The challenge of the increasing demand for joint replacement

The Impact on Life questionnaire: validation for elective surgery prioritisation in New Zealand prioritisation criteria in orthopaedic surgery

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Very low-carbohydrate diets in the management of diabetes revisited

Zombie pandemic preparedness: a cautionary observation
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<table>
<thead>
<tr>
<th>New Zealand subscription rates</th>
<th>Overseas subscription rates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individuals</strong>*</td>
<td>$298</td>
</tr>
<tr>
<td><strong>Individual article</strong></td>
<td>$25</td>
</tr>
</tbody>
</table>

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EDITORIAL
8
The challenge of the increasing demand for joint replacement
Gary Hooper

10
Zika virus threat
Lance C Jennings, John S Mackenzie

ARTICLES
16
Burden of disease from second-hand smoke exposure in New Zealand
Kylie Mason, Barry Borman

26
The Impact on Life questionnaire: validation for elective surgery prioritisation in New Zealand prioritisation criteria in orthopaedic surgery
Georgina Chan, Louret Bezuidenhout, Logan Walker, Robert Rowan

33
Perioperative mortality in New Zealand related to hip and knee replacement surgery: comparing administrative and registry data
P Hider, C Frampton, J-C Theis, L Wilson, A Rothwell

41
Cascade of Care for People Living with HIV Infection in the Wellington Region
Nigel Raymond, Kelly Bargh, Kyi Lai Lai Aung, James Rice

51
Excess cost associated with primary hip and knee joint arthroplasty surgical site infections: a driver to support investment in quality improvement strategies to reduce infection rates
N Gow, C McGuinness, AJ Morris, A McLellan, AE Hardy, JT Munro, SA Roberts

59
Rationing of hip and knee replacement: effect on the severity of patient-reported symptoms and the demand for surgery in Otago
David Gwynne-Jones, Ella Iosua

VIEWPOINT
67
Very low-carbohydrate diets in the management of diabetes revisited
Grant Schofield, George Henderson, Simon Thornley, Catherine Crofts

74
Regulating tobacco retail in New Zealand: what can we learn from overseas?
Lindsay Robertson, Louise Marsh, Richard Edwards, Janet Hoek, Frederieke S van der Deen, Rob McGee

CLINICAL CORRESPONDENCE
80
Case of takotsubo cardiomyopathy in a patient with COPD
Nirav S Patel, Smita I Negi, Aashish Anand, Anantha K Rao
LETTERS

84
Recent submissions to the New Zealand Government Health Select Committee on end-of-life choices
Philip Bagshaw, Sue Bagshaw, Stuart Gowland

86
Possible toxicity of olive leaf extract in a dietary supplement
Ian C Shaw

88
Assessing the response to follow-up recommendations in radiology reports
Danus Ravindran, Yassar Alamri, David Cranefield

91
Chronic misleading online advertising by chiropractors
Mark Hanna, Mark Honeychurch

94
Could New Zealand’s law on “New Psychoactive Substances” provide lessons for achieving the Smokefree 2025 Goal?
Nick Wilson, Richard Edwards, Janet Hoek, George Thomson, Richard Jaine

97
Zombie pandemic preparedness: a cautionary observation
Frank Houghton, Katie Del Monte, Daniel Glessner, Joyce Goff, Edward Hopkins, Krista Loney, Ghazal Meratnia, Jeremy Toms

METHUSELAH

100
100 YEARS AGO

101
The Friendly Societies’ dispute
April, 1916
SUMMARIES

Burden of disease from second-hand smoke exposure in New Zealand
Kylie Mason, Barry Borman
Exposure to second-hand continues to cause a substantial health loss in New Zealand, which is entirely preventable. Children accounted for 34% of the attributable health loss, particularly due to sudden unexplained death in infancy. Maori experienced five times the health loss of non-Maori.

Cascade of care for people living with HIV infection in the Wellington region
Nigel Raymond, Kelly Bargh, Kyi Lai Lai Aung, James Rice
Antiretroviral therapy (ART), with once or twice daily medication regimens, is highly effective in providing better health for people living with HIV infection (PLHIV) and greatly reduces the risk of HIV transmission to others. In NZ, as in many other developed countries, the rates of new HIV diagnoses have risen over the last decade compared with prior to 2000. For PLHIV, impairment of the immune system is mainly assessed by measuring the level of CD4 lymphocytes (normal is above 600 x 10^6/L), while the effectiveness of antiretroviral therapy is assessed by whether the HIV viral load is suppressed to a consistently low level. This study included all people known to be living with HIV in the Wellington region and assessed the ‘cascade of care’ which describes steps in delivering care: diagnosis, linkage and retention in care, and the provision and success of ART. The study described that main gaps in the cascade of care were the people with undiagnosed HIV infection (based on prior Auckland estimates) and those in whom treatment had not yet been initiated because their CD4 lymphocyte count was above the 500 cells/10^6/L threshold for publically funded ART, providing further evidence that earlier HIV diagnosis and increased access to ART are clinical and public health priorities.

Excess cost associated with primary hip and knee joint arthroplasty surgical site infections: a driver to support investment in quality improvement strategies to reduce infection rates
N Gow, C McGuinness, AJ Morris, A McLellan, AE Hardy, JT Munro, SA Roberts
We have shown that the excess length of stay in hospital and cost associated with infections following primary THA and TKA procedures is substantial. Although it is not possible to totally eliminate the risk of surgical site infection all efforts should be made to ensure that strategies known to reduce infection rates are implemented in a consistent manner and that infections, when they do occur, are managed promptly to minimise the long term impact on the patient. National programmes such as the Health Quality & Safety Commission’s National Surgical Site Infection Improvement programme and the Ministry of Health Enhanced Recovery After Surgery pathway are essential to facilitate the delivery of quality improvement initiatives that will lead to improvement in outcomes for patients and to minimise the unnecessary use of health resources required for managing surgical complications such as surgical site infections.
SUMMARIES

Rationing of hip and knee replacement: effect on the severity of patient-reported symptoms and the demand for surgery in Otago

David Gwynne-Jones, Ella Iosua

Patients undergoing primary elective total hip and knee replacement in Otago in 2014 are more severely disabled than between 2006-10. Patients currently being returned to GP due to funding constraints would have qualified for publicly funded surgery during the earlier period. The demand for elective TJR has increased by 19% since 2012. In 2014 the shortfall was 241 joints per year in Otago.

The Impact on Life questionnaire: validation for elective surgery prioritisation in New Zealand prioritisation criteria in orthopaedic surgery

Georgina Chan, Louret Bezuidenhout, Logan Walker, Robert Rowan

The Ministry of Health has rolled out a new scoring system for prioritising patients for elective surgery in public hospitals across New Zealand. Part of this tool uses the Impact on Life Questionnaire. We compared this with widely-used scores in orthopaedic surgery and found that they correlated well. Therefore, the Impact on Life Questionnaire can be reliably used to prioritise patients for surgery in orthopaedic surgery.

Regulating tobacco retail in New Zealand: what can we learn from overseas?

Lindsay Robertson, Louise Marsh, Richard Edwards, Janet Hoek, Frederieke S van der Deen, Rob McGee

Despite New Zealand’s reputation as a leader in tobacco control, the retail environment for tobacco is relatively unregulated, particularly when compared to the licensing regimes for alcohol products and psychoactive substances. This paper summarises tobacco retail licensing schemes implemented in countries overseas and reviews how effective these schemes might be as part of a comprehensive tobacco control strategy. We conclude that a positive licensing scheme could increase compliance with existing smokefree legislation, and enable the introduction of further measures to control the supply of tobacco. Reducing tobacco availability is an important part of the range of interventions needed to achieve a smokefree NZ, and we urge the Government to redress the lack of progress in this area.

Perioperative mortality in New Zealand related to hip and knee replacement surgery: comparing administrative and registry data

P Hider, C Frampton, J-C Theis, L Wilson, A Rothwell

Perioperative mortality rates for all New Zealanders having elective/waiting list joint replacement surgery can be estimated. Based on New Zealand data from between 2007–2011 for people undergoing an elective/waiting list procedure, the risk of dying within 30 days of having a first total hip replacement was less than 0.3%, the risk was less than 0.2% after a first total knee replacement and less than 0.5% for any revision procedures. That is, less than 3 in a 1,000 who had a first hip replacement died within 30 days of the procedure, less than 2 in a 1,000 died within 30 days of a first knee replacement and less than 5 in a 1000 died within 30 days following a hip or knee revision.
Very low-carbohydrate diets in the management of diabetes revisited

Grant Schofield, George Henderson, Simon Thornley, Catherine Crofts
Current dietary guidelines for the treatment of type 2 diabetes continue to emphasise the role of carbohydrate as a source of energy, and advise restriction of fat in the diet. However, RCTs (randomised clinical trials) show that a carbohydrate-restricted approach higher in fat is superior for the control of blood sugar than this usual approach. This article discusses the evidence for carbohydrate restriction as a safe and effective part of diabetes management, and explains some of the suggested reasons for its effectiveness. The relative safety of very low-carbohydrate diets, and the evidence with regard to type 1 diabetes, is also discussed. This valuable approach to diabetes management has been neglected until recently but deserves re-assessment.
The challenge of the increasing demand for joint replacement

Gary Hooper

In 1962, Sir John Charley implanted his first cemented total hip replacement and opened the world to an immediate remedy for hip arthritis. Over the last 50 years, countless patients have benefitted from this procedure with relief of pain and return to functional activities. New Zealanders, in the past, have had relatively good access to this procedure through the public health system. The ‘Joint Initiative’ in 2004 highlighted a growing need for surgical intervention in osteoarthritis, which resulted in increased Government funding. However, the ageing population and projected incidence of debilitating osteoarthritis has seen the rate of joint replacement increase to 363/100,000 in 2014, with projections of increasing to around 600/100,000 by 2026.\(^1\)

Gwynne-Jones et al\(^1\) have investigated the demand for joint replacement in the Otago region, concluding that the demand has increased by 19% since 2012, and that patients qualifying for surgery are more disabled than in previous years. They argue that more patients are being returned to their GPs for ongoing conservative management who would have qualified for joint replacement only 4 years ago. This is likely to have multiple effects. Firstly, replacing joints in patients who have lived with disabling arthritis for a significant period of time, and who have more co-morbidities, is likely to result in poorer outcomes with higher post-operative complications. Secondly, managing these patients in the community will require increased resources. Thirdly, operating on ‘end-stage’ osteoarthritis can be surgically demanding, resulting in the use of more expensive implants, more extensive rehabilitation and intensive nursing; all of which require added resources.

Gwynne-Jones et al rightly point out that the decision to reduce waiting list times and introduce a 4-month waiting list has compounded the problems of access to surgery. The narrowing of the time band for the procedure to be completed, combined with the significant financial penalties placed on non-compliant DHBs, has resulted in rigid monitoring of the waiting list, with patients being ‘dropped off’ the list in order to remain compliant. Rather than give patients surety of care, this has created uncertainty with large numbers of patients not even making the threshold, when only 4 years ago they would have been offered surgery.

Currently, the Ministry of Health and a number of surgical societies, including the New Zealand Orthopaedic Association, have been working on the development of a new scoring tool (CPAC) to assess a patient’s need for surgery. This tool has been trialled in two centres, and has been validated and shown to have good inter-observer reliability. It is about to be introduced nationwide for all orthopaedic departments. The hope is that this tool will identify the areas of increased need, such as that reported by Gwynne-Jones et al, and allow the appropriate re-direction of central funding. If used appropriately, it will document the unmet need and any inequalities of access occurring across the country.

Although joint replacement is often associated with a marked improvement in a patient’s quality of life, complications do occur, which can have devastating effects on both the patient and the surgical team. Infection is a rare event following arthroplasty surgery, but Gow et al\(^3\) have shown it results in significant increase in the hospital length of stay and cost, estimated to amount to up to 8 million dollars across all DHBs per year. This expense results in less funds for primary joint replacements, impacting significantly on waiting lists,
further limiting the access to care for some patients. They conclude that the National Surgical Site Infection Improvement programme, with its approach to universal antibiotic prophylaxis and improved antisepic techniques, needs to be communicated across all hospitals to reduce surgical site infection. Improving the communication within all DHBs is likely to close this ‘implementation gap’.

The problem with implant infections is that although many occur early in the life of the replacement, any patient with a joint replacement has a lifetime risk of infection from haematogenous spread. This is confirmed by the New Zealand Joint Registry, showing ongoing new joint infections 15 years after the index procedure. The marked increase in the rate of replacement surgery has resulted in a large catchment of patients within the community who are prone to infection and the subsequent costs associated with treatment. All doctors need to remain vigilant with patients who have potential sources of infection (urinary tract, respiratory tract) and have a joint replacement. Early aggressive treatment is likely to avoid a bacteraemia.

With a finite health budget, it is obvious that the demand for joint replacement and dealing with the subsequent problems—such as infection—will be extremely challenging to meet. There will always be rationing of public hospital resources, and the onus is on the Government to be transparent and inform the population of what they can expect from the public hospital and, if need be, give them alternative options to fund their health care. The time is right for a public debate on the role of a Government-backed health insurance scheme to help those that ‘fall outside’ the threshold for treatment in public facilities.

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The widening Zika virus epidemic in Central and South America, and the continuing spread of the virus in the Pacific, are having an escalating impact on public health services globally, including those in New Zealand. Concern about the reported increase in clusters of neonatal microcephaly in Brazil and mounting evidence of neurological disorders suspected of being associated with Zika virus infection—particularly Guillain-Barré syndrome—has culminated in the World Health Organization (WHO) declaring a Public Health Emergency of International Concern (PHEIC) 1 February 2016.1

Prior to the current Central and South American outbreak, Zika virus has been reported in Africa, Asia and the Pacific. Most infections with Zika virus are generally asymptomatic, however when disease does occur, it is usually mild and complications rare. Indeed, before 2007 only a handful of cases of clinical disease due to Zika virus were reported in Asia and Africa over the previous 50 years, despite a number of countries having serological evidence of virus circulation.2 The virus is spread to humans by *Aedes* sp. mosquitoes, mainly *Aedes aegypti*, which has a distribution throughout most of the tropical and sub-tropical regions of the world. Various primate species are believed to constitute the natural reservoirs of this virus. The limited capacity for laboratory diagnosis, along with the general lack of concern about this virus, has contributed to the many gaps in our knowledge base on Zika virus and the disease it causes.

Over the past decade, the virus has been reported in the Pacific (Federated States of Micronesia in 2007; French Polynesia in 2013) and most recently in the Americas (Brazil and Colombia) in 2015. As of the 1 March 2016, Zika virus transmission has been reported in 8 Pacific Island countries3 and 31 countries in Central and South America, suggesting the rapid geographic expansion of this virus.4

The current circulation of Zika virus in Tonga, the Marshall Islands, New Caledonia, Samoa and American Samoa presents a real threat to New Zealanders visiting these virus-affected areas.5

The virus

Zika virus is an emerging mosquito-borne virus member of the Flavivirus genus within the family *Flaviviridae*, first isolated from a sentinel Rhesus monkey in the Zika Forest in Uganda in 1947 and shortly after from the mosquitoes *Aedes africanus*,6 and from a human infection in Nigeria in 1954.7 The virus was first isolated in Asia in Malaysia from *Aedes aegypti* mosquitoes.8 Other closely related flaviviruses include yellow fever, Japanese encephalitis, West Nile and the dengue viruses. Genetic analysis has shown that Zika virus occurs as two lineages, an African lineage and an Asian lineage.9 Molecular analysis indicates that the virus spreading widely in the Americas is most closely related to an Asian lineage virus isolated from French Polynesia in 2013–2014.10

Virus transmission

The competent mosquito vectors for Zika virus spread to humans are *Aedes aegypti* and *Aedes albopictus*—the same mosquitoes that spread dengue, chikungunya and yellow fever viruses. These mosquitoes usually bite during the morning, and late afternoon/evening hours. The virus replicates within the mosquito and is then transmitted to a
human host via its saliva during the process of taking a blood meal. Humans are usually dead-end hosts for most arboviruses (with the exception of dengue and yellow fever), however it is not known whether Zika virus will grow to sufficiently high titres in humans for it to be able to infect a mosquito in order to maintain a transmission cycle, although epidemiological data would suggest it does. This is an important question as it has major implications in understanding transmission and in possible control strategies. While Zika virus has been isolated from a wide variety of mosquito species, the presence of the virus does not necessarily indicate a competence for the mosquito to be able to transmit the virus to a new host.\textsuperscript{11,12}

Much more work on vector competence is urgently needed, but it is probable that a number of other species of mosquito may be able to transmit under local conditions.

In New Zealand, competent vectors for Zika virus transmission are not known to exist, thus Zika virus infection is primarily a travel-related infection, occurring in travellers returning after living in or visiting Zika virus-affected countries.

There are major concerns that Zika virus may also be transmitted by infected pregnant women to their unborn babies,\textsuperscript{9,13} and there is mounting evidence that sexual transmission can also occur.\textsuperscript{14-16} Indeed, unlike other arboviruses, patients presenting with haematospermia have been shown to have infectious viral particles and ribonucleic acid (RNA) in their semen. Other routes of transmission may also occur, such as through blood transfusions, perinatal transmission during delivery,\textsuperscript{13} via breast milk, close contact after delivery via exchange of saliva or other bodily fluids,\textsuperscript{17} or via transplantation. Blood transfusions are an important potential mode of transmission, as demonstrated by the finding of Zika viral RNA in 2.8% of blood donors in French Polynesia,\textsuperscript{18} and must be of particular concern.\textsuperscript{19} In New Zealand, a suspected sexual transmission to a female who had not travelled to a Zika-affected country has been documented.\textsuperscript{20}

The disease

Zika virus infections are generally asymptomatic, however when illness occurs (in about 20% of infections) it is generally mild. After an incubation period of 3–12 days, the symptoms include a slight fever, muscle and joint pains, conjunctivitis, a maculopapular rash and general malaise.\textsuperscript{21} Zika illness is generally self-limiting with most symptoms resolving within 3–7 days.\textsuperscript{12}

Complications are rare, but recent reports of both neurological and congenital complications have led to the heightened awareness of this disease. The severe neurological complications, particularly cases of Guillain-Barré syndrome, were first observed in French Polynesia in 2013–14,\textsuperscript{22} and increased numbers of cases of Guillain-Barré syndrome have subsequently been observed in Brazil, Colombia, El Salvador and Venezuela.\textsuperscript{23} Because 88% of the cases described in French Polynesia reported a preceding clinical illness,\textsuperscript{22} and because Zika is said to be symptomatic in only 20% of cases based on the Yap outbreak,\textsuperscript{24} asymptomatic infection might pose a much lower risk of Guillain-Barré syndrome than does symptomatic disease. However, that is assuming that the case-to-infection ratio in the current outbreak is the same as that in the Yap outbreak, which is also yet to be confirmed.\textsuperscript{25}

Microcephaly is the most prominent and commonly reported clinical feature of suspected congenital Zika syndrome.\textsuperscript{26-28} The various manifestations of the syndrome have been reviewed by Chan et al (2016).\textsuperscript{12} While there has been some laboratory support for the possible causal link between Zika virus infection and microcephaly, including the detection of viral RNA in amniotic fluid of two pregnant women with ultrasonic evidence of microcephaly, in blood and brain tissues from deceased neonates, and in babies born with microcephaly,\textsuperscript{12,23,26,27} a causal link between these events is yet to be confirmed. Furthermore, the geographic variation in the incidence of congenital malformations might suggest that other factors or co-factors could be involved.\textsuperscript{23,29} Thus, further studies are urgently needed to clarify this.

Diagnosis

The clinical diagnosis of Zika virus infection is based on symptoms and a recent history of travel to an area where Zika virus is known to be present. However, dengue,
chikungunya and other viruses (including measles and rubella), which cause similar illnesses, may also be present in Zika virus-affected countries. Laboratory testing is the most reliable way to confirm a Zika virus diagnosis. Molecular testing by reverse transcriptase polymerase chain reaction (RT-PCR) is the test of choice with Zika virus RNA able to be detected in blood during the first week and urine during the first 2 weeks of an illness. The major limitation of this test is the relatively short time after acute onset of Zika virus illness, that viral RNA can be detected. Serological tests are also available and include IgM detection using immunofluorescence (IIFT), IgM-capture ELISA (MAC-ELISA) and plaque reduction neutralisation tests (PRNT). Zika IgM antibody is typically detectable from 4 days after symptom onset for approximately 12 weeks. In some instances, the detection of Zika virus IgG can be diagnostically useful, specifically if seroconversion can be demonstrated and infection with other circulating flaviviruses has been excluded.

The limitations of serological assays are that they are slow to perform and cross-reactions with other flaviviruses either as a result of infection or vaccination (yellow fever and Japanese encephalitis) can occur.29

In New Zealand, RT-PCR testing for Zika virus is available from LabPlus (Auckland), ESR (Wellington) and CHL (Christchurch). Also available are RT-PCR assays for the presence of dengue and chikungunya viral RNA, dengue NS1 antigen detection, dengue and chikungunya virus IgM and IgG antibody detection.

**New Zealand’s response**

Although the risk to New Zealanders is considered to be very low for Zika virus infection, the Ministry of Health has issued general advice including specific advice to health care professionals and interim guidance to health care professions dealing with Zika virus in pregnancy.31,32 This latter advice addresses the concerns of the population at increased risk of poor outcomes following infection.

Travellers are returning from Zika virus-affected countries who have been exposed to Zika virus and possibly other mosquito-borne viruses (dengue and chikungunya) present in these areas. Some are presenting to the healthcare system either because of illness or concern over their possible exposure. Clinical astuteness in obtaining a full clinical and travel history, the dates of travel and onset of symptoms and the timely collection of samples for laboratory testing are required. Laboratory testing has become more important for the confirmation of infection, however consultation with a microbiologist or infectious diseases specialist may be required to advise on laboratory test result interpretation as the diagnostic accuracy of RT-PCR assays, especially when applied to Zika virus exposed but asymptomatic individuals, is largely unknown.

A possible future risk to New Zealanders is the establishment of competent mosquito vectors in New Zealand. It is believed that the current conditions in New Zealand are unfavourable for the establishment *Aedes aegypti* and *Aedes albopictus* mosquitoes, reducing the likelihood of human infection from a locally transmitted source.33 However, ongoing surveillance—especially at our borders—for these vectors is essential to mitigate this risk.
EDITORIAL

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Burden of disease from second-hand smoke exposure in New Zealand

Kylie Mason, Barry Borman

ABSTRACT

AIM: To estimate the number of deaths and disability-adjusted life years (DALYs) attributable to second-hand smoke in New Zealand.

METHOD: Comparative risk assessment methods were used to estimate the attributable burden from second-hand smoke in children and non-smoking adults in New Zealand. Disease outcomes included were: ischaemic heart disease; stroke and lung cancer in adults; asthma; lower respiratory infections; otitis media; sudden unexpected death in infancy (SUDI); and low birthweight at term in children. Mortality data from 2009–2011 and DALY data from 2006 were used.

RESULTS: In New Zealand, second-hand smoke was estimated to have caused 104 deaths (plausible range: 66–137) in 2010, and led to the loss of 2,286 healthy years of life (DALYs) (1,465–3,177) in 2006. The main conditions accounting for this health burden were ischaemic heart disease and stroke in older adults. Children accounted for 34% of the attributable health loss in 2006, particularly due to SUDI. Māori experienced five times the health loss of non-Māori, after standardising for age differences.

CONCLUSION: Second-hand smoke continues to cause substantial health loss in New Zealand, and disproportionately affects children and Māori. Substantial health gains can be made by reducing exposure to second-hand smoke in New Zealand.

Second-hand smoke is a major source of indoor air pollution, and can cause illness and premature death. Health effects from second-hand smoke include cardiovascular disease, respiratory disease, cancer, reproductive outcomes and effects on childhood development.1,2

Globally, second-hand smoke was estimated to cause over 600,000 deaths in 2010.3 In New Zealand, an estimated 347 people died from second-hand smoke exposure in 1996/97 (plausible range 174–490), from ischaemic heart disease, stroke, lung cancer and sudden infant death syndrome (SIDS).4 An earlier study estimated that 273 people died from second-hand smoke exposure (due to heart disease and lung cancer) in 1989.5

More recently, the New Zealand Burden of Disease Study estimated that second-hand smoke led to 2,800 DALYs (disability-adjusted life years) in 2006.6 DALYs give an overall measure of healthy years of life lost from illness, disability and premature death, taking into account the age at which people die (through the years of life lost (YLL) component) and the severity of the illness or disability (through the years lived with disability (YLD) component). Additionally, the Global Burden of Disease Study 2010 suggested that 1,600 DALYs were caused by second-hand smoke in New Zealand.7 Since these studies were published, updated evidence on health effects1 and data on exposure to second-hand smoke for New Zealand8 have become available.

This study used recently published data to update estimates of the health burden from second-hand smoke in New Zealand, and identified any population groups (by age, sex and ethnic group) that were disproportionately affected, and potential sources of uncertainty in these estimates.

Method

A comparative risk assessment method, outlined by the World Health Organization (WHO),9 was used to estimate the burden of...
disease attributable to second-hand smoke in New Zealand, in terms of deaths (for 2010) and DALYs (for 2006).

**Study population**

This study estimated the attributable burden from second-hand smoke exposure for children and non-smoking adults in New Zealand. Current smokers were excluded from the main analysis, because most epidemiological evidence is for non-smokers, and therefore the health impact on current smokers is uncertain. Ex-smokers were included on the assumption that their risk is similar to never-smokers.  

**Estimating the attributable burden**

The number of deaths and DALYs attributable to second-hand smoke was calculated using the population attributable fraction (PAF). The PAF is the proportion of health outcomes attributable to a specific exposure, and is calculated with the standard formula $\text{PAF} = \frac{p(RR-1)}{p(RR-1)+1}$, where $p$ is the prevalence of exposure, and $RR$ is the relative risk. When the relative risk was not available, the odds ratio was used as an approximation, as per standard procedures.  

