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Unplanned pregnancies of women with chronic health conditions in New Zealand
Bryndl E Hohmann-Marriott

Unplanned pregnancies can be a health risk for those with chronic health conditions such as diabetes, asthma and depression. In a study of about 7,000 pregnant women in New Zealand, I found that 15% had been diagnosed with a chronic health condition. Nearly half of the pregnancies of these women with chronic health conditions were unplanned. This was higher than the number of unplanned pregnancies among women without chronic health conditions.

Three-month use of idarucizumab at Christchurch Hospital through the emergency department and MedChart™
Louisa J Sowerby, Jane Vella-Brincat

Idarucizumab is a high-cost medicine used to reverse the anticoagulant (anti-clotting) medicine dabigatran. We examined the use of idarucizumab from the emergency department and via the prescribing programme MedChart™. We looked at why it was being used and compared this to the national guidelines from PHARMAC and our own guidelines in Hospital HealthPathways. From 12 patients who received idarucizumab, all but one patient had idarucizumab prescribed for them according to both PHARMAC and local guidelines. The one exception had been a patient who had accumulated dabigatran in their body so there was high risk for the patient to have a bleed that could not be controlled.

Subsequent injuries experienced by Māori: results from a 24-month prospective study in New Zealand
Emma Wyeth, Michelle Lambert, Ari Samaranayaka, Helen Harcombe, Gabrielle Davie, Sarah Derrett

Māori, the indigenous population of New Zealand, experience a disproportionate burden of injury compared to non-Māori. The impact of injury can be exacerbated by subsequent injuries, ie, injuries that occur after, but not necessarily because of, an earlier injury. Using interview, ACC and hospital discharge data, this study aimed to describe subsequent injuries experienced by Māori to determine: the number and timing of subsequent injury claims reported to ACC in the 24 months following an earlier injury; the proportions of Māori experiencing subsequent injuries; and the nature of subsequent injuries. Findings show that 62% of Māori participants who had already experienced a profound injury went on to experience a subsequent injury that reported to ACC within a 24-month period. This suggests that the subsequent injury burden for Māori is considerable, and that preventive opportunities are potentially being missed.
An audit of patients with a diagnosis of idiopathic pulmonary fibrosis (IPF) in Canterbury, New Zealand

James Fulforth, Donna Thomson, Gordon Maxwell, Rachel Wiseman, Adrienne Edwards

Idiopathic pulmonary fibrosis is a condition of unknown cause which results in progressive reduction in lung function causing breathlessness and often resulting in death. Historically, treatments have been ineffective, but newer agents have shown some promise. This paper highlights the estimated number of patients living with this condition and highlights ways in which resources could be better utilised to help them. Hopefully this may result in better overall care for patients living with this condition.

Cost and resource implications of introducing intensive nodal surveillance for sentinel node positive melanoma in provincial New Zealand

Joseph Winstanley, Emma Cervenak, Christopher Harmston

Patients with melanoma skin cancer which has spread to their lymph glands are normally advised to have a further operation to remove these diseased glands. In the future, this will change because the second operation doesn’t make you live any longer. Instead, health boards will need to follow these patients with regular scans and clinic visits. Here we have calculated the financial cost of this change. It looks to be affordable for the average provincial health board in New Zealand.

How much rehabilitation are our patients with stroke receiving?

Stephanie Thompson, Annemarei Ranta, Karen Porter, Naomi Bondi

New Zealand community stroke rehabilitation guidelines identify how often and how soon after hospital discharge community rehabilitation should start. This service audit looked at how quickly after hospital discharge patients with stroke were seen by a Wellington-based community rehabilitation team, and how much rehabilitation they received in the first four weeks and three months after discharge. We compared this to the guidelines and have made suggestions to improve the service.
Point-of-care testing governance in New Zealand through the lens of quality: an update on a national regulatory framework
Samarina MA Musaad, Geoffrey CE Herd

Point of care testing (POCT) is testing outside of the main laboratory, like urine pregnancy testing at home and blood glucose testing at home for people with diabetes. These tests can be done by the patient or by a caregiver. The numerous POCT devices in the market means that without suitable advice and guidance, patients and healthcare workers who are not trained in laboratory medicine are at risk of purchasing devices that are not accurate or would not deliver what is medically (clinically) needed. Guidance should be provided at several levels, including: the government (Ministry of Health and Medsafe in New Zealand) through adequate regulation should provide devices that are safe and that are clinically fit-for-purpose; funders should support government by ensuring that devices they fund are defensible and safe; healthcare providers, eg, pharmacists and doctors, should receive comprehensive training on all aspects of using the device and testing, then ensure that when they provide a device to a patient, the patient has been fully informed about all technical intricacies of testing, what a result means, possible sources of erroneous results and who to contact for help if needed; and finally patients should know their rights, ask questions and take responsibility for their health, devices they use and tests that they undergo. New Zealand is updating its laws that govern medical devices. The Therapeutics Products Bill 2014 was released for consultation by the Minister of Health in December 2018. It is expected that the Bill will ensure that the new laws will be aligned with International Standards but should consider the uniqueness of individual populations, the New Zealand population. The authors propose a vision that is consistent with the aims of the Bill and also supports safe and fit-for-purpose POCT devices and tests are provided in New Zealand.

Doctors’ rights to conscientiously object to refer patients to abortion service providers
Angela Ballantyne, Colin Gavaghan, Jeanne Snelling

Our paper critiques the current legal situation and standards of practice in New Zealand regarding doctors’ rights to refuse to refer patients for abortions and/or refuse to arrange for the patient to be seen by a colleague who will process the referral. Allowing providers to object to direct referrals, when one of their core professional obligations is to navigate patients through the health system, is one thing. But when providers object to making indirect referrals, and thereby fail to ensure the safe transfer of the patient to the care of a colleague, this amounts to abandoning the patient. We consider this ethical issue in the context of proposed abortion law reform in New Zealand.
Older New Zealanders: addressing an emerging population of hazardous drinkers

Andy Towers, John McMenamin, David Newcombe, Janie Sheridan, Gillian White

A recent Lancet article forecasts that, despite a reduction since the 1990s, New Zealand's per capita alcohol consumption is expected to increase over the next decade. This contrasts with predicted declines in Australia and the UK over the same period. A critical question for New Zealanders is 'Who is driving this trend?' Both New Zealand and international data illustrate that those aged under 25 are not driving this trend. While those aged 25 and younger are still the age group with the greatest proportion of hazardous drinkers, there have been well-publicised reductions over the past decade in rates of such drinking in this cohort worldwide (including in New Zealand), and this trend shows no likelihood of stopping soon. Instead, New Zealand's projected increase in alcohol use over the coming decade is likely to be driven by those aged 50 and over.

Alcohol is still the drug of choice for an ageing 'Baby Boomer' cohort. While age-based alcohol legislation targeting youth is common (ie, purchase age restrictions; zero blood alcohol limits for learner drivers), few—if any—policy measures to limit alcohol availability for middle-aged and older adults are evident. Consequently, with the current transition of boomers into ‘older adulthood’ the rate of older drinkers now consuming alcohol at levels hazardous to their health has significantly increased, as has the rate of older adults with alcohol-related disorders and hospitalisations. Yet international evidence shows that addiction services (much like legislation) largely ignore older adults, indicating that our health systems may not be prepared to cope with this demographic shift in alcohol consumption.

New Zealand has seen a year-on-year doubling of addiction service users attending non-government organisations over the past decade. However, regional differences in funding of addiction services mean that we cannot determine the degree to which the rise in addiction service use over this time reflects rising use by a cohort of older hazardous drinkers. Our continued assumption that older adults are low-risk drinkers, our lack of understanding of their need for addiction services, and the potential ageism in this sector underlines why the UK Royal College of Psychiatrists identified older adults as ‘our invisible addicts’.

Rising alcohol use in older adults is concerning for a number of reasons. First, aging increases the risk of alcohol-related harms as we are less capable of processing and diluting ethanol, so each drink is relatively more toxic to an older body. Second, research shows that—contrary to popular belief—there are no health benefits of moderate drinking for older adults specifically. In fact, alcohol use may best be seen as a correlate—not a predictor—of health. Third, many older drinkers also use alcohol-interactive medication for chronic health conditions, so almost 20% of older adults may be at a serious risk of medication-alcohol interaction. In short, older adults are at considerably greater harm from alcohol use than younger drinkers.

In 2015, the New Zealand Health Promotion Agency (HPA) funded a joint team from Massey University’s Health and Ageing Research Team and the University of Auckland Centre for Addiction Research to explore drinking patterns, predictors and harms in older New Zealanders. This
research illustrated that New Zealanders aged 50+ consume alcohol more frequently and in higher quantity than their counterparts worldwide. Furthermore, between 35–40% drink at levels hazardous to their health due to the combination of drinking patterns and comorbidities (eg, chronic health conditions and medications that may interact with alcohol) that raise the risk of harmful outcomes.

In addition to identifying key prevalence and risk factors for older drinkers, this HPA-funded research identified two points relevant for potential intervention with this population. First, many older drinkers at-risk of alcohol-related harm would be missed by standard screens focusing on consumption only. Some of the most at-risk older drinkers in this research actually consumed at low levels, but in combination with chronic health conditions and medications that were all alcohol-interactive. Second, regardless of whether they drank or not, most older adults regularly saw their GP and those at most risk of alcohol-related harms were actually more likely to see their GP because of their comparative ill health. This highlights that primary healthcare services are an essential point of intervention for the wider health system to engage with older drinkers, screen for potential risk and identify a pathway for those in need of help.

