
<td>0.6</td>
<td>0.5–0.6</td>
<td>0.8</td>
<td>0.8–0.8</td>
<td>0.8</td>
</tr>
<tr>
<td><strong>Income Source (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income from employer</td>
<td>52.3</td>
<td>50.9–53.8</td>
<td>69.2</td>
<td>67.0–71.3</td>
<td>70.4</td>
</tr>
<tr>
<td>Invalids/sickness/accident benefits</td>
<td>3.5</td>
<td>3.1–4.0</td>
<td>5.3</td>
<td>4.5–6.2</td>
<td>7.0</td>
</tr>
<tr>
<td>Self-employment</td>
<td>11.1</td>
<td>9.9–12.3</td>
<td>18.5</td>
<td>16.8–20.3</td>
<td>10.6 *</td>
</tr>
<tr>
<td>Unemployment benefit</td>
<td>1.2</td>
<td>0.9–1.6</td>
<td>1.7</td>
<td>1.3–2.1</td>
<td>7.1</td>
</tr>
<tr>
<td>Domestic purposes benefit</td>
<td>1.5</td>
<td>1.2–1.8</td>
<td>4.6</td>
<td>3.9–5.3</td>
<td>4.3</td>
</tr>
<tr>
<td>Student allowance</td>
<td>2.5</td>
<td>2.0–3.1</td>
<td>3.0</td>
<td>2.3–4.0</td>
<td>9.2 *</td>
</tr>
<tr>
<td>Interest/dividends/rents/other investments</td>
<td>14.2</td>
<td>12.5–16.1</td>
<td>14.2</td>
<td>12.2–16.4</td>
<td>8.1 *</td>
</tr>
<tr>
<td>Retirement age benefits</td>
<td>25.8</td>
<td>25.0–26.6</td>
<td>5.3</td>
<td>4.5–6.2</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>4.0</td>
<td>3.4–4.6</td>
<td>5.9</td>
<td>5.0–6.8</td>
<td>7.6 *</td>
</tr>
<tr>
<td>No income</td>
<td>9.8</td>
<td>8.9–10.8</td>
<td>4.1</td>
<td>3.4–5.0</td>
<td>6.7</td>
</tr>
<tr>
<td><strong>Income (1,000s of dollars per annum, mean)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total personal income</td>
<td>34.6</td>
<td>33.4–35.7</td>
<td>48.7</td>
<td>46.7–50.7</td>
<td>35.0</td>
</tr>
<tr>
<td>Household income</td>
<td>33.8</td>
<td>33.1–34.6</td>
<td>41.8</td>
<td>40.7–42.8</td>
<td>37.0</td>
</tr>
</tbody>
</table>
The proportion of those who have never used cannabis in the three middle age groups lies between 43% and 49%.

Prioritised ethnicity

Ten percent of Māori reported using cannabis medicinally (10.2% (8.7–12.0)) and 14.5% (12.5–16.7) reported using cannabis non-medicinally. Māori have the highest rates of medicinal and non-medicinal use and also ex-use (39.1% (36.6–41.6)). However, European New Zealanders/Others make up 64.3% (60.2–68.2) of non-medicinal users and 67.9% (62.7–72.6) of medicinal users.

Demographic factors associated with medicinal use amongst cannabis users

Medicinal users of cannabis were more likely to have no school qualification (33.7% (29.1–38.7)) compared to non-medicinal users (19.6% (15.5–24.5)), and were more likely to be in Deciles 3 and 4 (11.7%* (8.2–16.4)) compared to non-medicinal users (19.6% (15.5–24.5)), and were more likely to be in Deciles 3 and 4 (11.7%* (8.2–16.4)) compared to non-medicinal users (19.6% (15.5–24.5)), and were more likely to be in Deciles 3 and 4 (11.7%* (8.2–16.4)).

Medicinal users had on average 2.7 (2.6–2.8) adults living in their household, whereas non-medicinal users had 2.9 (2.8–3.1). The difference, though small in a practical sense, was statistically significant (p=0.0022). The average number of children in the household was similar.

There were some differences in the income sources of medicinal and non-medicinal users. Medicinal users were more likely to get income from health-related benefits, eg, sickness benefit, invalids' benefit, or regular payments from ACC or a private work accident insurer (16.8% (13.6–20.5) vs 7.0% (4.8–10.0)), or from the Domestic Purposes Benefit (7.5% (5.9–9.4) vs 4.3% (3.3–5.8)), but less likely to get income from investments, eg, interest, dividends, rent, other investments (2.9*** (1.5–5.6) vs 8.1%* (5.6–11.6)).

Respondents were asked about their personal and household income. For these questions, a lot of data was missing: 20% for the former question, and 31% for the latter, of which “don’t know” was the response over 85% of the time. However, the proportions of missing data were similar in both

### Table 4 (cont): Demographic information about Cannabis users and non-users.

<table>
<thead>
<tr>
<th>Current Work Situation (col %)</th>
<th>Non-Users</th>
<th>ex-Users</th>
<th>Last Year Users: non-Medicinal</th>
<th>Last Year Users: Medicinal</th>
<th>p-value for difference between group 3 and 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working in paid employment</td>
<td>Statistic</td>
<td>55.1</td>
<td>Statistic</td>
<td>77.1</td>
<td>Statistic</td>
</tr>
<tr>
<td>Not working, looking for employment</td>
<td>Statistic</td>
<td>3.7</td>
<td>Statistic</td>
<td>3.5</td>
<td>Statistic</td>
</tr>
<tr>
<td>Not working, not looking for employment</td>
<td>Statistic</td>
<td>39.7</td>
<td>Statistic</td>
<td>38.5–41.0</td>
<td>Statistic</td>
</tr>
<tr>
<td>Other</td>
<td>Statistic</td>
<td>1.5</td>
<td>Statistic</td>
<td>1.1–2.0</td>
<td>Statistic</td>
</tr>
</tbody>
</table>

### Medical Insurance (%)

| Yes                                         | 36.0      | 34.1–37.9 | 38.8 | 38.8 | 36.7–41.0 | 22.5 | 18.4–27.1 | 19.7 | 14.7–26.0 | 0.4631 |

Notes: 1 - Wages, salaries, commissions, bonuses etc, paid by an employer; 2 - Invalids or Sickness benefit, regular payments from ACC or a private work accident insurer; 3 - Self-employment, or a business a person owns and works in; 4 - NZ Superannuation or Veterans Pension, other superannuation, pensions or annuities (not the war pension); 5 - Other government benefits (eg war pension) or any other income eg from people outside household; 6 - 20% of the data were missing for this calculation; 7 - 31% of the data were missing for this calculation; 8 - an estimate with RSE between 30% and 50% will be marked with an asterisk, estimates with RSE over 50% will be marked with a double asterisk and estimates that rely on a few respondents will be suppressed.
groups for each question, so if we assume that similar types of people were likely to not respond in each group, the difference in income is probably measuring something real. Under this assumption, household income is lower for medicinal users than non-medicinal users. This is not altogether surprising since the average number of adults in the household was different. Average personal income is similar between the two groups (p=0.4186), but after adjusting for age, sex and ethnicity, average personal income does become significant (p=0.0464) and is lower for medicinal users. This is the only difference that changed its interpretation after making such an adjustment.

Non-medicinal users were more likely to be working (67.4% (63.3–71.3) vs 59.2% (53.7–64.5)), and less likely to be not working and not looking for a job (20.7% (17.2–24.8) vs 28.0% (24.0–32.3)) compared to medicinal users.

**Reasons for Use**

Medicinal users were asked the reasons that they intentionally treated themselves with cannabis. The most common reason was pain, followed by anxiety/nerves and then depression (see Table 5). The largest grouping was “other” which was not further defined.

In order to understand if the medicinal users’ group was different in the proportion of people suffering pain, two further questions were analysed. Respondents were asked if they suffered from chronic pain, which was defined as pain suffered every day (although not always at the same intensity) for 6 months or more, or is likely to be suffered for more than 6 months. Non-users, (17.4% (16.2–18.6)) and ex-users (18.3% (16.6–20.0)) reported similar proportions of respondents with chronic pain. Non-medicinal users reported less chronic pain (10.8% (8.3–13.8)), whereas medicinal users reported a larger proportion of respondents with chronic pain (29.0% (24.5–33.9)). The second question was whether pain suffered within the last 4 weeks interfered with work in the home or elsewhere, with options “not at all”, “a little bit”, “moderately”, “quite a bit”, or “extremely”. The proportion answering “moderately”, “quite a bit”, or “extremely” was similar for non-users (14.4% (13.3–15.4)) and ex-users (15.7% (14.1–17.6)), was lower for non-medicinal users (9.9% (7.7–12.8)), and higher for medicinal users (25.8% (21.3–30.8)). For both questions, non-medicinal and medicinal users had significantly different proportions of respondents indicating chronic pain or pain interfering with work at home or elsewhere.

Respondents were asked about whether they felt that cannabis had a harmful effect on their physical or mental health in the last 12 months. The non-medicinal group (6.0% (4.2–8.5)) and the medicinal group (8.4% (6.1–11.5)) both reported similar proportions of physical harm from cannabis use (p=0.2150). However, the non-medicinal group (6.2% (4.3–9.0)) were less likely to report harm to their mental health compared to the medicinal group (11.4% (8.4–15.3), p=0.0129).

**Discussion**

About 5% of those aged 15+ report using cannabis medicinally. Because this is admitted use, rather than actual use, it is likely that this is an under-estimate of actual use. Alternatively, it could be argued that some respondents may say they need cannabis for medicinal reasons to explain away their illegal use to themselves or to others, making this an over-estimate of use. That a large proportion of cannabis users are medicinal users (41%) and that a large
proportion of medicinal users (69%) say they also use cannabis recreationally, for non-medicinal purposes, or to “get high”, would fit with this latter theory.

On the other hand, there is evidence that medicinal users are using cannabis for medicinal reasons. They reported more uptake of invalids’, sickness, and accident benefits, as well as being more likely to report chronic pain, or pain interfering—moderately or more—with household or other work (note that these pain questions were put to respondents before asking about their medicinal use of cannabis). This is more consistent with cannabis being used for a medicinal purpose rather than an excuse for recreational use.

In a near identical survey undertaken 10 years earlier, the New Zealand Health Survey 2002/03, respondents were presented with different, but more specific questions about pain; asking about their levels of pain and where they felt it. The survey also asked one question about cannabis use, which was frequency of marijuana use in the last year (rather than the wider category of cannabis use in the 2012/13 survey). In that data, an association between last year marijuana use and level of pain was found in a logistic regression model that adjusted for age, sex and ethnicity. The odds ratios appeared to increase with pain level. There were also different areas of the body, where last year marijuana users were more likely to feel pain. This data is reproduced from that paper and appears in Table 6.

In the New Zealand Health Survey 2012/13, the proportion of ex-users in the 35–44 and 45–54 age groups is around 42%, compared to 18% for those aged over 55+. This has implications as this cohort of people move out of middle age and into old age with the accompanying increase in age-related ill health. Having experience of cannabis use and its effects means they may be more willing to use cannabis medicinally if they experience ill-health.

### Table 6: The association of pain and last year marijuana use in a model adjusting for age, sex and ethnicity. The table is reproduced in part from Pledger and Cumming (2010) using data from the New Zealand Health Survey 2002/03.

<table>
<thead>
<tr>
<th>Pain</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>No bodily pain (reference)</td>
<td>1.00</td>
<td>(0.80, 1.44)</td>
</tr>
<tr>
<td>Very mild</td>
<td>1.07</td>
<td>(0.80, 1.44)</td>
</tr>
<tr>
<td>Mild</td>
<td>1.55</td>
<td>(1.18, 2.03)</td>
</tr>
<tr>
<td>Moderate</td>
<td>1.50</td>
<td>(1.15, 1.94)</td>
</tr>
<tr>
<td>Severe</td>
<td>1.97</td>
<td>(1.41, 2.75)</td>
</tr>
<tr>
<td>Very Severe</td>
<td>2.74</td>
<td>(1.36, 5.51)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Pain</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face, jaw, jaw joint</td>
<td>1.71</td>
<td>(0.96, 3.05)</td>
</tr>
<tr>
<td>Chest, ribs, sternum</td>
<td>1.60</td>
<td>(1.05, 2.45)</td>
</tr>
<tr>
<td>Back</td>
<td>1.55</td>
<td>(1.25, 1.92)</td>
</tr>
<tr>
<td>Stomach, abdomen, rectum, kidneys, bladder</td>
<td>1.41</td>
<td>(1.07, 1.86)</td>
</tr>
<tr>
<td>Head</td>
<td>1.25</td>
<td>(0.99, 1.57)</td>
</tr>
<tr>
<td>Neck</td>
<td>1.16</td>
<td>(0.91, 1.47)</td>
</tr>
<tr>
<td>Joints</td>
<td>1.06</td>
<td>(0.88, 1.29)</td>
</tr>
<tr>
<td>Dental, teeth</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>0.87</td>
<td>(0.57, 1.32)</td>
</tr>
</tbody>
</table>
The current study has some limitations. The New Zealand Health Surveys are highly complex surveys that have to satisfy a wide variety of users. Therefore, it is not possible to collect precise and detailed information about medicinal users and their use of cannabis. Important clinical information about how medicinal users use cannabis, and for how long, where they get their information from, and if they disclose their use of cannabis to their doctor, would be important next steps in future research, but unlikely to be possible through the New Zealand Health Survey.

The other limitation is that there was missing data and contradictory data around classifying respondents into cannabis-using groups. Although the number of respondents needing to be classified by rules a, b and c was small compared to the survey overall, it is large compared to the group of people who used cannabis in the last year. Sensitivity analysis was done to see if classifying people differently changed the results. The first case was to just use the drug module questions to classify people, and drop those who could not be classified. The second case was similar, but assigned a “yes” at the question where respondents answered “don’t know” or refused to answer. In both cases, the answers were similar to those already reported—the estimates usually changed by less than 1 percentage point. The only case where it made a large difference was for prevalences in the smaller ethnic populations, ie, the proportion of Asian people in the non-user group decreased from 91.1% to 89.6%. None of the hypotheses tested changed their interpretation.

There are contradictions in the responses between the main module question about cannabis use and the alcohol and drug module questions. The authors feel that this was due to: 1) the question in the main module being difficult to parse; and 2) that the questions in the main module asking about a range of drug use besides cannabis and the users could do a blanket refusal or “don’t know” when they may have been willing to answer for individual drugs, especially “softer” drugs like cannabis, but not heroin. The authors chose to use “admitted use” as their criteria for respondents’ inclusion in to cannabis use categories, as this is likely to reflect the type of people who will admit to use in the clinical setting. Even though these caveats must be kept in mind, this paper advances what we know about medicinal users of cannabis.

In earlier research exploring the use of complementary and alternative medicines (CAM) in New Zealand, an association was found between CAM use and being female, middle-aged, relatively rich, well-educated, and of European decent. In this study, medicinal cannabis use was associated with being male, younger, less well-educated and relatively poor. And while Māori have the highest prevalence of medicinal use, by weight of numbers, European NZ/Others are more likely to be medicinal users. In both cases, reported use was associated with reported conditions that were typically hard to manage.

Cannabis users in both groups had reported they felt physical or mental health harm from their cannabis use. It was also the case that a significantly larger proportion of medicinal than non-medicinal users reported that their cannabis use had a negative effect on their mental health. This is an important finding, suggesting that medicinal cannabis users may need to be monitored for the emergence of mental health problems. Making medicinal use of cannabis legal, but only with a prescription, may help reduce the harm to medicinal users as they would be able to get advice about how much cannabis to use, and safer methods of use, such as the use of a vaporiser or as a tea. This is contingent, however, on doctors having the knowledge to give to such users. That medicinal users of cannabis are young and male means that allowing GPs to prescribe the medicinal use of cannabis might mean capturing a group of people who would otherwise not access health care.
ARTICLE

Competing interests:
Nil

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We thank the respondents of the New Zealand Health Survey, 2012/13 for their participation in the survey. Access to the data used in this study was provided by Statistics New Zealand under conditions designed to keep individual information secure in accordance with requirements of the Statistics Act 1975. The opinions presented are those of the authors and do not necessarily represent an official view of Statistics New Zealand.

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ARTICLE


A vailability of synthetic cannabinoids (SCs) in New Zealand has increased since the late 2000s, along with concerns about their toxicity. Safety concerns were initially raised by the New Zealand Ministry of Health in 2009. Since 2010, reports from acute inpatient and forensic mental health services, poisons centres, and telephone helplines described substantial mental health harms associated with use of SCs specifically, development or worsening of mood, psychotic or other behavioural symptoms. The New Zealand Government responded to this situation with 3 legislative changes: an amendment to the Misuse of Drugs Amendment Bill in August 2011, creating a Temporary Drug Class Notice to ban currently available SCs; the Psychoactive Substances Act (PSA) in August 2013, which restricted the number of SC products and reduced points of sale; and the Psychoactive Substances Amendment Bill in May 2014, which prohibited the sale and possession of SCs.