The attributable burden was estimated by multiplying the PAF by the total health burden for each health outcome. For adults, the attributable burden was only estimated for non-smoking adults. To calculate this, the total burden of disease not due to smoking was calculated (by subtracting the attributable burden due to active smoking from the total burden), and the proportion of this burden among non-smokers was estimated, before applying the PAF.

**Health conditions and relative risks**

Health outcomes were selected if evidence from recent meta-analyses and reviews showed they were caused by second-hand smoke exposure, and if the health outcomes were quantifiable by health statistics. Eight conditions were identified as being causally related to second-hand smoke exposure, including stroke in non-smoking adults, for which evidence of causality was only confirmed in 2014. Other conditions included ischaemic heart disease and lung cancer in non-smoking adults, and lower respiratory infections, asthma, otitis media (middle ear infection), SUDI and low birthweight at term in children (Table 1).

**Table 1: Relative risks for second-hand smoke exposure.**

<table>
<thead>
<tr>
<th>Health outcome</th>
<th>Age group</th>
<th>Risk estimate* (95% confidence intervals)</th>
<th>Exposure</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung cancer (in non-smokers)</td>
<td>15+ years</td>
<td>RR 1.21 (1.13–1.30)</td>
<td>At home</td>
<td>US Surgeon General²</td>
</tr>
<tr>
<td>Ischaemic heart disease (in non-smokers)</td>
<td>15+ years</td>
<td>RR 1.27 (1.19–1.36)</td>
<td>At home or at work</td>
<td>US Surgeon General²</td>
</tr>
<tr>
<td>Stroke (in non-smokers)</td>
<td>35+ years</td>
<td>RR 1.25 (1.12–1.38)</td>
<td>At home or at work</td>
<td>Oono et al¹⁴</td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>0–1 year</td>
<td>OR 1.54 (1.40–1.69)</td>
<td>Any household member smoking</td>
<td>Jones et al¹²</td>
</tr>
<tr>
<td>Sudden infant death syndrome (SIDS/SUDI)</td>
<td>0 year</td>
<td>OR 1.94 (1.55–2.43)</td>
<td>Maternal postnatal exposure</td>
<td>Anderson and Cook¹³</td>
</tr>
<tr>
<td>Low birthweight at term</td>
<td>0 year</td>
<td>OR 1.38 (1.13–1.69)</td>
<td>Non-smoking mother exposed at home or work during pregnancy</td>
<td>Windham et al¹⁴</td>
</tr>
<tr>
<td>Otitis media (middle ear infection)</td>
<td>0–14 years</td>
<td>OR 1.32 (1.20–1.45)</td>
<td>Household smoker</td>
<td>Jones et al¹⁵</td>
</tr>
<tr>
<td>Asthma</td>
<td>0–14 years</td>
<td>OR 1.32 (1.23–1.42)</td>
<td>Either parent smokes</td>
<td>Tinuoye et al¹⁶</td>
</tr>
</tbody>
</table>

* RR = relative risk, OR = odds ratio. Where possible, risk estimates adjusting for potential confounders were used.
consistent with the New Zealand Burden of Disease Study approach. Relative risks for current smoking were used to estimate the attributable burden due to active smoking.

Sources of health outcomes data

Data on deaths came from the New Zealand Mortality Collection, using annual averages for the three-year period of 2009–2011. Deaths coded to improbable or imprecise ICD codes (‘garbage codes’) were redistributed to other codes according to the algorithm used in the 2006 New Zealand Burden of Disease Study.

For health loss, data on DALYs, YLLs and YLDs from the 2006 New Zealand Burden of Disease Study were used. Data were available by health outcome, age group, sex and ethnic group (Māori, non-Māori).

Sources of exposure data

For exposure in the home, the confidentialised unit record data from the New Zealand Health Surveys (1996/97, 2006/07 and 2012/13) were analysed, which included information on whether anyone smoked inside the respondent’s home and/or in the car they (or their child) travelled in, and on their smoking status. These data were used to estimate or interpolate exposure to second-hand smoke in the home (based on an exponential decay curve) for the required time periods, for children and non-smoking adults.

Appropriate time lags were applied to exposure data for health outcomes occurring in adults, to account for disease latency periods. Exposure data were lagged by 10–20 years for lung cancer (14 years for the 2010 analysis, and 10 years for the 2006 analysis), and 1–5 years for ischaemic heart disease and stroke (4 years for the 2010 analysis), based on recommendations by the WHO.

For low birthweight at term, data from the antenatal interview in the “Growing Up in New Zealand” longitudinal study were used to estimate the proportion of non-smoking pregnant women who had a partner who smoked, which was used as a proxy for exposure to second-hand smoke in the home.

For SUDI, exposure data were sourced from the nationwide Well Child/Tamariki Ora health checks programme for infants, which collects maternal smoking status at two weeks after birth.

Estimating the attributable burden by population group

For each health outcome, the attributable burden was estimated for each age-sex group, and summed to give the total attributable burden. To examine differences between Māori and non-Māori, the attributable burden was directly estimated for non-Māori; the Māori burden was then indirectly estimated as the difference between the non-Māori and total burden. This approach was chosen because using the direct measure for Māori gave results similar or greater than the total burden, likely due to uncertainties in the estimates for Māori. Differences between Māori and non-Māori were estimated using standardised rate ratios, based on direct age-standardisation using the WHO world standard population.

Sensitivity analyses

Estimates of attributable burden have many sources of uncertainty, including data inputs (such as relative risks and prevalence estimates) and assumptions. Following standard approaches, a sensitivity analysis approach was used, changing various inputs and assumptions one at a time, to test the impact of these sources of uncertainty. These sensitivity analyses provide an indication of the uncertainty, but cannot be interpreted as statistical bounds or confidence limits.

The sensitivity analyses tested the lower and upper limits of estimates of the relative risks to give plausible ranges for results, and the lower and upper confidence intervals of exposure prevalence estimates. Assumptions about the study population were also explored, by firstly including current smokers in the analysis, and secondly excluding ex-smokers. Other sources of exposure to second-hand smoke were also explored, including exposure in cars and workplaces. The sensitivity analyses also examined the impact of including health outcomes with less robust evidence, including asthma in adults, preterm births, pre-menopausal breast cancer and invasive meningococcal disease.
### Table 2: Estimated deaths attributable to second-hand smoke, 2010, total and in Māori.

<table>
<thead>
<tr>
<th>Health outcome</th>
<th>Age group</th>
<th>Total deaths in children and non-smoking adults</th>
<th>Deaths attributable to second-hand smoke (2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Number (%)</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>15+ years</td>
<td>4,649</td>
<td>65 (63)</td>
</tr>
<tr>
<td>Stroke</td>
<td>35+ years</td>
<td>2,236</td>
<td>28 (27)</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>15+ years</td>
<td>250</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Sudden unexpected death in infancy (SUDI)</td>
<td>0 year</td>
<td>54</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Asthma</td>
<td>0–14 years</td>
<td>2</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>0–1 year</td>
<td>9</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Otitis media</td>
<td>0–14 years</td>
<td>0</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Low birthweight at term</td>
<td>0 year</td>
<td>3</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>7,203</td>
<td>104 (100)</td>
</tr>
</tbody>
</table>

*Within age-group. Note: Figures may not sum to totals due to rounding.

### Table 3: Estimated DALYs attributable to second-hand smoke, in children and non-smoking adults, total and in Māori, 2006.

<table>
<thead>
<tr>
<th>Health outcome</th>
<th>Age group</th>
<th>Total estimated DALYs in children and non-smoking adults</th>
<th>DALYs attributable to second-hand smoke (2006)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Number (%)</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>15+ years</td>
<td>68,820</td>
<td>1,033 (45)</td>
</tr>
<tr>
<td>Stroke</td>
<td>35+ years</td>
<td>30,379</td>
<td>389 (17)</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>15+ years</td>
<td>4,377</td>
<td>96 (4)</td>
</tr>
<tr>
<td>SUDI</td>
<td>0 year</td>
<td>5,289</td>
<td>596 (26)</td>
</tr>
<tr>
<td>Asthma</td>
<td>0–14 years</td>
<td>2,969</td>
<td>93 (4)</td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>0–1 year</td>
<td>1,387</td>
<td>42 (2)</td>
</tr>
<tr>
<td>Otitis media</td>
<td>0–14 years</td>
<td>1,189</td>
<td>31 (1)</td>
</tr>
<tr>
<td>Low birthweight at term</td>
<td>0 year</td>
<td>244</td>
<td>6 (&lt;1)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>114,654</td>
<td>2,286 (100)</td>
</tr>
</tbody>
</table>

*Within age-group. Note: Figures may not sum to totals due to rounding.
Results

Exposure to second-hand smoke

In 2012/13, an estimated 150,000 non-smoking adults and children were exposed to second-hand smoke in their home in New Zealand. Exposure to second-hand smoke in the home almost halved between 2006/07 and 2012/13, among non-smoking adults (7.5% to 3.7%) and children aged 0–14 years (9.6% to 5.0%). In 2012/13, Māori continued to have higher rates of second-hand smoke exposure in the home (9.4% among non-smoking adults, and 9.2% among children), although these rates had decreased since 2006/07 (down from 16.0% and 18.9% respectively). The prevalence of exposure to second-hand smoke in cars (3.3% of non-smoking adults, and 6.1% of children) was similar to the prevalence of exposure in homes in 2012/13. Overall, 5.4% of non-smoking adults and 8.7% of children were exposed to second-hand smoke in their home and/or car in 2012/13.

For maternal smoking, from July to December 2012, 13% of mothers with newborns were smoking at two weeks after birth. The rate was much higher among Māori mothers (35%).

Deaths attributable to second-hand smoke

Exposure to second-hand smoke caused an estimated 104 deaths in New Zealand in 2010 (Table 2). The majority of deaths (98 of 104 deaths) were in non-smoking adults, with the main causes of death being ischaemic heart disease (65 deaths, 63% of deaths) and stroke (28 deaths, 27% of deaths). SUDI was the primary cause of death due to second-hand smoke in children, contributing six deaths (5% of deaths).

DALYs attributable to second-hand smoke

In 2006, an estimated 2,286 DALYS were caused by second-hand smoke exposure (Table 3). Ischaemic heart disease accounted for the largest proportion of the burden (1,033 DALYS, 45% of DALYs). Most health loss in adults was fatal, particularly for ischaemic heart disease (86% fatal), stroke (79%) and lung cancer (98%). For children, SUDI had a considerable health burden (78% of the attributable burden in children), while asthma, lower respiratory infections and otitis media also contributed to the burden in children.

Population differences

Health loss due to second-hand smoke was almost twice as high in males (1,395 DALYS) as in females (892 DALYS). Standardising for age, males had about 60% higher health loss from second-hand smoke exposure than females (standardised rate ratio, SRR = 1.62).

Children were disproportionately affected, experiencing 34% of the total health loss due to second-hand smoke in 2006, particularly from SUDI. About 11% of total DALYS

Table 4: Estimated number of deaths and DALYs attributable to second-hand smoke, by sex and ethnic group.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Rate*</td>
<td>SRR (Māori vs non-Māori)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Māori</td>
<td>17</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>Non-Māori</td>
<td>87</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>104</td>
<td>1.5</td>
</tr>
<tr>
<td>Males</td>
<td>Māori</td>
<td>10</td>
<td>3.9</td>
</tr>
<tr>
<td></td>
<td>Non-Māori</td>
<td>49</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>58</td>
<td>1.9</td>
</tr>
<tr>
<td>Females</td>
<td>Māori</td>
<td>8</td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>Non-Māori</td>
<td>38</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>46</td>
<td>1.1</td>
</tr>
</tbody>
</table>

* Rates are per 100,000 population, and have been age-standardised to the WHO world standard population. SRR = standardised rate ratio. Figures may not sum to totals due to rounding.
Table 5: Sensitivity analyses showing the effect of changing assumptions on deaths and DALYs due to second-hand smoke.

<table>
<thead>
<tr>
<th>Assumption in best estimate</th>
<th>Alternative condition</th>
<th>Effect on attributable burden (resulting total attributable burden)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline scenario</td>
<td></td>
<td>104 deaths</td>
</tr>
<tr>
<td>Best estimate for relative risk / odds ratio from meta-analysis</td>
<td>Use lower bounds of relative risks</td>
<td>Decrease by 36% (66 deaths)</td>
</tr>
<tr>
<td></td>
<td>Use upper bounds of relative risks</td>
<td>Increase by 31% (137 deaths)</td>
</tr>
<tr>
<td>Best estimate for prevalence</td>
<td>Use lower bounds of 95% confidence interval</td>
<td>Decrease by 32% (71 deaths)</td>
</tr>
<tr>
<td></td>
<td>Use upper bounds of 95% confidence intervals</td>
<td>Increase by 28% (133 deaths)</td>
</tr>
<tr>
<td>Use exposure in the home as proxy for regular exposure</td>
<td>Include exposure in the workplace for working-age population</td>
<td>Increase by 14% (119 deaths)</td>
</tr>
<tr>
<td></td>
<td>Ischaemic heart disease (exposure in 2006)</td>
<td>Increase by 9.2 deaths</td>
</tr>
<tr>
<td></td>
<td>Stroke (exposure in 2006)</td>
<td>Increase by 2.7 deaths</td>
</tr>
<tr>
<td></td>
<td>Lung cancer (exposure in 1996)</td>
<td>Increase by 3.2 deaths</td>
</tr>
<tr>
<td>Use exposure to second-hand smoke in the home</td>
<td>Use exposure to second-hand smoke in home and/or car</td>
<td>Increase by 18% (123 deaths)</td>
</tr>
<tr>
<td>Include health outcomes with best evidence (Level 1 conditions only)</td>
<td>Include conditions suggestive of causal relationships:</td>
<td>Increase by 5% (109 deaths)</td>
</tr>
<tr>
<td></td>
<td>Preterm birth complications</td>
<td>Increase by 2.7 deaths</td>
</tr>
<tr>
<td></td>
<td>Asthma in adults</td>
<td>Increase by 1.5 deaths</td>
</tr>
<tr>
<td></td>
<td>Pre-menopausal breast cancer</td>
<td>Increase by 0.4 deaths</td>
</tr>
<tr>
<td></td>
<td>Invasive meningococcal disease</td>
<td>Increase by 0.2 deaths</td>
</tr>
<tr>
<td>Current smokers are not included in the analysis</td>
<td>Include non-smoking burden in smokers (and exposure data for total population, not just non-smokers)</td>
<td>Increase by 90% (198 deaths)</td>
</tr>
<tr>
<td>Ex-smokers are included in the analysis</td>
<td>Exclude burden in ex-smokers</td>
<td>Decrease by 42% (60 deaths)</td>
</tr>
<tr>
<td>Estimate Māori burden as the difference between Total and non-Māori</td>
<td>Directly calculate Māori estimates, and sum Māori and non-Māori estimates to get total burden</td>
<td>Increase by 5% (109 deaths)</td>
</tr>
<tr>
<td></td>
<td>Increase Māori deaths from 17 to 22 deaths; increase the standardised rate ratios for Māori vs non-Māori</td>
<td>Increase Māori burden by 44% (from 883 to 1,270 DALYs); increase standardised rate ratios for Māori vs non-Māori</td>
</tr>
</tbody>
</table>

N/A = data not available.
from SUDI were attributable to second-hand smoke exposure. For children, health loss was mostly fatal (84%), including from SUDI (100%), low birthweight (100%) and lower respiratory infections (96%). However, for asthma and otitis media, most of the health loss was due to illness (7% and 0% of the health loss was fatal, respectively).

Disparities in health impacts from second-hand smoke were also seen for Māori. Māori experienced 17 deaths attributable to second-hand smoke, about 17% of the total (Table 4). Additionally, Māori experienced 883 DALYs attributable to second-hand smoke, about 39% of the total health loss experienced. Moreover, the attributable health loss was more likely to be fatal for Māori (90% fatal) than for non-Māori (82%). Standardising for age, Māori were about three times as likely to die from second-hand smoke exposure as non-Māori (SRR = 2.93), and they experienced five times the health loss from second-hand smoke as non-Māori (SRR = 5.09).

Five of the six SUDI deaths (and 85% of SUDI DALYs) attributable to second-hand smoke were in Māori children, despite Māori infants making up about 27–30% of children aged 0–12 months in New Zealand. Māori children also accounted for a disproportionately large amount of the attributable health loss from lower respiratory infections (73%), otitis media (56%) and asthma (47%).

Sensitivity analyses

The sensitivity analyses showed the effect of a range of alternative scenarios on the attributable deaths and DALYs (Table 5).

Using the lower and upper bounds of the relative risk estimates gave a plausible range of 66–137 deaths, and of 1,465–3,177 DALYs, for the attributable burden from second-hand smoke.

Including additional sources of exposure increased the attributable burden from second-hand smoke. Including workplace exposure to second-hand smoke for adults (with appropriate lag times between exposure and disease) resulted in a 14% increase in deaths (to 119 deaths) and a 27% increase in DALYs (to 2,896 DALYs), based on workplace exposure to second-hand smoke of 7.8% of non-smokers in 2006,25 and 19% and 6% in non-smoking men and women respectively in 1996.24 Including exposure in cars as well as homes increased the burden by 18% for deaths (to 123 deaths) and 17% for DALYs (to 2,665 DALYs).

Including health conditions with evidence suggesting (but not yet proving) a causal link, such as asthma in adults and preterm births, increased the attributable deaths by 5% (to 109 deaths) and the attributable DALYs by 38% (to 3,162 DALYs).

The largest impact was if current smokers were considered to be susceptible to second-hand smoke exposure. Including current smokers increased the attributable deaths by 90% (to 198 deaths) and the attributable DALYs by 70% (to 3,882 DALYs). Conversely, excluding ex-smokers from the analysis decreased the attributable deaths by 42% (to 60 deaths) and the attributable DALYs by 38% (to 1,407 DALYs).

Additionally, calculating the Māori attributable burden directly (rather than indirectly) increased the attributable deaths (by 5 deaths) and attributable DALYs (by 17%) among Māori, and increased the standardised rate ratios for Māori compared with non-Māori. These findings suggest that the main results for Māori are conservative.

Discussion

Exposure to second-hand smoke led to an estimated 104 deaths (plausible range: 66–137) in New Zealand in 2010, and health loss of 2,286 DALYs (1,465–3,177) in 2006. The majority of the health loss (84%) was due to premature death, mainly from ischaemic heart disease and stroke in adults, and SUDI in infants. Males experienced about 60% more health loss than females due to second-hand smoke, mainly driven by a higher attributable burden from ischaemic heart disease in males.

Children experienced 34% of the health loss from second-hand smoke in 2006, despite making up only 21% of the population. Much of this health loss was fatal, through SUDI deaths. Additionally, asthma and middle ear infections carried a substantial non-fatal burden for children, showing children are experiencing ill-health as a result of their exposure to second-hand smoke. Data from the Global Burden of Disease Study 2010 suggested that New Zealand children aged 0–4 years...
experienced a higher health loss from second-hand smoke than Australia, the US and Canada, when examining the health conditions of lower respiratory infections, upper respiratory infections and asthma. This study did not include SUDI in the list of health effects, so will be missing a sizeable amount of the attributable burden; given New Zealand's high SUDI rates, the disparity between New Zealand and other countries is likely to have been larger.

Māori experienced five times as much health loss from second-hand smoke exposure than non-Māori after standardising for age. Much of this difference was accounted for by SUDI, although a higher burden was also seen in older Māori. Factors likely to have contributed to these higher rates include a higher total disease burden in Māori than non-Māori, with inequalities seen for many health conditions. Māori also had higher rates of current smoking (39%) than non-Māori (14%) in 2012/13, and higher levels of exposure to second-hand smoke among those who did not smoke (about 9%). Māori mothers were also more likely to smoke at 2 weeks after birth (35%) than the national rate (13%). These findings suggest that even among Māori who do not smoke, tobacco use still impacts on their health, through second-hand smoke exposure.

A previous study estimated that second-hand smoke caused 347 attributable deaths in New Zealand in 1996/97, of which 247 deaths were from exposure in the home. In part, the higher burden estimate from this earlier study may be explained by the methods and data sources used. While our study included similar health conditions in attributable death calculations, the relative risks used in the earlier study were different from our study, and in particular were higher for stroke (RR=2.10 and 1.66 for men and women respectively) and SIDS (RR=5.3). Using the most current relative risks for health conditions would have lowered the attributable death count for exposure in the home in 1996/97 from 247 to 168 deaths. Additionally, the exposure data were not as robust or detailed (by age group) in the earlier study, which may have affected the precision of the results. The underlying burden of disease has also decreased over the past few decades (particularly for ischaemic heart disease and SUDI).

Nonetheless, a sizeable difference in attributable burdens from exposure in the home and workplace still remains unexplained by these methodological differences, and likely represents a true decreased burden from second-hand smoke. Many public health initiatives in New Zealand since the 1990s have worked to reduce smoking rates and exposure to second-hand smoke, starting with the Smoke-Free Environments Act 1990, which banned smoking in many indoor workplaces. These changes may have contributed to changed attitudes towards, and increased awareness of, the health dangers of second-hand smoke. During this period, smoking rates have dropped substantially, as have rates of exposure to second-hand smoke in the home and workplace, all of which would have contributed to a lower overall burden of disease attributable to second-hand smoke exposure in both the home and workplace. Taken together, these results suggest that the burden of disease from second-hand smoke has reduced considerably in New Zealand over the past 15 years.

Sensitivity analyses were useful in providing a plausible range for the estimated burden in our study, as well as investigating the impact of extending the analysis to include inputs and assumptions with a less robust evidence base. For example, if current smokers were as susceptible to second-hand smoke as non-smokers, as some evidence suggests, the attributable burden from second-hand smoke exposure would have almost doubled. Including in-car exposure would have also led to an increased burden; further evidence is needed about whether exposure in cars increases the health risk to the same extent as being exposed in homes. Including health conditions with suggestive evidence of causality with second-hand smoke (asthma in adults, preterm births, invasive meningococcal disease and pre-menopausal breast cancer) would have also led to a 20% increase in the potential attributable burden. These sensitivity analyses suggest that our estimates of the attributable burden may be conservative, and could be updated as the evidence base improves in the future.
Conclusions and implications for policy and public health initiatives

Second-hand smoke exposure is an entirely preventable cause of ill-health and premature death in New Zealand. This study found that 104 deaths were attributable to second-hand smoke exposure in New Zealand in 2010. While these results suggest a potential reduction in the burden over the last 15 years, they also highlight that there is no room for complacency, as some population groups remain disproportionately affected by second-hand smoke, particularly Māori and children. These findings also show scope for continuing health gains through providing smokefree environment in homes and cars, and ensuring women and their partners are smokefree during pregnancy and after their infant is born.

Competing interests:
The authors report grants from the New Zealand Ministry of Health during the conduct of the study.

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REFERENCES:


The Impact on Life questionnaire: validation for elective surgery prioritisation in New Zealand prioritisation criteria in orthopaedic surgery

Georgina Chan, Louret Bezuidenhout, Logan Walker, Robert Rowan

ABSTRACT

AIM: This cohort study tested the reliability and validity of the Impact on Life (IoL) patient-rated questionnaire for use in prioritising orthopaedic procedures.

METHODS: Three hundred and twenty-four patients completed the questionnaire during specialist orthopaedic assessments over a 5-month period in 2013. The reliability and validity of the IoL were tested against the SF-12 and Oxford scores. Correlation analysis was used to assess patient- and surgeon-rated scores. Internal consistency reliability was assessed using Cronbach's alpha. Patient- and surgeon-rated scores were further analysed between patients added to the waiting list and those that were not.

RESULTS: Participants' mean age was 58 years (range 18–88). Reliability analysis showed the IoL had excellent internal consistency with a Cronbach's alpha of 0.926, reaching the threshold for clinical application. Construct validity of the IoL was confirmed with significant correlation with other validated quality of life measures (p<0.01). T-tests indicated that patients placed on the waiting list had significantly higher surgeon and IoL scores (p<0.001), compared with those not placed on the waiting list.

CONCLUSION: Our results support the IoL as a valid and reliable method of assessing patient-rated quality of life and recommend its use in the Orthopaedic Clinical Priority Assessment Criteria score.
receive surgery within a given timeframe. There remain far more patients recommended for surgery than funding allows, hence the need for a prioritisation tool.