Primary care in New Zealand has demonstrated the capacity to routinely ask about patient alcohol use and offer brief advice. A demonstration project implemented in general practices in the Whanganui region in 2010 quickly achieved high rates of coverage with practices recording between 43% and 74% of adults' alcohol use within the first 10 months of the project. This coverage included up to 53% of Māori and 60% of New Zealand European/Pakeha attending practices. Subsequently, this approach—called the Alcohol ABC approach—has been used in a number of New Zealand general practices, most recently in the Counties Manukau District Health Board region where over half of all adults have had their alcohol use recorded in primary care in the last three years.

New Zealand’s primary care sector thus illustrates capacity for alcohol screening, but the current screening approach is not sensitive to the alcohol-related risks faced by a rising population of older drinkers. A three-module HPA-funded pilot project is now underway in Whanganui which is designed to assess a system that may work within the clinical context of long-term conditions management. First, this project integrates alcohol-related risk factors from a screening tool sensitive to older adults within an e-screening process to automatically identify those whose combined drinking, health and medication use place them at risk of harm. Second, this project integrates training in motivational interviewing based on Matua Raki’s Takitaki Mai guide to improve practitioner confidence in initiating and managing alcohol-related conversations with Māori and non-Māori populations. Third, a case study of the development, initiation and outcomes of this pilot project will—if successful—offer a blueprint for other district health boards to support the roll-out of this enhanced alcohol screening and management process for older drinkers.

The nature of alcohol use in New Zealand is changing. Youth, for a long time the focus of our attention, are reducing their consumption. Conversely, older adults, long assumed a population of low-level drinkers, now show a rise both in hazardous drinking and alcohol-related risk. Our health system, particularly primary care, needs to adapt to this change. This requires not only asking older adults about alcohol but understanding the degree to which even low-level consumption patterns raise risk of harm for those with comorbidities. This HPA-funded pilot is a first step in the process. Changing our attitude towards, and understanding of, alcohol use in later life is a culture change that will take a lot longer.
Competing interests:
All authors report grants from Health Promotion Agency during the conduct of the study.

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REFERENCES:
Unplanned pregnancies of women with chronic health conditions in New Zealand
Bryndl E Hohmann-Marriott

ABSTRACT

AIM: Chronic health conditions can pose risks for pregnancy and childbearing which may be mitigated by preconception care and pregnancy planning. The objective of this study is to identify the proportion of pregnancies reported as unplanned among women in New Zealand with chronic health conditions and the co-occurrence of these pregnancies with socioeconomic disadvantage.

METHOD: This study included 6,822 pregnant women in the Growing Up in New Zealand study. Nearly 15% identified a chronic health condition, including diabetes, heart disease, asthma, depression and anxiety.

RESULTS: Pregnancies were reported as unplanned by 45% of women with chronic health conditions, as compared to 39% of women without these conditions. Among women with chronic conditions, those who identified as Māori or Pacific Islander reported two-thirds of their pregnancies as unplanned, and those who were younger, had less education, were lower-income or did not have a co-resident partner reported between 50–80% of their pregnancies as unplanned.

CONCLUSION: Obstetricians and midwives in New Zealand should be prepared to provide care for women with chronic conditions who may have surprise pregnancies. Comprehensive family planning services, preconception care and systemwide reduction in health inequities are needed to help women with chronic health conditions enter pregnancy as healthy as possible.

In New Zealand, as in most low-fertility countries, there has been an increase in the number of pregnant women with chronic health conditions.1,2 This is at least partly due to the rising age at childbearing.3 These conditions increase the risk of adverse events and outcomes during and after pregnancy, including stillbirth, preterm birth, Caesarean delivery, low birth weight or macrosomia, hypertensive and cardiac complications, and postnatal depression.4–7 To address these risks, there is an increasing emphasis on preconception or interconception care for women with chronic health conditions.5,6 These forms of preconception care are predicated on the pregnancy being planned.

Planning pregnancy is often considered to be a necessity for increasing public health. However, this ‘pregnancy planning paradigm’ is problematic as it does not reflect the thoughts, feelings or behaviours of many, perhaps most, women (Aiken et al 2016). In New Zealand, a majority of pregnancies are reported as unplanned,9 suggesting that this is a normal part of life for most women. Although planning may not be necessary for most women, there are some women for whom planning may be beneficial. Planning allows for preconception care, with unplanned pregnancies receiving less preconception and antenatal care.10 For women with chronic conditions, preconception care may be able to decrease their potential elevated risks. Therefore, it will be useful to identify the extent of planning among women who may benefit from it.
The extent of pregnancy planning among women with a chronic health condition in New Zealand is currently unknown. In Europe and the US, women with chronic conditions do not appear to be planning their pregnancies any differently from women without chronic conditions. Women with diabetes, heart disease and hypertension have the same number of unintended pregnancies as women without these conditions. Depression has also been found to be associated with unplanned pregnancies. Most young women with diabetes are not practicing the full extent of recommended pregnancy planning, including reproductive health consultation and use of effective contraception if not intending pregnancy. Women with diabetes and hypertension may not be aware of the risks of pregnancy for women with their condition, and do not consider preconception care a priority. Like other women, women with chronic conditions may not have been using contraception because they believed that they would not become pregnant, did not consider using contraception, or were dissatisfied with their method of contraception. Moreover, their chronic condition could have made it difficult to find an effective contraceptive option. Because pregnancy planning is complex and most studies do not consider the range of women’s experiences, there may be further variations among women.

Ethnicity provides an important context for understanding the place of pregnancy and childbearing in family life. Planning that focuses on behaviour and medical intervention may hold a different meaning among Pākehā (European New Zealand) women than among Māori and Pacific Island women. This diversity in experiences of family life should be celebrated. Less positive, however, is that Māori and Pacific Island women face economic and health disadvantages. The interdependent links between economic disadvantage, chronic health conditions and unplanned pregnancies suggest a potential for exacerbation of health risks.

This is the first New Zealand study to observe unplanned pregnancies among women with chronic health conditions, including diabetes, heart disease, asthma, depression and anxiety. It leverages the unique capabilities of the Growing Up in New Zealand study to identify whether unplanned pregnancies occur among women with chronic health conditions, particularly if there is a co-occurrence of socioeconomic disadvantage, asking:

1. What proportion of pregnancies among women with a chronic health condition is reported as unplanned?
2. For pregnant women with chronic health conditions, which demographic and socioeconomic characteristics co-occur with reporting their pregnancy as unplanned?

Method

Data are from the antenatal wave of the Growing Up in New Zealand (GUiNZ) cohort study, a nationally-representative sample of pregnant women due to give birth in 2008/2009. Analysis uses the first interview, conducted during the last half of pregnancy. Chronic health conditions are identified by responses to a question asking the woman if she had an illness diagnosed by a doctor; these are coded as chronic if the respondent replied ‘before this pregnancy and during this pregnancy’. Illnesses include diabetes, heart disease or high blood pressure, asthma, depression and anxiety or panic attacks. Planning is identified by responses to a question asking the woman if she had an illness diagnosed by a doctor; these are coded as chronic if the respondent replied ‘before this pregnancy and during this pregnancy’. Illnesses include diabetes, heart disease or high blood pressure, asthma, depression and anxiety or panic attacks. Planning is identified by responses to a question asking the woman if she had an illness diagnosed by a doctor; these are coded as chronic if the respondent replied ‘before this pregnancy and during this pregnancy’. Illnesses include diabetes, heart disease or high blood pressure, asthma, depression and anxiety or panic attacks. Planning is identified by responses to a question asking the woman if she had an illness diagnosed by a doctor; these are coded as chronic if the respondent replied ‘before this pregnancy and during this pregnancy’. Illnesses include diabetes, heart disease or high blood pressure, asthma, depression and anxiety or panic attacks. Planning is identified by responses to a question asking the woman if she had an illness diagnosed by a doctor; these are coded as chronic if the respondent replied ‘before this pregnancy and during this pregnancy’. Illnesses include diabetes, heart disease or high blood pressure, asthma, depression and anxiety or panic attacks. Planning is identified by responses to a question asking the woman if she had an illness diagnosed by a doctor; these are coded as chronic if the respondent replied ‘before this pregnancy and during this pregnancy’. Illnesses include diabetes, heart disease or high blood pressure, asthma, depression and anxiety or panic attacks.

Question 1 is answered using chi-square tests comparing the proportion of women reporting planned and unplanned pregnancies for the total sample, within each chronic health condition, and for multimorbidity.

Question 2 focuses on women with chronic conditions, and uses chi-square tests to compare the proportion of women reporting planned and unplanned pregnancies by sociodemographic characteristics. Correlation analyses (not shown) confirm that all characteristics are highly correlated with one another. The analysis of individual characteristics must thus be mindful that each of these characteristics is closely tied with all others.
Results

Over 15% of the sample had at least one chronic health condition, as shown in the first column of Table 1. The most frequently occurring condition was asthma, reported by over 7% of the women, and the least frequent was diabetes, reported by less than 1% of the women. Just over 2% of all women reported multimorbidity (more than one condition), and of these 162 women, 81% were diagnosed with depression, 64% with anxiety, 43% with asthma, 21% with heart disease and 11% with diabetes. The presence of these conditions among pregnant women differed by ethnicity, with significant differences observed for all conditions except heart disease. For asthma, depression and multimorbidity, there were similar proportions of Māori and Pākehā women with the conditions, but a lower proportion among Pacific Island women and the lowest proportion for Asian women. Compared to Pākehā, all other groups showed elevated rates of diabetes and lower rates of diagnosed anxiety.