We previously reported a 50% reduction in numbers of patients using SCs presenting to one Emergency Psychiatric Service after implementation of the PSA in August 2013. This paper expands on the earlier report by examining 4-year national trends in hospital presentations associated with use of SCs, in particular changes around the time that legislative changes were implemented.
Methods

We requested a 4-year national dataset of patients presenting to hospital associated with use of synthetic cannabinoids from the New Zealand Ministry of Health’s National Minimal Dataset. The nonspecific ICD-10 code T43.8 is applied to use of synthetic cannabinoids (other psychotropic drugs, not elsewhere classified). The free text descriptors associated with each case were individually examined for mention of synthetic cannabis or brand names of specific products (eg, Kronic, K2, etc). The following data were also obtained: age; sex; ethnicity; length of hospital stay; and other diagnostic and symptoms codes. Data were described using summary statistics (means and SDs, medians and interquartile ranges (IQRs), or counts and percentages) prior to time series analysis. Differencing was used to produce a stationary time series before and after allowing for a linear trend. The stationary series was then investigated using autocorrelation and partial autocorrelation plots to identify the most appropriate Autoregressive Integrated Moving Average (ARIMA) model. Finally, each legislative event was separately added as an impact to the time series before all 3 were added in combination. Analysis was conducted using R 3.2.2, with two-sided p<0.05 considered statistically significant.

Results

The dataset provided was from March 2011 to June 2015. Of the 379 presentations coded T43.8, 326 (86%) referred to synthetic cannabis in free text fields, and were included in the analysis. There were approximately twice as many males as females (209:117, 64% male). Median (IQR) age at discharge was 21 (12) years. Ethnicity was not described for 3 patients and the remainder included 184 (57%) European, 107 (33%) Māori, 23 (7%) Pacific Islander, 7 (2%) Asian, and 2 (1%) Middle Eastern/Latin American/African. Over the entire sample, the mean (SD) duration of hospital stay was 1.2 (6.7) days, and amongst the 145 (44%) who were admitted, the mean (SD) was 2.6 (9.9) days. Of these, 8 (2%) were admitted for a week or longer, and the maximum duration was 116 days.

The monthly number of hospital presentations associated with synthetic cannabis use was irregular, with 3 peaks,
in mid-2011, from mid-2012 to mid-2013, and mid-2014 (Figure 1). Steep declines in numbers of presentations occurred between August and September 2011 (A in Figure 1), July and August 2013 (Figure 1, B), and May and June 2014 (Figure 1, C). These coincided with three law changes: the passage of an amendment to the Misuse of Drugs Amendment Bill in August 2011, banning the sale of existing SCs; passage of the PSA in August 2013, which limited the number of SC products available for sale, and reduced numbers of retail outlets; and passage of the Psychoactive Substances Amendment Act in May 2014, which stopped sale of all SC retail products.

The time series models included only differencing and drift, effectively giving ARIMA (0,1,0) with constant models. As shown in Table 1, all three events had estimated effects indicating decreases in presentation, but only the reduction in supply from August 2013 was statistically significant, being associated with a reduction of over 10 presentations per month (unadjusted p=0.037, adjusted p=0.023). There was also a tendency for reductions of over 8 presentations per month following the outright ban from June 2014 (unadjusted p=0.099, adjusted p=0.065). Similar results were obtained if the series was treated as difference stationary with the trend removed (results not shown).

The most commonly reported symptoms included tachycardia (15%), restlessness/agitation (14%); convulsions (11%), syncope or collapse (11%); somnolence (11%); psychosis was reported in 6% of cases. Overall 25% of patients had mental health disorder diagnoses associated with their hospital contact.

### Table 1: Effects of the legislative changes on number of presentations per month.

<table>
<thead>
<tr>
<th>Event</th>
<th>Modelled separately</th>
<th>Modelled simultaneously</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effect</td>
<td>95% CI</td>
</tr>
<tr>
<td>Initial ban (from September 2011)</td>
<td>-7.2</td>
<td>-17.0, 2.6</td>
</tr>
<tr>
<td>Reduction in supply (from August 2013)</td>
<td>-10.3</td>
<td>-19.9, -0.6</td>
</tr>
<tr>
<td>Outright ban (from June 2014)</td>
<td>-8.2</td>
<td>-18.0, 1.6</td>
</tr>
</tbody>
</table>

### Discussion

This analysis shows a relationship between number of hospital presentations associated with use of SCs and legislation affecting SC availability. When SCs were available, either as unregulated (pre-2011) or regulated products (until May 2014), hospital presentations associated with SC use tended to increase over time, presumably reflecting changes in patterns of use and/or marketing.

Legislation that reduced availability of SC products (2011, 2013) produced immediate, but temporary, reductions in hospital presentations. Even after all retail SC products were banned (May 2014), small numbers of hospitalisations associated with SCs still occurred, presumably reflecting their black market availability. Our modelling suggests that legislative changes were effective in decreasing presentations with statistically significant effects following the reduction in supply from August 2013 (by 10.6 per month), and a non-significant tendency for decreases following sales restriction in 2011 (by 7.6 per month) and the outright ban from June 2014 (by 8.6 per month).

The demographics and signs/symptoms reported by patients affected by SCs are consistent with our earlier reports.\textsuperscript{4,5} Patients presenting to hospital services tend to be younger males, with a range of emotional, psychological, behavioural and physiological symptoms, and contact with treatment services is brief.

The potential shortcomings of this audit should be acknowledged. This was a retrospective analysis of a central dataset. Use of SCs was established by self-report (ie, not based on toxicological...
analysis), and thus their involvement in hospital presentations is likely to be an underestimate. Symptoms at presentation were based on coding of clinical notes and thus may have missed more subtle observations.

In conclusion, we have identified substantial monthly changes in numbers of patients presenting to hospital services with toxicity associated with use of SCs, related to law changes around SC availability. The present findings and earlier reports\(^1\)\(^-\)\(^6\) identify that SCs marketed in New Zealand until now have clearly been unsafe, and thus it is not surprising that we observed reduced harms when their availability was reduced. The PSA offers a pathway for applicant companies to register psychotropics for recreational use.\(^12\) If there is still political will to allow regulatory approval and sale of recreational psychoactive drugs via the process described in PSA and related documents, the onus must be for manufacturers to demonstrate their safety before they are marketed.

**Competing interests:**
Paul Glue reports non-financial support from Demerx Inc, other from Kinex Pharma, and other from Douglas Pharmaceuticals, outside the submitted work.

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**REFERENCES:**
Achalasia: a 13-year, single-centre experience comparing endoscopic balloon dilatation and laparoscopic Heller myotomy

Alexander Huelsen, Ramadan Oumer, Anna Ashcroft, Ross H Roberts, Grant N Coulter, Steven J Kelly, Murray L Barclay

ABSTRACT

BACKGROUND: Idiopathic achalasia is a non-curable, primary motility disorder of the oesophagus. Most established long-term palliative treatment options are laparoscopic Heller myotomy (LHM) and endoscopic balloon dilatation (BD).

AIM: We aimed to compare the outcome of both therapies and the risk of serious complications, defined as perforation or death, in a single-centre series.

METHOD: In this retrospective study, patients with BD or LHM were identified from 1997–2010. The symptom score (modified Zaninotto score) before treatment and at time of interview was evaluated via a telephone questionnaire.

RESULTS: Ninety-nine patients fulfilled the inclusion criteria and treatment was provided with BD-only in 63, surgery-only in 23, BD crossover to surgery in 12, and surgery crossover to BD in one patient. Mean age was 62 years in the BD-only, and 39 years in the surgery-only group. One hundred and fifteen BD were performed on 76 patients with multiple dilatations required in 46 patients (38%). Sixty-four percent of all patients alive (n=81) were interviewed. Satisfactory outcomes were achieved in 79% in the BD group and in 88% in the surgery group, with a mean follow-up of 81 and 69 months, respectively. There was a single perforation in the BD group (0.9%) and no deaths occurred.

CONCLUSION: LHM and on-demand BD were safe and within the limitations of our study design both methods appeared similarly effective treatments for achalasia, resulting in a satisfactory outcome in 88% and 79% of patients with a mean follow-up of 69 and 81 months. Serious complications occurred in less than 1% of procedures and there were no deaths.

Achalasia is a rare and non-curable primary motility disorder of the oesophagus with an estimated incidence of 0.5–1.6 per 100,000/year. Symptoms include dysphagia to solids and/or fluids, regurgitation, chest pain, heartburn and weight loss. The classical features are a hypertensive lower oesophageal sphincter (LES) with incomplete relaxation, as well as a lack of peristalsis in the oesophagus due to inflammatory degeneration of the myenteric plexus. The established most effective treatment options are endoscopic balloon dilatation (BD) and trans-abdominal laparoscopic Heller myotomy (LHM) combined with an anti-reflux procedure. The later is currently recognised as the more definite long-term treatment. However, a recent interim report of a European, multicentre, randomised controlled trial showed that both therapies are similarly effective in the short term. The follow-up data from this study aims to reveal the medium to long-term outcome over the next...
decade, which may help to clarify the exact role of these therapies. Peroral endoscopic myotomy (POEM) is a further relatively new endoscopic treatment option developed in Japan in 2008. With this technique, the myotomy is performed endoscopically using a standard gastroscope, thus avoiding abdominal incisions. POEM is gaining fast and widespread popularity worldwide as a likely, similarly-effective minimally-invasive treatment option and may also be available in the near future in New Zealand. However, long-term outcome results of POEM and randomised trials comparing the three approaches will not be available for some years. Until such evidence becomes available, local data remains important to guide management, especially as BD is a relatively easy procedure that can be performed by any skilled endoscopist, whereas LHM can be technically challenging and requires adequate training and continuous exposure to achieve a good outcome. New Zealand is a small country, with a relatively low number of achalasia cases per surgeon compared to larger countries or centres. The great results reported by centres of excellence with a high-volume caseload might not be directly translatable to local clinical practice in hospitals with lower case volumes for surgeons.

The primary aim of this study was therefore to assess and compare symptom outcomes of the currently available treatments, LHM and BD, in a tertiary hospital in New Zealand. Secondary endpoints included serious complications defined as perforation or death and assessment of patient satisfaction with treatment.

Method

Christchurch Public Hospital is the largest hospital in the South Island of New Zealand, with a catchment area of over 450,000 people. The Christchurch Public Hospital endoscopy unit is the only service providing 30–40 mm balloon dilatation for achalasia in this region; consequently, all patients who underwent this procedure were identifiable through the endoscopy databases (Endoscribe v2.25 and Provation).

BD was provided following an “on demand” approach, starting with a 30mm diameter balloon (Rigiflex, Boston Scientific), with the option to increase balloon size on subsequent dilatations if there was ongoing or recurrent dysphagia. Generally, the balloon was inflated once—and in a few occasions twice—with 15 psi of air and held for 15–30 seconds. The decision to perform a primary or further BD, or to consider LHM, was made by the specialist (gastroenterologist and/or surgeon) on clinical grounds following a diagnosis of achalasia with manometry, and including the preference of the patient.

Over the defined study period, two upper GI specialist surgeons performed LHM in the Christchurch region, in both public and private hospital setting. This study excluded paediatric patients (< age 6) and not all private clinics could be incorporated; thus not all cases could be identified for certain. The LHM was performed largely following the method described by Hunter et al. Both surgeons had performed less than 50 LHMs throughout their career. Patients treated in Christchurch Public Hospital were identified using the hospital clinical coding system, and patients treated in the private sector were identified through the clinical coding system of the private surgeons.

The clinical records of all patients were retrieved and reviewed in the first part of this study to determine demographic characteristics, gastroscopy and manometry results, interventional treatment methods and documented severe complications, defined as perforation or death. Patients were included in the study if the diagnosis of achalasia was based on manometry criteria (achalasia subtype classification was not available and not recognised standard at the time of our study period), and a gastroscopy did not reveal other pathology. Patients were excluded if they had prior oesophageal surgery, anti-reflux surgery or myotomy, or if they were less than six years of age at first treatment.

In the second part of this study, clinical outcome data were collected through a telephone interview with patients using a standardised questionnaire, after obtaining informed consent. The questionnaire was a modified version of the one described by Zaninotto et al to score relevant clinical symptoms pre-treatment and at the time of the telephone interview. Patients who failed either surgical or endoscopic treatment, and crossed over to the other
treatment, were also interviewed regarding their symptoms prior to the second-line treatment. The symptoms evaluated were dysphagia, chest pain, heartburn and regurgitation, and these were scored according to their severity and frequency. An overall symptom score was calculated by combining the severity of each symptom (0 = none; 2 = mild; 4 = moderate; 6 = severe) with its frequency (0 = never; 1 = very occasionally; 2 = once a month; 3 = every week; 4 = twice a week; 5 = daily). The highest total score obtainable was 44.

All patients were also interviewed regarding their overall satisfaction with the treatment received (very unsatisfied; unsatisfied; satisfied; very satisfied).

Statistical analyses

The data collected were analysed using the Statistical Package for the Social Sciences (Windows version 11.5; SPSS Inc, Chicago, US). Continuous variables were expressed as medians with interquartile ranges (IQR), as the data showed significant skewing. Non-parametric tests were used to compare groups. Related-samples Wilcoxon signed-rank tests were used to compare before and after scores (both total and individual symptoms) within each group; Mann-Whitney U tests were used to compare overall differences between groups; and Kruskal-Wallis tests were used to compare individual symptom improvements and satisfaction across the three different treatment groups (BD only, BD prior to surgery and surgery only). A probability of <5% was considered to indicate statistical significance (p<0.05).

Results

Overall, 116 patients were identified through the database search, with 99 fulfilling the inclusion criteria. The number of patients in each treatment group, and number able to be interviewed for this study, are shown in Figure 1. Patient demographics are summarised in Table 1.

All but two LHM operations were combined with a fundoplication procedure. In three cases, a 360-degree fundoplication was used, and in all other patients, partial fundoplications, either Dor or Toupet, with varying wraps from 90 to 270 degrees, were performed.

Five intraoperative complications were reported, including: two gastric and one oesophageal perforation (all repaired, no subsequent leaks); one splenic tear (clipped); and one thoracic duct injury (clipped). Post-surgical convalescence was not affected. Following surgery, further treatments were required in 6 patients (17%) due to dysphagia or reflux (Table 2).

Four gastroenterologists performed 115 BD on 76 patients. Of these, 47 (62%) had only one BD during the study period and of these, 2 (2.6%) crossed directly over to LHM. More than one dilatation (2-4 BD) was
Table 1: Patient demographics.

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Age in years at first BD(^1)/LHM(^2) mean (range)</th>
<th>Gender M/F n</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD only</td>
<td>63 (9–95)</td>
<td>21/42</td>
</tr>
<tr>
<td>BD cross-over to surgery</td>
<td>45 (22–67)</td>
<td>6/6</td>
</tr>
<tr>
<td>Surgery only</td>
<td>39 (18–66)</td>
<td>14/9</td>
</tr>
<tr>
<td>Surgery cross-over to BD</td>
<td>65</td>
<td>1/0</td>
</tr>
</tbody>
</table>

\(^1\)Balloon dilatation; \(^2\)laparoscopic Heller myotomy

Table 2: Treatments following laparoscopic Heller myotomy.

<table>
<thead>
<tr>
<th>Patients (n)</th>
<th>Symptom</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>dysphagia</td>
<td>2 x 18mm BD, § and 1 x Savary dilatation</td>
</tr>
<tr>
<td>1</td>
<td>dysphagia</td>
<td>Cross-over to BD</td>
</tr>
<tr>
<td>1</td>
<td>dysphagia then dumping syndrome</td>
<td>Open thoracic revision of myotomy and fundoplication; BD; esophagogastrectomy; jejunostomy</td>
</tr>
<tr>
<td>1</td>
<td>reflux</td>
<td>Partial fundoplication converted to Nissen fundoplication with subsequent redo</td>
</tr>
</tbody>
</table>

\(^\text{§}\)Balloon dilatation

Figure 2: Number of balloon dilatations performed and balloon sizes used.
performed in 29 patients (38%), with the number of BD performed and balloon sizes shown in Figure 2.

In the group of patients requiring further dilatations, the median time to the second dilatation was 14 months (range 1–75), the median time to the third dilatation was 14 months (range 3–49), and the one patient with a fourth BD had this performed 11 months following the third BD.

In the BD group, one perforation occurred (0.9%) which was subsequently treated with open Heller myotomy the next day, without any further complications and a good clinical outcome. Overall, subsequent LHM was required in 12 patients (16%).

At the time of data collection, 18 patients had died, all belonging to the BD-only group. These cases were reviewed, and in none of the cases was death related to achalasia treatment. The mean age at death was 82 years (range 58–97).

Of the 81 patients alive at the time of data collection, 52 (64%) were contactable and consented to take part in a telephone interview and were included in the second part of the study (Figure 1).

The analysis of the standardised questionnaires revealed that, overall, symptom scores improved significantly in the BD group (including all patients that underwent BD) from a median of 27.0 (IQR 16–32) prior to BD, to 10.5 (IQR 3–17) after BD (p<0.01). The symptom scores of patients in the surgical group (including all patients that underwent LHM) also improved significantly (p<0.01) from a median of 26.0 (IQR 12–37.0) to 11.0 (IQR 4–23). No statistically significant difference was found in the degree of improvement between the two treatment groups (p=0.48).

Analysis of the surgery-only group and the 12 patients who had an initial BD prior to surgery, showed that both groups had significant improvements in symptom scores, with no statistically significant difference found between the two treatment groups (p=0.35). The surgery-only group demonstrated a median reduction of symptom scores (before-after) of 8 points (IQR: 5–24; p<0.01), with the group who had BD prior to surgery demonstrating a median difference of 6.5 points (IQR: 4–10; p< 0.03), as demonstrated in Figure 3.

The individual symptom score sub-categories dysphagia and regurgitation showed similar and significant improvement in the BD and surgery groups. Chest pain was significantly improved only in the BD group,
whereas the sub-category heartburn did not show any significant improvement in either treatment group, as illustrated in Figures 4 and 5.