The Clinical Priority Assessment Criteria (CPAC) was developed by national clinical working parties, which includes three dimensions: clinical, patient-experienced, and social. These dimensions generated a total score, to score patients from 0 to 100 (least to most urgent). The aim of priority criteria tools was to create equity, transparency and consistency to the process of allocating elective services.1,3-5 Evidence from the early 2000s suggests that there is still great variation among priority scoring systems. It was established that methods for calculating CPAC scores were inconsistent, and that surgeons often felt their clinical judgement was more effective in prioritising patients.3,6,7

Doughty and colleagues assessed the reliability of CPAC tools for elective surgery in New Zealand, concluding that vignette-based methods were feasible assessment tools,8 and there was a marked inter-surgeon variability when assessing the reliability of 3 different priority tools based upon clinical vignettes, highlighting the need for a reliable scoring system to ensure equity of access.9 Theis reported that generic priority criteria scores correlated well with quality of life measures and patients selected for surgery had significantly lower scores compared to those who were not, concluding that their tool had the ability to select patients with the highest need and ability to benefit.10 Patient centredness is vital to healthcare provision, as it has been shown to increase patient compliance and satisfaction. The disparity between patient and surgeon perception on how a certain condition affects the patient's life warrants even more involvement of the patient in the prioritisation process.11

Prioritisation criteria are most effective when objective and subjective measures are included. This means using a condition-specific measure as well as a general health score. The Impact on Life (IoL), therefore, is designed to be used alongside disease-specific measures and does not need to capture condition-specific information. The Western Canada Waiting List project emphasised the importance of ongoing evaluation of prioritisation tools. Characteristics associated with successful implementation and evaluation initiatives were outlined; for example, receptive management and steering committees as well as familiarity with tools.12 Criticism of prioritising tools was generally focused on the lack of validation prior to implementation.3,4,6,7,13

The IoL (Appendix 1) instrument was developed in conjunction with the Ministry of Health, specifically intended for use in prioritisation for elective surgery in New Zealand. It provides a unique approach to the assessment of impact of health conditions on everyday life. The IoL was first introduced for use in prioritising cataract surgery in 2005 and subsequently in plastic and reconstructive surgery in 2008. The intention of the Ministry is to implement its use across all surgical specialties in New Zealand. The IoL is a one-page, 6-item questionnaire applicable across a range of specialties, using a ‘think-aloud procedure’ completed by patients. It assesses the overall impact of health conditions on a patient's activities of daily living, assuming that one or more condition/s may affect several domains concurrently. Chamberlain and McGuigan demonstrated that the questionnaire was successful for use in patients with different conditions, of varying age and was generally easy to understand and administer.14

We are not aware of any other tool that assesses impact on life for the purpose of prioritisation. The IoL has not been previously validated for use in orthopaedic surgery. We examine the IoL and test its reliability and validity by comparing it with the SF-12 and Oxford scores, validated patient-rated health measures in orthopaedic surgery. The SF-12 and Oxford score were not designed as tests for surgical prioritisation, but have been used for this purpose in some hospitals in New Zealand. We chose to compare the IoL with these measures as they are scoring systems used at our hospital, and have been shown to predict patients' benefit prospectively.6 The SF-12 provides a measure of a patient's general health and the Oxford assesses how a specific joint affects an individual. This
study assessed only patients who have been recommended for surgery, to determine whether the IoL is a reliable and valid prioritisation tool.

**Methods**

All patients over the age of 18 years, who attended orthopaedic specialist assessments at Wellington Regional Hospital between July and November 2013, and who were recommended for surgery, completed the IoL, SF-12 and, where applicable, hip, knee or shoulder Oxford questionnaires. The surgeon completed a priority scoring tool based on their clinical assessment for each patient.

The IoL questionnaire consists of six dimensions: social interaction, personal interaction, ability to fulfil responsibilities to others, personal care, personal safety, and leisure activities. The surgeon priority scoring tool (Appendix 2) includes three dimensions: potential deterioration, expected benefit and surgeon-assessed severity. The weighted IoL score accounted for 25%, and the surgeon score 75% to the final orthopaedic CPAC score, ranging from 0 to 100 (best to worst possible health).

The SF-12 is a widely-used tool consisting of 12 questions covering 8 general health dimensions: physical functioning, physical role-performance, emotional role performance, mental health, bodily pain, vitality, social functioning and an overall rating of general health.15

The Oxford questionnaire consists of 12 questions which assess a patient's function and pain of a specific joint.16 Patients with hip, knee and shoulder problems completed the Oxford score and SF-12. Those who were recommended for surgery for other orthopaedic conditions completed only the SF-12. Patients under the age of 18 and those who failed to complete questionnaires were excluded. The worst response was adopted for questions which returned with more than one answer.

Analysis of the data was performed using SPSS Statistics Version 21 (IBM). Reliability testing was completed using Cronbach's coefficient alpha, which measures the internal consistency of questionnaires, and is commonly used to assess reliability.17 A Cronbach's alpha of greater than 0.7 indicates good reliability, with 0.9 being the recommended coefficient for clinical application.17 Construct validity was completed using correlation analysis. This was also performed to delineate any relationship between patient-rated score and surgeon-assessed severity. T-tests were completed to determine whether there were any differences between patient- and surgeon-rated scores with regards to those patients that were added to the waiting list compared to those that were not.

We did not measure inter-observer or intra-observer reliability for the IoL as it is a test applied to an individual to measure their disability at one instant in time.

**Results**

1,324 FSA patients were seen through our clinic between July and November 2013. 324 patients (53% female) were recommended for surgery and completed all questionnaires at their specialist assessment appointment (100% completion rate). The Oxford Score was completed by 146 patients (those who had hip, knee or shoulder problems). Fourteen surgeons were involved (100% departmental involvement), and completed surgeon assessment scores for their patients. The patients' mean age was 58 years (range 18–88, standard deviation 17). The elective procedures included all orthopaedic subspecialties except paediatric orthopaedics.

Cronbach's coefficient alpha for the IoL was 0.926. Construct validity was tested using Pearson correlation coefficients (Table 1).

Significant correlations were found between IoL and SF-12, as well as IoL and Oxford scores (-0.735 and -0.674, respectively). There was no correlation between surgeon scores and IoL or SF-12 scores. All correlations between subscales of the SF-12 and IoL were statistically significant. Table 2 shows that patients who were added to the waiting list had significantly higher surgeon scores (mean difference of 19.59) as well as IoL scores (mean difference of 4.23) compared to patients who were not added (p=0.000).

**Discussion**
Table 1: Pearson correlation coefficients comparing all questionnaires (p-value).

<table>
<thead>
<tr>
<th>Surgeon Score</th>
<th>IoL</th>
<th>PCS</th>
<th>MCS</th>
<th>SF-12</th>
<th>Oxford</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon Score</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IoL</td>
<td>0.077 (0.177)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-12 PCS</td>
<td>0.067 (0.237)</td>
<td>-0.580 (&lt;0.01)**</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-12 MCS</td>
<td>-0.056 (0.326)</td>
<td>-0.551 (&lt;0.01)**</td>
<td>-0.187 (0.001)**</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total SF-12</td>
<td>0.003 (0.962)</td>
<td>-0.735 (0.00)***</td>
<td>0.734 (0.00)***</td>
<td>0.804 (0.00)***</td>
<td>1</td>
</tr>
<tr>
<td>Oxford</td>
<td>-0.215 (0.011)*</td>
<td>-0.674 (&lt;0.01)**</td>
<td>0.678 (&lt;0.01)**</td>
<td>0.399 (&lt;0.01)**</td>
<td>0.691 (&lt;0.01)**</td>
</tr>
</tbody>
</table>

*Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed)

Table 2: Results of t-tests showing the difference in outcome measure scores between patients that were added to the surgical waiting list compared to those who were not added.

<table>
<thead>
<tr>
<th></th>
<th>Mean Scores</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Added to waiting list</td>
<td>Not added to waiting list</td>
</tr>
<tr>
<td>CPAC</td>
<td>78.13</td>
<td>52.62</td>
</tr>
<tr>
<td>Surgeon Score</td>
<td>66.61</td>
<td>47.02</td>
</tr>
<tr>
<td>IoL</td>
<td>10.41</td>
<td>6.18</td>
</tr>
<tr>
<td>SF-12 PCS</td>
<td>33.74</td>
<td>35.12</td>
</tr>
<tr>
<td>SF-12 MCS</td>
<td>44.98</td>
<td>49.58</td>
</tr>
<tr>
<td>SF-12 total</td>
<td>78.73</td>
<td>84.70</td>
</tr>
<tr>
<td>Oxford Score</td>
<td>14.73</td>
<td>21.55</td>
</tr>
</tbody>
</table>

*Mean difference is significant at the 0.05 level; **Mean difference is significant at the 0.01 level

This study found that the IoL questionnaire correlated well with other validated, patient-rated measures. The Cronbach's coefficient alpha of 0.926 suggests excellent internal consistency and exceeded the minimum value recommended for clinical application. Pearson correlation coefficients for all patient-rated questionnaires were good (>0.551) indicating a moderate to strong relationship between IoL and SF-12, as well as IoL and Oxford Scores.

The statistical significance of the reliability and validity measures of the IoL indicates that this is a statistically valid patient-generated assessment tool. The IoL is a measure of the disability caused by the surgical problem we plan to treat. It is more specific to surgical patients than the SF-12 which measures general quality of life and is more generalisable than the joint-specific Oxford score.

Patient-reported health measures are essential in clinical decision making. We must improve our ability to appraise patients' comfort and performance accurately, reliably and efficiently. Based on their justified results, Derrett and Paul suggested that quality of life measures should be used more widely in clinical practice, indicating it would improve quality of care. This was further supported by findings that patient-experienced health measures were strong predictors of benefit, and that priority criteria tools appropriately selected patients with highest need and ability to benefit.

Our results confirmed that quality of life measures correlate weakly with surgeon scores. This is in agreement with previous studies, where physicians were reported to rate patient quality of
life significantly better, while scoring pain intensity significantly lower than patients scored themselves.4, 6

**Conclusion**

This study provides the evidence to support the reliability and validity of the IoL as a patient reported health measure for the assessment of orthopaedic elective procedures. The IoL is a relevant, comprehensive and user-friendly tool for use in prioritisation for elective surgical services. It is the intention of the Ministry of Health that this tool be used nationwide as a standardised measure for prioritisation for elective surgical services in New Zealand. We recommend its use alongside disease-specific measures for use in orthopaedic prioritisation.

Further investigation is required to assess the validity of the complete priority criteria suggested for orthopaedic surgery (combined surgeon- and patient-rated scores). The need for a universal prioritising tool is evident in order to achieve nationwide consistency in the distribution of elective surgical services. Long-term studies will be vital to provide further evidence of the validity of the proposed orthopaedic priority scoring tool.

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**Appendix 1: Impact on Life Questionnaire**

**Patient Impact on Life Questionnaire**

We are interested in the degree of difficulty your condition places on your (or your child’s) life or how it may limit your (or your child’s) quality of life. Please focus on the general concept asked about in each question below. The examples given after each are simply to illustrate what the concept might mean - it doesn’t matter that some of these examples don’t apply to you. We do not want you to respond to the specific examples, just to think about the general concept, whatever that means for you (or for your child).

Please circle the number, which most represents the impact of your condition on this aspect of your life.

**Social Interaction** (Meeting friends, going out, joining in groups, going shopping, everyday activities outside the home)

- No difficulty
- Little difficulty
- Some difficulty
- Quite difficult
- Very difficult
- Extremely difficult

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
</table>

**Personal Interaction** (Potential intimate social relations; with partner, family members, close personal friends)

- No difficulty
- Little difficulty
- Some difficulty
- Quite difficult
- Very difficult
- Extremely difficult

<table>
<thead>
<tr>
<th>1</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
</table>

**Ability to fulfill your responsibilities to others**

(Do meaningful things for yourself or others; including caring for children, grandchildren, partner, employment (both paid and unpaid), including any impact of dependence on others)

- No difficulty
- Little difficulty
- Some difficulty
- Quite difficult
- Very difficult
- Extremely difficult

<table>
<thead>
<tr>
<th>1</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
</table>

**Personal care** (Looking after yourself, your health, personal hygiene, need for special clothing)

- No difficulty
- Little difficulty
- Some difficulty
- Quite difficult
- Very difficult
- Extremely difficult

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
</table>

**Personal safety** (Being safe from harm; from yourself, or others, and in your surroundings)

- No difficulty
- Little difficulty
- Some difficulty
- Quite difficult
- Very difficult
- Extremely difficult

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
</table>

**Leisure activities** (Sporting activities, getting exercise, hobbies, gardening, DIY activities, crafts, travel)

- No difficulty
- Little difficulty
- Some difficulty
- Quite difficult
- Very difficult
- Extremely difficult

| 1 | 2 | 3 | 4 | 5 | 6 |
Appendix 2: Surgeon Priority Scoring Tool

Competing interests:
Nil

Author information:
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URL:
REFERENCES:


Perioperative mortality in New Zealand related to hip and knee replacement surgery: comparing administrative and registry data

P Hider, C Frampton, J-C Theis, L Wilson, A Rothwell

ABSTRACT

INTRODUCTION: Perioperative mortality is of considerable importance, but few national assessments are available. New Zealand has a clinical registry and an administrative dataset that both capture national information about hip and knee arthroplasties. National perioperative mortality rates were compared between the two data sources.

METHOD: Data related to all patients undergoing an elective hip or knee replacement procedure (primary or revision) between 1 January 2007 and 31 December 2011 were separately extracted from the New Zealand Joint Registry and the National Minimum Dataset. The procedure date was used to define the occurrence of an event and dates were compared between datasets plus or minus 3 days. Date of death information was obtained from the National Mortality Collection and used to estimate 30 day mortality rates.

RESULTS: No statistically significant differences in perioperative mortality were evident between comparisons from the two data sources although more deaths were recorded among Registry-only procedures.

CONCLUSIONS: Estimates of 30 day perioperative mortality related to hip and knee arthroplasty procedures in New Zealand 2007–2011 are very similar regardless of data source. These data, coupled with perioperative mortality review using structured reports obtained from clinicians, could be used to develop a surveillance system to promote surgical safety.

Perioperative mortality is of pressing importance to consumers, practitioners and policy makers, and provides a focus for assessing the safety of new interventions, undertaking performance assessment and completing quality improvement initiatives. Websites, such as Dr Foster (http://www.drfosterhealth.co.uk/) in the UK, now publicly report perioperative mortality rates for specific hospitals, and international comparisons have been described. While practitioners and organisations can usefully assess their own perioperative mortality rates by auditing their clinical records, the completeness of these data are limited to information about deaths that have occurred within their institution. To obtain accurate information about mortality rates across all institutions that also include those deaths that occur after discharge, national assessments of perioperative mortality must be undertaken using specially designed clinical registries or harvested from existing databases. Each of these approaches has inherent strengths and weaknesses.

Clinical registries include customised clinical information focused on particular procedures or settings and are often well supported by professional organisations and clinicians. However, they are resource...
intensive to develop and maintain, and can include information that is recorded in ways that make comparisons difficult.8,10 Existing large administrative databases have the advantages that the data are already collected and have been coded in a standardised manner according to an international system.1,8,11 Despite these advantages, some researchers and clinicians remain wary of administrative data.10,12

Hip and knee arthroplasty are effective procedures that can reduce pain, improve morbidity and enhance quality of life related to arthritis.13 Utilisation numbers are forecast to rapidly increase with ageing populations in developed countries, including New Zealand.14,15 However, hip and knee arthroplasty procedures are significant surgical operations and perioperative mortality rates have been of international concern over many years.16 Increasing age and male gender are established risk factors for perioperative mortality following arthroplasty surgery.17,18 New interventions have been developed with a view to improving mortality and morbidity,19 and purpose-designed clinical registries have been established to help track improvements.20 Despite the development of these repositories, national estimates of perioperative mortality following hip or knee arthroplasty are rare.21

New Zealand has the unique advantage of a clinical registry (New Zealand Joint Registry (NZJR)) and an administrative dataset (National Minimum Dataset (NMDS)) that both capture national information about hip and knee arthroplasty procedures. The main aim of this study was to compare estimates of perioperative mortality following hip and knee arthroplasty using both administrative data and clinical registry information at a national level to assess their suitability for surveillance of perioperative mortality.

Methods

The NZJR was established in 1998 by the New Zealand Orthopaedic Association initially to record technical information about total hip and knee surgery performed in New Zealand, although data collection has expanded to include shoulder, elbow, elbow and spinal disc replacements.22 Demographic and joint replacement information are obtained from clinical staff at the time of operation using a purpose-designed form.22

The NMDS is maintained by the Ministry of Health and began in 1998 with public hospital discharge data dating back to 1988.23 Data are obtained electronically from public hospitals within 21 days of discharge, and from some private institutions. Data collection includes demographic information and the occurrence of up to 100 diagnoses and procedures coded according to ICD-10-AM and Australian Classification of Health Interventions standards.23 Data from the NMDS were collated for the Perioperative Mortality Review Committee as part of their ongoing assessment of perioperative mortality in New Zealand.24

Data from the NZJR were collated in relation to all patients undergoing either a hip or a knee full replacement procedure (primary or revision) between 1 January 2007 and 31 December 2011. Information was extracted from the NMDS for all people undergoing hip or knee arthroplasty procedures over the same period. The following ICD-10-AM ACHI Procedure Codes, Version 3, were used: hip arthroplasty, Blocks 1489 and 1492; and knee arthroplasty, Blocks 1518, 1519, 1523 and 1524. Mortality information was sourced from the NMC and as recorded in the NMDS. The following information was separately obtained from both sources: gender, age, admission date, procedure date, discharge date, type of procedure, hospital type (private or public). The NZJR excludes acute procedures so the data obtained from both sources were restricted to elective (waiting list) events. Ethnicity and domicile information were not included as they were not available from the NZJR. Comparisons were made between the data sets in relation to demographic characteristics and procedure data. The procedure date was used to define the occurrence of an event. When the procedure dates were consistent between the two data sets, the event was recorded as having occurred in the NMDS and the NZJR. An allowance of plus or minus 3 days was permitted for the comparison of procedure dates. Data about procedures included in one dataset that were not recorded in the other dataset were collated as NZJR-only or NMDS-only events. Available National Health Index and demographic data
Table 1: Comparison of 30-day mortality for NZJR and NMDS cases of hip and knee arthroplasty in New Zealand 2007–2011.

<table>
<thead>
<tr>
<th>Primary knees</th>
<th>Total</th>
<th>30-day Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n</td>
</tr>
<tr>
<td>Source</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR</td>
<td>28,391</td>
<td>46</td>
</tr>
<tr>
<td>NMDS</td>
<td>25,337</td>
<td>44</td>
</tr>
<tr>
<td>After combining</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR alone</td>
<td>6,056</td>
<td>6</td>
</tr>
<tr>
<td>NMDS alone</td>
<td>1,235</td>
<td>3</td>
</tr>
<tr>
<td>Both +/-7 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR</td>
<td>22,335</td>
<td>40</td>
</tr>
<tr>
<td>NMDS</td>
<td>22,335</td>
<td>40</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Revision knees</th>
<th>Total</th>
<th>30-day Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n</td>
</tr>
<tr>
<td>Source</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR</td>
<td>2,095</td>
<td>10</td>
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<tr>
<td>NMDS</td>
<td>1,430</td>
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<tr>
<td>After combining</td>
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<tr>
<td>NZJR alone</td>
<td>836</td>
<td>6</td>
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<tr>
<td>NMDS alone</td>
<td>171</td>
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<tr>
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<tr>
<td>NZJR</td>
<td>1,259</td>
<td>4</td>
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<tr>
<td>NMDS</td>
<td>1,259</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary hips</th>
<th>Total</th>
<th>30-day Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n</td>
</tr>
<tr>
<td>Source</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR</td>
<td>35,118</td>
<td>88</td>
</tr>
<tr>
<td>NMDS</td>
<td>28,209</td>
<td>49</td>
</tr>
<tr>
<td>After combining</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR alone</td>
<td>8,079</td>
<td>42</td>
</tr>
<tr>
<td>NMDS alone</td>
<td>1,168</td>
<td>3</td>
</tr>
<tr>
<td>Both +/-7 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR</td>
<td>27,039</td>
<td>46</td>
</tr>
<tr>
<td>NMDS</td>
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<table>
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<th>Total</th>
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<td>n</td>
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<tr>
<td>Source</td>
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<td>5,192</td>
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<tr>
<td>NMDS</td>
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<td></td>
</tr>
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<td>NZJR alone</td>
<td>2,399</td>
<td>12</td>
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<tr>
<td>NMDS alone</td>
<td>278</td>
<td>3</td>
</tr>
<tr>
<td>Both +/-7 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZJR</td>
<td>2,793</td>
<td>12</td>
</tr>
<tr>
<td>NMDS</td>
<td>2,793</td>
<td>12</td>
</tr>
</tbody>
</table>
were used to validate the comparisons. Date of death information was obtained from the National Mortality Collection (NMC) administered by the Ministry of Health. Using dates of procedure recorded in either data source and date of death information provided by the NMC mortality rates within 30 days of procedure, regardless of inpatient status, were calculated for both data sources.

**Results**

Across all four arthroplasty procedures the total number of operations recorded in the NZJR was consistently higher than the total number recorded by the NMDS (Table 1). The biggest difference in the total number of procedures recorded by the two datasets related to primary hip operations, where the NZJR listed 35,118 procedures compared with 28,209 in the NMDS. Related to these differences, some 6,056 primary knee replacements and 8,079 primary hip replacements were present in the NZJR data, but not in the NMDS, compared with 1,235 and 1,168 replacements solely recorded in the NMDS.

Most operations were recorded in both datasets for all four procedures. Between 88–96% of the four procedures recorded in the NMDS were identified in both datasets. Although a smaller proportion (54–79%) of NZJR procedures were captured by both datasets, the percentage of primary hip or knee operations that were described in both was relatively higher (77% and 79% respectively).

In relation to the four types of operations, the age and gender characteristics of the patients undergoing those procedures that were only included in one database remained very similar to those represented in both data repositories. A slightly higher proportion of patients undergoing primary hip or knee replacement surgery were female and slightly more males underwent revision procedures. For all procedures, most patients were aged between 65–79 years and revision procedures were more common among those aged over 79 years.

Across all four procedures most operations occurred in public hospitals. Relatively few hip revision procedures were undertaken in private hospitals. Primary hip or knee procedures that were only recorded by the NZJR were considerably more likely to be undertaken at a private hospital. More than 92% of the 6,056 primary knee replacement procedures only identified by the NZJR were carried out at private hospitals.

Thirty-day mortality rates were consistently low (<1.1%) and similar across all procedures, regardless of data source. No statistically significant differences were evident between results obtained from the two databases. With the exception of hip revision procedures, mortality rates associated with NMDS alone procedures were either the same or slightly lower than those obtained for patients included in only the NZJR. Using the data from both datasets, the mortality rate for primary knee procedure was 0.16% and primary hips was 0.25%. Although mortality rates were similar when compared between NZJR only (0.5%) and NMDS only procedures (0.3%), 42 additional deaths were recorded in relation to NZJR-only procedures compared with just three associated with NMDS only data. Similarly, NZJR-only data included an additional 12, and six deaths related to either hip or knee revision procedures respectively. Across all procedures, most deaths recorded in the NZJR-only data related to public hospital events.

**Conclusions**

NZJR data included more procedures than the NMDS in relation to hip and knee arthroplasty procedures in New Zealand between 2007 and 2011. A small number of procedures were solely identified by the NMDS. Most primary procedures were captured in both databases. The demographic characteristics of the patients who underwent the procedures were generally similar, regardless of whether they were included in just one database or both for each of the four types of arthroplasty procedures. Estimates of the 30-day perioperative mortality rate related to each of the arthroplasty procedures were very similar when based on either NMDS or NZJR data. Thirty-day perioperative mortality rates following hip or knee arthroplasty in New Zealand are generally low (<1%). Revision procedures have higher mortality than primary operations, and hip arthroplasty has a higher mortality.
than knee procedures. More deaths occur at public facilities compared with private hospitals, but this is likely to be due to differences in volumes and casemix. Public facilities include about half the proportion of ASA 1 patients and almost double the percentage of ASA 3 patients compared with private hospitals. Increasing ASA scores are highly associated with greater perioperative mortality. Thirty-day perioperative mortality rates across New Zealand hospitals, whether calculated from registry or administrative data, are consistent with international estimates. A recent meta-analysis reported a 30-day perioperative mortality rate of 0.3% related to hip arthroplasty based on 15 studies, although only two involved national data. Results from this study, whether generated by NMDS or NZJR data, are also consistent with other reports that have suggested there may be a higher perioperative mortality rate following revision procedures compared with primary operations, and following hip rather than knee arthroplasty procedures.

The findings from this study are also consistent with those obtained by a previous comparison of data from the Swedish hip arthroplasty register and a national administrative database. Like our study, the Scandinavian report confirmed that most procedures were recorded in both databases and there were no significant discrepancies in the characteristics or mortality outcomes associated with those procedures that were recorded in either one database or both. Likely explanations proposed by the Swedish researchers for events not being recorded in both databases are relevant to this study. Some of the discrepancies were attributed to missing data or data input errors in either database, while others related to differences in the definitions used by each database for the procedures.

This study restricted its analysis to elective procedures and total arthroplasty procedures (partial procedures were excluded) in an attempt to improve the reliability of the data comparison. The NZJR primarily includes elective procedures so it is more efficient to compare results between the NZJR and the NMDS, excluding acute events. It is unlikely that any discrepancies between the databases would be due to the misclassification of acute events as elective procedures. A possible source of error relates to the identification of revision procedures. NZJR data were captured using a purpose-designed form completed by clinicians at the time of operation. This information is likely to be more accurate than that obtained retrospectively by coders from the clinical record. In this study considerably more revision procedures were identified for both hip and knee arthroplasties (for example, 278 revision hip procedures were solely present in the NMDS compared with 2,399 in the NZJR). While patients may be included in the dataset related to undergoing left- or right-sided procedures, it is unlikely that more than one elective procedure would have been undertaken during the same inpatient stay or within a short period of time after an admission.

Administrative data in New Zealand includes all episodes of care at publicly funded providers in a repository that has already been collected and can be readily analysed. However, clinical registries offer key advantages too, especially when their coverage extends to including private providers whose data are not captured by the administrative resource. While clinical registries remain focused on a particular specialty and narrow collection of procedures, administrative data includes the full range of procedures. Extending coverage of administrative data to all providers would enhance the dataset. The more detailed procedure and device information available only in clinical registries further enhances their advantage. In future, it may be useful to explore the possibility of establishing some ongoing linkage between the datasets if the protected quality assurance activity status related to the Registry data could be extended.