Among all women, 39.6% reported their pregnancies as unplanned. Compared to this overall proportion, a higher percentage (from 43% to nearly half) of women with chronic health conditions reported their pregnancies as unplanned (second column of Table 1). Pregnant women who had been diagnosed with depression or asthma reported a significantly higher proportion of unplanned pregnancies than women without these conditions. Women with diabetes also had an elevated proportion with unplanned pregnancies, but due to the small number of women with this condition in the sample, the difference approached but did not reach conventional levels of significance. When the 15% of women with any of the conditions are considered as a group, they report 44.4% of their pregnancies as unplanned. With this large group of women with a higher proportion of unplanned pregnancies considered separately, women without any of the conditions show a smaller proportion with unplanned pregnancies (38.7%).

Characteristics associated with unplanned pregnancies for women with chronic conditions are shown in Table 2. Unplanned pregnancies were reported by women across all characteristics. Even at their lowest proportions, unplanned pregnancies represented one-fifth to one-third of substantial groups of women (ie, women with tertiary education, women aged 30–39). The highest proportions of unplanned pregnancies were reported by nearly 80% of women with incomes less than $30,000, three-quarters of young women, nearly three-quarters of women with no coresident partner, two-thirds of women identifying as Māori or Pacific Islander, and over half of women with less than a tertiary degree. Parity and migrant status were not associated with unplanned pregnancy.

<table>
<thead>
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<th>% Unplanned</th>
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<th>Women without condition</th>
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<tr>
<td>Asthma</td>
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<td>43.6</td>
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<td>Depression</td>
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<td>39.2</td>
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<td>Anxiety</td>
<td>2.6</td>
<td>42.5</td>
<td>39.5</td>
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<tr>
<td>Heart disease</td>
<td>1.4</td>
<td>39.4</td>
<td>39.6</td>
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<tr>
<td>Diabetes</td>
<td>0.9</td>
<td>47.5</td>
<td>39.5</td>
</tr>
<tr>
<td>Multimorbidity</td>
<td>2.3</td>
<td>45.7</td>
<td>39.4</td>
</tr>
<tr>
<td>Any</td>
<td>15.1</td>
<td>44.4</td>
<td>38.7</td>
</tr>
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Note: 6,822 pregnant women in the total sample of the first wave of GUiNZ. Chi-square tests examined the difference between planned and unplanned pregnancies for each condition.

†p<.1 *p<.05 **p<.01 ***p<.001.
Table 2: Socioeconomic characteristics of women with chronic conditions and pregnancies reported as unplanned.

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<th>% of pregnancies reported as unplanned</th>
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<td>Ethnic identification</td>
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<td>25–29</td>
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<tr>
<td>No coresident partner</td>
<td>20.1</td>
<td>74.4</td>
</tr>
</tbody>
</table>

Note: Data are from the first wave of GUiNZ, and include 1,030 pregnant women reporting a chronic health condition (asthma, heart disease, diabetes, depression and/or anxiety). Chi-square tests examined the difference between planned and unplanned pregnancies for each characteristic. ***p<.001.
As the characteristics are interrelated, these findings can best be understood by viewing them as a whole and recognising that unplanned pregnancies are a widespread experience across all characteristics, but are reported most frequently by women experiencing socioeconomic disadvantage.

Discussion

Unplanned pregnancies are reported by about half of all pregnant women with chronic health conditions in New Zealand. This was a higher proportion than among women without health conditions: Women with any chronic health conditions reported 45% of their pregnancies as unplanned, compared to 39% of women without health conditions. The proportion of unplanned pregnancies was particularly high among women with diagnosed depression (49%) and asthma (44%). Among women who identified as Māori or Pacific Islander and who had a chronic health condition, about two-thirds of pregnancies were reported as unplanned. For women with chronic conditions, the proportion of unplanned pregnancies was considerably higher among women whose characteristics indicate socioeconomic disadvantage. In particular, among pregnant women with chronic health conditions who were low-income, young, did not have a coresident partner and had less education, from half to nearly 80% of pregnancies were reported as unplanned.

Given the prevalence of each condition in the sample, the year 2008 in New Zealand would have seen an estimated 2,200 unplanned pregnancies of women with asthma, over 1,300 of women with depression, nearly 700 of women with anxiety, nearly 500 of women with heart disease/hypertension and nearly 400 of women with diabetes. This is a substantial number of women with unplanned pregnancies and chronic conditions who are at an elevated risk of not receiving preconception and antenatal care, and thus a higher chance of experiencing adverse events in their pregnancies. This risk can be mitigated by health practitioners, particularly midwives and obstetricians who are prepared to provide care to women with chronic health conditions whose pregnancies are a surprise.

The strength of this study is its population-based sample, which allows for the comparison of pregnant women with and without a range of chronic health conditions. The accompanying weakness is that the conditions are broadly grouped, obscuring the exact diagnosis. These are self-reported diagnoses, leaving open the possibility that the analysis missed women with diagnosed conditions who did not report them, as well as women with undiagnosed conditions. The results should therefore be interpreted as a conservative estimate. There are also only a very small number of women with diabetes in the sample. Given the suggestion of disproportionate numbers of unplanned pregnancies along with the serious consequences of a lack of preconception care for women with diabetes, further research focusing on women with Type I and Type II diabetes is warranted.

An additional limitation of this study is that it only includes women who are already pregnant. This means that it is not possible to identify the rate of pregnancy among women with chronic conditions. That calculation requires population-level data, and will be the target of future research. The dichotomous measure of planning used in this survey does not reflect the full range of women’s experiences. A more comprehensive approach to measuring pregnancy planning and perspectives is necessary, and should be considered for future surveys. Future studies could also examine the prospective childbearing intentions and contraceptive use of women with chronic health conditions, to illuminate the extent to which pregnancies are being planned and prevented.

Both chronic illness and unplanned pregnancy are more prevalent and pose greater risks in the presence of socioeconomic disadvantage. Together, they create a high-risk situation that is rarely considered. Current guidelines focus on preconception care, which advises and/or assumes planning pregnancies, as a key part of managing pregnancy with chronic conditions. Women with a chronic health condition are already engaged with the healthcare system, offering an enhanced opportunity for professionals to support them across their reproductive lifecourse.

Health professionals caring for women with
chronic conditions should ask all women about their childbearing intentions and provide them with a range of contraceptive options and preconception care.

Assistance with individual planning offers one option, but a more effective strategy takes a broader approach by improving the health of the entire population.8,22 This will only be possible if New Zealand’s stark health inequities, in particular those faced by Māori and Pacific Islanders, are addressed. The high rate of unplanned pregnancies among women with chronic health conditions adds urgency to the necessity of addressing the pregnancy and reproductive health of all women by improving access to healthcare and by ensuring a healthy environment for everyone.

REFERENCES:


Three-month use of idarucizumab at Christchurch Hospital through the emergency department and MedChart™

Louisa J Sowerby, Jane Vella-Brincat

ABSTRACT

AIMS: To examine idarucizumab use via the emergency department (ED), Christchurch Hospital; adherence to Hospital Medicines List (HML) criteria, licensed dosing and local coagulation monitoring guidelines.

METHODS: All patients given idarucizumab were recorded over three months. Data collected included demographics, coagulation tests, dabigatran dosing and timing of idarucizumab administration.

RESULTS: Twelve patients received idarucizumab. The median age (range) was 73 (56–83) years and male:female was 4:8. HML criteria were met in 11 patients. Eleven patients had idarucizumab administered within licence. Coagulation tests were taken pre-idarucizumab in all patients and post-idarucizumab in eight patients. The median thrombin clotting times pre- and post-idarucizumab were 153 and 16 seconds respectively.

CONCLUSION: The indications for idarucizumab use were within HML criteria and administration was as per licensed dosing regimen in 11 of 12 patients. Appropriate monitoring of coagulation parameters was carried out in all patients as per local guidelines prior to idarucizumab administration, and thrombin clotting times pre and post were as expected for all but one patient.

Idarucizumab is a monoclonal antibody fragment that acts as a reversal agent to the direct thrombin inhibitor dabigatran. It specifically binds protein bound and unbound dabigatran and its active metabolites to form complexes, thus stopping dabigatran’s anticoagulant effects. It irreversibly binds to dabigatran and has a rapid onset and slow offset. Idarucizumab binds dabigatran with an affinity 350 times stronger than dabigatran binds thrombin. While a 2g IV dose has been shown to be capable of reversing dabigatran in healthy subjects given 220mg orally twice a day of dabigatran, a 5g dose is used.1 Idarucizumab was first registered in New Zealand in December 2015. It was included in PHARMAC’s Hospital Medicines List (HML) in June 2016 for the reversal of the anticoagulant effects of dabigatran when required in situations of life-threatening or uncontrolled bleeding, or for emergency surgery or urgent procedures. It is licensed to be given as two consecutive doses of 2.5g, the second dose within 15 minutes of finishing the first dose.2 Each 5g dose of idarucizumab has a PHARMAC listed cost of $4,250.

Aims

1. To examine the use of idarucizumab via the emergency department at Christchurch Hospital
2. To examine adherence to PHARMAC’s HML, licensed dosing regimens and Canterbury District Health Board local guidelines (Canterbury Hospital HealthPathways)
Methods

All patients given idarucizumab via the emergency department were recorded prospectively during September to December 2017 on a data collection form situated next to the idarucizumab supply in the emergency department. This was completed by the nurse retrieving the idarucizumab and included the date and the NHI of the patient. Further data was collected from the paper medicine chart, the electronic patient management system Health Connect South, the electronic prescribing and administration system MedChart™ and the electronic dispensing system ePharmacy™. Data collected included demographics, idarucizumab dosing and timing, coagulation tests, dabigatran dosing and renal function. These were analysed using Microsoft Excel™.