All interviewed surgical patients (n=16) had their surgery performed by one of two specialist surgeons, with similar improvements in symptom scores for each surgeon. Participants reported their satisfaction with treatment as satisfied or very satisfied in 79% (n=33) in the BD group, with a mean follow-up of 81 months (median 81; IQR: 10–211), and in 88% (n=14) with LHM with a mean follow-up of 69 months (median 52; IQR: 11–141). No statistically significant difference was found in satisfaction rates between the treatment groups.

Figure 4: Sub-category symptom scores before (dark grey) and after (light grey) treatment in balloon dilatation patients.

Figure 5: Sub-category symptom scores before (dark grey) and after (light grey) treatment in the surgery-only group.
Discussion

Some authors describe LHM as a more permanent and superior treatment for achalasia compared to BD, with excellent initial and medium-term success rates of 90%. Supporting data are usually derived from specialised referral centres with highly experienced operators. However, published success rates may not be entirely translatable to centres with smaller patient numbers, such as in New Zealand. This concern was underlined by a large nationwide retrospective study from Canada that identified significantly higher retreatment requirements following LHM compared to high-volume specialist centres.

The results of our study revealed that LHM was performed safely and achieved a satisfactory outcome in 88% of the interviewed patients after a mean follow up of 69 months, which is consistent with the data provided by specialised referral centres. Intervenational retreatment following LHM was required in 17% and was due to symptoms of reflux or dysphagia. Similar retreatment rates of 18–21% after a mean follow-up of 5–6 years have been reported in other studies.

BD, on the other hand, has become somewhat less favoured since the introduction of LHM, due to higher symptom recurrence following a single dilatation. However, over the last decade it has become well recognised that a single BD should not be seen as sufficient to treat achalasia in the long-term in many cases. Eckart et al found that after 5 years, up to 50% of patients will have symptom recurrence following a single dilatation. This was also demonstrated in our study, where 47% of our interviewed BD-only cohort required more than one dilatation to achieve on-going symptom control.

Recent studies assessing BD with an on-demand and/or graded approach using repeat procedures with similar or increasing balloon sizes have provided excellent results, with success rates of over 90% after a follow-up of 6–10 years. In our cohort, BD with an on-demand approach achieved a satisfactory outcome in 79% of the interviewed patients after a mean follow-up of 81 months.

Crossover to LHM was required in 16% of the BD patients, including the single perforation case that occurred during our study period. A recent single-centre study from a high-volume institution reviewed 184 patients in their 12-year treatment experience, and found 8.7% underwent LHM following BD, including one perforation following BD. We speculate that in our institution, compared to higher volume centres, the threshold to crossover to LHM was possibly lower due to the predominant local opinion that LHM may offer a more definitive treatment.

Our study did not detect a statistically significant difference in outcome between our BD and LHM groups. However, it is important to note that the treatment groups were not equally matched in this retrospective study, and therefore success rates may not be entirely comparable. LHM was offered more frequently to younger male patients, following current evidence that male gender, and age under 40, are independent negative prognostic factors for BD. In such cases, LHM may offer a more permanent resolution of symptoms. In addition, our crossover group from BD to LHM had an average age of 45 years, compared to 62 years in the BD-only group.

An ongoing, multicentre, randomised controlled trial from Europe comparing LHM with graded BD is suggested to have enough power to clarify the appropriate role of these procedures in achalasia treatment. First interim reports after a 2- and 5-year follow-up period of 196 patients supports our short-term findings, and showed equal success rates, suggesting that both procedures can be used as initial treatment. Our results would also suggest that these results might be sustained in the medium-term.

BD has been reported to cause submucosal microhaemorrhages leading to local fibrosis that may increase the complication rate should a surgical myotomy then be attempted. Some experts therefore argue that LHM should be regarded as the first line treatment for achalasia, and BD should be reserved as second-line treatment; however, available data is conflicting. In our study, the crossover group showed significant improvement following LHM that did not differ statistically from the
LHM only group, however, the treatment cohorts were small with only 6 and 10 patients, respectively.

Looking at our symptom subcategories, there was no significant change in the rate of heartburn following either intervention. Heartburn is common in achalasia, and is usually not related to acid reflux episodes by pH monitoring prior to treatment; however, the development of gastro-oesophageal reflux disease (GORD) remains a concern in the long-term, especially following surgical treatment. Our study was based on symptom assessment via questionnaire only and cannot provide further data regarding GORD occurrence.

Chest pain was significantly improved following BD, but not following surgery. There is no obvious explanation for this difference between the treatment groups, and this finding should not be over-interpreted given the small sample size interviewed post-surgery. The cause of chest pain in achalasia is not known and a previous study found that both BD and LHM had only a small effect on this symptom. However, it was noted in this study that, in general, chest pain tended to improve in most patients over the course of several years, which may have also been the case in our study. Other studies found improvement in chest pain following LHM.

The secondary aims of our study were assessment of treatment-related perforations and deaths, and both treatments were found to be very safe in this regard. There was only one perforation (0.9%) following BD requiring subsequent LHM, and three intraoperative mucosal perforations during LHM that were identified and treated at the time of the index operation, without any subsequent complications. These results are excellent and in keeping with the international literature reporting 1.9% (range 0–16%) of perforations following BD and 7–15% following LHM.

No treatment-related deaths occurred during our study period, and the 18 patients in our study cohort that died prior to our data collection were on average 82 years old, which is in keeping with the current life expectancy in New Zealand. This finding is in line with previous reports that patients with achalasia have a normal life expectancy.

Our study design was based on a standardised telephone interview on an achalasia treatment cohort identified retrospectively. Such a design is clearly inferior to a prospective randomised controlled study, consequently the results have to be considered critically. We identified that treatment groups were not matched and mirror pre-existing evidence that age <40 and male gender are negative prognostic factors for BD. Furthermore, sample sizes were limited in several groups and sub-groups, which may impair statistical power in identifying small but clinically relevant differences. Treatment success or failure was not assessed objectively or pre-defined in this study compared to prospective trials, but rather assumed to correlate with the patient being satisfied or unsatisfied with the treatment result. One may speculate that patients may develop tolerance to symptoms that persist after treatment. On the other hand, satisfaction with treatment remains an important endpoint for any patient undergoing interventional treatment and therefore we believe our assessment of this is well justified.

Our research group modified the Zanninotto score to include chest pain as a well-recognised and distinct symptom of achalasia. The Zanninotto score, however, has never been validated in this form.

Lastly, newer evidence emerged in 2008 that led to the classification of Achalasia into three subtypes based on high-resolution manometry criteria. This is of clinical relevance as the treatment outcome differs between subgroups, and over representation of one subtype in one treatment group would have likely significantly skewed the data. High-resolution manometry with subtype classification is now standard in our unit, but was not available throughout the study period.

**Conclusion**

Our study in a medium-sized hospital setting in Australasia showed that LHM and on-demand BD were safe and within the limitations of our study design both methods appeared similarly effective for the treatment of achalasia. Satisfactory outcomes were achieved in 88% of the LHM group.
and 79% of the BD group over a medium follow-up of 69 and 81 months, respectively. Treatment-related perforation occurred during BD in only a single case (0.9%), which was subsequently closed surgically without any further complications. LHM led to three perforations (8.3%), however these were repaired during the index operation. There were no treatment related deaths.

### REFERENCES:


The costs of elective and emergency abdominal aortic aneurysm repair: a comparative single centre study

Kevin Niall Peek, Manar Khashram, J Elisabeth Wells, Justin A Roake

ABSTRACT

AIM: Population-based screening for abdominal aortic aneurysms (AAA) is being considered in New Zealand. However, there is lack of data to support its cost effectiveness in this country. The aim of this study was to compare the hospital costs of AAA repair in emergency and elective cases over a 3-year period in a single centre in New Zealand.

METHODS: A retrospective observational analysis of consecutive patients undergoing elective and emergency AAA repair during the study period (January 2009 to December 2011) was performed.

RESULTS: A total of 169 AAA repairs were performed during the study period, of which 114 (67%) were open repairs. Sixty-four of these were open elective AAA repairs, 40 were open ruptured repairs, and 10 were open symptomatic repairs. The mean inpatient cost was $38,804 for open ruptured AAA repair and $28,019 for open elective repair, a difference of $10,785 (95%CI: $249 to $21,321; p=.045). The costs of blood products and laboratory investigations were significantly greater in the ruptured group than the elective. There was no significant difference in length of hospital admission between the groups.

CONCLUSIONS: This study demonstrates that ruptured AAA repairs are more expensive than elective AAA repairs, despite no difference in length of hospital stay. The estimated inpatient costs documented in this study for each type of repair can be used for cost-effectiveness analysis in New Zealand. A screening program that reduces the incidence of surgery for ruptured AAA could decrease the average inpatient cost of AAA repairs.

A bdominal aortic aneurysms (AAA) are a significant cause of mortality in New Zealand accounting for about 236 deaths per year, of which 80% are attributed to ruptures.1 Recent international studies suggest that the prevalence of AAA is about 2% in men aged 65.2,3 The natural history of AAA is a progressive increase in diameter to the point of rupture. The risk of aneurysm rupture increases with increasing diameter.

Approximately, 30% of patients with a ruptured AAA die pre-hospital. Of those undergoing repair, the mortality rate is approximately 35%. There is an overall mortality rate of up to 85%.4 However, when detected prior to rupture, they can be treated electively by open or endovascular methods, with open surgical procedures carrying a mortality of 3–10%.5

Four randomised controlled trials summarised by a meta-analysis showed that ultrasound AAA screening was associated with a significant reduction of AAA-related mortality in men aged 65–79 years.5 There are six countries that offer screening or are in the process of developing screening programs for AAA.6 Currently, no such programme exists in New Zealand, although consideration has been given to initiating one. Nair and colleagues have documented the burden of AAA in New Zealand from 2002 until 2006.1 An average of 267 AAA were repaired electively, and a further 87 repaired as an emergency each year. Mortality rates for elective and emergency
repairs were 6.7% and 35.2% respectively. Almost all AAA deaths occurred in people aged over 65 years. Sandiford et al report declining incidence and mortality rates of AAA in New Zealand since 1991, which may be attributable to a reduction in smoking rates and the use of statins to control serum cholesterol. In New Zealand, the prevalence of AAA in the population is still unknown, but in a selected population undergoing CT colonography for gastrointestinal symptoms, a prevalence of 9.1% in men 65–75 years old was observed. This highlights the burden of AAA disease in New Zealand and the importance of an AAA screening program.

Cost analysis comparing open aneurysm repair (OAR) and endovascular aneurysm repair (EVAR) has been assessed in randomised controlled trials. However, inpatient costs of AAA repair in the contemporary clinical setting have not been assessed in New Zealand. The aim of this study was to compare the hospital costs of AAA repair in emergency and elective cases over a 3-year period in a tertiary referral vascular centre.

**Methods**

This was a retrospective, observational analysis of consecutive patients undergoing elective and emergency AAA repair, from 1 January 2009 until 31 December 2011, in a single New Zealand centre.

The exclusion criteria was: isolated iliac aneurysms with open or endovascular methods; non-aneurysmal aortic surgery for occlusive disease; complex fenestrated and branched endovascular aneurysm repair (EVAR) grafts; or treatment for infected aortic grafts or mycotic aneurysms.

The unit’s protocol for all patients undergoing open AAA repair was to stay in ICU for one night minimum. There is no routine ICU or HDU for EVAR patients. The majority of elective cases were admitted into hospital on the same day of surgery and EVAR patients receive their first imaging surveillance (ultrasound) at 6 weeks post-operatively, unless there were any clinical concerns.

Patients were identified using a prospectively-collected vascular database and the hospital’s decision support tool. Patients’ clinical presentations were defined into three groups: ruptured AAA repair; symptomatic but not ruptured AAA repair; or elective AAA repair. Information for each patient was extracted from the vascular database, including demographics, vascular risk factors and length of stay (LOS). The hospital’s decision clinical coding data was used to extract the cost of each admission. The costing system uses several techniques used to derive each inpatient costs. Inventoried items (eg, theatre materials, grafts, blood products) are recorded for each admission and are assigned a value based on the cost of the product to the DHB. There is a similar process with hospital services (eg, labs, ECHO, radiology). Nursing and doctor’s hours are assigned a value based on the time spent in a particular location of for the patient (eg, theatre, ICU, ward) which reflect the differences in staff numbers and salary for each. The time of other health care providers is also logged and includes physiotherapy, social work, phlebotomy, and inpatient specialist referral. The components used to determine the cost of each admission were examined and grouped into the following categories for analysis: pre-hospital (including pre-admission and air ambulance costs), operation, intensive care, blood products, laboratory and other.

Four separate analyses were performed:

1. The difference in costs of OAR between elective and ruptured groups was examined. EVAR patients were not included in the primary analysis as it was hypothesised that an unequal distribution of EVAR, with a high stent graft cost, in the elective group would affect the comparability of the groups. In addition, the use of EVAR for treating ruptured AAA has not been widely adopted at our institution.

2. OAR were examined, excluding patients who died in less than 4 days, as it was hypothesised that early mortality would lead to a lower difference of cost between the groups.

3. All patients presentations who had OAR and EVAR were analysed.

4. OAR was compared to EVAR in the elective cases only to provide context for the other analyses and to provide data for future modelling.
Table 1: Summary of demographics and risk factors for open AAA repairs.

<table>
<thead>
<tr>
<th></th>
<th>Elective</th>
<th>Ruptured</th>
<th>Symptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=</td>
<td>64</td>
<td>40</td>
<td>10</td>
</tr>
<tr>
<td>Median age (range)</td>
<td>73 (57–86)</td>
<td>77 (49–86)</td>
<td>74 (62–82)</td>
</tr>
<tr>
<td>Males (%)</td>
<td>46 (72)</td>
<td>34 (85)</td>
<td>8 (80)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>3 (4)</td>
<td>10 (4)</td>
<td>0</td>
</tr>
<tr>
<td>Smoking history (%)</td>
<td>37 (58)</td>
<td>17 (42)</td>
<td>6 (60)</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>34 (53)</td>
<td>18 (45)</td>
<td>7 (70)</td>
</tr>
<tr>
<td>Ischaemic heart disease (%)</td>
<td>20 (31)</td>
<td>6 (15)</td>
<td>2 (20)</td>
</tr>
<tr>
<td>On statin therapy (%)</td>
<td>35 (55)</td>
<td>13 (33)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>On antiplatelet therapy (%)</td>
<td>37 (61)</td>
<td>13 (33)</td>
<td>5 (50)</td>
</tr>
<tr>
<td>Median ASA† (range)</td>
<td>3 (2–4)</td>
<td>3 (2–5)</td>
<td>3 (2–3)</td>
</tr>
<tr>
<td>30-day mortality (%)</td>
<td>0</td>
<td>11 (28)</td>
<td>0</td>
</tr>
</tbody>
</table>

†American Society of Anesthesiologists physical status classification system

Figure 1: The number of open AAA repairs performed in each year of the study period stratified by the indication for surgery.
### Table 2: Costs and length of stay of open AAA repair in the primary analysis.

<table>
<thead>
<tr>
<th>Group</th>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Median (Q1–Q3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective (n=64)</td>
<td>Length of stay (days)</td>
<td>9 (5)</td>
<td>8 (6–11)</td>
</tr>
<tr>
<td></td>
<td>Total cost</td>
<td>$28,019 (16,306)</td>
<td>$24,628 ($21,012–$29,306)</td>
</tr>
<tr>
<td></td>
<td>Pre-hospital</td>
<td>$149 (200)</td>
<td>$159 ($50–$198)</td>
</tr>
<tr>
<td></td>
<td>Operation</td>
<td>$9,763 (2,880)</td>
<td>$8,413 ($6,568–$9,618)</td>
</tr>
<tr>
<td></td>
<td>ICU</td>
<td>$6,500 (10817)</td>
<td>$4,487 ($3,905–$5,113)</td>
</tr>
<tr>
<td></td>
<td>Blood products</td>
<td>$373 (954)</td>
<td>$49 ($0–$546)</td>
</tr>
<tr>
<td></td>
<td>Laboratory costs</td>
<td>$402 (337)</td>
<td>$327 ($237–$459)</td>
</tr>
<tr>
<td></td>
<td>Ward costs</td>
<td>$9,498 (3988)</td>
<td>$9,053 ($7,157–$11,790)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>$1,335 (2053)</td>
<td>$666 ($358–$1,225)</td>
</tr>
<tr>
<td>Ruptured (n=40)</td>
<td>Length of stay (days)</td>
<td>10 (8)</td>
<td>9 (4–16)</td>
</tr>
<tr>
<td></td>
<td>Total cost</td>
<td>$38,804 (30,620)</td>
<td>$31,895 ($24,691–$40,7301)</td>
</tr>
<tr>
<td></td>
<td>Pre-hospital</td>
<td>$241 (1,497)</td>
<td>$0 ($0–$0)</td>
</tr>
<tr>
<td></td>
<td>Operation</td>
<td>$9,682 (5,061)</td>
<td>$9,115 ($6,960–$11,346)</td>
</tr>
<tr>
<td></td>
<td>ICU</td>
<td>$13,250 (21,693)</td>
<td>$7,868 ($3,857–$14,166)</td>
</tr>
<tr>
<td></td>
<td>Blood products</td>
<td>$4,404 (6,069)</td>
<td>$2,328 ($1,195–$4,772)</td>
</tr>
<tr>
<td></td>
<td>Laboratory costs</td>
<td>$731 (591)</td>
<td>$549 ($422–$884)</td>
</tr>
<tr>
<td></td>
<td>Ward costs</td>
<td>$8,170 (7,431)</td>
<td>$7,400 ($610–$13,229)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>$2,327 (3559)</td>
<td>$1,248 ($562–$2,298)</td>
</tr>
<tr>
<td>Symptomatic (n=10)</td>
<td>Length of stay (days)</td>
<td>12 (9)</td>
<td>8 (7–15)</td>
</tr>
<tr>
<td></td>
<td>Total cost</td>
<td>$33,743 (19,351)</td>
<td>$25,891 ($21,973–$36,439)</td>
</tr>
<tr>
<td></td>
<td>Pre-hospital</td>
<td>$432 (869)</td>
<td>$0 ($0–$179)</td>
</tr>
<tr>
<td></td>
<td>Operation</td>
<td>$8,740 (1,414)</td>
<td>$9,083 ($8,315–$9,774)</td>
</tr>
<tr>
<td></td>
<td>ICU</td>
<td>$8,108 (7,079)</td>
<td>$4,679 ($3,975–$8,854)</td>
</tr>
<tr>
<td></td>
<td>Blood products</td>
<td>$905 (1,026)</td>
<td>$820 ($43–$1,225)</td>
</tr>
<tr>
<td></td>
<td>Laboratory costs</td>
<td>$666 (558)</td>
<td>$508 ($306–$764)</td>
</tr>
<tr>
<td></td>
<td>Ward costs</td>
<td>$13,050 (10,378)</td>
<td>$7,673 ($6,938–$17,071)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>$1,842 (1,612)</td>
<td>$1,344 ($617–$2,013)</td>
</tr>
</tbody>
</table>