NMDS data appears adequate for the purposes of surveillance to monitor trends in mortality risk associated with procedures identified by the NMDS. Either dataset could be used to generate risk-adjusted performance data to enable hospitals to compare their perioperative mortality risk. However, the information currently included in either of the datasets is not sufficient for quality improvement activities. To be suited for this purpose these
data need to be supplemented by more clinical information related to processes of care that are directly obtained from the practitioners involved with the care of the patient. The National Surgical Quality Improvement Programme (NSQIP) in the US provides the current surgical benchmark related to data collection to foster quality improvement and performance monitoring. Data is collected by nurse researchers from clinicians and detailed information related to patient characteristics, procedures and complications are collated. Such a system has been associated with major benefits related to reduced complication rates and overall cost savings for participating hospitals in the US. However, significant resources are required to establish and maintain the programme. Importantly, NSQIP’s impact on mortality has been modest. With relatively low rates of death for many operations, significant gains have been hard to accrue. An alternative option would be to foster the development of perioperative mortality review along the lines of initiatives in Australia and the UK. Information is collected from clinicians about perioperative deaths using structured reports. Participation is supported by professional colleges and recertification requirement. Data collection would need to be extended to non-fatal cases to focus on key areas for improvements. Coupled with a surveillance system that examined trends in risk-adjusted mortality, perioperative mortality review could promote New Zealand as a world leader in surgical safety.

Competing interests: Nil

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Cascade of Care for People Living with HIV Infection in the Wellington Region

Nigel Raymond, Kelly Bargh, Kyi Lai Lai Aung, James Rice

ABSTRACT

AIM: Antiretroviral therapy (ART) is highly effective in providing better outcomes for people living with HIV infection (PLHIV) and reducing the risk of transmission to others. The ‘cascade of care’ describes steps in delivering care: diagnosis, linkage and retention in care, and the provision and success of ART.

METHODS: The cascade of care for PLHIV in the Wellington region was reviewed during 2015. An estimate of 20% undiagnosed HIV infection was used from past New Zealand research. ‘Suppression of HIV infection’ by ART was defined as a viral load less than 200 RNA copies/mL as commonly used in other cascade of care studies.

RESULTS: There were 307 people identified with HIV infection. The median age was 48 years, and 54 (18%) were women. At the time of the audit, each of the 307 PLHIV were accounted for and not lost to follow-up. ART was being taken by 272 (89%). Those with a CD4 count >500 x 10^6/L accounted for 26/35 not on ART. Of those on ART 254/272 (93.3%) had a suppressed viral load, including 252/259 (97.3%) of those established on treatment >6 months. Overall, 254/384 (66.1%) were estimated to have a suppressed viral load.

CONCLUSIONS: The study indicated a high level of retention in care, and of effective HIV suppression, with ART. The main gaps in the cascade of care were the people with undiagnosed HIV infection and those in whom treatment had not yet been initiated because their CD4 count was above 500 cells/10^6/L.

Antiretroviral treatment (ART) provides considerable clinical benefit to people living with HIV infection. Since the availability of combination ART in the 1990s, there has been a fall in the mortality and number of those developing AIDS cancers and opportunistic infections. However, even with effective ART there is an observed increased occurrence of a variety of non-AIDS events, including cardiovascular, renal and liver disease and non-AIDS defining cancers, which could be best reduced by a combination of early and sustained control of the HIV infection together with other risk factor management and screening. The long-awaited START study, published in 2015, found that ART initiation at or soon after diagnosis leads to reductions in serious AIDS-related events, serious non-AIDS-related events, and death from any cause, although the absolute risk reduction may be small and treatment decisions will need to be individualised. This demonstrates that early diagnosis of HIV infection is of definite clinical benefit to the individual. Unfortunately, late diagnosis is still too common, as indicated by most of those diagnosed in New Zealand having a low CD4 count and some still presenting with AIDS. Antiretroviral treatment is highly effective in reducing the risk of sexual transmission to others. In New Zealand, as in many other developed countries, the rates of new HIV diagnoses have risen over the last decade compared with prior to 2000. The improved clinical prognosis may have diminished perceptions of individual risk and reduced the public health imperative. The UNAIDS has set a goal of ‘90-90-90’: 90% of all people with HIV infection should have the infection diagnosed, 90% of all people with diagnosed HIV infection should be consistently receiving ART and 90% of all people receiving ART should have a fully suppressed viral load. Even if these targets are fulfilled more than 25% of all people with HIV infection would not have their HIV fully suppressed on ART.
During the period of this study, publicly funded antiretroviral therapy was available to New Zealand residents with a CD4 count less than 500 x 10^6/L (normal > 600) or who were symptomatic. International research has shown that there is often considerable loss of engagement at each step in the ‘cascade of care’ from HIV diagnosis to those whose infection is ‘suppressed’ with a low or undetectable viral load on antiretroviral medication. The practical challenges in achieving high levels of engagement in each step of the cascade of care were highlighted in a 2011 study of engagement in care in the US, which estimated only 19% of those living with HIV had their infection suppressed. Reaching and engaging those with HIV infection in care is essential to the public health response and strategy to control HIV in the New Zealand community.

This audit aimed to describe the level of engagement in the cascade of care of people with HIV infection in the Wellington region.

Methods

Setting
Wellington regional HIV specialist services were provided by the Infectious Diseases Department, CCDHB based at Wellington Hospital, in conjunction with a smaller number of PLHIV cared for by the Immunology Department CCDHB, and since January 2015, by an Infectious Diseases Physician serving the Hutt Valley & Wairarapa DHBs. Some PLHIV not yet on antiretroviral medication were cared for by the Wellington Sexual Health Service. Most people with HIV infection were also under the care of a GP. Occasional patients have been cared for by their GP alone, although at the time of the audit none were. The audit was conducted in April 2015.

Information sources

Regional HIV clinical service
PLHIV under the care of the regional HIV service were recorded in a secure database (Excel file) maintained manually by the HIV clinical nurse specialist. The CCDHB hospital laboratory is the only laboratory providing HIV viral load testing in the region. The hospital laboratory system was queried for all HIV viral load tests, to ensure our HIV database was complete. An HIV care summary form on the main hospital clinical record system (Concerto) for each patient with HIV under care was used to identify the cohort of people with known HIV infection, and to record relevant clinical information (eg, antiretroviral treatment). This allowed reports to be generated for the cohort by the Information Services Department, including other electronically recorded information (eg, clinic attendance) or demographic information. Clinical information at Hutt Valley and Wairarapa DHBs was accessible to clinical staff using an ‘e-tree’ link. Laboratory results from the regional community provider (Aotea Pathology Ltd) for patients under specialist care were periodically copied to the CCDHB electronic clinical records. Selected GP care information, including diagnoses and results, were accessible from the hospital electronic clinical records.

Information from other providers and sources
In order for as complete inclusion as possible of those with diagnosed HIV infection, we sought further information from laboratory sources and other HIV care providers in the region.

The serology sections of the regional community (Aotea Pathology Ltd) and hospital laboratories had clinical oversight by senior medical staff who were also members of the regional HIV clinical service. New laboratory HIV diagnoses were individually followed up with the referring doctor and assistance was provided for referral to the regional HIV service.

Regional HIV care providers assisting with the study included the Wellington Sexual Health Clinic, HIV NGO Wellington offices (NZAF, Body Positive), and high case-load GPs.

Ethics
The study was undertaken as a registered audit by the Infectious Diseases Department compliant with institutional quality assurance policies at Capital and Coast DHB.

Definitions

Wellington region
The Wellington region was regarded as the area served by the Capital & Coast and
Hutt Valley DHBs. People with HIV infection who reside primarily in the Wellington region comprised the cohort which was the focus of the study.

Some people from the neighbouring Wairarapa DHB who historically received their HIV specialist care in Wellington, and a very few other PLHIV who had continued care from Wellington, were included. We included all those PLHIV who were diagnosed and initially treated outside the Wellington region and who transferred into the Wellington region following receipt of written communication from those services. We wrote to HIV services in other regions to transfer care when PLHIV under the care of our HIV service moved to reside out of the Wellington region.

We planned to exclude any occasional PLHIV temporarily residing in Wellington while receiving on-going specialist care from another region and communicated to us, although there were none at the time of the audit.

Cascade of Care

Estimated total of HIV infected

The total number of people with HIV infection is the sum of those with diagnosed and undiagnosed infection. An estimate of 20% undiagnosed was used in this study (based on past New Zealand research9) to calculate the “Estimated Total HIV Infected” (estimated total HIV infected = 100/80 x observed number diagnosed).

Diagnosed with HIV infection

Those diagnosed with HIV infection were defined as having positive serological or viral load tests regarded as true positives on further laboratory and clinical assessment. A positive card test result performed by a trained health provider (eg, Āwhina Centre, New Zealand AIDS Foundation) was also included as a serological test. PLHIV transferred to Wellington HIV services by specialist HIV services from another region with written correspondence confirming HIV infection were included.

Linked to care

Those diagnosed with HIV infection were defined as linked to care if they had been seen at least once by a medical practitioner (GP, sexual health physician, specialist HIV physician) for assessment and planning of ongoing management of the HIV infection following completion of an initial positive HIV test, in practice almost always with 3 months of diagnosis. We included GPs in the definition of linked to care, anticipating that some people with early HIV infection might initially remain under their GPs care alone, although there were none at the time of the audit.

Retained in care

Those diagnosed with HIV infection were defined as retained in care if they had been seen in a clinic within the last 1 year, or otherwise were continuing on current ART and in communication with the regional HIV service. For PLHIV who moved to another region, we noted details of care transfer correspondence to other HIV services or other patient assistance. PLHIV were defined as lost to follow-up when attempts to contact them by various means repeatedly failed.

Measures of clinic attendance were derived from the hospital electronic Patient Administration System. Details of circumstances affecting suboptimal retention in care for individual people were described by the treating clinical team.

Current antiretroviral therapy (ART)

PLHIV were defined as currently receiving ART based on verbal history at their most recent HIV clinic visit and supplemented by ID clinical nurse specialist communication with the patient, even if adherence was known to be suboptimal. PLHIV who had previously taken ART, but ceased over recent months were defined as not on current ART. PLHIV receiving antiretroviral therapy were further categorised as either recently ‘starting’ or ‘established’ on ART, based on whether they had been on treatment for less or more than 6 months. For people not on current ART we noted the most recent CD4 count and other known reasons.

Suppression of HIV infection

PLHIV were defined as having “suppression of HIV infection” or a “suppressed viral load (VL)” if they were in receipt of current ART and their most recent HIV VL test result was <200 RNA copies/mL for a test completed within the last 12 months. This is consistent with the epidemiologic definitions used in other literature reports of the HIV cascade of care,
which have used a threshold of 200–400 RNA copies/mL. The laboratory testing platforms available at the time of the study quantitated VLs down to 20 RNA copies/mL, below which they are reported as either <20 RNA copies/mL (if detectable) or “not detectable”. Therefore the term “suppressed VL” in the study refers to a higher threshold than similar common terms used clinically. For those PLHIV receiving ART we also categorised and tabulated the most recent VL test results.

Clinic attendance
Clinic attendance was obtained from electronic records from the hospital Patient Administration System. Clinic attendance for each patient over the last 2 years was assessed comparing the number of clinic appointments attended with the total number of clinics booked. We defined poor clinic attendance when people missed at least 4 or half their booked appointments.

General Practice
The GP or GP practice for those with HIV infection was that registered in the electronic patient administration system as most recently notified by the patient. A high case-load GP was defined as caring for 10 or more people with HIV infection.

Results
People diagnosed with HIV infection
There were 307 people identified with HIV infection. The median age was 48 years, with an age range of 16 to 80 years.

Ethnicity & gender
The ethnicity of those with HIV infection was New Zealand European 200 (65.1%), Māori 22 (7.2%), Asian 22 (7.2%), Pacific Island 12 (3.7%), African 37 (12.1%), and other 14 (4.6%). Women made up 54 (17.6%) overall with a disproportionately larger number of women (54%) in those of African ethnicity (Table 1).

Linkage to care
There were no people with HIV infection identified who were never linked to care after laboratory diagnosis. Members of the HIV service had overseen HIV testing in the local laboratories, and generally knew of positive test results before the referrer. Positive card test results following testing by NGOs were promptly referred to the HIV service usually with telephone contact.

Retention in care
Lost to follow-up (LTFU)
There were no people with HIV infection identified who were lost to follow-up at the time of the audit. It was observed that about 10 PLHIV per year moved out of the Wellington region, with handover of care to a receiving service, and a similar number moved into the Wellington region.

Current Antiretroviral Therapy (ART)
Of those with HIV infection, 272 (89%) were currently receiving antiretroviral therapy (ART). Characteristics of the remaining 35 people (21%) not receiving ART were: CD4 count >500 (26) (public funding criteria for ART were a CD4 count <500 or symptomatic), only recently diagnosed, re-referral or meeting criteria yet to start (4), and patient choice to decline or discontinue (5).

HIV viral load
Of those 272 people receiving antiretroviral therapy, 13 (4.8%) had recently started and 259 (95.2%) were established on ART (Table 2). Overall, 254/272 (93.4%) met the study definition of a suppressed VL below 200 copies/mL. Of those established on ART, 259/272 (95.2%) were suppressed.

### Table 1: Ethnicity & gender of those with HIV infection

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Female N</th>
<th>Male N</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ European</td>
<td>17</td>
<td>183</td>
<td>200</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>3</td>
<td>19</td>
<td>22</td>
</tr>
<tr>
<td>Asian</td>
<td>7</td>
<td>15</td>
<td>22</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>4</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>African</td>
<td>20</td>
<td>17</td>
<td>37</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>11</td>
<td>14</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>54</strong></td>
<td><strong>253</strong></td>
<td><strong>307</strong></td>
</tr>
</tbody>
</table>
Table 2: Relationship of viral level to antiretroviral treatment (ART) duration.

<table>
<thead>
<tr>
<th>HIV Viral Load (copies/mL)</th>
<th>Duration of ART</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Starting (&lt;6 months)</td>
<td>Established (&gt;6 months)</td>
</tr>
<tr>
<td>&gt;100,000</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>10,000–100,000</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>1,000–9,999</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>200–9,999</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>50–199*</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>20–49</td>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>&lt;20 or 'not detectable'</td>
<td>0</td>
<td>222</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>259</td>
</tr>
</tbody>
</table>

*Suppression of HIV infection was defined as <200 copies/mL (grey area)

Figure 1: Cascade of HIV care in the Wellington region—Proportion of People with HIV Infection Meeting Sequential Criteria.

*The estimated 20% of PLHIV undiagnosed is based on reported data elsewhere (see Methods)
252/259 (97.3%) met the study definition of achieving a “suppressed VL” below 200 copies/mL, whereas only 2/13 (15%) of those starting ART within 6 months of the VL test had yet to achieve a suppressed VL. The VL was below 50 in 243 (93.8%) and below 20 in 222 (85.7%) of those established on ART.

Cascade of HIV care in the Wellington region

The overall cascade of HIV care in the region is illustrated in Figure 1. Including the estimate of 20% undiagnosed together with the audit results for the other measures indicates an overall 66% of people in the region having a suppressed viral load (<200 copies/mL). The main contributors to the 34% who did not have an undetectable viral load were those PLHIV undiagnosed (estimated 61/307, 20%), those with a CD4 count above 500 x 10^6/L (26/307, 8.4%), and those who had recently started ART within 6 months and were yet to achieve a suppressed VL (11/307, 3.6%).

Clinic attendance

Overall, there was an 18% clinic appointment non-attendance rate. For individual PLHIV during the 2-year period there was a median of 5 clinic appointments scheduled (range 0–19) and 4 clinic appointments attended (range 0–14). With the definition used 11.8% of PLHIV were poor clinic attenders.

PLHIV per GP

The median number of PLHIV per GP or GP practice was one (range 1–41), with 142/150 (95%) GPs caring for 3 or less people with HIV infection. High case load GPs (10 or more PLHIV) cared for 22% of the PLHIV, while 5% of PLHIV had no regular GP.

Discussion

Early HIV diagnosis and antiretroviral treatment provides advantages for personal health, and protection of others. Antiretroviral therapy is highly effective in reducing the risk of sexual transmission to others for both heterosexual partners and men who have sex with men (MSM), and for mother-to-child transmission during delivery, when the viral load is consistently suppressed to undetectable or very low levels. ART is also protective, although evidence for the degree of protection varies in other settings, including breast feeding, occupational exposure and intravenous drug use. ART is therefore a key public health intervention, together with sustaining high rates of condom use in at-risk groups.10

The cascade of HIV care is a simple way to visualise an overview of the challenges, for both affected individuals and health services, of putting treatment as prevention into consistent practice.11,12 Interpretation of cascade of care estimates depends on the means of data collection and definitions used. These vary in other national and regional reports. There is considerable variation in the sampling approach used to estimate those undiagnosed. Most used mandatory notification of diagnosis. ART use has commonly been based on prescribing, and sometimes dispensing, data. Some jurisdictions have mandatory CD4 and VL reporting to health departments. Linkage to care is commonly defined as being within 3 months, and retention in care when seen during the last 1 year. Distinguishing migrations in and out of the region/country from lost to follow-up is important, but not always easy.13 In clinical practice this is reliant on good communication between regional services, the PLHIV providing new contact details, and maintaining service database records. When initiating ART it can normally take several months for the VL to become suppressed. In the cascade of care this could appear to be a treatment failure, while clinically it is not. We observed that PLHIV during the first 6 months of starting ART comprised an important subset of those on ART whose VL was not suppressed.

Overall, women comprised 54/307 (18%) of the cohort, of whom more were African and less were of New Zealand European descent. This in part reflects patterns of immigration from countries where heterosexual transmission is more common.

The estimated proportion of 66% having viral suppression of all those with HIV compares favourably to reported estimates from Australia (59%), the UK (62%) and the US (19%), noting some differences in methodology.8,14,15 In Australia, the Kirby Institute has estimated 59% of those infected to have a suppressed viral load <400 copies/mL, with an estimated 88% of those with HIV infection diagnosed.14 Public Health
England estimated that for HIV in the UK, 76% are diagnosed, 90% on treatment, and 90% undetectable. Lower rates of engagement in care and viral suppression have been observed in cascade studies for young adults, immigrants, intravenous drug users and females, whereas higher rates were observed for MSM, heterosexuals, and those in a universal healthcare system. This is consistent with the needs and challenges facing specific key groups with HIV as described in the 2013 UNAIDS Gap Report. Research studies have recently been reviewed on the cost-effectiveness of interventions to improve each step in the cascade.

For ART to have more impact on New Zealand’s increased rate of new diagnoses since 2000 would require us to do better for the remaining third we observed with unsuppressed HIV infection. The main gaps in the cascade of care identified in this study were for the estimated proportion of people not yet diagnosed with HIV infection and treatment initiation for those diagnosed with a CD4 count above 500 cells/10^6/L.

There is clearly a need to reach and test those who do not yet know they have HIV infection, and to engage those at high risk of HIV in care and prevention. The estimate of 80% of those with HIV knowing their diagnosis was based on an Auckland survey of MSM. This estimate is below the 90% UN goal. The high rate of HIV suppression on ART observed in this study implies that the undiagnosed group is a key driver of new cases in New Zealand and that an ambitious target is needed to reach people unaware of their HIV infection. The likely risk factors and other characteristics of people with undiagnosed HIV infection are estimated by national notifications of those recently diagnosed. HIV is diagnosed in a variety of primary and secondary care settings. If HIV is included in the differential diagnosis it should be tested for, with significant benefits of diagnosing even an occasional person. Diagnosis of acute seroconversion syndrome, which commonly presents with rash and flu-like symptoms, is of particular advantage due to the associated higher level of viraemia and transmission risk. The New Zealand AIDS Foundation, and other NGOs, have already done much work on optimising the national strategy for increasing and targeting HIV testing, and Ministry of Health support of these efforts and for earlier diagnosis in primary and secondary care is important.

In general, ART should be recommended soon after diagnosis of HIV infection, with the HIV infected person having an opportunity for open discussion and establishing a relationship with the treating service. While the majority of people are likely to choose to start ART early, it will still be a person’s informed choice. For those with a CD4 count in the normal range, the slow decline in the CD4 count will usually mean there is time for people to make a considered decision. A few ‘elite controllers’ with a very low viral load off-treatment may not warrant immediate ART. Removal of the PHARMAC CD4 count funding eligibility threshold is a priority.

Our audit indicates a high level of linkage and retention in care and of effective viral suppression with established antiretroviral treatment. It is acknowledged that the cascade of care aims to represent retention in care and the other steps in the cascade over time. The cross-sectional study design of this audit is a snapshot to estimate the continuum of care. Although at the time of the audit all of the known people with HIV infection had been linked to care and were at the time engaged in care, we are not claiming to demonstrate 100% linkage or retention over time. However, the results of the audit are consistent with our clinical observations over recent years of a very high level of linkage to care and of a high level of retention in care. There has been a very close link between HIV laboratory diagnosis in the region and linkage to the HIV specialist services, which were provided by a single regional hospital-based HIV service principally within the Infectious Diseases Department. For some years, specialists in the HIV service have had concurrent positions with each of the regional laboratories providing HIV testing, and have coordinated linkage to care for each person newly diagnosed with HIV infection with the HIV. More recently, with people diagnosed using rapid HIV card testing, there was a routine prompt link between the NGO staff performing the testing and the clinical nurse specialist with the HIV service. Each person had been
subsequently seen either in HIV service clinics or for a small number of people in the Sexual Health Clinic. Additionally, as part of the audit, we had widely enquired about any person with HIV infection not linked to care with healthcare staff providing HIV care in the region.

Retention in care will always be a challenge, as it involves sustaining treatment relationships over a prolonged time, with HIV infected people who have varied and sometimes complex needs. A variety of strategies were used to facilitate clinic attendance. Most people are being reviewed once or twice annually, attending clinics reliably over the longer term. Reasons for clinic non-attendance are multifactorial, including communication issues, practical patient issues with attending, and common factors affecting engagement in care. There were no PLHIV lost to follow-up at the time of the study, although this has occasionally occurred at other times. Active case management approaches were taken for clinic non-attenders, often by the clinical nurse specialist in discussion with the treating physician. This included lists and individual plans for at-risk people with assistance from the HIV social worker and ID pharmacist, not discharging people from clinic in the event of missed appointments, and continued antiretroviral prescription despite missed appointments. As the primary benefit of ART derives from viral suppression, we have prioritised supporting uninterrupted ART ahead of clinic attendance per se. The study was conducted in association with efforts to improve and update service database records, and we noted that transfers in and out of the region were not uncommon.

Coordination between community and hospital HIV services has been crucial for people with HIV infection to remain engaged in care and to keep their HIV infection under control. Community services include primary care general practitioners (GP), HIV NGOs, community pharmacies and the Sexual Health Service. Most of those with HIV had a GP, although most were not high HIV case-load GPs. HIV NGOs play a number of central roles. Community pharmacies play a key role in maintaining uninterrupted ART treatment and liaising with the HIV service about suspected adherence difficulties. We liaise with multiple pharmacies, as any retail pharmacy can now dispense antiretrovirals, although several pharmacies in the region dispense for the majority of PLHIV.

Ongoing challenges for engagement in care include understanding and responding to the broader social and health needs of different groups with HIV infection, including MSM, women, young adults, immigrants, and those aging with HIV. Substance abuse and mental health problems are particularly important. The increasing number of people living with HIV may pose challenges for small services to maintain the quality of care. While antiretroviral medications are much improved from the early combination regimens, there is still a need for safer medications for very long term use. Strengthening relationships with primary care will be needed with mainstreaming of preventative and general healthcare.

A key limitation of the study is that we have no specific estimates of the undiagnosed proportion of those with HIV infection in the Wellington region. The audit was a snapshot of care, whereas engagement in care often changes over time and HIV care is now a continuum over the longer term. It is possible that occasionally, PLHIV moved into the Wellington region unknown to us, having been diagnosed or under the care of HIV services in another region. This could have occurred if they remained under the care of the service in the other region and this was not communicated to us, or if they were lost to follow-up by the other service. We would expect our findings to be similar to those in other larger New Zealand cities.

In conclusion, the audit indicated a high level of continuing engagement of care and of effective viral suppression with established antiretroviral treatment. The main gaps in the cascade of care were for the estimated proportion of people with undiagnosed HIV infection and for treatment initiation of those diagnosed with a CD4 count above the 500 cells/10^6/L threshold for publicly funded antiretrovirals.
ARTICLE

Competing interests:
Nigel Raymond reports other grants from Gilead (NZ) Ltd and from MSD (NZ) Ltd outside the submitted work.

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Excess cost associated with primary hip and knee joint arthroplasty surgical site infections: a driver to support investment in quality improvement strategies to reduce infection rates

N Gow, C McGuinness, AJ Morris, A McLellan, AE Hardy, JT Munro, SA Roberts

**ABSTRACT**

**AIM:** To determine the excess costs attributable to surgical site infections (SSI) following primary hip and knee joint arthroplasty at Auckland City Hospital.

**METHODS:** A retrospective case-control study. Cases were patients who developed a SSI following primary hip (THA) and knee arthroplasty (TKA) surgery within 90 days of the procedure. Cases were matched 1:2 with controls; patients whose primary hip and knee arthroplasty procedures were not complicated by infection. Controls were matched for age, gender, date of surgery, type of surgery, and ASA category. The length of stay (LOS) and hospital costs for the initial admission and subsequent readmission for infection were calculated from the clinical costing system at Auckland District Health Board.

**RESULTS:** Eleven cases were identified; 3 following TKA, 7 following THA, and 1 following hemiarthroplasty of the hip. Infections were classified as superficial, 1, joint space, 1, and deep incisional, 9. Five SSIs were identified during the initial admission for joint arthroplasty and 6 patients were readmitted with an SSI. Compared to the control patients, SSIs were associated with an excess mean cost of $40,121 and an excess mean LOS of 42 days.