Results

Twelve patients were identified as having received idarucizumab; nine patients had stock obtained from ED while three patients had idarucizumab dispensed by the hospital pharmacy. The median age (range) was 73 (56–83) years and the M:F ratio was 4:8.

Idarucizumab was given to six patients for a life-threatening bleed (upper gastrointestinal bleed, rectal bleed, intracranial haemorrhage); to five patients before urgent surgery or procedure and once outside HML criteria to a patient with a high risk of bleeding due to poor dabigatran clearance from an acute kidney injury (AKI).

For the six patients considered to have a life-threatening bleed, five had a haemoglobin reduction of >20g/L. The one patient with a <20g/L haemoglobin decrease presented with intracranial haemorrhage.

Ten patients received idarucizumab as a 5g stat dose or as two 2.5g doses within 15 minutes of each other as recommended. Two patients received two 2.5g doses with an interval longer than 15 minutes.

All 12 patients had coagulation tests taken prior to idarucizumab administration. In 11 of these the coagulation tests thrombin clotting time (TT) and activated partial thromboplastin time (APTT) were consistent with being on dabigatran. The one patient with normal TT and APTT who received idarucizumab was to have alteplase thrombolysis pre-clot retrieval. Eight patients had coagulation tests done 12 hours post-idarucizumab administration and in seven patients these were within normal limits. The median thrombin clotting times pre-and post-idarucizumab were 153 and 16 seconds respectively post-idarucizumab. TT and APTT were above normal limits at 12 hours in one patient possibly due to rebound dabigatran effect in the setting of AKI (this patient’s coagulation tests were within normal limits immediately after idarucizumab administration).

Of the five patients who received idarucizumab prior to surgery or a procedure, two patients had coagulation tests measured at 15 minutes post-administration, which showed full dabigatran reversal.

The dabigatran dosing regimens for all 12 patients is shown in Table 2. The date and time of the last dose of dabigatran was available for only two patients. One had their last dabigatran dose 25 hours prior to

<table>
<thead>
<tr>
<th>PHARMAC HML criteria</th>
<th>Canterbury Hospital HealthPathways</th>
<th>Medsafe Datasheet – Idarucizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>For the reversal of the anticoagulant effects of dabigatran when required in situations of life-threatening or uncontrolled bleeding, or for emergency surgery or urgent procedures.</td>
<td>In addition to the HML criteria, coagulation screen including INR, APTT and thrombin clotting time should be done prior to administration unless the delay would be significantly detrimental. The coagulation results are used to determine if there is evidence of dabigatran effect.</td>
<td>Dose of idarucizumab is 5g intravenously, administered as two consecutive injections of 2.5g within 15 minutes of each other.</td>
</tr>
</tbody>
</table>
idarucizumab. The other had their last dose of dabigatran 8–9 days prior, however an AKI prevented dabigatran clearance.

Atrial fibrillation was the indication for dabigatran in all but one patient who was anticoagulated to treat a deep vein thrombosis.

**Discussion**

Our findings suggest idarucizumab is prescribed to reverse dabigatran in most instances for serious, life-threatening bleeds or pre urgent surgery/procedures, in accordance with licensed indication and PHARMAC HML funding criteria. One of our patients fell outside of these indications—accumulation of dabigatran in a patient with an AKI.

In a case report for a patient with high plasma concentrations of dabigatran as a result of an intentional overdose, although no active bleeding was present the decision was made to administer idarucizumab on the basis of increased bleeding risk. Fifteen hours after idarucizumab administration, TT showed a slight rebound but without any bleeding.3

A review by Levy et al suggests adding “high risk of recurrent bleeding associated with high dabigatran body load from either overdose or reduced clearance” as a further indication.4

PHARMAC have not further defined the meaning of urgent surgery/procedures or life-threatening bleeds. Local guidelines define life-threatening bleeding as bleeding with a reduction in haemoglobin of 20g/L or more, or requiring red blood cell transfusion of two units or more; or involving a critical area or organ, eg, intracranial, intraspinal, pericardial.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Idarucizumab indication</th>
<th>Dabigatran dose and frequency</th>
<th>Dabigatran indication</th>
<th>Serum creatinine on admission (micromol/L)</th>
<th>Calculated creatinine clearance (mL/min)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>73</td>
<td>Dabigatran accumulation (acute kidney injury)</td>
<td>110mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>698</td>
<td>6</td>
</tr>
<tr>
<td>56</td>
<td>Thrombolysis and clot retrieval</td>
<td>110mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>80</td>
<td>51</td>
</tr>
<tr>
<td>63</td>
<td>bleed</td>
<td>75mg every 24 hours</td>
<td>atrial fibrillation</td>
<td>527</td>
<td>13</td>
</tr>
<tr>
<td>80</td>
<td>bleed</td>
<td>110mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>106</td>
<td>57**</td>
</tr>
<tr>
<td>67</td>
<td>bleed</td>
<td>110mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>104</td>
<td>64</td>
</tr>
<tr>
<td>78</td>
<td>bleed</td>
<td>110mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>99</td>
<td>54</td>
</tr>
<tr>
<td>83</td>
<td>bleed</td>
<td>110mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>98</td>
<td>31</td>
</tr>
<tr>
<td>69</td>
<td>bleed</td>
<td>150mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>70</td>
<td>52</td>
</tr>
<tr>
<td>73</td>
<td>surgery</td>
<td>110mg every 12 hours</td>
<td>deep vein thrombosis</td>
<td>85</td>
<td>55</td>
</tr>
<tr>
<td>83</td>
<td>surgery</td>
<td>75mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>94</td>
<td>36</td>
</tr>
<tr>
<td>70</td>
<td>surgery</td>
<td>150mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>77</td>
<td>31</td>
</tr>
<tr>
<td>74</td>
<td>surgery</td>
<td>110mg every 12 hours</td>
<td>atrial fibrillation</td>
<td>132</td>
<td>38</td>
</tr>
</tbody>
</table>

*Cockcroft and Gault adapted **eGFR as not all information available to calculate CrCl.
Thrombolysis is contraindicated by the manufacturer in patients receiving effective anticoagulation as the combination might theoretically increase the risk of bleeding. This has not been well studied in direct oral anticoagulants (DOACs) and the precaution is extrapolated from warfarin and subsequent haemorrhage post thrombolysis.\textsuperscript{5,6} It has been suggested that a dabigatran concentration of <10 micrograms/L (or corresponding thrombin time) would be reasonable for thrombolysis; with further study that threshold may increase.\textsuperscript{6}

Xian et al observed no significant difference in bleeding outcomes between patients who were thrombolysed following an ischaemic stroke and patients on warfarin with INR <1.7, DOACs, or no anticoagulants. However, compliance, coagulation results and time of prior DOAC administration were not recorded.\textsuperscript{7}

Evidence around administration of idarucizumab prior to thrombolysis is limited to case-series. Outcomes from these studies have indicated dabigatran reversal prior to thrombolysis is likely to be safe and effective shown by patient improvement via the National Institutes of Health Stroke Scale (NIHSS) and the modified Rankin Scal (mRS).\textsuperscript{8,9}

Although 5g stat is the recommended idarucizumab dose, the way it was prescribed and administered varied. The licensed dosing regimen for idarucizumab is two 2.5g consecutive injections. The New Zealand Formulary prescribing guidelines have since changed to 5g stat, with separate administration instructions.

All patients had coagulation testing prior to idarucizumab administration as per local guidelines which show whether or not an anticoagulant effect from dabigatran is present, as shown particularly by raised TT and often raised APTT.

The date and time of the last dabigatran dose was not obtained in many of the patients so an investigation would require confirmation of patient compliance. The collection of such data may not have been possible in situations where the patient is unable to communicate, such as aphasia in acute ischaemic stroke, prior to idarucizumab administration.

The demographic in this audit tended to be older adults. The reason behind this is likely that both older people are more likely to have a bleeding event and AF increases in prevalence with advancing age. The majority of patients in this cohort were taking dabigatran for thromboprophylaxis in AF.

In our cohort, idarucizumab use appears to be within HML and licensed indications. Extension of indications into idarucizumab overdose and dabigatran low clearance patients might be useful. Appropriate monitoring of coagulation parameters was carried out in all patients prior to idarucizumab administration and thrombin clotting times pre and post were as expected for all but one patient. Dabigatran dosing at the time of idarucizumab administration was variable in relation to manufacturer’s guidelines. Further investigation may be needed to influence future guidance for dose-adjustment to prevent serious bleeding.
Competing interests:
Nil.

Acknowledgements:
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REFERENCES:

Subsequent injuries experienced by Māori: results from a 24-month prospective study in New Zealand

Emma Wyeth, Michelle Lambert, Ari Samaranayaka, Helen Harcombe, Gabrielle Davie, Sarah Derrett

ABSTRACT

AIM: Māori, the indigenous population of New Zealand, experience a disproportionate burden of injury compared to non-Māori. Injury burden can be exacerbated by subsequent injuries (injuries that occur after, but not necessarily because of, an earlier or ‘sentinel’ injury). Despite obligations under New Zealand’s Treaty of Waitangi, it appears no published studies have investigated subsequent injuries among Māori. This study aims to describe subsequent injuries experienced by Māori and reported to New Zealand’s no-fault injury Accident Compensation Corporation (ACC), and determine: the number and timing of subsequent injury (SI) claims reported to ACC in 24 months following a sentinel injury; the proportions experiencing ≥1 SI; and the nature of SIs.