\(^{33}\) patients

Analyses were carried out using SAS/STAT 12.1 software. All t-tests used the Satterthwaite approximation for unequal variances. Statistical significance was set at p<0.05. Although cost distributions were inspected and found to be skewed with long tails of high values, analyses focused on mean costs rather than the medians, as these are what are relevant to health care planners.\(^{12}\)

### Results

A total of 169 AAA were repaired during the study period. This consisted of 117 (69.2%) elective repairs (64 OAR and 53 EVAR), 42 (24.9%) ruptured repairs (40 OAR and 2 EVAR), and 10 (5.9%) symptomatic repairs (all OAR). The total number of ruptured AAA presenting to the hospital
during this period was 89, of which 47 (53%) were managed non-operatively, either dying before reaching the operating theatre or after having decided not to undergo operation. Demographics and risk factors for each group is summarised in Table 1. The median age for the elective, ruptured, and symptomatic groups was 73, 77 and 74 years, respectively. All three groups consisted primarily of male patients. The elective group had a higher proportion of patients with ischaemic heart disease, who were receiving statin and antiplatelet therapy compared to the other groups. The symptomatic group had the highest proportion of patients with a recorded history of smoking and hypertension. There was no 30-day mortality in the elective or symptomatic groups. The 30-day mortality of the ruptured aneurysms repaired was 11 out of 42 (26.2%).

Thirteen out of the 117 (11%) elective patients, and 7 out of the 42 (17%) of ruptured patients, were discharged to a rehabilitation facility. The median length of stay (LOS) in rehabilitation for the elective and rupture group was 8 and 12 days respectively.

Primary analysis: Costs of open AAA repairs between elective and ruptured groups

114 open AAA were repaired during the study period. Of those, 64 were elective repairs, 40 were ruptures and 10 were symptomatic repairs. Figure 1 demonstrates the number of open repairs performed annually stratified by the indication for surgery.

The costs and LOS amongst the groups included in the primary analysis is presented in Table 2. The mean cost per patient in the open elective group was $28,019. In the open ruptured group it was $38,804, and for the open symptomatic group it was $33,743. The distribution of the total cost per group is demonstrated by the box plots in Figure 2. The mean LOS was 9 days for elective, 10 days for rupture, and 12 days for symptomatic admissions. The most significant categories contributing to the total costs amongst the three groups were operation, ward and ICU costs, with overall means of $9,644, $9,343 and $9,009, respectively. The median time from start of anaesthetic until leaving operating theatre for the elective, rupture group and the symptomatic groups was 265, 205 and 224 minutes respectively.

Table 3 shows the statistical comparison between the open rupture and elective groups. There was a significant difference between the mean inpatient cost of open ruptured AAA repair and open elective AAA repair of $10,785 (95%CI: $249, $21,321; p=0.045). The cost of blood products was $4,031 greater (95%CI: $2,077, $5,985; p=0.0002), and the cost of laboratory...
Table 3: Statistical comparison of length of stay and costs between open ruptured and elective groups.

<table>
<thead>
<tr>
<th></th>
<th>Mean cost ruptured (SD) [n=40]</th>
<th>Mean cost elective (SD) [n=64]</th>
<th>Mean Difference</th>
<th>95% CI for difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay (days)</td>
<td>10 (8)</td>
<td>9 (5)</td>
<td>1</td>
<td>-2.4</td>
</tr>
<tr>
<td>Total cost</td>
<td>$38,804 (30,620)</td>
<td>$28,019 (16,306)</td>
<td>$10,785*</td>
<td>$249, $21,321</td>
</tr>
<tr>
<td>Pre-hospital</td>
<td>$241 (1,497)</td>
<td>$149 (200)</td>
<td>$92</td>
<td>-$389, $573</td>
</tr>
<tr>
<td>Operation</td>
<td>$9,682 (5,061)</td>
<td>$9,763 (2,880)</td>
<td>-$81</td>
<td>-$1,839, $1,677</td>
</tr>
<tr>
<td>ICU</td>
<td>$13,250 (21,693)</td>
<td>$6,500 (10,817)</td>
<td>$6,750</td>
<td>-$650, $14,150</td>
</tr>
<tr>
<td>Blood products</td>
<td>$4,404 (6,069)</td>
<td>$373 (954)</td>
<td>$4,031***</td>
<td>$2,077, $5,985</td>
</tr>
<tr>
<td>Laboratory costs</td>
<td>$731 (591)</td>
<td>$402 (337)</td>
<td>$329**</td>
<td>$123, $534</td>
</tr>
<tr>
<td>Ward costs</td>
<td>$8,170 (7,431)</td>
<td>$9,498 (3,988)</td>
<td>-$1,328</td>
<td>-$3,888, $1,231</td>
</tr>
<tr>
<td>Other</td>
<td>$2,327 (3,559)</td>
<td>$1,335 (2,053)</td>
<td>$992</td>
<td>-$247, $2,231</td>
</tr>
</tbody>
</table>

*p <0.05, **p <0.01, ***p <0.001

Table 4: Statistical comparison of length of stay and costs between open rupture and elective groups with early mortality (<4 days) excluded.

<table>
<thead>
<tr>
<th></th>
<th>Mean cost ruptured (SD) [n=31]</th>
<th>Mean cost elective (SD) [n=64]</th>
<th>Mean Difference</th>
<th>95% CI for difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay (days)</td>
<td>12 (7)</td>
<td>9 (5)</td>
<td>3*</td>
<td>5.6</td>
</tr>
<tr>
<td>Episode cost</td>
<td>$44,182 (32,582)</td>
<td>$28,019 (16,306)</td>
<td>$16,163*</td>
<td>$3,612, $28,714</td>
</tr>
<tr>
<td>Pre-hospital</td>
<td>$310 (1,700)</td>
<td>$149 (200)</td>
<td>$162</td>
<td>-$463, $787</td>
</tr>
<tr>
<td>Operation</td>
<td>$9,999 (5,546)</td>
<td>$9,763 (2,880)</td>
<td>$236</td>
<td>-$1,907, $2,380</td>
</tr>
<tr>
<td>ICU</td>
<td>$15,906 (23,938)</td>
<td>$6,500 (10,817)</td>
<td>$9,406*</td>
<td>$266, $18,546</td>
</tr>
<tr>
<td>Blood products</td>
<td>$3,743 (1,543)</td>
<td>$373 (954)</td>
<td>$3,370**</td>
<td>$1,159, $5,581</td>
</tr>
<tr>
<td>Laboratory costs</td>
<td>$849 (623)</td>
<td>$402 (337)</td>
<td>$447***</td>
<td>$208, $686</td>
</tr>
<tr>
<td>Ward costs</td>
<td>$10,454 (7,918)</td>
<td>$9,498 (3,988)</td>
<td>$956</td>
<td>-$1,747, $3,661</td>
</tr>
<tr>
<td>Other</td>
<td>$2,918 (3,851)</td>
<td>$1,335 (2,053)</td>
<td>$1,583*</td>
<td>$90, $3,076</td>
</tr>
</tbody>
</table>

*p <0.05, **p <0.01, ***p <0.001

investigations was $329 greater (95%CI: $123, $534; p=0.002) in the ruptured group than the elective group. There was no difference in pre-hospital, operation, ICU, ward or 'other' costs between the groups. There was no significant difference in LOS between the two groups.

Costs of open AAA repairs between elective and ruptured groups, excluding early (<4 day) mortality

Of the 40 patients with ruptured AAA who had a repair, nine died within four days. The mean difference of costs between ruptured and elective groups with early mortality excluded is presented in Table 3.

4. In this analysis, there was a significant mean difference of $16,163 (95%CI: $3,612, $28,714; p=0.01) between open ruptured AAA repair and open elective AAA repair. ICU, blood product, laboratory and ‘other’ costs were significantly higher in the ruptured group, while pre-hospital, operation and ward costs were not different.

Costs of all AAA repairs between elective and ruptured groups, including EVAR

There were 53 elective and two rupture EVARs. The mean total inpatient cost of elective EVAR was $31,023 per patient. The mean cost of the aortic stent graft for those
who underwent EVAR was $14,765. Table 5 shows the results of a cost analysis of all AAA repairs, including EVAR, during the study period. This analysis included 117 elective AAA and 42 ruptured AAA. The demographics and risk factors relevant to this analysis are summarised in Table 6. The mean total cost in the elective group was $29,380 and $38,590 in the ruptured group. There was a trend towards a lower mean cost in the elective group, but the mean difference of $9,210 was not statistically significant (95% CI: -$404, $18,825; p=0.06). Blood products and laboratory costs were significantly higher in the ruptured group. The mean length of stay was 3 days shorter in the elective group than in the rupture group (95% CI: 0.5, 6; p=0.02). When comparing the elective group including EVAR to the elective group excluding EVAR, there appears to be a higher operation cost and a lower ICU cost.

### Costs of AAA repair between EVAR elective and open elective groups

Table 7 shows the difference in mean cost between the 53 patients who had EVAR and the 64 patients who had open procedures as an elective case. The EVAR group had a 5 day (95% CI: -7, -4; p=0.0001) shorter

---

**Table 5:** Statistical comparison of length of stay and costs between rupture and elective groups including EVAR.

<table>
<thead>
<tr>
<th></th>
<th>Mean cost ruptured (SD) [n=42]</th>
<th>Mean cost elective (SD) [n=117]</th>
<th>Mean Difference</th>
<th>95% CI for difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay (days)</td>
<td>10 (8)</td>
<td>7 (5)</td>
<td>3*</td>
<td>0.5, 6</td>
</tr>
<tr>
<td>Total cost</td>
<td>$38,590 (29,880)</td>
<td>$29,380 (13,641)</td>
<td>$9,210</td>
<td>-$404, $18,825</td>
</tr>
<tr>
<td>Pre-hospital</td>
<td>$242 (697)</td>
<td>$129 (162)</td>
<td>$113</td>
<td>-$344, $568</td>
</tr>
<tr>
<td>Operation</td>
<td>$10,400 (5,912)</td>
<td>$17,537 (10,321)</td>
<td>-$7,137</td>
<td>-$9,750, $4,524</td>
</tr>
<tr>
<td>ICU</td>
<td>$12,619 (21,349)</td>
<td>$3,590 (8,602)</td>
<td>$9,029</td>
<td>-$2,206, $15,850</td>
</tr>
<tr>
<td>Blood products</td>
<td>$4,197 (5,992)</td>
<td>$260 (743)</td>
<td>$3,937***</td>
<td>$2,065, $5,809</td>
</tr>
<tr>
<td>Laboratory costs</td>
<td>$706 (586)</td>
<td>$291 (308)</td>
<td>$415***</td>
<td>$224, $606</td>
</tr>
<tr>
<td>Ward costs</td>
<td>$7,963 (7,307)</td>
<td>$6,191 (4,810)</td>
<td>$1,772</td>
<td>-$567, $4,202</td>
</tr>
<tr>
<td>Other</td>
<td>$2,460 (3,558)</td>
<td>$1,388 (1,885)</td>
<td>$1,072</td>
<td>-$75, $2,219</td>
</tr>
</tbody>
</table>

*p <0.05, **p <0.01, ***p <0.001

**Table 6:** Summary of demographics and risk factors for elective and rupture groups including EVAR.

<table>
<thead>
<tr>
<th></th>
<th>Elective</th>
<th>Ruptured</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=</td>
<td>117</td>
<td>42</td>
</tr>
<tr>
<td>Median age (range)</td>
<td>74 (57–86)</td>
<td>75 (49–86)</td>
</tr>
<tr>
<td>Males (%)</td>
<td>88 (75)</td>
<td>35 (83)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>11 (9)</td>
<td>4 (10)</td>
</tr>
<tr>
<td>Smoking history (%)</td>
<td>72 (62)</td>
<td>17 (40)</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>73 (63)</td>
<td>20 (48)</td>
</tr>
<tr>
<td>Ischaemic heart disease (%)</td>
<td>39 (33)</td>
<td>8 (19)</td>
</tr>
<tr>
<td>On statin therapy (%)</td>
<td>61 (52)</td>
<td>14 (33)</td>
</tr>
<tr>
<td>On antiplatelet therapy (%)</td>
<td>67 (57)</td>
<td>14 (33)</td>
</tr>
<tr>
<td>Median ASA† (range)</td>
<td>3 (2–4)</td>
<td>3 (2–5)</td>
</tr>
<tr>
<td>30 day mortality (%)</td>
<td>0 (0)</td>
<td>11 (26)</td>
</tr>
</tbody>
</table>
length of hospital stay than open AAA repair. However, there was no difference in total inpatient cost. The mean difference in operation cost was in the EVAR group, significantly higher than in the open group at $17,163 (95% CI: $14,861, $19,463; p<.0001), while the mean difference in ICU and ward costs were significantly lower.

**Discussion**

In this study, we observed a higher mean of inpatient costs of rupture compared to elective OAR despite no difference in LOS. The significantly more expensive costs were those of blood products and laboratory tests. By excluding early mortality, a larger difference was observed. When EVAR were included in the analysis a trend, but not a significant difference, was observed. As documented in other studies, the cost of the EVAR procedure was significantly more expensive than an OAR operation but the overall inpatient mean elective cost was similar between both EVAR and OAR.9

One of the important factors to weigh in the decision about initiating a screening program for AAA in New Zealand is cost effectiveness. AAA ruptures have declined following screening programs in other parts of the world because patients with large aneurysms would have been referred for surgical consideration, and small AAA would undergo regular surveillance.5,13 A screening program that reduces the incidence of ruptured AAA would decrease the average individual inpatient cost of AAA repairs. However, it is still necessary to determine the other expenses involved in screening, including the cost of providing the test, the cost of surveillance of detected small aneurysms and the cost of repairing a larger number of AAA electively. Further research could also determine the cost per quality-adjusted life year gained after AAA repair.

In 2000, Patel et al determined that the cost of repairing ruptured AAA was acceptable compared to no intervention.14 There are five historical published papers comparing hospital costs of ruptured and elective AAA repairs.15-19 Three of these papers were from the US,15,16,18 one from Australia,17 and one from Canada.19 Table 8 compares the presented data to each of the studies. The results of each study examined show that ruptured AAA repair have a higher mean hospital cost than elective AAA repair, and this difference reached statistical significance in all cases during the last 35 years. The current study is similar in methodology to two of the American studies, Roher et al15 and Pasch et al.16 The other three papers did not include consecutive patients from each group for comparison.17-19 The current study has the second largest group and highest, when EVAR included. In addition, this study was the first to include symptomatic, but not ruptured, emergency AAA repairs and provides cost data of this group. Study dates of the previously published papers ranged from the 1970s.

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**Table 7:** Statistical comparison of length of stay and costs between EVAR elective and open elective groups.

<table>
<thead>
<tr>
<th></th>
<th>Mean cost EVAR elective (SD) [n=53]</th>
<th>Mean cost open elective (SD) [n=64]</th>
<th>Mean Difference</th>
<th>95% CI for difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay (days)</td>
<td>4 (3)</td>
<td>9 (5)</td>
<td>-5***</td>
<td>-7, -4</td>
</tr>
<tr>
<td>Total cost</td>
<td>$31,023 (9,380)</td>
<td>$28,019 (16,306)</td>
<td>$3,004</td>
<td>$-1,777, $7,786</td>
</tr>
<tr>
<td>Pre-hospital</td>
<td>$107 (134)</td>
<td>$149 (200)</td>
<td>$-42</td>
<td>$-98, $14</td>
</tr>
<tr>
<td>Operation</td>
<td>$26,926 (5,061)</td>
<td>$9,763 (2,880)</td>
<td>$17,163***</td>
<td>$14,861, $19,463</td>
</tr>
<tr>
<td>ICU</td>
<td>$77 (231)</td>
<td>$6,500 (10,817)</td>
<td>$-6,423***</td>
<td>$-9129, -3,717</td>
</tr>
<tr>
<td>Blood products</td>
<td>$125 (308)</td>
<td>$373 (954)</td>
<td>$-248</td>
<td>$-499, $4</td>
</tr>
<tr>
<td>Laboratory costs</td>
<td>$147 (189)</td>
<td>$402 (337)</td>
<td>$-255***</td>
<td>$-354, -156</td>
</tr>
<tr>
<td>Ward costs</td>
<td>$2,199 (1,630)</td>
<td>$9,498 (3,988)</td>
<td>$-7,299***</td>
<td>$-8,358, -6,213</td>
</tr>
<tr>
<td>Other</td>
<td>$1,453 (1,675)</td>
<td>$1,335 (2,053)</td>
<td>$118</td>
<td>$-564, $801</td>
</tr>
</tbody>
</table>

*p <0.05, **p <0.01, ***p <0.001
ARTICLE

until the 1990s, so the current paper provides more recent cost information.
The current study also provides cost figures from New Zealand and is therefore useful when considering a national screening program. The results of the paper concur with the results from Asher et al,\(^1\) and Chew et al,\(^2\) that blood product costs contribute significantly to the total costs difference, however, Asher et al\(^1\) also found that ICU and ward costs were higher in the ruptured group.