**CONCLUSIONS:** There is a significant increase in LOS and cost associated with SSI following primary THA and TKA at Auckland City Hospital. In addition to the excess cost associated with SSI, there are also opportunity costs resulting from their impact on elective surgical waiting lists. This reinforces the significant positive economic impact a successful strategy to reduce SSIs associated with primary joint arthroplasty procedures will have.
likelihood of reoperation and death within 30 days of the procedure.\textsuperscript{5,6}

In the US, it is estimated that in 2012 the total annual cost for the five major HAIs was $9.8 billion (95% CI, $8.3–$11.5 billion), with SSI contributing the most overall costs (34% of the total).\textsuperscript{7} In Australia, it was estimated in 2005 that the annual costs of all HAI was at least $1 billion.\textsuperscript{8} More recent costing data for SSI following total hip and knee arthroplasties estimated an annual cost in Australia of $97 million.\textsuperscript{9} In New Zealand, there is only limited information, mostly from a single hospital, about the cost of HAI.\textsuperscript{10,11} Infection rates determined by point prevalence studies in the 1990s at the same hospital has subsequently been used to estimate the annual cost of HAI in New Zealand. In 2003, this was estimated at approximately $137 million per annum.\textsuperscript{12}

SSI, along with dislocation and prosthesis loosening, are the most common complications of total hip arthroplasty (THA) and total knee arthroplasty (TKA) with worldwide reported infection rates of approximately 1–2%.\textsuperscript{13,14} The cost of SSI associated with hip and knee arthroplasty is unknown in New Zealand. The aim of this study was to determine excess cost and length of stay (LOS) associated with SSI following these procedures. This will allow for more informed decision making when planning quality improvement initiatives aimed at reducing SSI rates.

**Methods**

This study was conducted at Auckland City Hospital, a 710 bed tertiary referral centre, using data obtained as part of the New Zealand Health Quality and Safety Commission’s Surgical Site Infection Improvement (SSII) Programme.

Data was collected prospectively on all hip and knee arthroplasty procedures. Where possible data was extracted electronically from existing Auckland District Health Board (ADHB) data warehouses. Data collected included: patient demographics; admission and procedure date and LOS; type of procedure (TKA, THA, or hemiarthroplasty of the hip, primary or revision); surgical antimicrobial prophylaxis; duration of surgery; American Society of Anaesthesiologists’ (ASA) physical status category; presence of an SSI; type of SSI (superficial, deep incisional or joint space); the organism(s) identified; and timing of SSI.\textsuperscript{15} The US National Healthcare Safety Network (NHSN) definition for SSI was used.\textsuperscript{16}

**Matching**

A case-control study was performed with a 1:2 match for all patients with a SSI following joint arthroplasty in the first year of the SSII programme (1 March 2013–28 February 2014). A case was defined as a patient who met the criteria for a SSI. A control was a patient who did not get an SSI.

During the study period, 17 patients met the definition for SSI. However, six patients were excluded because the SSI followed revision surgery and the small number of revision procedures prevented matching. Cases were matched as follows: age (+/- 5 years); gender; type of surgery (hemi/full arthroplasty, hip vs knee); date of surgery (+/- 3 months); and ASA category.

Population size/power calculations were not performed. Non-parametric tests (Mann-Whitney U test) for continuous variables; contingency tables to determine Pearson’s chi-squared and linear chi-squared functions for categorical data were used. P values ≤0.05 were considered statistically significant.

**Costing**

Data to assess the cost relating to admission for cases and controls were extracted from ADHB clinical costing system (Power Performance Manager, Power Health Solutions). The cost of individual patient care is identified by capturing every item of utilisation on each patient during their stay. Expenditure is allocated according to utilisation. The cost of admission for the initial arthroplasty (initial admission) and any subsequent admissions within 90 days of the initial surgery related to complications of surgery (subsequent admissions) were calculated. The impact on LOS was calculated as the mean difference between cases and matched controls. Hospital costs arise from costs associated with laboratory testing, allied health input, radiological investigation, drug therapy, and bed costs. Impact on cost was calculated as mean difference. Excess cost and LOS is presented.
Results

During the first year of the SSII programme, there were 517 primary hip and knee arthroplasties performed at ACH, and 11 procedures (2.7%) were complicated by a SSI. The SSI followed THA, 7, TKA, 3, and hemiarthroplasty of the hip, 1. The SSI were classified as a superficial SSI, 1, deep incisional SSI, 9 and joint space SSI, 1. Five deep incisional SSI occurred during the initial admission; the other 6 SSI resulted in readmission. All 11 cases required surgical intervention for the management of the SSI. The median (range) number of procedures was 2 (1–4).

The 11 cases were matched with 22 controls. There was no significant difference in the patient characteristics between the cases and controls for the matching criteria (Table 1). Also, there was no significant difference in the length of the operation.

The SSI occurred a median of 15 (range 7–70) days after the procedure. A microorganism was isolated in 9 cases; two cases were infected with methicillin-susceptible *Staphylococcus aureus*, one case each was infected with methicillin-resistant *S. aureus*, *Streptococcus Group G*, *Streptococcus pyogenes*, *Clostridium perfringens* and *Enterobacter* sp., and two cases had polymicrobial infections with *S. epidermidis* and *Corynebacterium* sp., and *Proteus mirabilis* and *Serratia marcescens*. Two cases with deep/organ space infections had tissue sent for culture, but the cultures were negative.

The overall mean (±SD) LOS was significantly longer for the cases compared to the controls; 49.6 ± 37.6 days for cases and 7.7 ± 9.1 days for the controls (p <0.0001). The mean excess LOS was 41.9 days. Overall, the 11 cases stayed an excess 262 days in hospital.

The mean cost of the initial and subsequent admissions for the cases was $61,157 ± $41,414 compared to the mean cost for the controls of $21,035 ± $6,296 giving an excess cost associated with the SSI of $40,414.

Table 1: Patient demographics, total and excess length of hospital stay, average and excess cost for cases and controls

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cases (n=11)</th>
<th>Controls (n=22)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: median years (range, IQR)</td>
<td>69 (49–78, 61.5–75.5)</td>
<td>62.5 (52–80, 60–74.75)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Type of surgery:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TJ A Hip</td>
<td>7</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>TJ A Knee</td>
<td>3</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>HA Hip</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>ASA physical status category (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Length of operation median hours (range)</td>
<td>1:40 (1:12–2:05)</td>
<td>1:52 (1:14–2:36)</td>
<td>0.55</td>
</tr>
<tr>
<td>LOS (mean days ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial admission (SSI not diagnosed)</td>
<td>5 ± 0.55</td>
<td>7.7 ± 9.1</td>
<td></td>
</tr>
<tr>
<td>Initial admission (SSI diagnosed)</td>
<td>75 ± 39.5</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Re-admission for SSI</td>
<td>16 ± 19.6</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Total LOS</td>
<td>49.6 ± 37.6</td>
<td>7.7 ± 9.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Excess LOS (mean days)</td>
<td>41.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cost NZD 2015</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial admission (mean ± SD)</td>
<td>55,255 +/- 49,211</td>
<td>21,035 ± 6,296</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Re-admission (mean ± SD)</td>
<td>42,936 +/- 36,869</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (mean ± SD)</td>
<td>61,157 ± 41,414</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excess cost per SSI</td>
<td>$40,121</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TJA = total joint arthroplasty; HA = hemiarthroplasty of hip; ASA = American Society of Anaesthesiologists; LOS = length of stay.
Discussion

In New Zealand in 2013 there were approximately 16,000 primary and revision hip and knee arthroplasties performed in District Health Board (DHB) hospitals and private surgical (third-party funded) hospitals. The SSII Programme reports an overall infection rate for hip and knee arthroplasty procedures performed in DHB hospitals of 1.3%.

Therefore, we estimate that just over 200 patients each year in New Zealand have an SSI requiring inpatient care following these procedures. At an excess cost of $40,000 per SSI, the cost to the DHBs would amount to about $8 million per year.

This is probably a gross underestimate of the true cost of SSI for a number of reasons. Firstly, this cost does not include the personal costs to the patient, or their family and whānau, or the costs covered by the Accident Compensation Corporation (ACC). ACC provides a comprehensive ‘no faults’ personal injury cover for all New Zealand residents and visitors to New Zealand. This includes ‘treatment injuries’, such as SSI, occurring during medical treatment. Secondly, it does not cover the costs associated with managing infections in the community. Up to a third of all SSI occur after discharge from hospital and a significant proportion will be managed by primary care providers. And finally, it does not take into account the long-term economic consequences for these patients arising from the physical and psychological impact of the SSI.

This study confirms the finding of other studies that there is a significant excess cost associated with surgical site infections complicating hip and knee arthroplasty procedures. A case-control study performed at a US tertiary university hospital and a community hospital showed orthopaedic SSIs accounted for 15 days excess hospitalisation, four-fold increased cost, and adversely affected quality of life when compared with surgery not complicated by SSI. A nested case-control study conducted between 2000 and 2004 estimated the impact of hip arthroplasty-associated SSI on morbidity and LOS. Cases with a SSI had a median excess LOS of 32.5 days; this was even more pronounced in the deep-wound subset at 49 days. The Victorian Nosocomial Infection Surveillance (VICNISS) programme reviewed 20 months of total joint arthroplasty SSI in 2006, and found an average cost following hip arthroplasty infection of AU$34,138 and knee arthroplasty infection of $40,940. More recently, a study conducted at a single centre in Melbourne showed that the base cost of hip and knee arthroplasty surgery without modifying factors was AU$13,000, or an estimated AU$1.13 billion per year. The complication of SSI accounted for 74% of readmissions in the first 30 days following surgery and added AU$97 million to arthroplasty costs.

The excess costs are incurred because of the increased LOS required for diagnosing and managing the infection. The clinical costing software programme used in this study captures both direct costs (those associated with the delivery of care to each individual patient) and indirect costs (those not directly linked to individual patient care). A significant proportion of the excess cost, up to 85%, is a fixed cost that occurs regardless of whether the bed is occupied or not. This fixed cost covers the daily operational costs for the hospital, including staff salaries. Variable costs are those costs arising from the consumable items used to diagnosis and manage the infection. In the absence of an SSI these costs are avoided and resources can be allocated elsewhere. One of the strengths of this study is the completeness of the costing data including both direct and indirect costs.

A review of 16 studies looking at increased costs resulting from SSI reported that not only is the cost of a patient with an SSI approximately twice the amount of a patient without an infection, but that the LOS also more than doubles. This is comparable to New Zealand data which showed that in 2003 a SSI prolonged the LOS by a median 12 days in surgical patients and was associated with an excess cost of $32,134. When the bed occupancy is high, such as in DHB hospitals, the increase in LOS associated with SSI may impact upon elective surgery waiting lists. Using the data from this study, we estimate that on average about 8,400 fewer orthopaedic bed-days will be available for elective surgery admissions annually.
ARTICLE

because these beds are occupied by patients receiving treatment for a SSI following a hip and knee arthroplasty procedure.

It is difficult to compare the cost of these infections between different studies because the approaches used to capture the cases and the cost varies (Table 2). Care provided after discharge, including outpatient and primary care visits, was not included in our study but may have been included in other studies. The cost and approach to healthcare delivery between countries varies. Regardless of these differences, the excess cost associated with SSI following THA and TKA is significant.

Strategies aimed at reducing the rate of SSI have been shown to reduce SSI rates by as much as 60%. However, the implementation of these strategies is often poor because of the so called ‘implementation gap’ for infection prevention, ie, we know what we should do to reduce infections but we don’t do it. In 2013, the New Zealand Health Quality & Safety Commission (the Commission) established the National Surgical Site Infection Improvement (SSII) Programme. The aim of the Programme is to reduce the harm and cost associated with SSI. The Programme, in collaboration with all DHBs, has implemented a consistent, evidence-based approach for collecting and reporting quality data following hip and knee arthroplasty.

### Table 2: Comparison of the method for determining the excess cost and length of stay associated with surgical site infections following hip and knee joint arthroplasty.

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedures</th>
<th>Number (SSI rate)</th>
<th>Surveillance method</th>
<th>Costing method</th>
<th>Excess cost ($)</th>
<th>Excess length of stay (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whitehouse, 2002 US ²⁴</td>
<td>Orthopaedic including THA and TKA</td>
<td>5050 (1.2%)</td>
<td>CDC (NNIS), follow-up for 1 year</td>
<td>Fixed and variable costs obtained from hospital accounting system. Outpatient costs not captured</td>
<td>US$18,000</td>
<td>15</td>
</tr>
<tr>
<td>Jorda, 2006 Spain ²³</td>
<td>THA</td>
<td>1260 (2.6%)</td>
<td>CDC (NNIS) Length of follow-up unclear</td>
<td>No costing performed</td>
<td>Not provided</td>
<td>31</td>
</tr>
<tr>
<td>VICNISS, 2006 Australia ²¹</td>
<td>THA and TKA</td>
<td>Not recorded</td>
<td>CDC (NNIS), 1 year follow-up</td>
<td>Cost per bed day, treatment, diagnostic and procedure costs</td>
<td>AUS$34,000 and AUS$41,000</td>
<td>27</td>
</tr>
<tr>
<td>Miletic, 2014 US ²⁸</td>
<td>THA and TKA</td>
<td>7658 (1.3%)</td>
<td>AHRQ surveillance ICD-9-CM, 1 year follow-up</td>
<td>MarketScan Commercial Claims and Encounter database and Medicare Supplemental database</td>
<td>US$20,000</td>
<td>7.4</td>
</tr>
<tr>
<td>Peel, 2014 Australia ³</td>
<td>THA and TKA</td>
<td>827 (4%)</td>
<td>CDC (NNIS), 30 day follow-up</td>
<td>Hospital administrative databases. Fixed and variable costs using a &quot;bottom-up&quot; approach</td>
<td>Population not individual cost calculated</td>
<td>Not provided</td>
</tr>
<tr>
<td>Gow, 2015 New Zealand (this report)</td>
<td>Primary THA and TKA</td>
<td>517 (2.7%)</td>
<td>CDC (NHSN), 90 day follow-up</td>
<td>Power Performance Manager, Power Health Solutions</td>
<td>NZ$40,414</td>
<td>41.9</td>
</tr>
</tbody>
</table>

CDC = Centers for Disease Control and Prevention, USA, NNIS = National Nosocomial Infection Surveillance programme and NHSN = National Healthcare Safety Network, THA = total hip arthroplasty, TKA = total knee arthroplasty, AHRQ = Agency for Healthcare Research and Quality, US.
these interventions will reduce the SSI rate and hence avoid the unnecessary excess cost associated with these infections. This will result in better outcomes for patients and a freeing up of health resources for other initiatives aimed at improving care. Other national programmes, such as the Ministry of Health’s ‘Enhanced Recovery After Surgery (ERAS) Pathway’, may also be contributing to an improvement in clinical outcomes and a reduction in overall LOS by standardising the clinical care pathway and incorporating the Commission’s SSII programmes infection prevention best practice interventions into its guidance.

This study has a number of limitations. It involved a single centre and included a relatively low number of procedures and patients with SSI. The excess LOS was determined by the local approach to managing these infections. Different strategies in other centres may have resulted in shorter lengths of stay and hence, lower costs. To reduce the bias from a single centre’s SSI rate when extrapolating the national annual cost of these infections, we used the aggregated national SSI rate. However, the national annual cost may be falsely high for the same reason mentioned above. We are also unaware of the SSI rates in the private surgical hospitals—the rates may be lower than in the DHB hospitals leading to an over-estimate of the overall annual cost. However, we included these patients in our estimate because typically patients who develop a deep or joint space infection following surgery in a private hospital will be managed in a DHB hospital. While we matched cases with controls to minimise bias, we could not totally eliminate it. We did not capture data on all risk factors associated with infection and it is possible that our patients had risk factors associated with increased LOS regardless of whether they developed an infection or not. We also did not determine if other post-operative complications may have contributed to an increased LOS.

In summary, we have shown that the excess LOS and cost associated with primary THA and TKA procedures is substantial. Although it is not possible to totally eliminate the risk of SSI, all efforts should be made to ensure that strategies known to reduce SSI rates are implemented in a consistent manner and that SSI, when they do occur, are managed promptly to minimise the long-term impact on the patient. National programmes such as the SSII programme and the ERAS pathway are essential to facilitate the delivery of quality improvement initiatives that will lead to improvement in outcomes for patients and to minimise the unnecessary use of health resources required for managing surgical complications such as SSI.
Competing interests:
AJ Morris reports they are the Clinical Lead for the New Zealand Surgical Site Infection Improvement Programme. JT Munro reports personal fees from Zimmer Biomet and DePuy Synthes outside the submitted work.

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Rationing of hip and knee replacement: effect on the severity of patient-reported symptoms and the demand for surgery in Otago

David Gwynne-Jones, Ella Iosua

ABSTRACT

AIM: A key Government health target has been to increase access to elective surgery. Despite this, there is a growing concern about unmet demand and increasing numbers of patients are being declined elective surgery. This study aims to determine whether there has been an increase in the severity of osteoarthritis of the hip and knee in patients undergoing publicly-funded elective total joint replacement (TJR) and any increase in demand for TJR in Otago.

METHOD: Demographic details and preoperative patient reported outcome scores (Oxford hip or knee score (OHS,OKS) and a reduced Western Ontario and McMaster Osteoarthritis Index (WOMAC) score (RWS)) were collected prospectively in an historical cohort of patients undergoing total hip and knee replacement (THR, TKR) between 2006–2010. These were compared with all patients undergoing THR and TKR in the 12-month period commencing 1 November 2013, and all patients waitlisted during this period but returned to GP due to capacity issues. An estimate of current demand was made by adding all waitlisted public patients from the 12-month period to surgical numbers from private and those funded by ACC.

RESULTS: In the 2006–2010 group of 613 patients, the mean OHS was 13.6 (SD 6.7) and OKS 15.4 (SD 6.5) and RWS 30.5 (SD 8.0). Three hundred and sixty-seven patients who underwent surgery in 2013/4 had significantly poorer scores (OHS 9.9 (SD 4.9), OKS 10.6 (SD 3.8), RWS 34.8 (SD 6.7)). The scores of 194 patients returned to GP in 2013/4 were the same as the historical surgical group (OHS13.0 (SD 6.2, OKS 15.2 (SD 5.9), RWS 30.8 (SD 8.4)). Six hundred and eight patients were wait-listed for public surgery and 356 joints were performed in private or under ACC in the 12-month period. The current intervention rate in Otago is 371/100,000 per year, while the demand has risen from 417/100000 in 2010–12 to 494/100,000 per year. In 2014, the shortfall was 241 joints per year.

CONCLUSION: Patients undergoing primary elective total hip and knee replacement in Otago in 2014 are more severely disabled than between 2006–2010. Patients currently being returned to GP would have qualified for publicly funded surgery during that period. The demand for elective TJR in Otago has increased by 19% since 2012.

Hip and knee replacement are two of the most successful interventions in orthopaedic surgery. The population of New Zealand is both ageing and growing, and it is predicted that there will need to be a large increase in the numbers of joint replacements over the next 10 years.1,2 The public health system is under significant funding constraints, and joint replacements are relatively expensive to provide. However, in the long term they are highly cost effective.3-5 In New Zealand, the ‘Joint Initiative’ ran from 2004 to 2008, which led to a significant increase in the number of joint replacements performed nationally. From 2008 onwards, the funding was no longer ringfenced and was included in the orthopaedic volumes of District Health Boards (DHBs). An increase in funding for orthopaedic procedures including joint replacement was signalled in the 2015 budget.
DHBs are required to prioritise patients and operate on the most in need. However, they are also obliged to meet Elective Surgical Performance Indicators (ESPIs). These include ESPI 5 (time to surgery from a certainty decision). This target was initially 6 months but reduced to 5 months in June 2013, and to 4 months in December 2014. This target has resulted in the so called ‘financial threshold’ score. If a patient is judged to benefit from surgery but capacity constraints mean that they cannot have surgery within the ESPI target, then they can be placed on Active Review if just below the threshold or returned to General Practitioner (GP).

In our district we have had significant problems with excess demand over capacity. The problems are longstanding, and in 2006 there was a well-publicised ‘cull’ of patients who had waited too long for surgery. Between 2010 and 2012 we estimated that the demand for elective hip and knee replacement was 41.7/10,000 per year. The main drivers were the age of the population and a backlog of cases due to under-provision relative to demand.

Despite using each new scoring system, we found that the mismatch between supply and demand drove the financial threshold up in order to ensure ESPI compliance. Increasingly, this is being seen in other centres in New Zealand. The drive for shorter wait times for elective surgery has not been matched by any significant increase in joint replacement numbers in our region. In turn, we have noticed an increase in the severity of disease of those patients who do qualify for surgery.

In response to concerns around capacity and unmet demand, a programme funded by the National Health Board was developed to address patient flow. It was decided that all scoring for joint replacement surgery in our hospital would be by a single experienced orthopaedic nurse, the prioritisation nurse (PN), to ensure consistency and avoid accusations of surgeons ‘gaming the system’.

The purpose of this study is to compare patient reported scores from a historical cohort of patients undergoing primary elective THR or TKR from 2006–2010 with patients undergoing surgery in 2013–2014, and those waitlisted but returned to GP for being below the financial threshold during the same period. A secondary goal was to determine whether the current level of demand in our local population for elective THR and TKR had increased since our previous report looking at the years 2010–2012.

**Methods**

In October 2013, prior to the programme commencing, the threshold for hip and knee replacement in our hospital was 80 points using the New Zealand Orthopaedic Association hip and knee prioritisation tool (NZOA score). This tool was developed by the Orthopaedic Working Group of the National Waiting Times Project and introduced in 2008. There were 106 patients with certainty, 83 on active review and 181 other patients had been listed for joint replacement but returned to GP. After analysis of the waiting list figures, capacity, contracted volumes, and ESPI compliance, the financial threshold was set at 71 points commencing 1 November 2013. Active review would no longer be used and all patients falling below threshold would be returned to their GP. All patients were to be scored by the prioritisation nurse using the NZOA tool. Criteria for the use of the five components of the score, especially the consequence of delay, were agreed and policed.

Data were retrieved from our department database of patients who had undergone primary hip or knee replacement (including unicompartimental knee replacement (UKR)) between 2006 and 2010. Patient details, including pre-operative scores, had been prospectively recorded in our departmental database. The patient completed a pre-operative Oxford hip or knee score (OHKS) and a reduced Western Ontario and McMaster Osteoarthritis Index (WOMAC) score (RWS). The modified Oxford score (0–48, where 0 is worst and 48 best) was used. The reduced WOMAC score (RWS) uses 5 pain questions and 7 function questions (scored 0–4, where 0 is best) giving a worst score of 48. Preoperative scores were available on 613 of 945 patients on the database.

Details of all patients undergoing elective primary total hip or knee replacement...
ARTICLE

Articleduring the same period and their outcomes were also collected prospectively. This included details and scores of patients returned to GP care. The historical group, study group and return to GP group were then compared by age, gender, OHKS and RWS. Independent sample t-tests were used to compare means, and the test for a difference in proportions was used to estimate differences between the 3 cohorts (2006–2010, 2013/2014 Surgery, and 2013/2014 Return to GP). The two-sided significance level α = 0.05 was specified for all statistical tests. Stata software version 13.1 was used for all statistical analyses.

Demand was calculated as in our previous paper by including all publicly funded patients listed for the 12-month study period and adding those performed under ACC, plus all primary joints performed at Mercy Hospital, Dunedin. Hip replacements for fracture were excluded. Unicompartmental knee replacement was included. Bilateral simultaneous procedures were counted as two joints. The population of Otago less Queenstown was taken as 194,800 at June 2013. The New Zealand intervention rate was calculated from Joint Registry data using the New Zealand population as 4,442,100, based on 2013 census data.15,16

Unicompartmental knee replacements comprised only 5–9% of knee replacements across the whole study period and so were not analysed separately.

Ethics approval was given by the University of Otago Ethics Committee (Health) for this study.

Results

Demographics

The historical cohort from 2006–10 comprised 613 patients (355 hips (58%) and 258 knees (42%)). It was well matched with respect to age, gender and proportion of hips to knees with the study period (Table 1).

The two-sided significance level α = 0.05 was specified for all statistical tests. Stata software version 13.1 was used for all statistical analyses.

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Results

Demographics

The historical cohort from 2006–10 comprised 613 patients (355 hips (58%) and 258 knees (42%)). It was well matched with respect to age, gender and proportion of hips to knees with the study period (Table 1).

During the study period in 2013/4, 367 primary elective hip and knee replacements were performed. There were 204 hip (56%) and 163 knee (44%) replacements. The mean age was 69.3 years, with hips a little younger than knees (68.5 years vs 70.3 years). The mean NZOA score was 78.8 (hip 79.8, knee 77.7).

A consultant scored 137 patients (37%) who had been given certainty before the start of nurse prioritisation. The PN had scored 230 (63%). There were no significant differences between those scored by nurse or surgeon with respect to age, gender, proportion of hips or knees, NZOA score, Oxford or RWS.

Table 1: Comparison of demographic characteristics between 2006-10 surgery group, 2013/4 surgery group and 2013/4 return to GP group.