METHODS: The Subsequent Injury Study analysed interview, ACC and hospital discharge data. SIs were classified as injury events involving an ACC claim within 24 months of a sentinel injury.

RESULTS: Of 566 participants, 349 (62%) experienced ≥1 SI in the 24 months post-sentinel injury. Those with moderate/high alcohol use, or cognitive difficulties, before the sentinel injury were more likely to experience SIs. Fewer SIs occurred between 0–3 months after a sentinel injury compared to later periods. Spine dislocations/sprains/strains were the most common SI type.

CONCLUSIONS: Despite their descriptive nature, our findings point to both the complexity of SI and the need for a greater research, ACC and health service focus on SI if the burden of injury for Māori is to be truly addressed. That 62% of Māori who had already experienced a profound sentinel injury went on to experience ≥1 SIs reported to ACC within a 24-month period suggests that the burden is considerable, and that preventive opportunities are being missed. Additional analyses are now underway to investigate factors predicting SI, while accounting for potential confounders, in order to assist in the development of SI prevention initiatives for Māori at multiple points in the complex post-injury pathway.

INJURY is the leading cause of disability worldwide. Post-injury burden can be further exacerbated by subsequent injuries (i.e., injuries that occur after, but not necessarily because of, an earlier ‘sentinel’ injury). Subsequent injuries may also be more detrimental, both financially and physically than a sentinel injury. Therefore, investigating and developing injury prevention interventions and initiatives aimed at preventing subsequent injuries provides a specific avenue for reducing the overall injury burden. Despite this, there is limited knowledge of the pathways and predictors of subsequent injuries among general ‘all injury’ populations. An extensive search failed to uncover specific literature relating to subsequent injuries for Māori or other indigenous populations. However, one US study found differences in repeat trauma admissions according to ethnicity.
Recent studies have highlighted that Māori, the indigenous population of New Zealand, experience a disproportionate burden of injury compared to non-Māori,\textsuperscript{1,3,7,8} and the health-related loss due to injury for Māori is at least twice that for non-Māori.\textsuperscript{7} Our previous research has found that Māori experience poorer outcomes, at both three and 12 months post-injury compared with non-Māori.\textsuperscript{9,10} Additionally, Māori who have been hospitalised for injury have a 70% increased risk of disability 24 months post-injury compared with non-Māori.\textsuperscript{1}

New Zealand researchers and healthcare workers have particular responsibilities and requirements to address health inequities for Māori.\textsuperscript{12} These are outlined in a number of key documents, including legislation such as the Public Health and Disability Act 2000.\textsuperscript{13,14} Our injury outcomes research is underpinned by such responsibilities.\textsuperscript{12,15}

The current study aims to increase our understanding of subsequent injuries, specifically for Māori, in order to identify key characteristics and potential for future interventions to improve Māori post-injury pathways.\textsuperscript{3} Injured Māori were recruited following an Accident Compensation Corporation (ACC; New Zealand’s no fault injury insurer) entitlement claim; a type of claim for injuries likely to require income compensation for more than a week off work or other additional rehabilitation such as home-help.\textsuperscript{16}

Methods

This paper uses data from the Subsequent Injury Study (SINs),\textsuperscript{3,8,17} which combined data from three sources: 1) Interview data from the Prospective Outcomes of Injury Study (POIS),\textsuperscript{12,15,18,19} a study of 2,856 injured New Zealanders (including 566 Māori), 2) administrative data from ACC for SI claims in the 24 months following each participant’s sentinel injury, and 3) hospital discharge data from the National Minimum Dataset (NMDS) for those who were hospitalised. Participants aged between 18 and 64 years were recruited following a sentinel injury event involving an ACC entitlement claim between 2007 and 2009. People who experienced injuries as a result of self-harm or sexual assault were not recruited, however SI claims of this nature were included in our analyses. Ethical approval was obtained from the New Zealand Health and Disability Multi-Region Ethics Committee (MEC/07/07/093).

The analyses presented here use data collected from the 566 Māori POIS participants, 20% of the cohort.\textsuperscript{18} During the first interview, all participants were asked to report their ethnicity using the New Zealand Census question, which allows participants to self-identify with more than one ethnic group.\textsuperscript{20} Those who identified Māori as one of their ethnic groups were included in the Māori cohort.

Information about a variety of pre-injury, injury-related and post-injury factors was collected during interviews held, on average, three, 12 and 24 months post-injury.\textsuperscript{18,21–23} Age, sex and occupation were collected from participants at the first interview using questions from the New Zealand Census.\textsuperscript{20} Participants were asked if they were in paid employment at the time of their sentinel injury, and if so they were asked about the nature of their main job, classified as professional, technical, trade/manual or unclassifiable.\textsuperscript{24} Participants were asked about their adequacy of household income (classified as ‘adequate’ if participants reported having ‘enough’ or ‘more than enough’ household income to meet every day needs and ‘inadequate’ if they reported ‘not enough’ or ‘just enough’).\textsuperscript{26} Additionally, participants were asked whether the sentinel injury was unintentional or intentional (ie, assault), was work-related, and if they perceived their sentinel injury to be a threat to life or long-term disability at time of injury.\textsuperscript{17,21,27} Information was collected about pre-injury depressive-type episodes (using two screening questions from the Diagnostic and Statistical Manual of Mental Disorders-III),\textsuperscript{23,28} disability (using the World Health Organization Disability Assessment Schedule II; WHODAS),\textsuperscript{29} health-related quality of life (using the EQ-5D),\textsuperscript{29,30} and
alcohol use (using the brief Alcohol Use Disorders Identification Test; AUDIT-C) where participants were grouped as ‘no or low’ (males AUDIT-C score 0–4; females 0–3), ‘moderate’ (males 5–7; females 4–6) or ‘high’ (males 8–12; females 7–12).21,29–31

Information about the nature, body region and severity of sentinel injuries and SIs were derived from ACC injury diagnosis codes.21 In these analyses, 12 injury type variables, derived from the most common sentinel injury nature and body region groupings, have been used for both sentinel injuries and SIs. Participants could have had more than one injury type resulting from each injury event (both sentinel and subsequent) and could also have more than one SI event. New Injury Severity Scores (NISS) derived to measure the severity of an injury event were categorised as 1–3 (least severe), 4–6 and >6 (most severe).32,33 Hospitalisation for sentinel injuries and SIs was determined using probabilistic data linkage to the NMDS of hospital discharges,34 with participants classified as being hospitalised if they had been admitted to hospital or treated at an emergency department for ≥3 hours within seven days of the injury event.21

Sentinel injuries were all entitlement claims, however, SI events could be of any ACC claim type; categorised as ‘entitlement claims’, ‘medical fees only claims’ (whereby participants received treatment from a health professional but no additional rehabilitation support),4 ‘other claims’ (eg, those involving additional assessments), and ‘unclassified’ (those claims without a specified type, eg, where district health board bulk funding was associated).35,36 Statistical analyses are descriptive, as per the aims of this paper, and were carried out using Stata® version 14.2.36

Results

Of the 566 Māori participants, 238 (42%) had at least one SI in the 12 months after their sentinel injury event, and by 24 months, 349 (62%) had at least one SI. The mean age of those who did not have an SI in the 24-month period was 40.0 years (standard deviation (SD) 11.9) compared to 38.2 years (SD 12.7) for those who had at least one SI.

Table 1 presents pre-sentinel injury socio-demographic and health characteristics of Māori participants according to whether or not they had at least one ACC SI claim in the 24 months after their sentinel injury. In the 24-month period, those with lowest proportions of SI were: females compared to males (58% versus 63%); those in professional occupations compared to other occupations (57% versus 61–76%); and those living with family compared to those living alone or with non-family (60% versus 68% and 72%). However, there was insufficient evidence to conclude that any of these observed differences were statistically significant. Those experiencing cognitive problems prior to their sentinel injury were more likely to have a SI compared to those reporting no cognitive problems (82% versus 60%). Those reporting moderate or high alcohol use pre-sentinel injury were also more likely to have a SI compared to those reporting no or low alcohol use (69% and 62% compared to 56%, respectively).

Those who had a sentinel injury event involving a lower extremity fracture were less likely to have a SI (44% versus 65%); as were those who had a sentinel injury event involving a lower extremity open wound (45% versus 63%) (Table 2). Participants hospitalised for their sentinel injury were also less likely to have a SI (55% versus 64%). Those whose sentinel injuries were categorised as ‘other’ were less likely to have a SI (49% versus 65%), however this category includes a mixture of different and less common injury types.

Of the 566 participants, 349 (62%) experienced at least one SI in the 24-month period after their sentinel injury; 27% (n=152) experienced one SI event, 18% (n=103) experienced two SI, and 8% (n=47) experienced three or more SI. The total number of SI events was 755 with a range of 0 to 14 SI events per person. Four percent of the SI events resulted in hospitalisation. Overall, 12% of the SI were entitlement claims, 77% were medical fees only claims, and 11% were other or unclassified claims.
Table 1: Pre-sentinel injury sociodemographic and health characteristics of Māori participants according to ACC-reported subsequent injury (SI) status in the 24 months after sentinel injury.