In New Zealand, the proportion of elective AAA treated with EVAR remains at 55–60% (Australasian Vascular Audit). This figure is different from Australia and the US, where 70–80% of AAA are managed with EVAR.\(^3\) The influence of an AAA screening program in New Zealand is unlikely to change this proportion for several reasons. First, on average the ratio of treatment modality (OAR vs EVAR) has remained fairly constant in the last 5 years. Secondly, there is no overall difference in patient survival following AAA repair with either method, and decision to choose the most appropriate modality remains clinician and patient based. Finally, 5-year data from the UK AAA screening programme has shown that the 46.2% of patients had an EVAR and the remaining patients had an OAR (personal communication).

Limitations to the study included the large variability in the costs which were examined. It is suspected that for this reason a significant difference in ICU cost was not observed in the primary analysis, and that ICU cost was in fact the main driver of the cost difference. This study did not show a significant difference between groups when the analysis was performed including EVAR, but it is believed that there is a convincing trend towards a lower inpatient cost in the elective setting which is also driven by lower ICU cost. Additionally, it is expected that patients with ruptured aneurysms would require more post-operative rehabilitation or further community district costs. These costs were not collected in this analysis. Other limitations include the relatively small number of patients studied and the retrospective nature of the study. It is worth noting that patient and family, community care and associated rehabilitation costs were not included in this study.

### Table 8: Presented data from the current study and five comparable papers.

<table>
<thead>
<tr>
<th></th>
<th>Rohrer et al(^1)</th>
<th>Pasch et al(^1)</th>
<th>Bagia et al(^7)</th>
<th>Ascher et al(^8)</th>
<th>Chew et al(^9)</th>
<th>Current study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country</strong></td>
<td>USA</td>
<td>USA</td>
<td>Australia</td>
<td>USA</td>
<td>Canada</td>
<td>New Zealand</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>Retrospective, Consecutive patients</td>
<td>Retrospective, Consecutive patients</td>
<td>Retrospective, Randomly-selected patients, stratified by age</td>
<td>Retrospective, Matched controls</td>
<td>Retrospective, Consecutive ruptures, random controls</td>
<td>Retrospective, consecutive patients</td>
</tr>
<tr>
<td><strong>N=</strong></td>
<td>30</td>
<td>129</td>
<td>40</td>
<td>20</td>
<td>89</td>
<td>114 (169(^\dagger))</td>
</tr>
<tr>
<td><strong>Ruptured</strong></td>
<td>14</td>
<td>20</td>
<td>20</td>
<td>10</td>
<td>41</td>
<td>40 (42(^\dagger))</td>
</tr>
<tr>
<td>10 &lt;80 yrs,</td>
<td>10 &gt;80 yrs</td>
<td>10 &gt;80 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Elective</strong></td>
<td>16</td>
<td>109</td>
<td>20</td>
<td>10</td>
<td>48</td>
<td>64 (117(^\dagger))</td>
</tr>
<tr>
<td>10 &lt;80 yrs,</td>
<td>10 &gt;80 yrs</td>
<td>Symptomatic = 10 (10(^\dagger))</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean cost rupture</strong></td>
<td>35,500</td>
<td>18,223</td>
<td>&lt;80 = 33,600; &gt;80= 37,347</td>
<td>126,305</td>
<td>18,899</td>
<td>38,804 (38,590(^\dagger))</td>
</tr>
<tr>
<td><strong>Mean cost elective</strong></td>
<td>26,000</td>
<td>10,114</td>
<td>&lt;80=8,081; &gt;80=10,305</td>
<td>33,165</td>
<td>12,324</td>
<td>28,019 (29,380(^\dagger))</td>
</tr>
<tr>
<td><strong>Significant difference?</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
<td>Yes (No)</td>
</tr>
</tbody>
</table>

\(^\dagger\)Information in brackets including EVAR
study. The costs generated are likely to slightly underestimate the overall costs of AAA repair. In conclusion, OAR cost more when performed in an emergency setting than when done electively. Potential cost savings in prevention of AAA ruptures and minimizing associated costs in treating rupture AAA can be directed into an AAA screening strategy. The estimated inpatient costs documented in this study for each type of repair can be used for cost-effectiveness analysis in New Zealand.

**Competing interests:**
Nil

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**URL:**

**REFERENCES:**


The diagnostic role of ventilation/perfusion scans versus computed tomography pulmonary angiography in obstetric patients investigated for pulmonary embolism at Wellington Hospital from 2010 to 2012

Sally Easther, Fali Langdana, Dushyant Maharaj, Peter Abels, Richard Beasley, James Entwisle

ABSTRACT

AIM: To develop best practice clinical guidelines for the use of ventilation/perfusion (V/Q) scanning and computed tomography perfusion angiography (CTPA) in pregnancy and the postpartum period.

METHOD: Retrospective analysis of the clinical findings and radiologic investigation for pulmonary embolism (PE) in obstetric women at Wellington Hospital from 2010 to 2012.

RESULTS: Fifty-four women were investigated for PE with a V/Q scan or CTPA, including 29 antenatal women and 25 postnatal women. Eleven (37.9%) antenatal women had V/Q scans and 18 (62%) had CTPAs. Five (20%) postnatal women had V/Q scans, 19 (76%) had CTPAs and one (4%) had a V/Q scan followed by a CTPA. Three of the 54 women (5.6%) had a positive radiologic finding of PE (two by V/Q scan and one by CTPA). Four (22.2%) antenatal women and 5 (25%) postnatal women had a diagnosis made on CTPA, which was not seen on chest x-ray.

CONCLUSION: This audit found that clinicians varied in their investigation of cases suspected of PE. We have proposed a clinical pathway for the investigation of PE in pregnancy and the postpartum period.

Pulmonary embolism (PE) is the leading cause of non-obstetric mortality during pregnancy and the peripartum period in the developed world, and accounts for 10% of all maternal deaths.\textsuperscript{1-5} Investigation of suspected PE usually follows a pathway which includes physical symptoms and signs, an ultrasound investigation of any underlying deep vein thrombosis (DVT), a chest x-ray and imaging of the lungs with either ventilation/perfusion (V/Q) scanning or computed tomography pulmonary angiography (CTPA). The preference of imaging modality for diagnosing PE in the non-pregnant population has been studied by the Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) Trials, which provided level one evidence that CTPA is superior to ventilation-perfusion (V/Q) scans in diagnosing PE.\textsuperscript{2} These trials, however, specifically excluded pregnant women, and are often
misinterpreted by some clinicians who presume that the findings are also valid in pregnancy. This may not be the case, as the underlying physiological changes which occur during pregnancy—such as alterations in cardiac output, changes in plasma volume and distribution of fluid between body compartments—reduces the accuracy of CTPA. Furthermore, the general population has a disproportionate number of indeterminate V/Q scans due to the inclusion of older patients with higher rates of underlying cardiac and lung disease. Pregnant women tend to be younger and healthier with lower rates of indeterminate V/Q scans.

There are currently no national or local guidelines for the management of PE in obstetric patients. Current widely-used international guidelines leave the choice of imaging modality to individual clinicians and do not specify recommendations based on gestation or for during the post-partum period. This audit aimed to look at the management of PE in obstetric patients at Wellington Hospital, particularly looking at the choice of imaging modality. It further aimed to calculate the yield of positive scans in these patients and to use this data to support the development of a local clinical pathway for best practice in pregnant women, taking into consideration the risks of radiation to both the mother and foetus.

### Methods

Data were collected for all antenatal and postnatal inpatient and outpatient women investigated for PE with either a V/Q scan or CTPA at Wellington Hospital from 2010–2012. The patient cohort was identified from the electronic records held by the Department of Radiology by selecting all patients from the Women’s Health Department for whom V/Q scans or CTPA were performed during that time period. Records of all women in the cohort were screened and collected by the author from patient files and the electronic patient database used at Capital and Coast District Health Board (Concerto®), and gynaecology patients were excluded. The cohort was divided into antenatal and postnatal subgroups and analysed separately. The positive yield of PE for V/Q scans and CTPA was calculated as percentages.

### Results

Between 2010 and 2012, 54 obstetric patients (29 antenatal and 25 postnatal) were investigated for PE with either a V/Q scan or CTPA. Of the antenatal women, 11 (37.9%) had a V/Q scan and 18 (62%) had a CTPA. Five (20%) of the postnatal women had a V/Q scan, 19 (76%) had a CTPA and one (4%) had a V/Q scan followed by a CTPA (Table 1).

<table>
<thead>
<tr>
<th>Scan Type</th>
<th>Antenatal</th>
<th>Postnatal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>V/Q Scan only</td>
<td>11 (37.9%)</td>
<td>5 (20%)</td>
<td>16 (29.6%)</td>
</tr>
<tr>
<td>CTPA only</td>
<td>18 (62%)</td>
<td>19 (76%)</td>
<td>37 (68.5%)</td>
</tr>
<tr>
<td>V/Q Scan -&gt; followed by CTPA</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
<td>1 (1.9%)</td>
</tr>
<tr>
<td>Total</td>
<td>29</td>
<td>25</td>
<td>54</td>
</tr>
</tbody>
</table>

Three of the 54 patients (5.6%) had a positive radiological test with a high probability of PE. Two were antenatal patients, both diagnosed by V/Q scan (Table 2) and one was a postnatal patient diagnosed by CTPA (Table 2).

Six of the 29 antenatal women (20.7%) had a CTPA despite a normal chest x-ray, and three (10.3%) had a V/Q scan despite an abnormal chest x-ray. Chest x-rays were not performed in seven (21.4%) of the antenatal women (Table 3). Three postnatal women (12%) had a V/Q scan despite an abnormal chest x-ray. All the postnatal women had chest x-rays performed (Table 3).

There were 18 antenatal and 20 postnatal women who had a CTPA. Of the women who had normal chest x-rays followed by a CTPA (15), nine (24%) had a diagnosis
Table 2: Positive yield of imaging (Antenatal n=2/29 and Postnatal n=1/25).

<table>
<thead>
<tr>
<th>Yield</th>
<th>V/Q Scans</th>
<th></th>
<th>CTPA</th>
<th></th>
<th>V/Q Scan -&gt;CTPA</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antenatal</td>
<td>Postnatal</td>
<td>Antenatal</td>
<td>Postnatal</td>
<td>Antenatal</td>
<td>Postnatal</td>
</tr>
<tr>
<td>Positive</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>9</td>
<td>5</td>
<td>18</td>
<td>18</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Subtotal</td>
<td>11</td>
<td>5</td>
<td>18</td>
<td>19</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td></td>
<td>37</td>
<td></td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Scans performed following chest x-ray antenatal and post-natal women (n= 29) (one postnatal patient had both a V/Q scan and CTPA).

<table>
<thead>
<tr>
<th>Imaging</th>
<th>Normal CXR</th>
<th>Abnormal CXR</th>
<th>CXR not performed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antenatal</td>
<td>Postnatal</td>
<td>Antenatal</td>
</tr>
<tr>
<td>V/Q Scan</td>
<td>8 (27.6%)</td>
<td>3 (12%)</td>
<td>3 (10.3%)</td>
</tr>
<tr>
<td>CTPA</td>
<td>6 (20.7%)</td>
<td>9 (36%)</td>
<td>5 (17.2%)</td>
</tr>
<tr>
<td>Subtotal</td>
<td>14</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

made by CTPA, which was not seen on chest x-ray. This included six cases of pneumonia, and one case each of pericardial effusion, pleural effusion and pulmonary embolism.

**Discussion**

This study showed that there was wide variation in the choice of imaging modality used to diagnose PE, with inconsistencies in the application of imaging choices in relation to timing throughout pregnancy and the puerperium. In addition, only a proportion of women had a chest x-ray (87.03%) prior to further diagnostic imaging. The results reinforce the need to have clarity in evidence-based guidelines for the investigation of these women.

The major strength of this study is the use of data from a cohort of patients combined with empirical evidence to propose refinements of existing algorithms. Our clinical pathway has expanded on previous guidelines by including specific recommendations for each trimester of pregnancy and post-partum. We recognise that our study uses a small cohort from a single hospital and has the limitations associated with retrospective analysis of data, such as primary statistics could not be measured and a reliance on accurate record keeping.

It is controversial as to whether V/Q scans or CTPA is the preferred diagnostic modality for PE in pregnancy. Two retrospective studies by Cahill et al2 and Ridge et al8 concluded that pregnant women who had V/Q scans were more likely to have a confirmed diagnosis compared to pregnant women who had a CTPA, particularly if they had a normal chest x-ray (30% compared with 5.6% with an adjusted odds ratio of 5.4).2,8 Studies by Shahir et al9 and Revel et al5 found that both tests have equivalent accuracy, however, they concluded that CTPA can be more useful in some cases as it allows for better diagnosis of alternative pathologies.5,9

The need for specific guidelines in relation to obstetrics is due to concerns about the risk of radiation to the foetus from any form of ionising radiation. The exact threshold dose of radiation to the foetus before detrimental effects occur is unknown, and is estimated to range between 50–100 mGy.3,4,10-13 V/Q scanning delivers considerably more radiation to the foetus than CTPA due to the pooling of contrast in the maternal bladder. The mean foetal radiation dose from a V/Q scan ranges between 0.1–1.8 mGy, depending on the dose of contrast, and if both ventilation and perfusion scanning are used.3,9,10,12-17 In contrast, the mean dose to the foetus from CTPA is estimated to range from 0.003 mGy to 0.66 mGy, with doses increasing with gestational age.3,9-17

In contrast, maternal radiation is significantly higher with CTPA than
**Risk factors for VTE in pregnancy:**
- Age of ≥35 years
- Obesity
- Multiparity
- Gestation <36 weeks
- Inherited clotting disorders or strong family history
- Previous thrombotic event
- Recent trauma
- Immobilisation (>4 days of bed rest)
- Long-haul travel ≥4 hours
- Instrument-assisted or caesarean delivery
- Haemorrhage
- Prolonged labour
- Pre-eclampsia

**Clinical suspicion of VTE in pregnancy and postpartum**
- Full history and examination
- Assess risk factors (see box to left)
- FBC, Finger probe oxygen saturations
- DO NOT TAKE D-DIMER

**High pre-test clinical likelihood of PE**
Other pathologies considered unlikely

**Clinical pathway for investigation of VTE in pregnancy & postpartum.**

**Figure 1:** Clinical pathway for investigation of VTE in pregnancy & postpartum.

- **Doppler USS**
  - Clinical signs and symptoms of DVT
  - YES
  - Treat with anticoagulation and monitor
  - NO
  - CXR

- Review of CXR by SMO/senior RMO
  - Consider medical review
  - No alternate diagnosis
  - Further imaging required
  - Alternative diagnosis made on CXR

- Call duty radiologist
  - Treat pathology as appropriate

- **Q Scan**
  - Normal CXR
  - Use as first line in the 2nd and 3rd trimesters and postpartum as reduces radiation to maternal breast tissue
  - Breast feeding: Decision made on a case by case basis

- **CTPA**
  - First trimester (lower radiation dose to fetus)
  - Suspected massive PE
  - Abnormal CXR (makes V/Q scan indeterminate)
  - Breast feeding: No cessation of breastfeeding

- CT scan
  - Other pathologies considered unlikely

- **CT**
  - First trimester (lower radiation dose to fetus)
  - Suspected massive PE
  - Abnormal CT scan (makes V/Q scan indeterminate)
  - Breast feeding: No cessation of breastfeeding

- **V/Q**
  - Other pathologies considered unlikely
  - No alternate diagnosis
  - Further imaging required
  - Alternative diagnosis made on CT scan

- Call duty radiologist
  - Treat pathology as appropriate

- **Gastric plethysmography**
  - Other pathologies considered unlikely
  - No alternate diagnosis
  - Further imaging required
  - Alternative diagnosis made on CT scan

- Call duty radiologist
  - Treat pathology as appropriate

- **Endovascular ultrasound**
  - Other pathologies considered unlikely
  - No alternate diagnosis
  - Further imaging required
  - Alternative diagnosis made on CT scan

- Call duty radiologist
  - Treat pathology as appropriate
V/Q scanning, particularly to the breast tissue. It is estimated that CTPA delivers between 10–70 mGy of radiation per breast, whereas a V/Q scan is estimated to deliver between 0.11–0.31 mGy per breast. The background risk of breast cancer in women of childbearing age is approximately 1 in 200. It is estimated that the delivery of 10 mGy of radiation to a women's breast increases this risk by approximately 14%. It is theorised that this risk is further increased in pregnancy due to increased radiosensitivity of the proliferating breast tissue. This is supported by a study which has shown that pregnant women treated with radiotherapy for Hodgkin's disease have a significantly higher risk of subsequently developing breast cancer than non-pregnant women. The risk of breast radiation from CTPA can be reduced by up to 57% by using thin-layered bismuth breast shields. Nevertheless, CTPA still delivers significantly more radiation to the breast tissue than V/Q scanning.