<table>
<thead>
<tr>
<th></th>
<th>2006–10 surgery</th>
<th>2013/4 surgery</th>
<th>2013/4 Return to GP</th>
<th>Difference (95% CI)</th>
<th>p</th>
<th>Difference (95% CI)</th>
<th>p</th>
<th>Difference (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined</td>
<td>n= 613</td>
<td>n= 367</td>
<td>n=194</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>260 (42.4)</td>
<td>166 (45.2)</td>
<td>91 (46.9)</td>
<td>-2.8 (-9.2, 3.6)</td>
<td>0.389</td>
<td>-4.5 (-12.5, 3.5)</td>
<td>0.271</td>
<td>-1.7 (-10.3, 7.0)</td>
<td>0.705</td>
</tr>
<tr>
<td>Age (SD)</td>
<td>69.3 (10.1)</td>
<td>69.3 (10.4)</td>
<td>67.3 (9.0)</td>
<td>-0.0 (-1.3, 1.3)</td>
<td>0.979</td>
<td>1.9 (0.4, 3.5)</td>
<td>0.016</td>
<td>2.0 (0.2, 3.7)</td>
<td>0.027</td>
</tr>
<tr>
<td>Hips</td>
<td>n= 355</td>
<td>n= 204</td>
<td>n=84</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hips %</td>
<td>57.9</td>
<td>55.6</td>
<td>43.3</td>
<td>2.3 (-4.1,8.7)</td>
<td>0.477</td>
<td>14.6 (6.6,22.6)</td>
<td>&lt;0.001</td>
<td>12.3 (3.7,20.9)</td>
<td>0.006</td>
</tr>
<tr>
<td>Male (%)</td>
<td>153 (43.1)</td>
<td>90 (44.1)</td>
<td>39 (46.4)</td>
<td>-1.0 (-9.6, 7.5)</td>
<td>0.815</td>
<td>-3.3 (-15.2, 8.5)</td>
<td>0.580</td>
<td>-2.3 (-15.0,10.3)</td>
<td>0.720</td>
</tr>
<tr>
<td>Age (SD)</td>
<td>68.1 (10.8)</td>
<td>68.5 (10.9)</td>
<td>66.0 (10.6)</td>
<td>-0.4 (-2.3, 1.5)</td>
<td>0.668</td>
<td>2.1 (-0.5, 4.7)</td>
<td>0.107</td>
<td>2.5 (-0.2, 5.3)</td>
<td>0.073</td>
</tr>
<tr>
<td>Knees</td>
<td>n= 258</td>
<td>n= 163</td>
<td>n= 110</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knees %</td>
<td>42.1</td>
<td>44.4</td>
<td>56.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>107 (41.5)</td>
<td>76 (46.6)</td>
<td>52 (47.3)</td>
<td>-5.2 (-14.9, 4.6)</td>
<td>0.299</td>
<td>-5.8 (-16.9, 5.3)</td>
<td>0.304</td>
<td>-0.6 (-12.7,11.4)</td>
<td>0.916</td>
</tr>
<tr>
<td>Age (SD)</td>
<td>70.9 (8.6)</td>
<td>70.3 (9.6)</td>
<td>68.4 (7.4)</td>
<td>0.6 (-1.1,2.4)</td>
<td>0.487</td>
<td>2.5 (0.7, 4.4)</td>
<td>0.007</td>
<td>1.9 (-0.2, 4.0)</td>
<td>0.078</td>
</tr>
</tbody>
</table>
During the study period, 608 patients were waitlisted for primary THR or TKR. Four hundred and fourteen (68%) were given certainty for surgery and 194 (32%) were returned to GP care. The return to GP group was younger by 2 years (p=0.027) and had a significantly higher proportion of knee (57%) than the two surgical groups (Table 1). Of the 194 returned to GP, 50 were re-referred and given certainty within the 12-month study period (mean 5 months).

**Patient-reported scores**

The Oxford scores and RWS scores were significantly worse for both hips and knees in 2013/4 compared with the historical cohort. The difference in Oxford score of 3.7 for hips and 4.7 for knees and RWS (hip 3.4, 11% change from baseline, and knee 5.4, 19% change from baseline) is likely to reflect a clinically important difference.\(^{12,17,18}\)

The Oxford and RWS scores of those patients returned to GP in 2013/4 were the same as for those receiving surgery in 2006-10 (Table 2).

**Demand**

During the 12-month study period, 608 patients were waitlisted, 464 patients were given certainty and 367 patients had undergone surgery. The number of patients waiting with certainty had increased from 106 to 164 and the numbers on Active Review had fallen from 83 to 23. Demand was 241 (67%) in excess of supply. Even after sending back 194 patients, the imbalance was 47 joints (13% excess), which rose to 97 (26% excess) when those re-referred and given certainty were included.

During the same period, an additional 8 hip replacements were performed in the hospital under ACC, and 348 hip and knee replacements were performed in the private sector, giving a total of 723 joints performed during the year. The current intervention rate for primary hip and knee replacement in Otago is 371/100,000. The demand, assuming no unmet need in private, is now approximately 495/100,000.

In New Zealand, 16,104 hip and knee replacements, including unicompartmental replacement of knee, were performed in 2014, after excluding those for acute fracture.\(^{16}\) This gives a New Zealand intervention rate of 363/100,000 for 2014.

**Discussion**

There will always be excess demand in the public sector leading to the need for some form of prioritisation or rationing. This paper shows that prioritisation is being implemented effectively. Patients undergoing surgery have mean scores that are poorer than those returned to GP. We have previously reported that nurse scoring is as effective as consultant scoring.\(^{11}\) It removes inconsistencies and accusations of attempts to ‘game’ the system. However, there are problems around the threshold score.\(^{11}\)

The patient-derived scores were significantly worse for the study period when

| Table 2: Comparison of preoperative Oxford and reduced WOMAC scores (RWS) between surgery 2006-10, surgery 2013/4 and return to GP group 2013/14. |
|---|---|---|---|---|---|---|
| | | | | Difference (95% CI) | p | Difference (95% CI) | p | Difference (95% CI) | p |
| **Hips** | | | | | | | | | |
| Oxford | 13.6 (6.7) | 9.9 (4.9) | 13.0 (6.2) | 3.7 (2.4, 4.9) | <0.001 | 0.6 (-1.5, 2.7) | 0.577 | -3.1 (-4.9, 1.2) | 0.001 |
| RWS | 31.7 (7.9) | 35.2 (6.9) | 31.7 (8.5) | 3.4 (4.9, 1.9) | <0.001 | 0.0 (-2.5, 2.5) | 0.982 | 3.4 (0.9, 6.0) | 0.008 |
| **Knees** | | | | | | | | | |
| Oxford | 15.4 (6.5) | 10.6 (3.8) | 15.2 (5.9) | 4.7 (3.4, 6.1) | <0.001 | 0.2 (-1.7, 2.1) | 0.855 | -4.6 (-6.1, -3.0) | <0.001 |
| RWS | 28.9 (7.8) | 34.3 (6.3) | 30.1 (8.2) | 5.4 (7.1, 3.6) | <0.001 | -1.3 (-3.6, 1.1) | 0.290 | 4.1 (1.7, 6.5) | <0.001 |
| **Combined** | | | | | | | | | |
| Oxford | 14.3 (6.7) | 10.2 (4.5) | 14.2 (6.1) | 4.1 (3.2, 5.0) | <0.001 | 0.1 (-1.3, 1.5) | 0.862 | -4.0 (-5.2, -2.8) | <0.001 |
| RWS | 30.5 (8.0) | 34.8 (6.7) | 30.8 (8.4) | 4.3 (5.4, 3.1) | <0.001 | -0.3 (-2.0, 1.4) | 0.735 | 4.0 (2.2, 5.7) | <0.001 |
compared with the historical cohort. The return to GP group were similar to those qualifying for surgery in the historical group. Knees were more likely to be returned to GP than hips. This reverses the ratio seen for those qualifying for surgery in both the historical and study group. In general, patients with hip OA are more disabled than knees. Knees in the historical group had better scores than hips, but that difference is now less.

The difference on Oxford score of 4.1 points (hips 3.7, knees 4.7) is comparable with the minimum clinical difference of 2 to 5 points reported for the Oxford score. Similarly, the change in RWS of 4.3 points (hips 3.4, knees 5.4) is greater than 6% of maximum (2.9 points) and the 12% change from baseline WOMAC (3.7 points), and therefore is likely to be clinically significant.

There is no absolute value of RWS or Oxford score that indicates the need for surgery. Large series from the UK show an average preoperative Oxford score of 18–20 points for knee replacement, with public hospital patients scoring worse than private. In Canterbury, the mean preoperative OHS was 18 in a prospective observational study between 2009 and 2011 of 726 hips. The mean scores seen in all three groups in this paper are all significantly worse than these studies. They fall into the bottom three deciles for hip, and bottom two deciles for knee, by Oxford score. However, Singleton et al reported similar scores in both Māori (OHKS 10.1, WOMAC 76.2%) and non-Māori (11.26, 73.5%) in the Bay of Plenty between 2005 and 2009.

The Oxford scores for hip replacement are a little lower (worse) at 16–19 points, with public hospital patients scoring worse than private. In Canterbury, the mean preoperative OHKS was 18 in a prospective observational study between 2009 and 2011 of 726 hips. The mean scores seen in all three groups in this paper are all significantly worse than these studies. They fall into the bottom three deciles for hip, and bottom two deciles for knee, by Oxford score. However, Singleton et al reported similar scores in both Māori (OHKS 10.1, WOMAC 76.2%) and non-Māori (11.26, 73.5%) in the Bay of Plenty between 2005 and 2009.

It has been reported that worse preoperative Oxford scores lead to poorer postoperative scores, though the improvement is greater. We have not collected postoperative scores on the study group, but have reported postoperative scores similar to New Zealand Joint Registry averages in other studies, especially since introduction of ERAS protocols. We estimated the demand for primary THR and TKR in Otago to be 41.7/10,000 between 2010 and 2012, with 55% of TJR publicly funded. Using the same methodology, the demand in 2014 increased by 18.5% to 49.5/10,000, while both the total number of joint replacements and the intervention rate have fallen slightly.

This figure may still be an underestimate of the need in the community. Behaviour of both GPs and surgeons may have changed, and patients with less severe disease may be less likely to be referred or offered surgery. We introduced a physiotherapy and nurse-led clinic (Joint Clinic) in 2012 in which patients with less severe disease are managed nonoperatively. Approximately 50 patients with Oxford scores less than 20 points were under Joint Clinic care during the study period.

Nationally, the overall intervention rate (all funders) has climbed from 330/100,000 in 2011 to 363/100,000 in 2014. The raw overall intervention rate in Otago of 371/100,000 is similar to the national rate. However, population demographics mean that after age and ethnicity standardisation it is likely to be lower.

New Zealand has a relatively high rate of provision compared with other developed countries. It is predicted to rise to around 600/100,000 by 2026. The increase in demand is less than anticipated in the US and it has been suggested that rather than reflecting over-servicing in New Zealand, it demonstrates a response by the health service to an identified area of high need. Since our original report there has been a lot more publicity about unmet demand for orthopaedic surgery across New Zealand. Nationally, increased numbers of TJR have been performed over this period, but age and ethnicity standardised rates of TJR vary widely across DHBs. We do not think that the situation in Otago is necessarily different from the rest of New Zealand, but we do appear to be several years ahead for a number of reasons. New Zealand has an ageing population, and Otago has a higher proportion of older patients than the New Zealand average. We have previously identified the backlog of patients awaiting surgery due to under-provision in previous years as a factor. Despite this, there has been no increase in publicly-funded
surgery in Otago between 2010 and 2014. We estimate 61–65% of TJR are publicly funded based on the National Minimum Data Set (NMDS) and Joint Registry figures. In contrast, only 51% of TJRs in Otago were publicly funded in 2014. This has fallen from 55% in 2010–12. We believe that this difference is due to under-provision in the public sector in Otago rather than over-servicing in private. Many of these patients have chosen to self-fund their procedure due to problems with access to the public sector.

Other centres in New Zealand have reported on unmet demand, with 33% of patients listed for TJR in Northland and 41% in Hawkes Bay declined due to threshold. The average NZOA score in Hawkes Bay for patients qualifying for surgery was 76.9 points, which is similar to ours (78.8), while in Northland it was 70.6 points. However, as no other outcome score was used and multiple consultants scored the patients, it is not clear whether the differences seen in their study are true differences in the incidence and severity of disease, or whether they reflect surgical capacity or different interpretations and use of the scoring tool.

A strength of this study is that all patients in the return to GP group had been prioritised by a single nurse to ensure consistency using the NZOA tool. Criteria for its use were agreed and policed. We have used patient-reported outcome scores to assess the severity of patient symptoms. These are validated scores in common usage. They were not designed as prioritisation tools and it is possible that patients have inflated their scores in an attempt to qualify for surgery. However, the Oxford or RWS does not directly influence the NZOA score which was used to determine qualification for surgery. There were still problems with access to TJR in 2006–2010 when we started using these scores and we had no reason to believe that patients were consistently attempting to game the system.

A weakness is that the historical cohort does not include all cases performed between 2006 and 2010. This may result in some bias. However, the historical cohort was well matched with respect to age, gender and proportion of hip to knee with the study period.

It has been predicted that the demand and projected numbers of hip and knee replacement will rise significantly. It is unclear how this can be funded. While the budget announcement of increased numbers of TJR from 2016 onward is welcome, the numbers are inadequate to match demand. The indicative increase of Southern DHB (including Southland) is provisionally for only 62 extra joints spread over 3 years. The onus therefore is on individual DHBs to decide the allocation of their scarce resources. If orthopaedic volumes are not increased, then other orthopaedic procedures will need to be cut if additional joint replacements are to be done. The alternative is to raise thresholds for TJR to an unacceptable level to achieve ESPI compliance.

Prioritisation and process change may help efficiency and allow more timely surgery. However, the 4-month target is artificial and by itself does nothing to increase capacity. The worst patients may be getting their surgery sooner, but there is no sign that the numbers of severely affected patients is decreasing.

The public needs to be given realistic expectations. There is explicit rationing and, although cost effective, public funding for hip and knee replacement will soon only be for the most severely affected. Others need to consider private insurance, or self-funding their surgery.

**Conclusion**

Patients undergoing primary elective total hip and knee replacement in Otago in 2014 are more severely disabled than between 2006–2010. Patients currently being returned to GP would have qualified for publicly-funded surgery during that period. The unmet demand for TJR in Otago has increased by 19% since 2012.

This paper confirms that the increasing demand that is not matched by an increase in supply leads to a recognisable and measurable increase in the severity of disease using validated patient-reported measures in patients qualifying for surgery. The problems we describe are likely to become increasingly widespread across New Zealand.
ARTICLE

Competing interests:
David Gwynne-Jones reports grants from the Ministry of Health during the conduct of the study, and grants from DEPuy NZ Ltd outside the submitted work.

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VIEWPOINT

Very low-carbohydrate diets in the management of diabetes revisited
Grant Schofield, George Henderson, Simon Thornley, Catherine Crofts

ABSTRACT
Humans can derive energy from carbohydrate, fat, or protein. The metabolism of carbohydrate requires by far the highest secretion of insulin. The central pathology of diabetes is the inability to maintain euglycaemia because of a deficiency in either the action or secretion of insulin. That is, because of either insulin resistance often accompanied by hyperinsulinaemia, or insulin deficiency caused by pancreatic beta cell failure. In individuals dependent on insulin and other hypoglycaemic medication, the difficulty of matching higher intakes of carbohydrates with the higher doses of medication required to maintain euglycaemia increases the risk of adverse events, including potentially fatal hypoglycaemic episodes. Thus, mechanistically it has always made sense to restrict carbohydrate (defined as sugar and starch, but not soluble and insoluble fibre) in the diets of people with diabetes. Randomised clinical trials have confirmed that this action based on first principles is effective. The continued recommendation of higher-carbohydrate, fat-restricted diets has been criticised by some scientists, practitioners and patients. Such protocols when compared with very low-carbohydrate diets provide inferior glycaemic control, and their introduction and subsequent increase in carbohydrate allowances has never been based on strong evidence. The trend towards higher-carbohydrate diets for people with diabetes may have played a part in the modern characterisation of type 2 diabetes as a chronic condition with a progressive requirement for multiple medications. Here we will introduce some of the evidence for very low-carbohydrate diets in diabetes management and discuss some of the common objections to their use.

Data from the 2008/2009 New Zealand Nutrition Survey placed the prevalence of diabetes among adults at 7%. The incidence of pre-diabetes, defined as HbA1c, 41 to 49 mmol/mol (5.8% to <6.7%), was 25.5%, predicting a further increase in the incidence of diabetes in coming decades.1 The systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes by Ajala et al (2013) found that the low-carbohydrate diet “appeared to provide superior weight loss, glycemic control, and lipid profile compared with low-fat diets and, in one of 2 studies, was superior to the low-GI diet for all 3 variables”.2 Yet there is still resistance to the acceptance of low-carbohydrate diets in New Zealand. The Ministry of Health’s document Eating and Activity Guidelines for New Zealand Adults (2015) advises a low-fat diet supplying most energy from starch, and counsels the use of lean meat and low-fat dairy products to meet saturated fat recommendations.3 Although weight control is important for diabetes prevention, the ‘Topical Questions and Answers’ supplement to the guidelines is briefly dismissive of low-carbohydrate diets for weight control, and does not refer to any other benefits such as improved glycaemic control. A similarly low-fat diet plan can be found on the Diabetes New Zealand website, which states that, Most people need 3–4 serves of carbohydrate food at each of the three main meals [ie, 135–180g/day]. Very active people may need larger serves of carbohydrate foods or between meals snacks to maintain blood glucose levels.4 However, it is our view that the current evidence is sufficiently in favour of the modern, nutritionally adequate, very low-carbohydrate diet as belonging in the front rank of dietary treatments for type 2 diabetes.
We also present some evidence supportive of benefit from carbohydrate restriction in type 1 diabetes. We accept that there are useful methods of managing diabetes aligned with carbohydrate restriction, including glycaemic index (GI), Mediterranean diet, ancestral diets designed on evolutionary principles, and drugs such as metformin and acarbose. However, our focus will be on carbohydrate restriction itself and the relative effect of carbohydrate and fat as sources of energy. The basic principle of carbohydrate restriction in the management of diabetes underlies many of these other approaches, and sufficient clinical evidence supports its use. We highlight evidence relating to very low-carbohydrate diets, to best illustrate the mechanisms and effects of carbohydrate restriction.

Is dietary carbohydrate necessary?

Some authorities consider dietary carbohydrate essential to provide fuel, especially for the brain, and are concerned about an increased possibility of hypoglycaemia or ketoacidosis when carbohydrate is restricted. Although very low-carbohydrate diets still supply some carbohydrate from non-starchy vegetables and low-sugar fruits, as well as optimal amounts of fibre, there is little evidence that dietary carbohydrate is essential in the human diet. The claim sometimes made that carbohydrates are necessary in the diet of people with type 2 diabetes is also not supported by the physiology of the disease. Type 2 diabetes is characterised by a higher than usual hepatic production of glucose from amino acids and glycerol. In normal metabolism this production of glucose is reduced whenever carbohydrate is consumed, but in type 2 diabetes it is not, and this, as well as delays in peripheral glucose clearance due to insulin resistance, results in post-prandial and fasting serum glucose elevation. A person with type 2 diabetes who is not using glucose-lowering medication is thus an unlikely candidate for symptomatic hypoglycaemia on a low-carbohydrate diet. If glucose-lowering drugs are being used, then doses will need to be adjusted appropriately (an all-important caveat). Glucose requirements are also reduced by the switch to utilising fat and ketone bodies for fuel when carbohydrate is unavailable for prolonged periods. Ketone bodies are sufficiently supportive of brain function and neuronal health that it is well-recognised that a ketogenic diet is a viable treatment option for certain forms of epilepsy and other neurological disorders.

Type 1 diabetes results from the autoimmune destruction of beta cells, which no longer supply insulin to lower serum glucose and inhibit lipolysis. A diagnosis
of type 1 diabetes is often a medical emergency and will require the life-long use of exogenous insulin, whereas people with type 2 diabetes are potentially able to reverse dependence on medication through diet and lifestyle changes. Insulin is the hormone that facilitates the removal of glucose from the bloodstream, and the use of insulin introduces a risk of hypoglycaemia if insulin dose is not matched exactly to food intake. People with insulin-dependent diabetes, including those on very low-carbohydrate diets, are advised to use glucose tablets or ‘emergency foods’ to treat hypoglycaemic episodes.14

Although rare cases of ketoacidosis have been reported in people without diabetes using very low-carbohydrate diets for weight loss, we have only found one report of ketoacidosis in a person with diabetes using a low-carbohydrate diet. A 32-year-old woman with Prader-Willi syndrome and type 2 diabetes had tolerated the diet for 11 years, but developed ketoacidosis when prescribed the SGLT2 inhibitor ipragliflozin.15 A very low-carbohydrate, high-fat diet was used to prevent diabetic ketoacidosis in the pre-insulin era.6 This limited evidence suggests a low risk of ketoacidosis from using very low-carbohydrate diets for diabetes management.

Is there evidence for the safety of higher-carbohydrate diets for diabetes?

Are high-carbohydrate diets safe for people with diabetes? Low-carbohydrate diets have been used to treat type 2 diabetes since 1797, and until the discovery of insulin in 1921 carbohydrate restriction or severe energy restriction, or both, were the most reliable methods used to treat diabetes, defined by glycosuria. If carbohydrate or protein in excess of glucose tolerance was fed to these patients, they developed glycosuria and were at risk of diabetic ketoacidosis. The starvation diet developed by Frederick Allen from 1914 has caught the attention of medical historians, but it is less well known that from 1918 Newburgh and Marsh developed an adequate energy, very low-carbohydrate, high-fat diet similar in composition to today’s diets.8 The efficacy of this diet was shown in clinical practice and its safety in terms of blood sugar, blood lipids, and ketoacidosis was tested experimentally throughout the 1920s and 1930s. The first high-carbohydrate diet for diabetes that did not carry a high risk of diabetic ketoacidosis dates from 1926 and required the initiation of insulin treatment.16 Low-carbohydrate, high-fat diets therefore have a long history of usefulness in the treatment of diabetes and only went out of fashion when the diet-heart hypothesis (proposing a link between saturated fat and heart disease) emerged. The safety net provided by glucose-lowering drugs, earlier diagnosis of type 2 diabetes, and increasing access to self-monitoring equipment provided a context that allowed higher-carbohydrate diets to flourish. To our knowledge, no trials that compared very low-carbohydrate and low-fat, low-saturated fat (<30% fat, <10% saturated fat) diets were carried out before low-fat diet advice for the management of diabetes was introduced.

One problem with high-carbohydrate diets in type 2 diabetes is that progressive increases in medications are often required to prevent hyperglycaemia, yet often glycaemic control remains poor because of the risk of hypoglycaemia. In the UK Prospective Diabetes Study, a well-designed, long-term cohort study (n=4,075), only 8% of those randomised to a high-carbohydrate, high-fibre, low-fat diet (similar to New Zealand recommendations) achieved fasting plasma glucose levels of less than 7.8 mmol/L (140 mg/dL) after 9 years, and only 9% achieved HbA1c levels below 7% (53 mmol/mol). These are very mediocre levels of glycaemic control given the increased risk of cardiovascular disease and microvascular complications associated with higher HbA1c. Due to the risk of hypoglycaemia when glucose-lowering medications are used to cover high-carbohydrate meals, lower targets were not considered realistic in this study even when multiple medications were used.17

Conversely, trials of restricted carbohydrate regimes show evidence of improved glycaemic control, including limited evidence from small uncontrolled trials suggestive of a decreased risk of hypoglycaemia during the intensive management
of glycaemia with insulin in people with type 1 diabetes. In one small case-series of intensive glycaemic control with drugs and diet, subjects diagnosed with type 1 diabetes (n=10) and type 2 diabetes (n=20) were placed on the same very low-carbohydrate diet (30g/day carbohydrate). HbA1c in those with type 1 diabetes was reduced in all cases, the mean reduction being from 6.8% to 5.5% (50.8 to 36.6 mmol/mol). In participants with type 2 diabetes, the mean HbA1c reduction was from 8.4% to 5.8% (68.3 to 39.9 mmol/mol). No cases of severe hypoglycaemia were reported over the study period of 21.4 months (standard deviation (SD): 22.3). In a small clinical audit (n=48) of a low-carbohydrate diet (defined as 75g/day carbohydrate) for type 1 diabetes, mean HbA1c in those adherent to the diet for the full 4-year period (48%) was reduced from 7.7% to 6.4% (60.7 to 46.4 mmol/mol). The mean rate of symptomatic hypoglycaemia was reduced from 2.9 (SD: 2.0) to 0.5 (SD: 0.5) episodes per week.

What is the evidence for the safety of the high fat content of the very low-carbohydrate diet?

A frequently heard criticism of very low-carbohydrate diets for diabetes is that “eating more protein and fat may increase your risk of heart disease in the long term”. It is well-known that a diagnosis of diabetes greatly increases the risk of cardiovascular disease. It is less well-known that there is also a reciprocal relationship; a cardiovascular event predicts a future diabetes diagnosis. We would submit that few things can be worse for the coronary arteries than the metabolic and hormonal changes that result in a diagnosis of type 2 diabetes. Reversing the progression of diabetes and the related metabolic syndrome should be the first priority.

Support for the safety of high-fat diets in people with diabetes comes from trials which show improved markers of cardiovascular risk in the low-carbohydrate, compared to the usual care group. A recent, well-designed, randomised controlled trial (n=115) by Tay et al (2015) compared a very low-carbohydrate diet with the conventional low-fat diet for type 2 diabetes over 52 weeks. In this trial, in which saturated fat was restricted, lipids, including low-density lipoprotein cholesterol (LDL-C) improved on the very low-carbohydrate diet. In a 2008 very low-carbohydrate weight-loss randomised controlled trial in obese subjects without type 2 diabetes (n=88) by the same group, saturated fat was not restricted (saturated fat was 20% of energy) in the very low-carbohydrate arm.

High-density lipoprotein cholesterol (HDL-C) and triglycerides improved, while LDL-C decreased overall but increased by 10% in 24% of the participants. However, apolipoprotein beta (ApoB) did not increase in this subgroup. It is notable that LDL-C is a calculated proxy for ApoB, small, dense LDL-C particles (sdLDL), and other atherogenic factors within the LDL-C fraction. Evidence for the effect on cardiovascular health of low-carbohydrate diets to date seems to show overall improvement in glycaemic and lipid metabolic risk factor surrogate endpoints compared to other diets in low-carbohydrate diet trials, in only some of which saturated fat was restricted. We have argued previously that analyses of long-term cardiovascular disease risk diet trials which restricted saturated fat (but did not include low-carbohydrate arms) have not shown any major detrimental or beneficial effect of saturated fat restriction on overall mortality.