<table>
<thead>
<tr>
<th>Variable</th>
<th>No SI (N=217)</th>
<th>SI (N=349)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>136 (37)</td>
<td>235 (63)</td>
<td>0.3</td>
</tr>
<tr>
<td>Female</td>
<td>81 (42)</td>
<td>114 (58)</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional</td>
<td>55 (43)</td>
<td>74 (57)</td>
<td></td>
</tr>
<tr>
<td>Technical</td>
<td>43 (36)</td>
<td>74 (63)</td>
<td></td>
</tr>
<tr>
<td>Trade/manual</td>
<td>98 (49)</td>
<td>156 (61)</td>
<td></td>
</tr>
<tr>
<td>Unclassifiable workers</td>
<td>5 (24)</td>
<td>16 (76)</td>
<td></td>
</tr>
<tr>
<td>Non-workers</td>
<td>16 (36)</td>
<td>29 (64)</td>
<td>0.5</td>
</tr>
<tr>
<td>Household income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>189 (38)</td>
<td>307 (62)</td>
<td></td>
</tr>
<tr>
<td>Not adequate</td>
<td>26 (39)</td>
<td>40 (61)</td>
<td>0.8</td>
</tr>
<tr>
<td>Living arrangements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>13 (33)</td>
<td>27 (68)</td>
<td></td>
</tr>
<tr>
<td>With non-family</td>
<td>13 (28)</td>
<td>34 (72)</td>
<td></td>
</tr>
<tr>
<td>With family</td>
<td>189 (40)</td>
<td>284 (60)</td>
<td>0.2</td>
</tr>
<tr>
<td>General health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>201 (39)</td>
<td>318 (61)</td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>14 (31)</td>
<td>31 (69)</td>
<td>0.3</td>
</tr>
<tr>
<td>EQ-5D mobility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No problems</td>
<td>206 (39)</td>
<td>323 (61)</td>
<td></td>
</tr>
<tr>
<td>Problems</td>
<td>11 (30)</td>
<td>26 (70)</td>
<td>0.3</td>
</tr>
<tr>
<td>EQ-5D self-care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No problems</td>
<td>214 (39)</td>
<td>340 (61)</td>
<td></td>
</tr>
<tr>
<td>Problems</td>
<td>3 (25)</td>
<td>9 (75)</td>
<td>0.3</td>
</tr>
<tr>
<td>EQ-5D usual activities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No problems</td>
<td>205 (39)</td>
<td>327 (61)</td>
<td></td>
</tr>
<tr>
<td>Problems</td>
<td>12 (35)</td>
<td>22 (65)</td>
<td>0.7</td>
</tr>
<tr>
<td>EQ-5D pain/discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No problems</td>
<td>197 (39)</td>
<td>307 (61)</td>
<td></td>
</tr>
<tr>
<td>Problems</td>
<td>20 (33)</td>
<td>41 (67)</td>
<td>0.3</td>
</tr>
<tr>
<td>EQ-5D anxiety/depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No problems</td>
<td>202 (39)</td>
<td>321 (61)</td>
<td></td>
</tr>
<tr>
<td>Problems</td>
<td>15 (36)</td>
<td>27 (64)</td>
<td>0.7</td>
</tr>
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</table>
Table 1: Pre-sentinel injury sociodemographic and health characteristics of Māori participants according to ACC-reported subsequent injury (SI) status in the 24 months after sentinel injury (continued).

<table>
<thead>
<tr>
<th></th>
<th>No problems</th>
<th>Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EQ-SD cognition</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No problems</td>
<td>211 (40)</td>
<td>320 (60)</td>
</tr>
<tr>
<td>Problems</td>
<td>6 (18)</td>
<td>28 (82)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td><strong>Depressive-type episodes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>157 (38)</td>
<td>261 (62)</td>
</tr>
<tr>
<td>Yes</td>
<td>56 (39)</td>
<td>86 (61)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Social relationships</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td>203 (38)</td>
<td>326 (62)</td>
</tr>
<tr>
<td>Not satisfied</td>
<td>12 (34)</td>
<td>23 (66)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.6</td>
</tr>
<tr>
<td><strong>Chronic conditions</strong></td>
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<td></td>
</tr>
<tr>
<td>0</td>
<td>110 (39)</td>
<td>171 (61)</td>
</tr>
<tr>
<td>1</td>
<td>53 (36)</td>
<td>96 (64)</td>
</tr>
<tr>
<td>≥2</td>
<td>47 (39)</td>
<td>75 (61)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td><strong>Disability (WHODAS)</strong></td>
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<td></td>
</tr>
<tr>
<td>0–9</td>
<td>202 (39)</td>
<td>317 (61)</td>
</tr>
<tr>
<td>≥10</td>
<td>15 (34)</td>
<td>29 (66)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Physical activity</strong></td>
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<td></td>
</tr>
<tr>
<td>&lt;5 days a week</td>
<td>88 (38)</td>
<td>143 (62)</td>
</tr>
<tr>
<td>≥5 days a week</td>
<td>123 (38)</td>
<td>199 (62)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30 kg/m²</td>
<td>123 (39)</td>
<td>194 (61)</td>
</tr>
<tr>
<td>≥30 kg/m²</td>
<td>76 (36)</td>
<td>137 (64)</td>
</tr>
<tr>
<td>Undisclosed</td>
<td>18 (50)</td>
<td>18 (50)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.3</td>
</tr>
<tr>
<td><strong>Alcohol use</strong></td>
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</tr>
<tr>
<td>No or low</td>
<td>85 (44)</td>
<td>108 (56)</td>
</tr>
<tr>
<td>Moderate</td>
<td>56 (31)</td>
<td>123 (69)</td>
</tr>
<tr>
<td>High</td>
<td>72 (38)</td>
<td>117 (62)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Smoking</strong></td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>119 (38)</td>
<td>194 (62)</td>
</tr>
<tr>
<td>Yes</td>
<td>97 (38)</td>
<td>155 (62)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Recreational drug use</strong></td>
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</tr>
<tr>
<td>No</td>
<td>154 (39)</td>
<td>246 (62)</td>
</tr>
<tr>
<td>Yes</td>
<td>62 (38)</td>
<td>103 (62)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.8</td>
</tr>
</tbody>
</table>

*P-values obtained from chi-squared tests; tests exclude those with missing data.
Notes: Some percentages sum to more than 100, due to rounding. Results presented are descriptive only and have therefore not been adjusted for any potential confounding factors.
Table 2: Sentinel injury-related characteristics of Māori participants according to ACC-reported subsequent injury (SI) status.

<table>
<thead>
<tr>
<th>Variable</th>
<th>No SI (N=217)</th>
<th>SI (N=349)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td><strong>Type of injury</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head/neck intracranial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>213 (39)</td>
<td>336 (61)</td>
<td>0.2</td>
</tr>
<tr>
<td>Yes</td>
<td>4 (24)</td>
<td>13 (76)</td>
<td></td>
</tr>
<tr>
<td>Head/neck superficial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>208 (38)</td>
<td>340 (62)</td>
<td>0.3</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (50)</td>
<td>9 (50)</td>
<td></td>
</tr>
<tr>
<td>Spine dislocation/sprain/strain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>185 (39)</td>
<td>288 (61)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32 (34)</td>
<td>61 (66)</td>
<td>0.4</td>
</tr>
<tr>
<td>Upper extremity fracture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>192 (40)</td>
<td>294 (60)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25 (31)</td>
<td>55 (69)</td>
<td>0.2</td>
</tr>
<tr>
<td>Upper extremity dislocation/sprain/strain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>192 (39.0)</td>
<td>300 (61)</td>
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</tr>
<tr>
<td>Yes</td>
<td>25 (33.8)</td>
<td>49 (66)</td>
<td>0.4</td>
</tr>
<tr>
<td>Upper extremity open wound</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>208 (39)</td>
<td>322 (61)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9 (25)</td>
<td>27 (75)</td>
<td>0.09</td>
</tr>
<tr>
<td>Upper extremity superficial</td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>204 (38)</td>
<td>326 (62)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13 (36)</td>
<td>23 (64)</td>
<td>0.8</td>
</tr>
<tr>
<td>Lower extremity fracture</td>
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<tr>
<td>No</td>
<td>168 (35)</td>
<td>310 (65)</td>
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<tr>
<td>Yes</td>
<td>49 (56)</td>
<td>39 (44)</td>
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<tr>
<td>Lower extremity dislocation/sprain/strain</td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>162 (38)</td>
<td>262 (62)</td>
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<tr>
<td>Yes</td>
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<td>87 (61)</td>
<td>0.9</td>
</tr>
<tr>
<td>Lower extremity open wound</td>
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</tr>
<tr>
<td>No</td>
<td>199 (37.3)</td>
<td>334 (63)</td>
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</tr>
<tr>
<td>Yes</td>
<td>18 (55)</td>
<td>15 (45)</td>
<td>0.05</td>
</tr>
<tr>
<td>Lower extremity superficial</td>
<td></td>
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</tr>
<tr>
<td>No</td>
<td>204 (38)</td>
<td>328 (62)</td>
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</tr>
<tr>
<td>Yes</td>
<td>13 (38)</td>
<td>21 (61.8)</td>
<td>1.0</td>
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Table 2: Sentinel injury-related characteristics of Māori participants according to ACC-reported subsequent injury (SI) status (continued).

<table>
<thead>
<tr>
<th>Other body regions/nature</th>
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</tr>
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<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>165</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>Injury severity (NISS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3 (least severe)</td>
<td>164</td>
<td>84</td>
<td></td>
</tr>
<tr>
<td>4–6</td>
<td>143</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td>&gt;6 (most severe)</td>
<td>31</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalised</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>265</td>
<td>148</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>84</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td>Injury cause</td>
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<tr>
<td>Unintentional</td>
<td>328</td>
<td>203</td>
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</tr>
<tr>
<td>Intentional (assault)</td>
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<td>12</td>
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</tr>
<tr>
<td>Self-perceived threat to life</td>
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<td></td>
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<tr>
<td>No</td>
<td>291</td>
<td>178</td>
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<tr>
<td>Yes</td>
<td>51</td>
<td>35</td>
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<tr>
<td>Self-perceived threat of long-term disability</td>
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<tr>
<td>No</td>
<td>185</td>
<td>116</td>
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</tr>
<tr>
<td>Yes</td>
<td>160</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>Work-related injury</td>
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<tr>
<td>No</td>
<td>227</td>
<td>142</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>120</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Access to healthcare services</td>
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</tr>
<tr>
<td>No trouble</td>
<td>317</td>
<td>195</td>
<td></td>
</tr>
<tr>
<td>Trouble/mixed</td>
<td>31</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

*P-values obtained from chi-squared tests; tests exclude those with missing data.
**Twelve separate variables. Participants could have more than one type of injury in a given injury event.
Notes: Some percentages sum to more than 100, due to rounding. Results presented are descriptive only and have therefore not been adjusted for any potential confounding factors.