There is debate regarding the best imaging modality in the post-partum period, particularly if a woman is breast-feeding. Factors that need to be addressed are maternal breast radiation and the effect of the isotope and contrast material on the breastfeeding infant. As already mentioned, CTPA scanning exposes the breast to much larger doses of radiation than V/Q scanning, therefore V/Q scanning is preferred in the lactating woman.

Although several governing bodies and review groups have taken the above factors into consideration, and developed recommendations for the diagnosis of PE in pregnancy and the postpartum period, this has not been translated into a gestation-specific clinical pathway. Using the findings from our audit and the principles from international review groups, we have proposed a clinical pathway for the investigation of PE in the three trimesters of pregnancy, and the postpartum period (Figure 1).

When there is a suspicion of venous thromboembolism, any pregnant or post-partum woman, at first, should have a full history taken and an examination performed, assessing for risk factors for PE (see Figure 1). Initial investigations should include a full blood count (FBC), and finger oxygen probe saturations should be taken. A D-dimer should not be taken, as levels are normally high during pregnancy and cannot be used to reliably rule out PE.

Patients with signs and symptoms of a DVT should have a compression ultrasound Doppler study of the affected leg. If positive, this needs to be treated with therapeutic anticoagulation, and further investigations for PE can cease because treatment for PE and DVT is the same, and imaging exposes the mother and foetus to unnecessary radiation.

If there are no signs or symptoms of DVT, but high clinical suspicion of a PE, women should then have a chest x-ray, as it can help diagnose or rule out other causes of the symptoms, such as pneumonia or pneumothorax, and to decide whether a V/Q scan or CTPA is appropriate. All women suspected of having a massive PE should have a CTPA, as should women with an abnormal chest x-ray suspected of having a PE when a clear diagnosis cannot be made. V/Q scans are less useful for diagnosing PEs with abnormal chest x-rays because the abnormalities make ventilation-perfusion matching difficult.

We suggest that women in the second and third trimester with a normal chest x-ray have a perfusion (Q) scan as first-line imaging for PE, because of the greater diagnostic accuracy in pregnancy as compared to CTPA, and delivery of lower radiation. We recommend the use of low-dose perfusion contrast and omission of the ventilation component.

During the first trimester, the foetus is most susceptible to the teratogenic effects of radiation. A case could be made for CTPA over Q scanning, while accepting that there are still some risks of radiation to maternal breast. For a 25-year-old whose background risk of developing breast cancer in the following 10 years is 0.1%, the extra risk of radiation from CTPA increases the risk by 13.6% of 0.1%, which is an increased absolute risk of 0.0136%. We feel the increased risk of teratogenesis to the foetus in the first trimester outweighs this very small increased risk of breast cancer to the mother.

During the postpartum period, Q scanning is recommended as first-line imaging to
avoid maternal breast radiation received from CTPA scanning, unless the women has an abnormal chest-x-ray or is suspected of having a massive PE. Women who are breastfeeding do not need to interrupt feeding after having a CTPA scan, however evidence is lacking as to whether women need to stop breastfeeding after having a V/Q scan. We recommend that women should express breast milk prior to the Q scan so they can feed their infant after the scan. If women are unable to express milk prior to scanning, a decision on whether to stop expressing for the following 12 hours should be made on a case-by-case basis.

In our study, eight other disorders were diagnosed by CTPA in women with normal chest x-rays; these included three cases of pneumonia and one case of pericardial effusion in our antenatal sub-group, three cases of pneumonia, and one of pleural effusion in our postnatal subgroup. It is uncertain if these pathologies would have been eventually detected if a Q scan was performed rather than a CTPA as recommended by our clinical pathway. This also highlights the importance of ongoing clinical assessment and investigation in patients where a diagnosis has not been confirmed and the illness does not resolve.

We believe that this clinical pathway would be a useful guide for clinicians in the investigation of PE in pregnancy and the postpartum period. Using the best evidence currently available, it evaluates the radiation risks to both the foetus and mother during the three trimesters of pregnancy and post-partum. Subsequent evaluation of its impact on investigation use and clinical management will be important.

Competing interests:
Nil

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REFERENCES:
6. Royal College of Obstetricians and Gynaecologists. Thromboembolic disease in pregnancy and the
ARTICLE


16. Huda W. When a pregnant patient has a suspected pulmonary embolism, what are the typical embryo doses from a chest CT and a ventilation/perfusion study? Pediatr Radiol. 2004;35:452-453.


Clinical utility and outcome analysis of faecal calprotectin in Hawkes Bay District Health Board
Wayne Bai, Thomas Boswell

**ABSTRACT**

**AIM:** An audit to review the outcome in the use of faecal calprotectin (FCP) to differentiate irritable bowel syndrome (IBS) from active inflammatory bowel disease (IBD) patients, and to detect active flares in known IBD patients in the local Hawkes Bay District Health Board (HBDHB) population from October 2013 to October 2014.

**METHOD:** Retrospective review of all FCP specimens requested in the HBDHB region from October 2013 to October 2014. Their indication, final diagnosis from clinical records, and endoscopic results are reviewed.

**RESULTS:** There were 104 FCP registrations during this period. They were ordered by gastroenterologists (67%), followed by medical specialists (31%), GPs (4%) and surgeons (2%). There were 85 FCP samples requested to differentiate IBS from active IBD. Thirty were diagnosed with IBS. The mean FCP level for the 30 patients was 27.23 mcg/g (range 14.1–41.4), which was exclusive of 50 mcg/g. Using the null value of 50 mcg/g from international studies, its p-value was <0.001. There were 19 FCP samples requested to detect a flare in known IBD patients. Seven patients were diagnosed with an active flare endoscopically. The mean FCP for the 7 patients was 378.4 mcg/g (range 275.1–481.8). This was exclusive of 250 mcg/g. Using the null value of 250 from international studies, its p-value was 0.007.

**CONCLUSION:** The use of FCP is effective to both differentiate IBS from active IBD patients, and to detect flares in known IBD patients in the HBDHB population.

Faecal calprotectin (FCP) is a stool-based biochemical test that serves as a marker of intestinal inflammation. This assay measures a zinc and calcium binding heterodimer protein that is abundant in the cytoplasm of neutrophils. Emerging evidence supports the use of FCP in two distinct clinical scenarios: differentiating irritable bowel syndrome (IBS) from inflammatory bowel disease (IBD); and in monitoring disease activity in patients with known IBD. FCP has increasing popularity as an accurate, reliable, economical and non-invasive marker of intestinal inflammation, but it can be elevated in other organic conditions, such as resolving infectious colitis, diverticulitis, non-steroidal anti-inflammatory drug (NSAID)-induced colitis, colonic adenomas or malignancies. Therefore, FCP results should be interpreted with caution.

IBS is a common condition affecting an estimated 10–20% of patients in the Western world, and it is reported to be one of the top 10 reasons for general practitioner (GP) visits. Assessment of patients with IBS, and differentiating this condition from IBD, makes up a significant proportion of the gastroenterology outpatient workload. In the absence of known organic disease, a cut-off value at 50 mcg/g has a 93% sensitivity and 91% specificity to differentiate between active IBD and IBS. FCP assessment has been very helpful in this setting, in which it is incorporated into the National Institute for Health and Care Excellence (NICE) guidelines. It has been estimated that its introduction has reduced the demand for colonoscopy to distinguish IBS from IBD by 50%, using a 50 mcg/g cut-off value.
The combination of Crohn’s Disease Activity Index (CDAI), Simple Clinical Colitis Activity Index (SCCAI), serum markers and colonoscopy are traditionally used to monitor response to IBD treatment and detect relapse. The CDAI and SCCAI are symptom-based, and may not accurately reflect mucosal healing. Serum markers are relatively insensitive and non-specific. Colonoscopy is resource-intensive and it conveys procedural risks to patients. For patients with known IBD, a cut-off value of >250 mcg/g has a 90% sensitivity to detect clinical disease activity when compared to both colonoscopy and histology. It is interesting to review the manner in which FCP is being used at a secondary-level New Zealand hospital, and whether it is effectively helping to differentiate IBS from IBD without the need for colonoscopy. It is also interesting to review the manner of FCP to monitor disease activity in patients with known IBD. Hence, the 1-year local data on FCP use from Hawke’s Bay District Health Board (HBDHB) is presented.

**Aim**

An audit to review the outcome in the use of FCP to differentiate IBS from active IBD patients and to detect active flares in known IBD patients in the local HBDHB population from October 2013 to October 2014.

**Method**

**Patient selection/sample group**

Hastings Memorial Hospital, Hawke’s Bay, provides gastroenterology service to patients in the HBDHB region with an estimated population of 157,000. All FCP specimens requested in the HBDHB region are registered with the hospital laboratory, and the patients with FCP specimens ordered from October 2013 to October 2014 were recruited into the study.

**Clinical and biochemical evaluation**

Clinical and endoscopic data were collected from hospital records to assess indication and review end diagnosis. All FCP specimens were sent to the Canterbury DHB laboratory for processing. Only the first FCP measurement within the study period was included in the analysis of this audit. The FCP level recorded in the study must be a specimen produced within 1 week from the clinical assessment date, either in the community or inpatient setting. Any FCP level of more than 500 mcg/g did not proceed to have further dilutional studies to confirm its actual titre, and the results were analysed as “500 mcg/g” for the purpose of this study.

Clinical data obtained include age, date of birth, ethnicity, FCP level, any endoscopy and its histology results.

**End diagnosis**

A diagnosis of IBS was made on the basis of normal investigations and a compatible history fulfilling the Rome Criteria as per Box 1. A diagnosis of active IBD or IBD flare was made from a combination of endoscopic and histological investigations.

**Statistical analysis**

The data were analysed using Microsoft® Excel® for Mac 2011 Version 14.1.0. The faecal calprotectin level expressed in the two clinical groups was expressed as a 95% confidence interval (CI).

A two-tailed test with a p-value <0.05 was considered statistically significant.

**Ethics Approval**

This study was an audit. A Health and Disability Ethics Committees (HDEC) review was not necessary. (HDEC ref: 15/NTA/147)

**Results**

There were 121 FCP registrations at HBDHB from October 2013 to October 2014. Fourteen were excluded on the basis of having more than one FCP sample collected from the same patient within this time period. Only the first FCP level within this time period was analysed for the purpose of this study. An additional three patients were excluded due to incomplete clinical information. The remaining 104 FCP samples were all collected within 7 days from the assessment date.

In the 104 FCP samples remaining, 67 (64.4%) were ordered by gastroenterology.

**Box 1: Rome III Criteria for diagnosis of IBS.**

Recurrent abdominal pain or discomfort for at least three days/month in the last three months with symptom onset at least six months before diagnosis associated with two or more of the following:

- Improvement with defaecation
- Onset associated with a change in frequency of stool
- Onset associated with a change in form of stool
consultants, 31 (29.8%) by general medical consultants, 4 (3.8%) by GPs, and 2 (1.9%) by general surgeons, as shown in Figure 1.

FCP was used for two indications. There were 85 (81.7%) specimens ordered with the indication to differentiate IBS from IBD patients, and 19 (18.3%) specimens ordered with the indication to detect a flare of disease in known IBD patients.

Indication to detect IBS from IBD patients
There were 85 FCP specimens ordered with the indication to differentiate IBS from IBD. Thirty (35.3%) patients were diagnosed with IBS, 4 (4.7%) were diagnosed with active IBD, 2 (2.4%) were diagnosed with microscopic colitis, 3 (3.5%) were diagnosed with bile salt malabsorption and 46 (54.1%) had no diagnosis identified.

Figure 2 presented the FCP values of the 30 patients diagnosed with IBS. The average FCP level in the 30 patients diagnosed with IBS was 27.23 mcg/g (SD 39.46). Given the sample size of 30, its 95% CI was between 14.12 and 41.35 mcg/g, which was exclusive of 50 mcg/g. Using 50 μg/g as the null value, the p-value was <0.001. A null value of 50 μg/g was chosen because internationally published data proved a high sensitivity and specificity to detect a diagnosis of IBS from active IBD patients when FCP level was less than 50 ug/g.6

There were four out of the 30 patients diagnosed with IBS with a FCP level higher than 50mcg/g. They all had either endoscopic investigations and were followed up at the gastroenterology clinic to confirm the diagnosis of IBS.

Indication to detect disease flare in known IBD patients
There were 19 FCP specimens ordered with the indication to detect a flare in known IBD patients. Only eight patients proceeded for endoscopic assessment, and seven were diagnosed with an active IBD flare.

Figure 2 presented the FCP levels of the seven patients diagnosed with an active IBD flare. The average FCP level was 378.4mcg/g with a SD of 139.5. Given its sample size of 7, its 95% CI was between 275.1 and 481.8mcg/g. This was exclusive of 250 mcg/g. Using 250 ug/g as the null value, the p-value was 0.007 (<0.05). FCP level of 250 mcg/g was chosen as the null value because internationally published data proved a high sensitivity and specificity to detect an IBD flare when the FCP level was more than 250 ug/g.10
Conclusion

The use of FCP is effective to both differentiate IBS from active IBD patients and to detect flares in known IBD patients in the HBDHB population.

Discussion

FCP is used at HBDHB to predominantly differentiate IBS from IBD patients. The use of FCP level of <50 mcg/g to confirm IBS and >250 μg/g in known IBD patients to detect a flare fit our population well.

FCP is being used in HBDHB primarily to help differentiate IBS from IBD patients. The test performs well in this setting with a cut-off value of <50 mcg/g. Its useful negative predictive value is well established in this setting, and it will be useful to help limit the use of more invasive diagnostic modalities, such as endoscopic investigations. It is, however, important to be aware of the limitations of this test when used in this setting, particularly due to its non-specificity.

A secondary use of FCP in HBDHB is in assessing activity of disease in patients with known IBD. This makes up a smaller proportion of investigations undertaken in the region. Although the six FCP specimens that exceeded 500 mcg/g did not have further dilutional studies to confirm its actual titre, the performance of this test is still in keeping with international published data.

There are several limitations to this study. The sample size is relatively small, and it is not clear from our data what proportion of patients with suspected IBS had a FCP specimen requested. Similarly, the uptake of the test in patients with known IBD to monitor disease activity is likely to represent a small proportion of the local IBD population.

Essentially, FCP is a reliable biomarker of intestinal inflammation to help distinguish patients with IBS from those with active IBD, and to detect flares in known IBD patients in the local HBDHB population. Further research is required to observe its wider role at a national level.

Figure 2: FCP levels in patients diagnosed with IBS and a flare in patients with known history of IBD.

Dotted line depicts the null value.

(50mcg/g for the IBS group. 250mcg/g for the IBD flare group)
ARTICLE

REFERENCES:


Competing interests: Nil

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After the legalisation of cannabis: the Cannabis Incorporated Society (CIS) regulatory model for recreational cannabis in New Zealand

Chris Wilkins

There is a growing appetite worldwide for alternative policy approaches to cannabis beyond the traditional prohibition with criminal sanctions. This desire has crystallised recently with the full legalisation of cannabis in four States in the US (Colorado, Oregon, Washington, Alaska),1,2 and in Uruguay.3 It is important to be aware that the regulatory choices available for cannabis law reform are more than those seen in the profit-driven commercial markets we are familiar with for alcohol and tobacco.2 Indeed, the historical experience of the alcohol and tobacco sectors is of marketing which targets young and heavy users, expansion of retail availability, normalisation of use, denial of health risks and social harms, capture of regulatory agencies by industry, and ongoing political lobbying by industry for weaker regulation.4-7

We recognise that cannabis use is associated with a range of health issues including respiratory illness, low educational achievement, mental illness, drug dependency and vehicle crashes.8 Approximately 10% of cannabis users develop dependency, and this increases to 17% of adolescent users and one third of daily users.9 A number of studies have shown a relationship between cannabis use in adolescence and the risk of developing psychotic symptoms.9 Daily cannabis use in adolescence is associated with a range of negative outcomes including early school-leaving, cognitive impairment, increased use of other drugs, depression and suicidal ideation.9

Yet, both alcohol and tobacco use are also associated with serious health risks and they are legally available under a range of restrictions.4,8 To be consistent, the comparison of health risks between substances has to be between cannabis use under a regulated legal market (ie, age limits, potency control, product tax, etc.) and alcohol and tobacco under their current regulated markets, not between illegal unregulated cannabis and legal regulated alcohol and tobacco.10,11 There is also the important but under-researched issue of whether legal cannabis use might displace the use of alcohol and tobacco, and even other illegal drugs.12

These questions however, are beyond the scope of this viewpoint. Instead we start with the proposition that the decision to legalise cannabis has been made and, consequently, there is a requirement to develop a regulatory regime for legal recreational cannabis. We believe it is important to have this discussion now as recent experience with the Psychoactive Substances Act 2013 shows that once politicians have decided there is a need for policy change, the fundamental aspects of the new approach can be decided quite quickly.13,14

The Cannabis Incorporated Society (CIS) model we outline here is an attempt to balance the provision of legal cannabis with promoting healthier and more responsible cannabis use, while also avoiding the expansion of use via a profit driven commercial market. Cannabis clubs have
operated in other countries for a number of years, notably in Spain and Belgium. However, these are informal arrangements set up by users themselves and, consequently, have varying structures and rules, no clear official legitimacy have little engagement with treatment and other health services. They also do not generally involve any official sales of cannabis, and as a result, no tax is collected to support cannabis-related health services and regulatory enforcement.