Some studies show better metabolic health in people who consume higher intakes of full-fat dairy foods. In the most recent meta-analysis of epidemiological prospective cohort studies of saturated fat and trans-fat consumption, highest versus lowest consumption of the naturally-occurring trans-fats found in dairy was associated with a significant reduction (relative risk 0.58, 95%, CI: 0.46–0.74) in the incidence of type 2 diabetes. In a recent prospective cohort study [n=26,930] from Malmö, Sweden, which used a 7-day food diary and a 1 hour interview, as well as a food frequency questionnaire to assess dietary intake, both dairy fat consumption (including butter and cream) and intake of the short- and medium-chain saturated fats (C4:0–C14:0) found in dairy were associated with a significantly reduced incidence of...
Lean red meat consumption was associated with type 2 diabetes, but fatty red meat consumption was not. This evidence seems to contradict the low fat, saturated fat-restricted diabetes prevention recommendations of New Zealand authorities, who continue to advise the consumption of low-fat dairy foods.3,4

**Does the very low-carbohydrate diet have any unique advantages over other dietary approaches?**

The conventional approach to diet, weight loss and glycaemic control in type 2 diabetes can fairly be summarised as “all diets improve glycaemic control if they cause weight loss, all diets that reduce energy intake cause weight loss if adhered to, therefore there is little reason to prefer one type of diet over another”. However, some trial evidence contradicts these assertions. In a 2014 subgroup analysis of subjects with type 2 diabetes (n=46) within a 48-week, well-designed, randomised controlled weight-loss trial, serum glucose improved significantly more on a very low-carbohydrate diet compared to a low-fat diet plus orlistat, even when weight loss was equal.26 Furthermore, in a series of well-designed carbohydrate restriction experiments, improvements in glycaemic control and hormonal and lipid parameters were demonstrated under conditions where patients were maintained at a constant weight.5,27

One suggested explanation for these results is that triglycerides stored in different parts of the body have different effects on insulin sensitivity. In the aetiology of type 2 diabetes, hyperinsulinaemia and hyperglycaemia result from the accumulation of triglycerides in the liver and subsequently in the pancreas, impairing endocrine and paracrine insulin signalling.28 The development of non-alcoholic fatty liver disease (NAFLD) leads to a higher output of hepatic glucose and triglycerides and is associated with an increased risk of type 2 diabetes and cardiovascular disease.29 The reduced insulin and blood sugar response to a very low-carbohydrate diet rapidly leads to the mobilisation and oxidation of accumulated hepatic lipids.30 In the pilot trial of Unwin et al (2015) of a very low-carbohydrate diet for type 2 diabetes, serum gamma-glutamyl transferase (GGT), a surrogate marker of NAFLD, decreased from 76.9 iu/L (95% CI: 58.3, 95.6) to 49.8 iu/L (95% CI: 33.0, 50.3) in the patients for whom data was available (n=64/68).9 It is notable that this change was not correlated with weight loss. If metabolic improvement is less dependent on weight loss on a very low-carbohydrate diet compared to other diets, this is a potentially important advantage for patients who do not lose weight easily, or for normal-weight individuals diagnosed with type 2 diabetes.

It should be noted that low-carbohydrate diets as advised in practice necessitate higher quality, micronutrient-dense food, such as non-starchy vegetables, nuts and seeds, and low-sugar fruits. The importance of micronutrient status in the management of diabetes and metabolic syndrome, and the benefit from a higher intake of nutrient-dense foods, are well-documented.31

Motivated people with diabetes can be advised to restrict their carbohydrate intake. Adherence to this advice has the potential to improve their quality of life, decrease their dependence on drugs, and reduce their risk of mortality based on their metabolic profile. In people with insulin-dependent diabetes, the risk of hypoglycaemic episodes is also likely to improve. As we have outlined, this alternative approach, which challenges high-starch, low-fat guidelines, is supported by many lines of evidence. We suggest that clinical dietary advice for the treatment of diabetes, as well as population prevention guidelines, be urgently revised.
Competing interests:
Nil

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Regulating tobacco retail in New Zealand: what can we learn from overseas?

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ABSTRACT
Despite New Zealand’s reputation as a leader in tobacco control, the retail environment for tobacco is relatively unregulated, particularly when compared to the licensing regimes for alcohol products and psychoactive substances (eg, synthetic cannabis and other ‘legal highs’). There are currently no restrictions on who can sell tobacco, nor where it can be sold. The lack of an accurate tobacco retail register presents a challenge for those enforcing retail legislation. This paper summarises tobacco retail licensing schemes implemented in overseas jurisdictions, as these represent precedents on which New Zealand policies could be based. We also review how effective these schemes might be as part of a comprehensive tobacco control strategy. We conclude that a positive licensing scheme could increase compliance with existing smokefree legislation, and enable the introduction of further measures to control the supply of tobacco. Reducing tobacco availability is an important part of the range of interventions needed to achieve a smokefree New Zealand, and we urge the Government to redress the lack of progress in this area.

As the first country in the world to set a goal of becoming a smokefree nation, and an active tobacco control programme that has spanned more than 40 years, New Zealand is often considered at the forefront of tobacco control. Yet despite tobacco being highly addictive and toxic, and apparently easily available to many young people who smoke, the retail environment remains relatively unregulated. There are no restrictions on where tobacco can be sold, on the type of outlets able to sell tobacco, or on the age of those permitted to sell tobacco. Consequently, tobacco is available at as many as 8,000 retail outlets throughout New Zealand, including supermarkets, service stations and dairies, where it is sold alongside everyday products such as milk, bread and petrol and in settings freely accessible to children. Considering the importance of distribution or ‘place’ as a key marketing principle, the widespread availability of tobacco remains a major form of promotion. The ubiquity of tobacco also presents a challenge for enforcement, since there is no accurate list of New Zealand tobacco outlets. We identified 5,008 retail outlets from District Health Board lists, which represents 1 outlet per 617 adults, or 1 outlet per 129 smokers in New Zealand. Half of New Zealand secondary schools have at least one tobacco outlet within a 500m walk. However, industry data suggest around 8,000 outlets sell tobacco in New Zealand, a far larger estimate.

By contrast, the Psychoactive Substances Act, which came into effect in July 2013, requires retailers to have a licence to sell approved products (ie, party pills, synthetic cannabis and other ‘legal highs’), stipulates a minimum vendor age, places restrictions on the types of outlet permitted to sell approved products, restricts sales to premises where children are not allowed, and allows territorial authorities to determine who is granted a licence and thus where products may be sold. Retailers wishing to sell alcohol in New Zealand are required to apply for a licence, a process which involves assessment of applicants’ training and suitability to sell alcohol. Local stakeholders (eg, Police, Medical Officers of Health) may make submissions on alcohol licensing applications and thus influence who obtains a licence. Liquor legislation also restricts the hours of sale, prohibits certain types of outlets (eg, dairies, service stations) from selling...
alcohol, and children under 18 years of age are not permitted to enter liquor stores unless accompanied by an adult.

Evidence suggests the widespread retail availability of tobacco has serious consequences. It may encourage smoking initiation among youth, some retailers may continue to sell tobacco to minors and it may undermine smokers’ quit attempts. Many children who smoke report that they usually obtain tobacco by purchasing from a shop, which suggests that current restrictions on sales to minors are not completely effective. The higher density of retailers in more deprived neighbourhoods is likely to contribute to the higher smoking prevalence amongst those who are socioeconomically disadvantaged and consequently to health inequalities.

Following its inquiry into the tobacco industry, the Māori Affairs Select Committee (MASC) recommended that the government consider reducing the number of retail outlets, investigate giving local authorities the power to control the number and location of tobacco retailers, and consider imposing sales bans on retailers breaching smokefree legislation. In its response to the inquiry, the government agreed to investigate further options to reduce the supply of tobacco. However, in the 5 years since the inquiry, no progress has been made towards these particular recommendations. The National Smokefree Working Group has consistently argued for restrictions on the supply of tobacco, as well as stronger enforcement of existing retail-level legislation. However, in a recent presentation to the MASC on progress towards the smokefree goal, the Ministry of Health indicated that interventions to reduce availability and supply of tobacco were considered ‘low priority’. This lack of action does not support the Government’s own commitment to reducing smoking prevalence and tobacco availability to minimal levels by 2025.

Despite New Zealand’s reputation as a leader in tobacco control, several other countries and jurisdictions have made far greater progress in regulating the tobacco retail environment through retailer registration or licensing schemes. In this paper, we summarise some of the regulatory approaches from these jurisdictions, as these represent precedents on which New Zealand policies could be based.

**Negative licensing schemes**

Negative licensing schemes require retailers to notify government authorities that they are selling tobacco. Retailers neither have to seek permission, nor prove their suitability, to sell tobacco, but they may be removed from the register and have the right to sell tobacco revoked on a temporary or permanent basis. For example, in New South Wales (NSW) all retailers of tobacco are legally required to be registered with the Government Licensing Service. In Scotland and Ireland, mandatory tobacco retailer registration schemes make it illegal to sell tobacco without registration, and authorities can ban or suspend retailers from selling tobacco if they breach legislation. In Fiji, New York (NY) State, and several Canadian jurisdictions (eg, Ontario, Nova Scotia, Quebec and British Columbia), tobacco retailers are required to annually register or apply for a permit, and these schemes may entail annual fees. In NY State, violations of smokefree legislation can result in suspensions or revocation of retailers’ ability to sell not only tobacco, but also alcohol and lottery tickets.

**Positive licensing schemes**

A positive licensing scheme, such as those implemented in five Australian states, requires retailers to apply for a tobacco retail licence. This licence is only granted if conditions are met and a fee is paid. In Australia, annual fees range from $200 to $510 AUD, though conditions on obtaining a licence are minimal. Singapore and Finland both have positive tobacco retail licensing with an annual fee set by local authorities, and the Finnish licensing system requires retailers to submit satisfactory operational plans and reports in order to successfully renew the licence each year. Within NY State, local licensing systems operate in conjunction with state-level registration. In NY City, retailers apply biannually for a licence to sell cigarettes, paying a $110 USD
fee. Similarly, in Dutchess County (NY) a permit is required to sell tobacco. In each of these cases, licences can be revoked for violations of smokefree legislation.16

Stronger tobacco licensing schemes have begun to be introduced in some areas. In Santa Clara County (California), for example, tobacco retailers are required to apply for a permit, with no permits granted to any retailer applying to operate within 1,000 feet of a primary or secondary school or within 500 feet of another tobacco retailer. Since permits cannot be transferred if a business is sold, this approach supports a gradual reduction in retailer density. In 2011, a law change in Huntington Park (California) prohibited any tobacco retail licences being issued to retailers in residential zones, within 500 feet of ‘youth-populated areas’ (ie, schools, childcare centres, playgrounds, libraries, parks and arcades), or within 200 feet of another tobacco retailer. Furthermore, no more than one licence is granted per 1,000 residents.16

A particularly innovative approach has been introduced in Hungary, where legislation enacted in 2013 mandated that tobacco could only be sold at a limited number of government-licensed outlets.24 This measure dramatically reduced the number of tobacco stores from around 42,000 to 7,000. Applicants wishing to sell tobacco were required to submit a business plan and pay a flat fee; successful bids were granted a 20-year concession to sell tobacco. The quota for tobacco licences is linked to the population size: in a municipality with fewer than 2,000 residents the maximum is one; for municipalities with more than 2,000 residents, one licence is issued for every 2,000 residents (Julia Berki, email to author, 3 August 2015).

In addition to these examples, San Francisco officials have recently approved the Tobacco Sales Reduction Act, a law that imposes a limit of 45 tobacco retailing permits for each of the 11 city districts.25 This state law does not affect existing permit holders, which are expected to decline from the current 1,000 permits to 495 through attrition, over the next 10 to 15 years. The Cook Islands have also recently approved a licensing scheme for tobacco retailers as part of a reform of the national tobacco legislation.26

Evidence of effectiveness of tobacco retailer licensing

Although published evaluations are limited, tobacco retail licensing schemes appear to increase compliance with youth access restrictions and reduce the retail availability of tobacco. An evaluation of the NSW scheme indicates that registered tobacco outlets are less likely than unregistered outlets to breach smokefree legislation.12 Research on the South Australia (SA)27 and Santa Clara County28 schemes suggests that introducing an annual licence fee and application process may be sufficient in and of itself to reduce the number of retailers selling tobacco. In SA, when the cost of a tobacco retail licence fee increased from $12 to around $200 AUD, the number of tobacco retail licences decreased by 24% over 2 years, with the largest decline in licences occurring for on-licensed venues (ie venues where alcohol is available for consumption on the premises).27 The licensing scheme in Finland is also believed to have reduced the number of outlets selling tobacco,29 though there is no official data to support this conclusion (Reeta Honkanen, email to author, 8 July 2015). A New Zealand modelling study suggests that drastically reducing the number of tobacco outlets in New Zealand could help reduce smoking prevalence over the long term.30 In that study, the estimated effect on smoking prevalence was modest in size, however the particular analyses undertaken were based on certain assumptions that may have resulted in conservative estimates. The impact of retailer licensing schemes on youth uptake and smoking prevalence has yet to be investigated.

Discussion

The inconsistency between the ubiquity of tobacco in New Zealand and the Government’s commitment to reducing tobacco availability to “minimal levels”9 is a primary justification for a positive licensing scheme. Such a scheme could include a limit on the number of tobacco retail licences issued and this could be...
introduced as an immediate measure, as in Hungary.\textsuperscript{24} Alternatively, a limit on the number of licences could be introduced in a similar manner to San Francisco City\textsuperscript{25} or Huntington Park,\textsuperscript{16} where a large reduction in outlet density will be realised over the long term. Alternatively, or additionally, restrictions on tobacco sales around schools and other youth-populated areas could be adopted, similar to Santa Clara County and Huntington Park.\textsuperscript{16} Given that the point-of-sale (POS) tobacco display ban now greatly reduces the exposure of children and young people to tobacco in shops, it could be argued that restricting tobacco availability around schools is less justifiable in New Zealand than in jurisdictions without POS bans. However, the POS display ban does not address the problem of easy access to tobacco around schools.\textsuperscript{4} Further, the New Zealand public\textsuperscript{31,32} and tobacco retailers themselves\textsuperscript{33} tend to be particularly supportive of restricting tobacco sales around schools, hence it may be more likely to gain political traction than other policies, and could still result in significant reductions in tobacco outlet density.\textsuperscript{30}

The second justification for introducing a positive licensing scheme stems from evidence that many retailers in New Zealand continue to sell tobacco to children younger than 18 years of age.\textsuperscript{6} Around 12% of underage smokers report that they usually obtain their tobacco from retail sources, and this proportion has remained consistent for several years.\textsuperscript{2} Licensing is likely to enhance enforcement of bans on retail sales to minors and effective enforcement of these laws can reduce youth smoking.\textsuperscript{34} Currently in New Zealand, Smokefree Enforcement Officers, who enforce smokefree legislation, compile lists of tobacco retailers through searching business directories and from local knowledge.\textsuperscript{4} This is inefficient and unlikely to be completely accurate. A licensing scheme would efficiently provide Smokefree Enforcement Officers with accurate data on local tobacco retail outlets, and support their enforcement efforts. Furthermore, licensing may enhance enforcement as the risk that their ability to sell tobacco could be suspended or revoked may deter retailers from selling to minors more than infringement fines alone.\textsuperscript{12} Lastly, a licensing scheme could provide a revenue stream to fund enforcement efforts, and if accompanied by an appropriate licence fee, may also reduce retailer numbers and tobacco availability.\textsuperscript{27,29}

The New Zealand government could also adopt additional measures as part of a positive licensing model. These measures have not yet, to our knowledge, been introduced by any country or jurisdiction. One measure would be to require those selling tobacco to be aged 18 or over, which would align with the recommendation in Article 16 of the WHO Framework Convention on Tobacco Control.\textsuperscript{35} Additionally, tobacco sales could be prohibited at on-licensed premises, such as bars and nightclubs. The link between alcohol use and smoking uptake and relapse is well established.\textsuperscript{36} Therefore not allowing tobacco sales at locations where alcohol is consumed might be an important way to reduce the alcohol and smoking link, and reduce smoking initiation and relapse after cessation. Other strategies that would greatly reduce tobacco availability include restricting tobacco sales to specialist outlets where children are not allowed, such as off-licensed liquor stores. This idea is well supported by New Zealand smokers,\textsuperscript{32} would result in a large reduction in the number of tobacco outlets,\textsuperscript{30} and given that these outlets are already licensed, fewer resources may be needed to implement this change. Pharmacy-only tobacco sales is another option that merits further investigation.\textsuperscript{37}

Conclusion

Evidence that several other countries and jurisdictions have made considerably more progress in regulating tobacco retailing should galvanise action to ensure New Zealand’s continuing status as a leader in tobacco control. Reducing tobacco availability is a component of the Government’s smokefree 2025 goal and is an important part of the strategy needed to achieve minimal levels of smoking by 2025. We urge the Government to redress the lack of progress in this area.


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CLINICAL CORRESPONDENCE

Case of takotsubo cardiomyopathy in a patient with COPD

Nirav S Patel, Smita I Negi, Aashish Anand, Anantha K Rao

Takotsubo cardiomyopathy (TCM) is a transient, reversible form of acute left ventricular (LV) dysfunction often presenting as acute myocardial infarction (AMI). It accounts for approximately 1.7 to 2.2% of all suspected cases of AMI more frequently seen in females between 59–72 years of age.\textsuperscript{1,2} It is believed that the LV dysfunction is caused by a surge in catecholamine levels, precipitated by one, or a combination of, acute emotional/physical stressors, iatrogenic stressors, neurologic triggers, or pre-existing cardiovascular factors and endothelial dysfunction.\textsuperscript{1} We describe a case where TCM developed acutely during hospitalisation for COPD exacerbation.

Case presentation

A 62-year-old woman with a history of long-standing COPD (on inhalers), hypertension, hypothyroidism, smoking, and essential tremor, presented with acute respiratory distress. On presentation, she was febrile, tachypneic and hypoxemic with an oxygen saturation of 91% on room air. Her blood pressure was 220/85 mmHg with a pulse rate was 126 beats per minute (bpm). She displayed bilateral expiratory wheezing, with decreased air movement. Cardiovascular examination was unremarkable.

Electrocardiogram (ECG) showed sinus tachycardia at 103 bpm (Figure 1), with no evidence of ischemia. Initial chest radiograph showed hyperinflation without consolidation. She was started on bilevel positive airway pressure (BiPAP) and 6 hourly nebulised albuterol sulfate and ipratropium bromide, as well as high dose oral corticosteroids. Troponin-I (TN-I) level of 0.279 ng/mL was obtained with a CK-MB of 5.6 ng/mL and N-terminal pro b-type Natriuretic Peptide (NT-proBNP) was 599 pg/mL. A two-dimensional (2D) transthoracic echocardiogram (TTE) (Figure 2) showed an ejection fraction (EF) of 65%, with no regional wall abnormalities.

ECG on day 2 showed atrial fibrillation with rapid ventricular response (160–180 bpm), converted back to normal sinus rhythm using amiodarone. She denied any palpitations, light-headedness, dizziness or chest pain during the episode. The TN-I peaked at 0.5 ng/mL on day 4, prompting cardiac catheterisation. No significant obstruction of epicardial coronary vessels was noted on selective coronary angiography (Figure 3); however, left ventriculogram (Figure 3C) revealed apical ballooning suggestive of TCM, with a mildly reduced EF of 45%. In view of her down trending cardiac biomarkers and improvement in her symptoms, she was discharged on aspirin, advised to be cognisant of her inhaler use, and close follow-up.

Discussion

Recent case reports have identified COPD exacerbation as a possible physical stressor triggering TCM. It has been hypothesised that excessive beta-2 adrenergic receptor (ADRB2) agonist use can trigger TCM in an already distressed patient with COPD exacerbation.\textsuperscript{3-6} Interestingly, Rajwani and Hall proposed a new subtype of TCM, ‘Bronchiogenic Stress Cardiomyopathy’.\textsuperscript{4}

Generally, the sympathetic nervous system works to have a positive inotropic effect on the myocardium mediated by norepinephrine and epinephrine predominantly via beta-1 adrenergic receptors. Epinephrine has a higher affinity for ADRB2s, and at physiological levels contribute to the positive inotropic effect on the heart. In experimental models, high
Figure 1: ECG on admission. Sinus tachycardia at 103 bpm, no evidence of ischemic changes.

Figure 2: 2D TTE on day 2 of hospital admission. Apical 4-chamber view showing normal LV function on diastole (A) and systole (B).

Figure 3: Cardiac catheterisation with selective angiography (A, B) and left ventriculogram (C) on day 4 of hospital admission. No significant obstruction in the right (A) and left (B) coronary systems. Left ventriculogram showing apical ballooning during systole and mildly reduced LV function.
levels of epinephrine can paradoxically have a negative inotropic effect on the myocardium mediated via ADRB2s. This epinephrine “biased agonism” is thought to be cardio-protective against the apoptotic effects on myocytes due to excessive simulation of ADRB2s. The apex of the heart has a higher concentration ADRB2s than the base, which might help to explain the unbalanced LV dysfunction in TCM, especially the apical ballooning. This is clinically important because ADRB2 agonists are part of the standard or care of COPD, and at high doses they might mimic the effect of high levels of epinephrine on the myocardial tissue contributing to LV dysfunction.

Our patient had not been using her albuterol inhaler at home for a year until 2 days prior to presentation. In the hospital, she received nebulised albuterol sulfate/ ipratropium bromide solution every 4 hours on presentation with COPD exacerbation prior to cardiac catheterisation. She was also treated with a long-acting ADRB2 agonist, formoterol daily, along with tiotropium bromide and steroid therapy. High levels of ADRB2 agonists to treat COPD superimposed on the increased sympathetic nervous system activity secondary to hypercapnia and hypoxaemia contributed to the TCM in this patient.

TCM should be considered in patients presenting with COPD exacerbation, abnormal cardiac biomarkers, and continuing chest pain. Its recognition can alter a patient’s medical therapy and follow-up. Due to akinetic segments of the ventricles, up to 5% of TCM patients can develop ventricular thrombi, leaving them susceptible to embolic events, especially in the setting of poor ambulation and acutely sick state. Upon discharge, these patients require close follow-up, with repeat TTE and ECG evaluation. Beta-blockers and ACE inhibitors for LV systolic dysfunction may also be considered, however it is unclear what the cardio-protective effects in this subset are due to lack of data. In fact, there have been cases of recurrent TCM in patients on beta-blocker therapy. Additionally, a multidisciplinary approach may be required when addressing ADRB2 agonist inhaler and/or cardio-selective beta-blocker use in such patients as the pathogenesis of TCM is still not well understood.

Competing interests:
Nil

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Recent submissions to the New Zealand Government Health Select Committee on end-of-life choices

Philip Bagshaw, Sue Bagshaw, Stuart Gowland

We are gratified to see that the New Zealand Medical Association has taken a strong leadership position against doctor-assisted suicide (DAS), which is central to the current issue of end-of-life choices. It was, however, with concern that we learned that our medical colleges (Royal Australasian College of Surgeons, and The Royal New Zealand College of General Practitioners) did not make submissions to the Health Select Committee on this issue. They did, however, suggest that their members and fellows could make personal submissions. By this sidestep, they made DAS into an individual conscience issue for doctors.

Clearly, death is a natural process, and doctors have been caring for patients through this process, with varying degrees of skill, for millennia. In order to ensure the dying process is managed these days for everyone with dignity and consideration, and without undue pain and distress, universal access to expert palliative care is required, rather than the socioeconomic expedient of lethal injection. The Dutch experience with the latter is often quoted in support of DAS. It is therefore concerning that their annual report for 2013 gives as one of the “due care criteria” for the sanctioning of assisted suicide that, “the attending physician must have come to the conclusion, together with the patient, that there is no reasonable alternative in the patient’s situation”. From this criterion it can be concluded that either modern, palliative, medical care is not universally available in the Netherlands, or it is not considered as a reasonable alternative to assisted suicide, in that country.

The Dutch report also shows that their national annual incidence of “euthanasia and assisted suicide” increased from 2,636 cases in 2009, to 4,829 cases in 2013. These statistics include significant numbers of patients with dementia and mental disorders, which is causing concern in that country. Furthermore, in February 2010, a citizens’ initiative called ‘Out of Free Will’ demanded that all Dutch people over 70, who feel tired of life, should have the right to professional help in ending it. The organisation collected many signatures in support of this proposed change to Dutch legislation, including former ministers, academics, physicians and other nationally prominent citizens. It can only be hoped that such a deterioration of ethical standards never eventuates in New Zealand.

We contend that our New Zealand medical colleges should have taken a leadership role in explaining to the Health Select Committee, and the public, that DAS will inevitably have an adverse long-term effect on the doctor-patient relationship; a consequence that is unlikely to be mentioned by any of the DAS advocates. The doctor-patient relationship will, and should always, depend on an element of trust. This trust has already been damaged in recent years by the general
indifference of our profession to some public healthcare issues, by highly publicised cases of malpractice (genuine or fabricated), and by the destructive health-reforming actions of governments.

It is fashionable to claim that we now practice in ‘a post-Hippocratic era’, with ‘a new professionalism’, and should therefore be prepared for significant change in our work and relationships.5,6 We should, however, never be willing to accept any change that degrades the doctor–patient relationship by further reducing the trust element. All doctors should feel free to speak out about any issue that affects this relationship and the trust on which it is based.

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LETTER

Possible toxicity of olive leaf extract in a dietary supplement
Ian C Shaw

I recently advised on a case involving a 67-year-old woman who suffers from severe hay fever, but experiences side effects associated with anti-histamines which limits her treatment options. She visited a pharmacy and was advised to take a dietary supplement containing extracts of olive (Olea europaea) leaf, horseradish (Armoracia rusticana) root and eyebright (Euphrasia officinalis) for sinus and hay fever relief. She had been taking another dietary supplement containing olive leaf extract (OLE) for approximately 2 years, with no untoward effects, and she continued to take this supplement with the sinus and hay fever relief supplement. Her total OLE dose was equivalent to 5.5 g dry olive leaf/day (ie, dry leaf equivalent).