The distribution of SI increased between each of the first three three-month periods (ie, from 0–3 months to 3–6 months and from 3–6 months to 6–9 months after the sentinel injury; p<0.001). After which, the frequency of SI remained relatively stable, except for 12–15 months after the sentinel injury where the distribution of SI was very similar to the 6–9-month period and for 21–24 months where the distribution was more similar to the 3–6-month period (Figure 1).

Table 3 presents information about the types of SI sustained by participants in the 24 months post-sentinel injury. The 755 SI events resulted in 962 injuries, since multiple injuries were possible from one event. Spine dislocations/sprains/strains were the most common SI type (23%), followed by lower extremity dislocations/sprains/strains (18%). Participants could also have multiple SI events of the same injury type during the 24-month period.
Table 3: Frequency of ACC-reported subsequent injury (SI) in the 24 months following the sentinel injury event by the type of injury for Māori participants.

<table>
<thead>
<tr>
<th>Type of injury</th>
<th>Number of SI of this type of injury</th>
<th>Number of SI events with this type of injury</th>
<th>Number of participants with this type of SI</th>
<th>Claims per person with this type of SI†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intracranial</td>
<td>N (1)</td>
<td>N (1)</td>
<td>N (2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Head/neck superficial</td>
<td>19 (2)</td>
<td>18 (2)</td>
<td>17 (5)</td>
<td>1.06</td>
</tr>
<tr>
<td>Spine dislocation/sprain/strain</td>
<td>220 (23)</td>
<td>184 (22)</td>
<td>119 (34)</td>
<td>1.55</td>
</tr>
<tr>
<td>Upper extremity fracture</td>
<td>24 (2)</td>
<td>23 (3)</td>
<td>22 (6)</td>
<td>1.05</td>
</tr>
<tr>
<td>Upper extremity dislocation/sprain/strain</td>
<td>142 (15)</td>
<td>129 (16)</td>
<td>95 (27)</td>
<td>1.36</td>
</tr>
<tr>
<td>Upper extremity open wound</td>
<td>63 (7)</td>
<td>58 (7)</td>
<td>53 (15)</td>
<td>1.09</td>
</tr>
<tr>
<td>Upper extremity superficial</td>
<td>14 (1)</td>
<td>12 (1)</td>
<td>12 (3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Lower extremity fracture</td>
<td>12 (1)</td>
<td>12 (1)</td>
<td>12 (3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Lower extremity dislocation/sprain/strain</td>
<td>169 (18)</td>
<td>155 (18)</td>
<td>114 (33)</td>
<td>1.36</td>
</tr>
<tr>
<td>Lower extremity open wound</td>
<td>24 (2)</td>
<td>24 (3)</td>
<td>24 (7)</td>
<td>1.00</td>
</tr>
<tr>
<td>Lower extremity superficial</td>
<td>4 (0.4)</td>
<td>4 (0)</td>
<td>3 (1)</td>
<td>1.33</td>
</tr>
<tr>
<td>Other</td>
<td>265 (28)</td>
<td>217 (26)</td>
<td>164 (47)</td>
<td>1.32</td>
</tr>
<tr>
<td>Total</td>
<td>962*</td>
<td>755**</td>
<td>349***</td>
<td></td>
</tr>
</tbody>
</table>

*Each SI event could involve more than one type of injury.
**Column total sums to 842 because each SI event could involve more than one injury diagnosis of the same injury type in a single injury event (eg, an ankle dislocation and a knee sprain would be classified as two lower extremity dislocations/sprains/strains).
***This is the total number of participants who had at least one SI. Participants could have more than one SI event and each event could involve more than one type of injury. Therefore, the total percentages exceed 100%.
†Claims per person for a particular injury type is the total number of claims with that type of injury divided by the number of claimants with that type of injury.
For example, 155 SI events involved lower extremity dislocations/sprains/strains, yet these were experienced by only 114 people showing that some participants had multiple lower extremity dislocations/sprains/strains during this period (Table 3). Spine dislocations/sprains/strains had the highest number of claims per person (1.55) during the 24 months followed by both upper and lower extremity dislocations/sprains/strains (each with 1.36 claims per person) (Table 3).

Discussion

A considerable proportion of injured Māori had at least one SI event in the 12- and 24-month periods after their sentinel injury event (42% and 62%, respectively). We found that those who reported moderate or high alcohol use, or who were experiencing cognitive difficulties prior to their sentinel injury, were more likely to have an SI in the 24 months following a sentinel injury. High use of alcohol is a strong risk factor of injuries both worldwide and in New Zealand, so finding it to be associated with SI is not unsurprising. Cognitive impairment or difficulties can affect physical performance or function. A systematic review and meta-analysis showed that those who had experienced a sports-related concussion were at increased odds of sustaining a later musculoskeletal injury compared to those who had not sustained a concussion. The authors of that review pose that physical effects of concussion are often resolved more readily than other more persistent effects such as cognitive and behavioural changes, therefore those concussed require additional attention to reduce the risk of subsequent musculoskeletal injuries.

Those with a lower extremity fracture or lower extremity open wound sentinel injury were less likely to have an SI in the following 24 months, as were those who were hospitalised for their sentinel injury. These findings align with our previous non-Māori-specific work investigating self-reported subsequent injuries. It seems plausible that those with a lower extremity injury, or hospitalised, might be less mobile than others after such a sentinel injury and might be less able to participate in their usual activities, therefore reducing their likelihood of SIs.

The timing of SI events for Māori participants in the 24 months after a sentinel injury is similar to our observation for the entire SInS cohort (ie, a lower frequency of SI was observed in the first three months after a sentinel injury, this then increased for 3–6 months and then again for 6–9 months after a sentinel injury). These variations may be due to a number of reasons, for example in the earlier periods after a sentinel injury, people may not be fully participating in their everyday activities and are therefore at less risk of SI. Alternatively, people might be more careful or aware of SI after their ‘entitlement claim’ sentinel injury, which warranted additional rehabilitation and support beyond medical fees only, or may have received injury prevention information or advice at the time of their sentinel injury. One Canadian study investigating subsequent injuries found that the majority of such injuries among a cohort of performing artists occurred between 2–12 months after someone’s ‘return to full participation’ (measured either by a performance after their injury or the last medical treatment for their initial injury). Another study investigating the timing of subsequent injuries after being hospitalised for injury found that the highest rate ratio of subsequent injuries was 6–12 months after the sentinel injury. However, this study only examined the first subsequent injury experienced by participants, and only injuries that resulted in further hospitalisation or death.

A strength of our study is that it addresses a topic about which very little is known, especially for Māori, a significant population group that experiences significant injury burden and injury outcome inequities. Our study contributes to the limited body of knowledge in this important area by describing subsequent injuries over a 24-month period for a cohort of injured Māori who have previously accessed ACC for an entitlement claim. Additional strengths include that our study is of injured Māori who have experienced a range of different types of injuries, who were both hospitalised and not hospitalised for injury and both work-related and non-work-related.
injuries. Limitations of our study include the descriptive nature of the analyses presented, however, this is a very complex area and so a detailed understanding of the proportions, frequencies, numbers, time periods and nature of SI is required before examining predictive factors and potential confounders, which was beyond the scope of this paper. Other limitations include that the ‘sentinel’ injury for which participants were recruited is unlikely to be their ‘first ever’ injury. Despite this, the focus our study is to examine SIs after an ACC entitlement claim injury, not to capture participants’ first ever ACC entitlement claim. While our cohort is relatively small, it appears to be the largest research cohort of injured Māori who have sustained a range of injury types, causes and severities, and importantly we have been able to use ACC information about SI claims and not rely on participants’ self-report information for these.

In this study we have analysed SIs from a cohort of Māori who had already accessed ACC for their sentinel injury. It is a limitation that we have not been able to investigate SIs for those who did not access ACC for injury. Like other health services in New Zealand, Māori experience barriers to accessing ACC. Importantly though, our findings show that there are differences in pre-sentinel and sentinel injury characteristics for Māori who experienced a SI. This highlights the importance of understanding SIs for Māori, particularly as those who do access ACC present a potential point for future interventions.

We have described the proportions, frequencies, nature and time periods of subsequent injuries for Māori. Despite their descriptive nature, our findings point to both the complexity of SI among an ‘all injury’ Māori cohort, and to the need for a greater research, ACC and health service focus on SI if the burden of injury for Māori is truly to be addressed. That 62% of Māori who had already experienced a profound sentinel injury went on to experience at least one SI reported to ACC within a period of only 24 months suggests both that the burden is considerable and that preventive opportunities are being missed. Additional analyses are currently underway by our team to investigate factors predicting SI, while accounting for potential confounders, in order to assist in the development of SI preventive initiatives at multiple points in the complex post-injury pathway specifically for injured Māori.
Competing interests:
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An audit of patients with a diagnosis of idiopathic pulmonary fibrosis (IPF) in Canterbury, New Zealand

James Fulforth, Donna Thomson, Gordon Maxwell, Rachel Wiseman, Adrienne Edwards

ABSTRACT

AIM: In light of new therapies and guidelines for the management of idiopathic pulmonary fibrosis (IPF), and in the absence of local epidemiological data, we sought to ascertain a current estimate of the prevalence of IPF in Canterbury and to audit local practices.