Cannabis Incorporated Societies, or CIS, are registered clubs which will be permitted to sell cannabis to their members, but must also work toward a number of statutory cannabis health objectives. Incorporated Societies are used to organise a range of sports, music, cultural and activist groups under the *Incorporated Societies Act 1908*. New legislation will be required for CIS to establish the additional health and other responsibilities required. As with all incorporated societies, CIS cannot earn profits for their members or other private individuals. Any activity carried out by the Society must fall within the scope of the societies stated purpose and objectives. CIS will be required to meet the following statutory objectives:

1. Selling approved cannabis products to their members only
2. Promoting awareness of the health risks of cannabis use
3. Promoting awareness of local drug treatment services and other health services
4. Preventing the sale and use of cannabis by minors
5. Minimising cannabis related harm

CIS will be required to work toward these health objectives, but will be free to determine how they do this. For example, they can distribute pamphlets on the health risk of cannabis, set up a website which details the health risk of cannabis use, establish online forums to discuss the health risks of cannabis, provide advice about drug treatment and counselling options, and organise social events where members can meet drug counsellors and other health experts. These resources and events will be paid for by the CIS from their membership fees and from the sale of cannabis to members. CIS will not be permitted to advertise cannabis products, or sell alcohol or tobacco.

CIS will only be permitted to sell approved healthier versions of cannabis products to their members, such as edibles and cannabis suitable to be used in e-cigarettes and vapourisers (ie, to avoid the health risks related to smoking). Approved products will have a maximum level of THC (the active ingredient which causes intoxication), and must have a minimum level of CBD (the natural anti-psychotic in cannabis). Approved products cannot include alcohol or tobacco or any other psychoactive compounds as ingredients. The semi-processed and packaged form of these products will help distinguish them from natural plant cannabis sold on the black market. They will also reduce third party health risks from smoking, and the public profile of use (ie, edibles and e-cigarettes avoid smell and smoke).

Like all Incorporated Societies, CIS must have a managing committee which administers and controls the Society, including a President, Secretary, Treasurer and at least three committee members. A CIS management committee will be required to submit a written annual plan to the government regulator outlining the activities they intend to undertake to meet their health objectives given their projected budget from membership and cannabis revenues. A government regulator will be established who will initially review and license CIS who meet all statutory requirements, including appropriate objectives and committee membership. The Authority will regularly audit CIS to determine they are working toward their cannabis health objectives. Licenses can be withdrawn if CIS fail to pursue their health objectives or act inappropriately.

Cannabis users can legally purchase and use approved cannabis products by joining a CIS. Members of a CIS must be adults aged 18 or older. They will pay a membership fee, receive a membership card and can purchase up to one ounce equivalent of approved cannabis products per month to use as they wish. They must agree to receive information from the CIS on the health risks of cannabis and local treatment and counselling services.
The Government will contract private horticultural and food companies to grow cannabis and process it into approved cannabis products. They will be the sole producers of approved cannabis products and these will then be sold only to licensed CIS. The Government will set a fixed minimum price for cannabis products which will be competitive with the prevailing black market price. This high fixed price will ensure there is sufficient money to ensure security of crops, tracking of individual plants and secure transport, and also to reduce consumption and prevent price competition. The money the Government earns will fund enforcement of the new regime and regulatory authority, as well as investment in drug and alcohol treatment, drug education and drug prevention, etc.

To conclude, CIS offer a middle ground option between prohibition with criminal penalties and a profit-driven commercial market. The advantages of CIS is they avoid making selling cannabis a profit-driven business which necessitates expanding use, do not involve public retail outlets, allow for the promotion of information on health risks from cannabis use, and awareness of drug treatment and other health services. CIS also promote healthier cannabis products and administration practices, and set maximum consumption limits. CIS will permit controlled cannabis sales and the resulting tax revenue can be used to support drug treatment and other health services. Those purchasing cannabis from CIS will no longer be subject to arrest and this will free up some criminal justice resources.

As with all regulatory approaches, CIS have important limitations. Some cannabis users will not want to join a CIS, use approved cannabis products, or only consume 28 grams of cannabis per month. Consequently, the black market for cannabis will continue, albeit in a reduced state. As trust and understanding of the CIS model grows among cannabis users, and they benefit from legal and convenient cannabis purchasing, healthier forms of cannabis, and improved access to health services, there will be further pressure on the black market.

However, while CIS have a number of conceptual strengths, the success of this approach will depend greatly on the effectiveness of its implementation. If restrictions on CIS are too great, cannabis users will not sign up to be members and the black market will continue. If the government cannabis regulator is not effective, then CIS will be seen as promoting cannabis use. The recent experience with the implementation of Psychoactive Substances Act illustrates all too well that a good idea can become derailed by insufficient planning and resources, and lack of engagement with the general public and local communities.\textsuperscript{17-20}

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VIEWPOINT

Pertussis control strategies: A consistent approach for New Zealand
Synopsis of Ministry of Health Workshop, April 2015
Mary Nowlan, Nikki Turner, Tomasz Kiedrzynski, Diana Murfitt, Nina Sawicki

ABSTRACT

In the past decade, pertussis has made a global resurgence, driving reconsideration of national immunisation schedules and vaccine usage. A workshop held by the Ministry of Health in 2015 discussed New Zealand’s pertussis disease control strategies. Data were presented from current research into vaccine safety during pregnancy and the effectiveness of the immunisation schedule in preventing pertussis throughout childhood. The greatest burden of disease and mortality remains in infants under 1 year of age, especially infants too young to be immunised, those of Māori and Pacific ethnicity, and those living in deprivation. The workshop considered strategies including the timing of the scheduled vaccines, maternal immunisation, improving immunisation coverage, vaccination timeliness and service delivery to reduce inequalities and overall disease burden. It concluded that the current infant schedule appears to be working well to protect older infants from severe pertussis. Significant gains for reducing severe disease in vulnerable young infants could be made with improvements in maternal vaccine uptake. Other strategic directions include attention to schedule adherence and timeliness of vaccine delivery, and more effective communication approaches for healthcare professionals and the public.

Pertussis is a highly contagious bacterial respiratory disease characterised by a prolonged paroxysmal cough. A major pertussis epidemic in New Zealand, peaking from August 2011 to December 2013, resulted in the hospitalisation of hundreds of infants aged under 1 year, and the death of three infants under 6 weeks of age—too young to have started the primary immunisation course. A resurgence in pertussis has also been seen internationally, especially in countries using the acellular pertussis vaccines.

The first pertussis vaccines contained whole inactivated *Bordetella pertussis*. Although effective, these whole-cell pertussis (wP) vaccines are more reactogenic. In 2000, the less reactogenic acellular pertussis (aP) vaccine replaced the wP vaccine on the New Zealand National Immunisation Schedule (the Schedule). The currently used New Zealand vaccine contains three pertussis antigens with pivotal roles in pertussis immunity. However, aP vaccines appear not to be as effective, nor produce as long-lived immunity, as the wP vaccines, and may be associated with the worldwide resurgence of pertussis.1,2

The elimination of pertussis by vaccination is not currently possible, because pertussis is widespread in the community, aP vaccine immunity is not long-lasting, and transmission can occur even with vaccinated individuals. Therefore, immunisation strategies are primarily focused on reducing severe pertussis in infants. In New Zealand, three doses of vaccine are given for a primary course in infancy at 6 weeks, 3 months and 5 months, with boosters at 4 and 11 years of age. Whether this vaccine schedule provides adequate protection, or how rapidly immunity wanes, is unknown.

In 2015, the Ministry of Health (MoH) held a workshop to bring together expertise and experiences to discuss pertussis disease control strategies and a consistent approach for New Zealand. The aim was to minimise the impact of future pertussis outbreaks on those most vulnerable.
Following presentation of current international and national research, key areas were discussed: the effectiveness and timing of the Schedule; the use and delivery of maternal pertussis immunisation to protect infants; improving communication around pertussis immunisation for healthcare professionals and the public; improving immunisation coverage and service delivery to reduce inequalities; and evaluation of data collection, disease reporting and surveillance.

Pertussis disease burden and prevention strategies in New Zealand and internationally

The burden of pertussis is a global issue. Infants too young to have received the primary course are at highest risk of severe disease, hospitalisation, and death. Mild disease, especially in adolescents and adults, is often under reported and/or undiagnosed. Although the vaccines are effective at preventing pertussis disease, including the cough, a study in nonhuman primates has shown that acellular pertussis vaccine did not protect them from acquiring the infection and readily transmitting *Bordetella pertussis* to contacts.3

In New Zealand, pertussis epidemics occur every 3 to 5 years. Disease notifications showed that between 2000 and 2014, nine infants under 8 weeks of age and one unvaccinated 3-year-old with underlying chronic lung disease died as a result of pertussis. During the height of the most recent New Zealand epidemic, almost half of all the infant cases notified, aged under 1 year, were hospitalised with pertussis (eg, 182/414 infant cases were hospitalised in 2012). This proportion is approximately ten times greater than across all age groups and demonstrates how vulnerable infants are severely affected. The 70 years or older age group were also at increased risk from severe disease, once they become sick, with about 10% of the notified cases hospitalised. Pacific and Māori pertussis hospitalisations rates were much higher than New Zealand Europeans, eg, three to four times higher in 2012 (Prioritised ethnicity was used in these data analyses).

National Immunisation Register (NIR) data showed that the overall, three-dose coverage at 6 months of age remained under 80% during the period August 2011–December 2013. Ethnicity and high deprivation (NZDep 9–10, in particular) were identified as risk factors for low immunisation coverage. Coverage at 6 months of age improved from 67% in March 2011, to 78% in December 2013, and from 89% to 94% at 12 months of age. Despite good improvements, disparities remain at 6 months of age, particularly for Māori infants, infants living in high deprivation, and to a lesser degree, Pacific infants.

Pertussis-containing vaccines provide a good level of control for severe pertussis, even when delivered through a variety of immunisation schedules worldwide. Adherence to the Schedule and timeliness of delivery of the primary series is most important to prevent severe pertussis.4 Although immunisation has reduced the burden of pertussis deaths and severe disease in infants overall, a cohort of infants less than 6 months of age—too young to have completed the primary series—remains susceptible. Various strategies are being evaluated worldwide to prevent severe pertussis in the youngest infants.

The World Health Organization recommended in July 2014 that countries using aP vaccines should consider a booster dose sometime between the ages of 1 to 6 years, preferably in the second year of life, at least 6 months after the last dose of the primary course.5,6 Currently, the only high income countries not to include a toddler booster in their schedules are Australia, England and Wales (E/W), and New Zealand, which have had similar rates of reported pertussis deaths in children aged under 1 year over the last decade (average deaths per million per decade [95% CI]: Australia 4.2 [2.2–7.4], E/W 7.4 [5.5–9.7], New Zealand 8.2 [2.7–19.2]).

One key risk factor for pertussis is large family size, with parents or siblings more likely to transmit disease to infants.7 The degree to which vaccination reduces transmission is not clear; however, the risk of severe pertussis for infants may be halved when both parents are vaccinated more than 4 weeks prior to disease onset.8 ‘Cocooning’ of infants by giving vaccine
booster doses to close contacts relies on high coverage, which is difficult to achieve. Toddlers are a likely source of sibling transmission and may be justification for a toddler booster dose.

In general, cocooning strategies have not been shown to work on a population base, and are being superseded by antenatal immunisation. Transplacental transfer of high levels of maternal antibodies help to protect the infant from birth. Maternal immunisation has been shown to be 91% (95% CI 84–95%) effective in preventing pertussis in infants up to 3 months of age.\(^9\) Since antibody levels decline rapidly between pregnancies, revaccination is required for each pregnancy. Historically, a lack of data on vaccine safety in pregnancy has hindered uptake. However, data are now accumulating: a large study in the UK shows good evidence that acellular pertussis-containing vaccines are safe when given in pregnancy,\(^10\) and as discussed below, New Zealand data support this safety profile.

Immunisation of pregnant women at 28–38 weeks gestation was introduced in New Zealand as a control strategy during the epidemic to provide passive antibody protection to infants too young to be fully vaccinated; limited data suggest that the uptake is very low. The ‘during epidemic’ criteria was removed in August 2015.

Neonatal vaccination is a potential alternative to immunising mothers during pregnancy. Baboon infants have been shown to be protected against severe pertussis by either maternal or neonatal vaccine.\(^3\) A pilot clinical study conducted in Australia demonstrated significantly higher pertussis antibody levels by 2 months of age in infants who receive aP vaccine at birth and 1 month, which persisted to 6 months of age.\(^11\) Further studies are underway.

### Outbreak control—lessons learnt in New Zealand

During the recent pertussis epidemic in New Zealand, control strategies and improvements in immunisation delivery were necessary. Various lessons were learnt across the country as illustrated by both Hawkes Bay and Nelson-Marlborough District Health Boards (DHBs). Prior to the epidemic, Hawkes Bay DHB was proactive in maintaining high coverage for childhood immunisations. Although approximately 50% of the birth cohort in the district were Māori or from areas of high deprivation—and therefore deemed to be at high risk—during the epidemic fewer cases of pertussis were notified compared to other regions, as shown in Figure 1 for 2012.\(^12\)

In this district, education of parents, childcare and healthcare providers is seen as an important priority. As of December 2014, coverage by 8 months of age was 96%
in Māori, 100% for Pacific people and 98% for those within the most deprived quintile as measure by the New Zealand deprivation score, demonstrating closure of many traditional equity gaps. Antenatal vaccination clinics are run weekly to immunise pregnant women and to promote immunisation of infants: anecdotally, Hawkes Bay DHB has found that mothers who are immunised during pregnancy commonly immunise their infants on time.

In contrast, in the Nelson-Marlborough DHB an outbreak response plan was implemented to manage the high number of pertussis cases during the epidemic. In predominantly rural areas, pertussis spread quickly through schools and preschools to unimmunised children. Further improvements in vaccine education, coverage and timeliness were recognised as necessary. Revised measures were implemented to improve disease control, to reduce transmission and to improve surveillance and communication. These included increased collaborative work cross-sectoral and within the health sector to improve vaccination uptake. A resource pack for pregnant women was developed and sent to lead maternity carers, and local media campaigns recommended maternal immunisation. Special attention to disease notification was also given in this DHB which may, in part, have accounted for the high number of notifications.

**Pertussis vaccine research in New Zealand**

Duration of vaccine effectiveness provided by current Schedule

International concerns around possible early waning in immunity following a primary course of acellular pertussis vaccine raised the issue of whether New Zealand should be considering an earlier booster dose than the current 4-year-old dose. A case-control study, *Effectiveness of Pertussis Immunisation in Children* (EPIC), commissioned by the MoH and Health Research Council, was conducted in 2015 by linking existing data sets to evaluate the effectiveness and duration of protection provided by the Schedule against pertussis.

Two age groups, children aged 6 weeks–4 years and aged 4–8 years, were evaluated. Interim results showed no evidence of waning immunity prior to the children’s fourth birthdays following the three-dose primary series, nor following the primary series plus a booster up to 7 years of age.

In conclusion, the EPIC study data provides evidence that the current Schedule protects against severe pertussis in vaccinated infants and young children. However, it is possible that there may be a small group of children at higher risk from pertussis that would not be identified by a study of this nature for whom further booster doses could be considered. This warrants further study of existing data to assess the risk in a New Zealand context.

**Research on attitudes and knowledge in pregnancy**

As previously discussed, infants too young to be immunised are at highest risk from severe pertussis infection. Immunisation during pregnancy has been shown in the UK to be effective in reducing the severity of pertussis in these very young infants. However, uptake of pertussis vaccine in pregnancy appears to be poor in New Zealand.

A survey was sent to all birth notifications between June and October 2013 in Canterbury DHB; this was the first DHB to offer funded pertussis vaccine during late pregnancy. Findings showed that, in general, those mothers who accepted the vaccine did so to protect their baby, followed health professional advice, and/or had an awareness of the severity of pertussis. Those who did not receive a vaccination were either unaware of the vaccine, were not encouraged or were discouraged by health providers (especially general practitioners), or had safety concerns about vaccination in pregnancy. This survey was conducted as part of a larger study investigating the safety of vaccines in pregnancy.

An audience research study in 2015, commissioned by the MoH, investigated the barriers to immunisation in pregnancy across a range of DHBs, ethnic, and socio-economic groups. To improve uptake of antenatal vaccine, the study found that women need positive assurance from their
lead maternity carers that the vaccine will protect their baby. Specifically, that it is safe for the unborn baby when given in pregnancy, and that it is free. As observed in Hawkes Bay DHB, this study also found that vaccinated mothers were more likely to immunise their infants on time.16

**Vaccine safety**

As shown by audience research, confidence in vaccine safety for the unborn child is a major factor for receipt of pertussis vaccine in pregnant women. Until recently, historically there have been few studies that have actively investigated the safety of pertussis vaccines given during pregnancy, although there are no biologically plausible reasons why or evidence that inactivated vaccines would pose a risk to the fetus, and passive surveillance systems support the safety in pregnancy. Pregnancy itself is high risk and adverse outcomes frequently occur. Combined data from two New Zealand studies investigating the safety of pertussis vaccination given in pregnancy show that no serious adverse events were causally associated with the vaccine in 793 pregnant women. Minor local reactions were common, however systemic events, including headache, fatigue and nausea, were uncommon, occurring in fewer than 7% of vaccinees.17 These results support a large observational study of the infant outcomes following exposure to Tdap vaccine during pregnancy.15

**Workshop discussions**

Following reflection of the presented data, the workshop provided suggestions for improvement, and highlighted areas in need of further research in relation to the effectiveness of the current pertussis control strategies and surveillance, the Schedule, and inequities in pertussis disease burden. The areas discussed, recommendations and comments are summarised in Table 1.