As with many other dietary supplements, OLE is marketed broadly, including anti-aging, as an immunostimulator, antioxidant, anti-hypertensive, cardio-protective, blood-sugar regulating, and as an antibiotic. While there is some animal (eg, blood-pressure lowering) and clinical (eg, blood-pressure lowering) data to support some of these ‘claims’, the evidence is scant, and sometimes contradictory.

The woman is usually a calm, considerate person, but after taking the sinus and hay fever relief supplement, she felt more easily annoyed and argumentative, and after several weeks of the recommended daily dose, she reported often feeling tearful, angry, easily annoyed, negative, reactive and lacking control. All of these uncharacteristic behavioural traits disappeared several days after stopping taking the sinus and hay fever relief supplement.

These interesting and out of character behavioural responses might be explained by the ingredients of OLE, namely oleuropein and hydroxytyrosol (Figure 1).

Oleuropein is thought to agonise the G-protein oestrogen receptor, which is unlikely to explain the effects seen in this case. On the other hand, hydroxytyrosol has significant structural analogy with the neurotransmitter dopamine. Dopamine, in conjunction with serotonin, is involved in mood and aggression and perturbation of its synaptosomal levels are thought to result in mood changes (eg, in attention-deficit/hyperactivity disorder (ADHD)). Interestingly, it is possible that esterase-catalysed metabolic cleavage of the oleuropein ester bond (Figure 1) would liberate hydroxytyrosol which might further exacerbate the postulated dopamine-related mood effects of OLE.

OLE, like all other dietary supplements, is regulated as a food rather than a medicine. 33 means that it has not undergone the rigorous risk/benefit toxicity/efficacy testing to which medicines are subjected with the quid pro quo that it cannot have a medicinal claim. However, OLE, like other dietary supplements, is often sold in pharmacies and therefore most customers would likely regard the product in a medicinal, not food, context.

The woman had tolerated 500 mg/day OLE for at least 2 years, but 38 additional 5 g/day (dry leaf equivalent) in the sinus and hay fever relief supplement caused toxicity. The woman’s weight is approximately 65 kgs, which suggests that an OLE (dry leaf equivalent) dose of 85 mg/kg body weight is toxic.

This case is further evidence that we should require dietary supplements to undergo toxicity and efficacy testing before they are approved for marketing in New Zealand if they are to be used in a medical, rather than a food, setting.
Figure 1: Dopamine (A) and hydroxytyrosol (B) showing their structural analogies, and oleuropin (C) showing its postulated esterase-catalysed metabolism to release hydroxytyrosol.

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Assessing the response to follow-up recommendations in radiology reports

Danus Ravindran, Yassar Alamri, David Cranefield

Until recently, there has not been a standardised approach to the written radiology report. In 2013, the Royal Australian and New Zealand College of Radiologists' published a set of guidelines in attempt to improve the quality of the written report by providing evidence-based recommendations for good practice. These include:

“If further imaging, investigations, referral or treatment is to be suggested, the report should describe:
1. How it is expected that this will contribute to the diagnosis and/or management of the patient's current medical problem;
2. The exact nature of the further investigation/referral/treatment that is recommended;
3. The suggested timing of this further investigation/referral/treatment, if relevant, especially if this is urgent.”

The reported uptake of recommended follow-up radiological assessment by the referring clinical team has generally been low. In a group of patients (n=65) where a pulmonary nodule was identified on chest computed tomography (CT), only 29% were followed-up. A similar rate of follow-up imaging (32%) occurred in a group of 74 patients with adrenal incidentalomas, where all had been recommended further imaging by the reporting radiologist.

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.

The remaining 26 recommendations that were not performed were for repeat CXR (n=23), for 2 CT scans to investigate a possible hollow viscus perforation (n=1) and a lung opacity (n=1), and for cardiac ultrasound scan to further investigate possible pericardial effusion (n=1); see Figure 1.

Follow-up timeframe

Of the 108 reports with recommendations for further imaging, 29 reports (27%) included a specific timeframe within which the repeat imaging study (all were CXR) was to be performed. Twenty-six reports recommended repeat CXR in 4-8 weeks to check the resolution of consolidation. One recommendation was to repeat a CXR in 24 hours to ensure the resolution of a small pneumothorax, while 2 recommendations suggested repeat CXR in one week to clarify the progression or resolution of an opacity.

Discussion

Our results indicate that a sizeable proportion of the reports (24%) contain
recommendations which have not been carried out. While lower than other reported studies,2,3 not following-up on patients who may require further medical assessment is far from ideal. It is unclear as to what the underlying reason(s) are, some of which may not have even been documented by the referring team. Our speculation is that it is likely to be multifactorial. The referring clinical team may have purposefully chosen to forego recommendations for follow-up CXR due to perceived futility. The traditional wisdom has been to repeat the CXR 4–8 weeks after community-acquired pneumonia to screen for underlying malignancy.4,5 However, newer studies6 and guidelines7 have cast doubt on the utility of such approach, except perhaps in patients 50 years and over. Moreover, patients may have undergone the follow-up radiological studies at a different facility, which could have been missed.

Further research is warranted in order to identify the proportion of clinical response to recommendations made in radiological reports of other modalities and the impact on patient outcomes. This, in turn, could be fed back to the reporting radiologists. It is also hoped that a repeat study in the future (ie, once the recommendations discussed 74 have been implemented) is conducted, to see if there has been an improvement and if hurdles have been overcome.

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**Figure 1:** Uptake of recommended follow-up imaging by clinical teams. USS = ultrasound scan.
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The authors would like to thank John Greenwood for his help in conducting the PACS search.

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Chronic misleading online advertising by chiropractors

Mark Hanna, Mark Honeychurch

In March 2016, the Chiropractic Board of Australia—the Australian regulator of chiropractors—published a Statement on advertising relating to unsubstantiated claims made by many Australian chiropractors:

“Claims suggesting that manual therapy for spinal problems can assist with general wellness and/or benefit a variety of paediatric syndromes and organic conditions are not supported by satisfactory evidence. This includes claims relating to developmental and behavioural disorders, ADHD, autistic spectrum disorders, asthma, infantile colic, bedwetting, ear infections and digestive problems.”

The phenomenon of chiropractors making claims that are not supported by evidence is not new, nor is it restricted to Australia. In 2010, Ernst and Gilbey evaluated 200 websites advertising chiropractors based in Australia, Canada, New Zealand, the UK, and the US, and found that 190 of them made unsubstantiated claims regarding one or more of the specific conditions they were looking for.

In 2015, we systematically evaluated 137 websites for chiropractic clinics based in New Zealand, taken from the first 30 pages of Google search results for “Chiropractor New Zealand”. We looked for claims that chiropractic manipulation can treat or improve ADHD, allergies, bed wetting, colic, or ear infections, as well as for any health testimonials used to promote their services.

These conditions were chosen because we had previously observed chiropractors failing, when challenged via complaints to the Advertising Standards Authority, to provide evidence to substantiate claims that these conditions can be treated with chiropractic. Our own review of the literature also failed to find satisfactory evidence to substantiate any of these claims.

There is regulation in place to prevent misleading and unsubstantiated claims being made in advertisements. Both the Fair Trading Act 1986 and the Advertising Standards Authority's Codes of practice have clauses prohibiting misleading and unsubstantiated claims. The New Zealand Chiropractic Board’s Advertising Policy also requires that:

“All advertising must… be presented in a manner that is accurate, balanced, and not misleading”

Health testimonials were included in the search, as they can be both very convincing and very misleading. They are prohibited in this context by the Medicines Act 1981 Section 58(1)(c)(iii), as noted in the New Zealand Chiropractic Board’s Advertising Policy:

“A chiropractor shall not advertise any material which relates to the chiropractor’s qualifications, practices, treatment or the premises where they practice chiropractic if the material…uses testimonials whether from patients or any other person (see section on Medicines Act)”

Interestingly, the Medical Council of New Zealand, whose role as the statutory regulator of medical professionals is equivalent to the New Zealand Chiropractic Board, notes in its recent proposal to amend their statement on advertising that:

“Council is proposing to prohibit the use of testimonials in medical advertising because they can be unreliable and misleading” [emphasis ours]

Findings

We found that 54% of the websites claim that at least one of the conditions could be
treated or improved by chiropractic manipulation, and 35% of the websites contained health testimonials.

At least in their online advertising, the majority of New Zealand chiropractors make therapeutic claims that are not substantiated by the available evidence, and many have ignored the regulations surrounding the use of health testimonials. Of the chiropractor websites we surveyed, fewer than a third of them were free from both testimonials and claims of being able to treat the conditions we checked for.

Although, technically, chiropractors are regulated in New Zealand under the Health Practitioners Competence Assurance Act, our findings indicate that the regulations to ensure chiropractors in New Zealand behave ethically and legally are inadequate. Chiropractors making unsubstantiated claims when advertising their treatments is an established problem. There are regulations in place that should address this issue, but these regulations appear to have not been effective. In our opinion, the Chiropractic Board's hands-off regulation leaves New Zealanders wide open to potentially harmful misinformation.

In the interests of public safety, the New Zealand Chiropractic Board needs to follow the example set recently by the Chiropractic Board of Australia. The board should make a public statement giving clear direction to chiropractors to remove testimonials in their advertising, as well as claims to help any health condition where rigorous evidence of the efficacy of chiropractic treatment is lacking. The board should then follow through with sanctions, up to and including deregistration, for chiropractors who ignore the board's direction.

### Table: Claim Frequencies

<table>
<thead>
<tr>
<th>Claim</th>
<th>Quantity</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>34</td>
<td>25%</td>
</tr>
<tr>
<td>Allergies</td>
<td>48</td>
<td>35%</td>
</tr>
<tr>
<td>Asthma</td>
<td>54</td>
<td>39%</td>
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<tr>
<td>Bed Wetting</td>
<td>43</td>
<td>31%</td>
</tr>
<tr>
<td>Colic</td>
<td>59</td>
<td>43%</td>
</tr>
<tr>
<td>Ear Infections</td>
<td>55</td>
<td>40%</td>
</tr>
<tr>
<td>Any condition</td>
<td>74</td>
<td>54%</td>
</tr>
<tr>
<td>Testimonials</td>
<td>48</td>
<td>35%</td>
</tr>
<tr>
<td>Any condition or testimonials</td>
<td>96</td>
<td>70%</td>
</tr>
<tr>
<td>Total</td>
<td>137</td>
<td>100%</td>
</tr>
</tbody>
</table>

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Could New Zealand’s law on “New Psychoactive Substances” provide lessons for achieving the Smokefree 2025 Goal?

Nick Wilson, Richard Edwards, Janet Hoek, George Thomson, Richard Jaine

In response to the growing use of new psychoactive substances (NPS), including products such as synthetic cannabis, the New Zealand Government passed a law in 2013 to establish a regulated legal market for ‘low-risk’ NPS. The new law attracted significant academic interest, with comments suggesting potential benefits, but also outlining possible limitations. We consider the possible lessons from this novel legislation for limiting supply of another drug: tobacco. In particular, we aimed to consider the relevance of aspects of this new NPS legislation to achieving the New Zealand Government’s Smokefree 2025 Goal.

In August 2015 we reviewed published literature commenting on the Psychoactive Substances Act [PSA] 2013, since its enactment. Our work was informed by previous work some of us have done, including a blog by one of us, a conference presentation, and other work on legal frameworks to advance tobacco control in New Zealand.

We identified several components of the PSA that could be relevant to a new tobacco control law, as outlined in Table 1. We suspect that all these components could promote incremental advances toward the Smokefree 2025 Goal, which from a health burden perspective is far more important than enhanced control of new psychoactive substances. Even so, to increase the chances of achieving the Smokefree 2025 Goal, New Zealand probably requires additional measures, such as regular large tobacco tax increases, a sinking lid on supply, or more comprehensive legal solutions.

Some of the ‘in-field experience’ of the PSA in New Zealand suggests that novel features of this law have had impacts on NPS access and use. For example, as a result of the licensing requirements in the PSA, the “number of NPS retail outlets fell from 3,000–4,000 largely convenience stores to 156 specialty stores, and the number of legally available NPS products fell from 200 to fewer than 46”.

The reduced availability also appears to have reduced some NPS-related harm, as emergency psychiatric services reported fewer incidents associated with synthetic cannabinoids in the months after the PSA was passed.

Nevertheless, the PSA has not yet facilitated a ‘low-risk’ NPS market that can compete with the illegal substances market. This may partly reflect a 2014 amendment to the PSA, which further increased requirements for NPS suppliers (ie, it prohibited use of animal testing to demonstrate a ‘low risk’ of NPS harm). This, along with such other factors as the associated costs to producers of the approval process, may explain why the PSA has not actually approved any products to date (as of February 2016). But from a tobacco control perspective, this is not an issue since the goal is a smokefree New Zealand rather than allowing a market for ‘low-risk’ tobacco products.
**Table 1:** Components of the Psychoactive Substances Act 2013 that may have relevance to advancing tobacco control in New Zealand.

<table>
<thead>
<tr>
<th>Component of the PSA</th>
<th>Possible relevance to tobacco control in New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>New products cannot be introduced to the market unless manufacturers demonstrate to an “Expert Advisory Committee”, that they pose only a low risk of harm to users and to public health.</td>
<td>This component could potentially be used to stop the introduction of any product innovation which was aimed at increasing sales of tobacco products eg, products with new flavours, thin cigarettes, etc. New products continue to appear in the New Zealand market.</td>
</tr>
<tr>
<td>Introducing detailed licencing requirements and comprehensive restrictions on retail supply.</td>
<td>Such restrictions in the PSA include shops not employing people less than 18 years; selling to those under 18 years; no sales in: dairies, convenience stores, grocery stores/supermarkets, petrol stations, temporary structures (eg, tent/marquees) and any place where alcohol is sold. Internet sales are also prohibited. If applied to tobacco, these requirements would help with enforcement of restrictions on sales to youth and reduce their exposure to tobacco products. This component would also allow for outlet restriction over time, which New Zealand modelling work suggests could help lower smoking prevalence. It could even facilitate adoption of the “tobacco-free generation” proposal by allowing licences to be removed from retailers involved in illegal sales to those born after a certain date (eg, the year 2000).</td>
</tr>
<tr>
<td>Requirements around packaging and labelling (including health warnings).</td>
<td>This component of the PSA is consistent with current plans for enhanced controls on standardised packaging for tobacco which are currently before the New Zealand Parliament (as of February 2016). Nevertheless, the proposed legislation could either be modified, or subsequent regulations be developed, to cover further improvements. These could include: (i) adding regulations that explicitly prevent the proliferation of brand variant names or descriptors (a problem that occurred in Australia) and that enhances the appeal of tobacco products; (ii) allowing for unattractive colours and warnings to be required on the actual cigarette sticks (as per New Zealand research); and (iii) requiring improvements to how Quitline information is presented on packs (as per other New Zealand research).</td>
</tr>
</tbody>
</table>

New Zealand's PSA law has features that could potentially be part of new tobacco control legislation to advance the Government's Smokefree 2025 Goal. Particularly promising aspects include components that have the effect of greatly reducing retail supply and restricting the development of new tobacco products.

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LETTER

Zombie pandemic preparedness: a cautionary observation

Frank Houghton, Katie Del Monte, Daniel Glessner, Joyce Goff, Edward Hopkins, Krista Loney, Ghazal Meratnia, Jeremy Toms

The theme of zombies has been utilised as a student engagement tool across a range of disciplines, including international relations, geography, microbiology, physics, and epidemiology. Perhaps most notably, this theme has been adopted to explore mathematical modeling of disease diffusion. The zombie theme has also been used to engage with and educate the public about the danger of re-emerging infectious diseases, like rabies. The popularity of zombies in the entertainment industry offers the hope that using this theme will lead to increased public awareness, as well as interest and engagement in emergency preparedness.

Aware of this potential, the US Centers for Disease Control and Prevention (CDC) responded to widespread apathy towards emergency preparedness by launching a new initiative, Preparedness 101: Zombie Pandemic, in 2011, in an effort to reach younger populations. The initial blog posting, entitled “If you’re ready for a zombie apocalypse, then you’re ready for any emergency,” generated phenomenal interest. The unprecedented level of public interest was demonstrated by the CDC’s original tweet’s strong trending on Twitter and the overflow of traffic to the CDC’s website, which caused it to crash. Not surprisingly, this extraordinary level of interest raised hopes and expectations concerning the engagement of young adults in emergency preparedness. However, current results of research exploring the use of this tactic have been disappointing.

A randomised study of 340 undergraduate students conducted by Kruvand & Bryant, found that the group exposed to the CDC’s zombie blog post were no more likely, and possibly even less likely, to either retain preparedness information or express intent to prepare to develop an emergency kit or plan. The authors conclude that, “trivialization of the preparedness topic may have occurred in the zombie campaign.” A somewhat similar study of students, conducted by Fraustino & Ma, investigated the use of media type and a humorous ‘tongue-in-cheek’ zombie theme compared with a more traditional preparedness message. The authors reported that the zombie-themed group reported significantly weaker intentions to engage in preparedness.

Eastern Washington University’s (EWU) Master of Public Health program at Spokane (Washington State, US) was invited to take part in a Sleep-Over For Science event as part of a federally-funded Area Health Education Centre (AHEC) initiative aimed at attracting rural youth into health science careers. Because the event took place just after Halloween 2015, and because event organisers were familiar with the CDC Zombie preparedness campaign, including its comic novella, posters, and Zombie Disease Detectives activities, the decision was made to incorporate a zombie theme to promote emergency preparedness.

Participants were 4–6 grade elementary school children, aged 9–12 years, with an average age of 10 (SD = 0.9). Thirty-eight percent of the participants were male, and all participants were living in rural areas. Fifty-four responses were collected from a pool of 80 participants, yielding a response rate of 68%. Active parental consent was a precondition of participation. Ethical permission for the study was given by the University’s Institutional Review Board.

Following an activity to demonstrate the potential ease of disease diffusion, participants watched a specially prepared 3-minute video depicting a zombie
outbreak developing into a worldwide pandemic. The room was decorated with posters depicting boarded-up houses and graphics from the CDC Zombie Preparedness website. None of the posters, and no element of the video, featured firearms or weaponry. Participants were then asked to list the required elements of a survival kit. These emergency kit lists were subsequently examined and form the basis of this analysis. Participants were then given a copy of a Federal Emergency Management Agency (FEMA) brochure outlining 11 essential and 20 additional suggested elements of an emergency supply list; a discussion of this supply list followed.

The average number of items listed in each ‘emergency kit’ was 8.2 (SD=3.3), ranging from 3 to 16. Although the majority of kits mentioned food (87%) and water (76%), most other FEMA-suggested items were absent. Not only did the kits lack key elements necessary for a prepared emergency response, alarmingly, 56% (30) of lists clearly included weapons and firearms. Some children were very precise in their choice of firearms, with one respondent stating “Hatchet, AR 15, lots of ammo, M9”, while others simply noted “guns, amo, a lot of weapons” or “gun, knife, extra gun, bullets [sic]”.

Firearm and knife-related injuries and deaths among young people are a major global public health issue, particularly in countries such as the US. The results from this event, given the lack of basic emergency kit items and the explicit focus on weaponry, suggest a note of caution in using a zombie theme to promote emergency preparedness. A potential byproduct of zombie preparedness may be an unanticipated focus on, and glorification of, guns and knives. Further research is required to explore this potential adverse focus in more depth.

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Association between concurrent use of warfarin and common sulfonylureas and series hypoglycaemic events?

In this retrospective cohort analysis, data concerning the concurrent usage of warfarin and glipizide or glimepiride and the incidence of serious hypoglycaemia has been reviewed. The reviewers found that hospital admission or emergency department visits for hypoglycaemia were more common in patients taking warfarin and sulfonylurea than in those on sulfonylurea alone (OR 1.22).

The study involved patients who were 65 years or older. It was noted that that risk was higher in those using warfarin for the first time. The conclusion reached was that these findings suggest the possibility of a significant drug interaction between these medications.

BMJ 2015;351:h6223

Incidence of dementia over three decades in the Framingham Heart Study.

The prevalence of dementia is expected to sore as the average life expectancy increases, but recent estimates suggest that the age-specific incidence of dementia is declining in high-income countries.

Participants in the Framingham Heart Study have been under surveillance for incident dementia since 1975. The study includes information concerning 5,205 persons aged 60 years and older. The incidence of dementia occurring during the four decades since 1975 has been documented. The 5 year cumulative hazard rate for the incidence of dementia has declined from 3.6 per hundred in the 1970s and 1980s to 2 per hundred in the 2000s and 2010s.

The researchers observe that contributing factors for the decline have not been identified. They also point out that the participants were overwhelmingly of European ancestry, so their findings may not necessarily apply to other races and ethnic backgrounds.


Outcomes after thrombus aspiration for ST elevation myocardial infarction

Two large trials have reported contradictory results at 1 year after thrombus aspiration in ST elevation myocardial infarction (STEMI). This report concerns a randomised trial in which patients with a STEMI were treated by thrombectomy follows by percutaneous coronary intervention (PCI) or PCI alone.

Over 5,000 patients were in each group. The primary outcomes sought at 1 year were cardiovascular death, myocardial infraction, cardiogenic shock or heart failure. The primary outcome occurred in 8% of each group, and included 4% cardiovascular deaths in each group. At 1 year, a stroke had occurred in 1.2% of the thrombectomy group, and in 0.7% of the PCI alone group.

The conclusions reached were that routine thrombus aspiration during PCI for STEMI did not reduce long-term clinical outcomes and might be associated with an increase in stroke. Ads a result, thrombus aspiration can no longer be recommended as a routine strategy in STEMI.

Lancet 2016; 387:327-35

URL:
We believe that the relation of the lodge doctors and the friendly societies is felt to be very unsatisfactory throughout the Dominion at the present time. In various places the difficulties have given rise to negotiations between the two interested bodies, in some cases, with partial satisfaction to both sides, more of ten with only slight amelioration of the abuses under which the doctors work, being essentially only a patched-up truce, neither side being content, and in the other cases, of which Wellington is the present chief example, there is open conflict, neither side willing to yield at all.

At the 1914 Conference, in Auckland, a standard agreement was decided upon as a basis for negotiating with the lodges all through New Zealand. It was intended to give notice to the lodges to bring the agreement into force at the beginning of 1915, but this was cancelled, chiefly on account of the outbreak of the war.

However, the conditions of contract lodge service, which before the war had been such as to induce the branch to spend a great part of two successive annual meetings, as well as the current council meetings, and numerous sub-committee meetings, etc., upon the subject, became almost unbearable with the progress of the war and the consequent emphasis of the abuses attendant on contract lodge practice. One by one the different bodies of lodge doctors asked for better terms, until it became so general that the evidence of dissatisfaction throughout our ranks could not be disregarded.

We believe that the fight with the lodges now going on in Wellington is watched with very keen interest by all members who do lodge work throughout the Dominion, and now that the dispute has been referred to the Minister of Public Health, who must find some solution, it behoves us the more strenuously to see that our cause does not suffer.

Briefly, the facts are as follows: The lodge doctors, after intimating their intention to the Division, approached the various lodges as a body and asked for better terms. They drew up an agreement based on the standard agreement of 1914 asking for 24s. instead of 30s., and asked the lodges to adopt it, at the same time handing in their resignations under the old agreement to take effect at the end of the next quarter, then four months off, ie, 31 December 1915. Some of the lodges immediately entered into negotiations amicably and adopted the new agreement in toto, except that till six months after the war the rate per member is 21s. instead of the 24s. asked for. The remainder and larger section of the societies in Wellington refused to accept the new agreement, and would not offer any increase on the 15s. rate of the old agreement. They immediately circularised likely medical men throughout the Dominion seeking applicants on their terms. The lodge doctors then called upon the local Division to declare the Wellington divisional area proscribed according to section (b) of the ethical rules relating to contract practice. Meantime, the resignations took effect, and these lodges were without doctors, the lodge members were treated at their dispensary, and where thought necessary were sent to any doctor they chose, the lodge promising the member to pay his account.

One doctor accepted the friendly societies' appointment and worked at the dispensary for one week and then left. The lodges then approached the Minister of Public Health for relief in their predicament. The Minister asked the members
of the medical profession to meet him to
give their views, which we accented and
were able to correct certain mistakes in the
statement of the societies’ deputation, and
advance arguments and reasons for our
own action. As an outcome, the Minister
asked that he be allowed to convene a
meeting of delegates from both bodies to
try to come to a settlement. At a meeting of
the Division, subsequently held to discuss
what our action should be, it was decided
to adhere to our original demand, and it
remains to be seen whether the conference
will eventuate or what will be the next
move. Meantime, the members of these
lodges are being treated as private patients
and charged ordinary fees, the lodges being
finally responsible for the payment of them.
These are the facts of the case.

It is felt that this is a very critical time in
the history of the medical profession and
the lodges, and that if we fail now we need
never make an attempt again to better the
conditions of contract lodge work. We would
ask that where there is any dispute pending
between doctor and lodge at the present
time no settlement be come to till the result
of the Wellington dispute is settled, unless by
reason of the locality the terms agreed upon
are equally good or better.

If it comes to the worst, and a deadlock
ensues, the whole dispute must become a
branch affair involving all the members
throughout the Dominion, and it will then
be a question whether the original standard
agreement in toto should not be presented
for settlement.

Members of the BMA are warned to
recognise the gravity of the present issue,
and be ready to take their part by showing a
determined loyalty and strong combination,
when we must win without the necessity
of further fighting, remembering that our
aim is to benefit the individual doctor
and the and the profession generally, and
indirectly the lodges and their members by
giving them a better and more satisfied, and
therefore more satisfactory, service.

It is also requested and hoped that
members will keep the General Secretary in
Wellington posted with any facts and data
bearing on this question as obtaining in
their respective areas. He does not promise
to answer or even acknowledge every
communication, but members can be sure
that any facts and data that are useful will
be tabulated and used at the proper time.

P. S. Since the above was written a conference has been held but no agreement in regard to the rate per
member could be arrived at. Each side is consulting its members, but we are confident about the issue.