**Conclusions**

The workshop concluded that New Zealand’s current National Immunisation Schedule is working well to prevent severe pertussis in older infancy and childhood. Regular reviews of the schedule will be conducted by PHARMAC and the Ministry of Health. The workshop provided an insight into the areas of pertussis disease control and immunisation that require further discussion or improvements.

Adherence to the immunisation schedule is required to ensure that infants aged under 1 year are fully immunised on time. However, the burden of severe disease and mortality is primarily in infants younger than 6 months of age—too young to have been fully immunised with the primary course—particularly, those of Māori and Pacific ethnicity, and those living in deprivation.

More focus on communication and education of the health sector and the public is needed to promote immunisation—especially for those at greatest risk of severe pertussis—to improve coverage, adherence to the Schedule, and timeliness of delivery for young infants; and to address any safety concerns.

Alongside timely immunisation with the primary schedule, vaccination during pregnancy is an important strategy to protect young infants. Improvements in coverage and access to vaccines for pregnant women are required. Improved communication, starting in early pregnancy, is recommended to increase awareness of the vaccines availability and to address any safety concerns, taking into consideration the needs of different ethnic and socio-economic groups. The Ministry of Health are actively working to improve uptake of Boostrix® during pregnancy and working towards changes to the National Immunisation Register (NIR) to enable capture immunisation events during pregnancy.

Currently in New Zealand, an additional pertussis booster in the second year of life does not appear to be necessary. However, further research is needed to determine if a booster may benefit children at high risk, such as those with chronic lung disease or other chronic health issues, as provided for influenza and pneumococcal disease.

Although the rates of pertussis notifications are low in the elderly, which may be due to lack of awareness in this age group, there is an increased risk of hospitalisation amongst the cases. Further studies are also needed to investigate the burden of pertussis in the elderly and to assess whether a funded
### Table 1: Pertussis workshop feedback.

<table>
<thead>
<tr>
<th>Area of discussion</th>
<th>Recommendations</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunisation schedule timing</td>
<td>Current Schedule</td>
<td>Retain current Schedule</td>
</tr>
<tr>
<td>Schedule reviews</td>
<td>Set regular review periods</td>
<td>PHARMAC and the MoH to work with PHARMAC’s PTAC Immunisation Subcommittee to regularly review the Schedule.</td>
</tr>
<tr>
<td>Maternal immunisation</td>
<td>Strategy to be continued</td>
<td>Consider giving Tdap concurrently with the influenza vaccine to protect infants and improve vaccine uptake.</td>
</tr>
<tr>
<td>Neonatal dose</td>
<td>Awaiting further research</td>
<td>May be beneficial if the mother has not been vaccinated during pregnancy.</td>
</tr>
<tr>
<td>Toddler dose</td>
<td>Currently not required in New Zealand</td>
<td>There may be a group of infants at higher risk than others from pertussis who may benefit from a pertussis dose in their second year of life - further research is needed to assess the risk in a New Zealand context.</td>
</tr>
<tr>
<td>Adolescent booster</td>
<td>Vaccination effectiveness in New Zealand setting</td>
<td>Consider giving Tdap concurrently with HPV vaccine. Adolescents may be transmitting disease to family, particularly in large families.</td>
</tr>
<tr>
<td>Occupational immunisations</td>
<td>Current international advice for 10 yearly boosters still holds</td>
<td>Optimal frequency of booster to prevent pertussis transmission is unclear.</td>
</tr>
<tr>
<td>Antenatal pertussis immunisation and communication</td>
<td>Maternal immunisation programme</td>
<td>Implement a maternal immunisation programme</td>
</tr>
<tr>
<td>Communication about immunisation early in pregnancy</td>
<td>To improve vaccine uptake</td>
<td>Pregnant women need to be informed that they can be immunised against pertussis as soon as pregnancy is confirmed and during pregnancy. Address any safety concerns the pregnant women may have about maternal immunisation. Pharmacists could promote immunisation when folic acid vitamin supplements and pregnancy tests are purchased. Consider different information needs for each pregnancy and for different socioeconomic and ethnic groups.</td>
</tr>
<tr>
<td>Health professional education</td>
<td>To encourage maternal vaccination advice and recommendations by the LMC/midwife and GP</td>
<td>Dispel myths on vaccine safety, eg antibody not vaccine is passed to baby. Will enable positive discussions with decliners by having ‘courageous conversations’. Severity of pertussis for infants – eg, use of personal stories. Add vaccination precalls in to the practice management system at first pregnancy appointment with a general practice to prompt when vaccines are due.</td>
</tr>
<tr>
<td>Improving coverage and service delivery</td>
<td>Inequalities remain</td>
<td>Improve vaccine uptake for groups at greatest risk from pertussis</td>
</tr>
<tr>
<td></td>
<td>Improve trust in vaccines</td>
<td>To increase vaccine uptake and respond to misinformation and trends</td>
</tr>
</tbody>
</table>
### Table 1 (cont): Pertussis workshop feedback.

<table>
<thead>
<tr>
<th>Area of discussion</th>
<th>Recommendations</th>
<th>Further comments</th>
</tr>
</thead>
</table>
| Data collection, surveillance and reporting | Data collection | To improve quality and scope | NIR improvements needed to address:  
- NIR accessibility for all immunisation providers  
- NIR flexibility and scope (eg to record pregnancy immunisations)  
Improve data collection on cases (eg practice management system interface, emergency department surveillance)  
Consistency in notifications of cases |
| Data usage | To be improved | More systematic use of and improved links between existing datasets  
Use data to inform public health strategies and assess immunisation effectiveness |

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### Tdap booster at 65 years of age may help to reduce this burden.
Australian research underway around grandparent cocooning doses may provide an insight into the potential of such a booster.

New Zealand has more readily available sources of data and data linking than many other countries. The existing data could be better used to describe pertussis epidemiology and immunisation schedule effectiveness to identify those at greatest risk from pertussis. Using data from practice management systems and emergency departments may provide useful additional information about pertussis cases and help improving consistency of notifications.

Planned improvements to the NIR will provide better quality data to evaluate vaccine coverage and effectiveness. High quality surveillance and coverage data are required to make appropriate disease control decisions, to monitor and close ethnic and socioeconomic inequity gaps and to reduce the impact of pertussis outbreaks in the future.


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### Competing interests:
Nikki Turner, was an investigator on the PIPS study looking at safety in pregnancy with pertussis-containing vaccines which was funded by GlaxoSmithKline New Zealand Ltd.

### Acknowledgements
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REFERENCES:


Eric Charles Parr
12 June 1925–18 October 2015

MBChB, FRCOG

Eric Parr, the first obstetric and gynaecological specialist at Middlemore Hospital, died recently at the age of 90 following a courageous battle with inclusion body myositis.

Eric was born in Dublin in 1925, into a medical family. As a small child he went to China. His father intended to become a medical missionary, but political unrest prevented this and he taught English at Peking University.

His family immigrated to New Zealand when Eric was seven. He attended King's School, was a foundation pupil of St. Peter's School, Cambridge, briefly attended Wanganui Collegiate, and completed his secondary education at Takapuna Grammar. He passed his medical intermediate in Auckland, then entered Otago Medical School and Knox College, graduating MBChB in 1949. Following house surgeon years in Auckland, and a brief period in general practice, he sailed for England as a ship's doctor.

During 7 years’ post graduate obstetric and gynaecological training in the UK (MRCOG, 1957) he worked in the Manchester Withington Hospital Group, including Boundary Park, Oldham. James Newman’s hand-written reference for Eric to New Zealander, Bill Hawksworth, for a registrar position at the Radcliffe in Oxford, was brief: “Herewith Eric Parr, one of my spies—don’t shoot him”. He completed his training as a senior registrar at the Lewisham Hospital in London.

There were no hospital positions available on his return to New Zealand in
OBITUARY

1960, so he commenced private practice in Papatoetoe. The following year, the new Middlemore Hospital Obstetric building was opened and Eric—soon to be joined by John Taylor and Liam Wright—were appointed as the first specialist obstetricians. Eric lived nearby in Papatoetoe, providing immediate cover of the obstetric unit for the benefit of labouring women and the education of the local general practitioner obstetricians. Caesarean section facilities were not available until 1965. Specialists generally spent a relatively short period of time at Middlemore before moving to positions in central Auckland. In the late 1960s, Ross Blue joined Eric and shared the obstetric cover. In 1980, Bill Mercer became the first full-time obstetrician and gynaecologist. Eric's commitment and dedication to Middlemore provided the foundation of the modern unit, which now has 20 specialist positions, and over 7,000 births a year. Eric declined an opportunity to join the staff of the National Women's Hospital because of the “unhappy work environment”, instead playing a major role at Middlemore, where doctors and midwives enjoyed working together. David Ansell joined Eric's practice in 1984 and Eric retired in 1990.

Eric had an eternally youthful appearance, an open engaging personality, an enthusiasm for life, and a mischievous sense of humour. He was a born conversationalist—no doubt reflecting his Irish origins. His interests were wide: his bach at Matheson Bay, sailing, skiing, photography, and music; he loved classical music and was a member of the Auckland Choral Society. He was a man without guile, artifice, ambition, or interest in medical politics. However, he did become frustrated by the ‘new’ hospital management system. He will be remembered by his many grateful patients, and his colleagues for his caring nature, infectious joy and enthusiasm for life.

A large number of family, friends and colleagues joined members of the Auckland Choral Society at St. Mark's, Remuera, to celebrate Eric's life and his deep Christian faith. For 51 years he was happily married to Wyn Gould, and to her and their daughters, Anna, Jenny and Elisabeth, we extend our deepest sympathy.

Author information:
Ron Jones and David Ansell

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Efficacy and safety of betahistine treatment in patients with Meniere’s disease

Patients suffering from Meniere's disease may be subject to severe vertigo. Betahistine is often prescribed in such patients to prevent the vertigo. However, there is doubt that this treatment is efficacious.

This randomised, double-blind trial compared the use of betahistine in either low or high dosage with a placebo. Seventy-three patients were treated with betahistine 24mg twice daily, 74 with 48mg three times per day, and 74 with placebo.

The primary outcome sought was the number of attacks of vertigo per 30 days during assessment period at months 7 to 9. Incidence of attacks did not differ between the 3 groups. The treatments were well tolerated, with no safety issues.

BMJ 2016;352:h6816

Medication adherence 1 month after hospital discharge

Adherence to prescription medications as reported in the literature is suboptimal, with studies reporting non-adherence rates between 20 and 50%. This paper reports on a study evaluating this issue in Australia.

The researchers conducted a prospective cohort study of 68 patients, comparing admission and discharge medication regimens to self-reported regimens 30–40 days after discharge from hospital. They found that 27 of the 68 patients (39.7%) were non-adherent to one or more of their regular medications at follow-up. Intentional and unintentional non-adherence contributed equally.

It was noted that the presence of a carer responsible for medications was associated with a significantly lower non-adherence rate. They suggest that the prescribing physicians need to establish a better therapeutic relationship with their patients as this may reduce intentional non-adherence.

Internal Medical Journal 2016;46,185-192

Metformin versus placebo in obese pregnant women without diabetes mellitus

Obesity is associated with an increased risk of adverse pregnancy outcomes. Metformin improves insulin sensitivity and in pregnant patients with gestational diabetes it leads to less weight gain than occurs in those who do not take metformin.

This trial aimed to assess whether metformin administered to obese pregnant women from 12–18 weeks of gestation would reduce the median neonatal birth weight as well as the incidences of adverse neonatal outcomes. There were 202 women in the metformin group and 198 in the placebo group.

There was no significant difference in the median neonatal birth weights between the metformin and placebo groups. There were also no differences between the groups in the incidence of gestational diabetes, large-for-gestational-age neonates, or adverse neonatal outcomes.


URL:
In The New Zealand Medical Journal of December, 1904, and again in the same journal of 1911, I recorded the steps taken to render some relief to a case coming under the above heading. In January last I completed what I trust is its final surgical interference. As the journals in which the two preceding reports appeared may not be within the reach of all the readers of today, it may be well to recapitulate the principal points of procedure. The child had a normal prepuce and glans, but no urethra through it and no scrotum. The labii were normal, but no vagina. It had been registered as a male, so I converted the labii into a urinary channel and penis. Afterwards, I made a urethra through the glans, and finally joined the glans to the body of the new penis. This semi-artificial penis has remained sound and well, and is quite a satisfactory male urinary organ.

In 1911, military service induced him to have two well developed mammae removed. Some time before then, menstruation had been established, and it passed through the penis. This caused him no inconvenience, further than more frequent micturition during the period. At that time I remarked that his face, frame, voice, and manner participated more of the female than the male, but that all his feelings and desires were those of the male. The war has excited his military ardour, and he decided to have an operation performed to check menstruation. This operation I performed in January last, and no sooner had he recovered than he enlisted for military service. On opening the abdomen I found a small and apparently normal uterus, but minus any trace of the ovaries. The tubes were normal, and from the side of the left tube extended a thin cord down into the inguinal canal. Here, outside the peritoneum, was a small round body, evidently an undescended testicle or a misplaced ovary. The right ovary or testicle could be easily felt from without, lying in the right inguinal canal. Now, with my hand and eyes in the peritoneal cavity I could find no connection between this organ and the uterus or the abdomen. Both tubes and both glands were far apart from each other, but possibly some means of connection existed which escaped my observation. The vagina was represented by a small, tough, cordlike body, which was found to be open, though undeveloped. I removed the uterus and found it to be normal in its inner chamber, and an opening passed down from it through the cord-like vagina. I did not interfere with the ovaries or testicles in the inguinal canals, and left them in situ. It is possible that the right ovary or testicle may continue to be sensitive to the touch, and if so its removal may be demanded, but it is equally possible that it may atrophy or lose its sensitiveness. The left one, owing to its position, will give no trouble. He made a speedy recovery, and I sincerely trust that this will end his disabilities so far as surgery can do so.

Remarks

He has grown to be a strong, healthy young man, and takes a keen interest in all that concerns men. The practised eye, however, can at once detect the female, but to the ordinary observer he is a genuine male. The struggle betwixt the two sexes is peculiar, and one wonders if this is an attempt of Nature to revert to the alleged monogony of all life in its early stages. One set of thinkers say that we from all time have been amphigenetic, whilst others, with equal authority, assert that in our early stages we were monogenetic, and
merely became amphigenetic by process of evolution. The case is one that lends itself to endless speculation.

I do not see how the theory of the fimbriated extremity of the tubes embracing the ovaries during ovulation could possibly occur in this case, owing to their distance apart, and both glands being outside the peritoneal cavity and fixed in the inguinal canals. Yet it is likely—indeed fairly conclusive—that ovules or spermatazoa from one or other gland found their way into the uterus and were discharged per the cord-like vagina and artificial penis. A normal uterus minus its natural appendages is functionless, so the uterus in this case must have been stimulated to its duty by the presence of the glands, though not connected with it. Again, whether the glands produced ovules or spermatazoa, or a mixture of both, is uncertain. This case has led me to think that the serious character and health changes that frequently follow in the wake of ovarotony in young women—or, indeed, women of any age—might be arrested by transplanting a piece of ovary into some part of the body. It will be exceedingly interesting to watch in this case how the mind, character and general health of the individual will be influenced. Total extirpation of the sexual glands in either sex undoubtedly has an injurious effect upon the life of every individual who is compelled to submit to it. I expect that from environment, training, and operative procedure the male characteristics will develop more and more, and the female ones become less marked. No hair has as yet appeared upon the face, but it is probable that now or in the near future some hair will appear. As things have transpired, it is exceedingly fortunate that he had been registered as a male, and especially gratifying it is that the glands have been left in situ. The battle of life is much easier for a defective male than a defective female. Fortunately he is engaged in rural pursuits, and is already on the road to moderate independence. He finds the life of a Territorial much to his liking, but whether he succeeds in satisfying the demands of the medical military staff for service abroad remains to be seen. In any case, he deserves success, for his courage and determination to fill the role of a useful and patriotic citizen has been phenomenal.
Assessing the response to follow-up recommendations in radiology reports

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The passage:

“We recently audited chest X-ray (CXR) reports at our institution to identify the proportion of cases where recommendations for further imaging made in the radiology report have been acted upon; and to investigate the discrepancy between the suggested timeframe 28 follow-up imaging, and the time it actually occurred.

Follow-up recommendations

In 2014, there were 108 reports containing recommendations for repeat imaging to further clarify an abnormality seen or ensure resolution of disease process. Of these, only 33 recommendations (76%) were enacted. There were 71 recommendations for repeat CXR, 34 of which were done except 4, where CT was instead utilised. Furthermore, there were 10 recommendations for follow-up CT, all of which were performed, except 1 where a 36 CXR was thought to suffice. The final recommendation was for an ultrasound scan to investigate pleural effusion.”

Should read:

“We recently audited chest X-ray (CXR) reports at our institution to identify the proportion of cases where recommendations for further imaging made in the radiology report have been acted upon; and to investigate the discrepancy between the suggested timeframe for follow-up imaging and the time it actually occurred.

Follow-up recommendations

In 2014, there had been 108 reports containing recommendations for repeat imaging to further clarify an abnormality seen or ensure resolution of disease process. Of these, only 82 recommendations (76%) were enacted. There were 71 recommendations for repeat CXR, all of which were done except four where CT was instead utilised. Furthermore, there were ten recommendations for follow-up CT, all of which were performed, except one where a repeat CXR was thought to suffice. The final recommendation was for an ultrasound scan to investigate pleural effusion.”

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