METHODS: We performed a retrospective observational study of patients with IPF in Canterbury, New Zealand and the wider region. Patients were identified through a systematic search of hospital records and included if they were alive on 1 January 2017, had a histological or radiological diagnosis of usual interstitial pneumonia and clinical correlation consistent with a diagnosis of IPF. Clinical data was extracted from the clinical record. Follow up was complete until April 2018.

RESULTS: Sixty-eight patients were included, median follow up 33 (14–49) months. Fifteen (22.1%) patients died during follow up, median survival 19 (6.5–54) months. Estimated prevalence of IPF was 6.53/100,000 persons. Six (8.8%) patients were discussed at the Interstitial lung disease multi-disciplinary meeting. Resting SpO2 and end-of-life discussions were documented in 44 (64.7%) and 19 (27.9%) patients respectively, while oxygen therapy was prescribed to 15 (22.7%). 20/36 (55.5%) patients eligible for pirfenidone were treated. Those treated were more likely to have undergone a six-minute walk test (5/20 vs 3/48, p<0.05) or have been hospitalised in the last 12 months (12/20 vs 3/48, p<0.05). 7/20 patients remained on treatment at the end of follow-up (eight discontinued, five deceased).

CONCLUSION: In this study the estimated prevalence of IPF in the Canterbury region is 6.53/100,000 persons. Furthermore, we have identified limitations in local practice relevant for service development.

 idiopathic pulmonary fibrosis (IPF) is an incurable progressive lung disease characterised by cough and exertional dyspnoea. Although disease course varies, the majority develop progressive respiratory failure, culminating in death within five years of diagnosis unless lung transplantation is possible.1 Worldwide prevalence is estimated to be between 1.25 and 63 per 100,000, depending on the population studied and definition of IPF,2 while incidence appears to be increasing globally.3 At present the epidemiology of IPF in New Zealand is unknown. In Canterbury, outpatient IPF diagnoses are not coded, making us reliant on inpatient coding which underestimates the true impact of disease.

Although there is no cure for IPF, the anti-fibrotic medications pirfenidone and nintedanib have been shown to reduce the decline in forced vital capacity (FVC) in patients with IPF in phase III trials.4,5 Data has since emerged about their effectiveness in real-world IPF patients, including from the Australian IPF registry.4 In New Zealand, pirfenidone has been available since January 2017 under a special authority scheme for patients with a diagnosis of IPF and FVC between 50 and 80% predicted, while nintedanib only became funded in October 2018. However, at present there is no IPF registry or outpatient coding allowing us to capture data on their efficacy.
In addition to anti-fibrotic therapies, supportive and non-pharmacological care maintains a central role in the management of this condition. Pulmonary rehabilitation is beneficial in terms of six-minute walk test (6MWT) and health-related quality of life in patients with IPF. Domiciliary oxygen therapy benefits patients with IPF, and its use is recommended where appropriate. The role of palliative care is under-recognised but is crucial given the unremitting symptoms of this disease which significantly impacts on quality of life.

Recently published position papers from the Thoracic Society of Australia and New Zealand highlight the importance of making an accurate diagnosis of IPF in the context of an interstitial lung disease (ILD) multidisciplinary meeting (MDM) with the aim of optimising the holistic care of patients with IPF. In response to this, Canterbury District Health Board (DHB) instituted a dedicated monthly ILD MDM in 2017, with the ability to accept referrals both locally and from the surrounding regions. One year on from the institution of the MDM, and the availability of pirfenidone in New Zealand, the aims of this study were therefore; to establish an estimate of the prevalence of IPF in the Canterbury and neighbouring regions; to assess current practice with respect to the aforementioned position statements; and to review the early experience with pirfenidone in our community.

Methods

We performed a retrospective observational study of patients with idiopathic pulmonary fibrosis managed in secondary or tertiary care across the four Northern district health boards (DHB) in New Zealand's South Island: Canterbury DHB, South Canterbury DHB, West Coast DHB and Nelson and Marlborough DHB. Patients were identified through keyword searches for “usual interstitial pneumonia” (UIP), “idiopathic pulmonary fibrosis” and “cryptogenic fibrosing alveolitis” in radiology reports and clinical communications stored in the electronic record, through ICD-10 coding of discharge summaries over the last 10 years up to April 2018 and from a database of patients discussed in the ILD MDM. Private providers in Canterbury were also invited to provide patients for inclusion in the study.

In order to capture all patients who had been treated with pirfenidone, those who were alive on 1 January 2017 then underwent manual review of the case notes and were included if they had a radiological or histological finding of definite UIP and documented clinical correlation consistent with a diagnosis of IPF. Patients with a radiological finding of possible UIP were included without lung biopsy, provided the treating clinician felt the clinical picture was one of IPF. Follow up was complete until April 2018 or the time of death. The prevalent cohort included those alive in April 2018 and prevalence was estimated using the Ministry of Health projected populations for the regions studied.

Clinical, physiological and demographic data were collected using a pre-formatted spreadsheet. Physiological data collected included forced vital capacity (FVC) and where available; diffusion capacity (DLCO), six-minute walk test (6MWT) and oxygen saturation (SpO2). This included the most recent measurements and, in those treated with pirfenidone, measurements immediately prior to commencing treatment. Clinical data collected included diagnostic investigations (radiology and histology), MDM discussion; the presence of complications including hospitalisation and death; documentation of end-of-life discussion or advance care plans (ACP); and prescriptions for pirfenidone and domiciliary oxygen therapy. Palliative care, nurse specialist and pulmonary rehabilitation referrals were collected for those patients in the Canterbury DHB region only.

Descriptive data is presented as n (%), mean (standard deviation) or median (interquartile range). Comparative statistics were performed using students t test for continuous data and Fisher’s Exact test for categorical data. Results were considered significant with a p value <0.05.

As a retrospective audit, this study was exempted from ethical review by the New Zealand Health and Disability Ethics Committee. Approval for this study was granted by the Canterbury DHB Clinical Audit Department.
Results

Three hundred and forty-nine records were reviewed and 68 patients who met the inclusion criteria were identified. Fifty (73.5%) were male and the median age was 80 years (72–84). Seven (10.3%) patients were of non-European descent (three (4.4%) New Zealand Māori, four (5.9%) Asian, 52 (76.5%) New Zealand European, nine (13.2%) other European). Median follow-up was 33 months (14–49). Fifteen (22.1%) patients died during follow-up, therefore 53 patients made up the prevalent cohort in April 2018, providing an estimated prevalence of IPF of 6.53 cases/100,000 persons.

All patients underwent high-resolution computed tomography as the initial investigation of choice. Sixty-five patients had radiological features consistent with UIP (63 definite, two possible) and required no further investigation. One patient underwent a non-diagnostic transbronchial biopsy and proceeded to surgical lung biopsy. Two further patients underwent surgical lung biopsy to establish the diagnosis of IPF. One patient had an incidental finding of UIP in a lobectomy sample following surgery for non-small cell lung cancer. Overall, six (8.8%) patients from this cohort had an FVC above the treatment threshold of 80% predicted. In total 20 (29.4%) patients were prescribed pirfenidone between 1 January 2017 and the end of follow-up, 18 of whom met the special authority criteria and two who were treated outside of this guidance with an FVC <50% predicted. Patients prescribed pirfenidone were no more likely to have been discussed in the ILD MDM (2/20 vs 4/48, p>0.05) than those not prescribed pirfenidone, but were more likely to have undergone a 6MWT (5/20 vs 3/48, p<0.05) or to have been hospitalised in the last 12 months (12/20 vs 11/48, p<0.05) (Table 1).

Seven patients were still taking pirfenidone at the end of follow-up. Among those who discontinued therapy, five died during follow-up and eight (40%) discontinued therapy due to side effects. No patients had discontinued therapy due to progressive disease at the end of follow-up.

Eighteen patients eligible for pirfenidone were not prescribed treatment. Reasons for this were documented in the clinical record in nine cases and included active decisions not to treat due to ‘stable/slowly progressive disease’ (n=4), ‘comorbidity’ (n=1), ‘patient decision’ (n=1), and ‘treatment decision still under consideration’ (n=3).

Fifteen (22.1%) patients died during follow-up with a median survival of 19 months (6.5–54). These patients had significantly lower FVC (2.16L vs 2.64L, p<0.05) than those who survived. They were also more likely to have undergone a 6MWT (5/20 vs 3/48, p<0.05) or to have been hospitalised in the last 12 months (9/6 vs 14/53, p<0.05). Among patients in the Canterbury DHB region (n=53), 10 (18.9%) had been referred to a respiratory nurse specialist, 10 (18.9%) for pulmonary rehabilitation and nine (16.9%) to palliative care services respectively. Five patients in this region died without a referral to palliative care services.
Discussion

In this study we have estimated the prevalence of IPF in secondary and tertiary care centres across Northern regions of the South Island of New Zealand to be 6.53/100,000. This is comparable with worldwide prevalence rates of between 1.25 and 63/100,000. Our estimate is at the lower end of this range, and may reflect the fact that patients were only captured if they had come into contact with a physician in a secondary or tertiary centre, thereby underestimating the true prevalence of IPF in the community. Nevertheless, the population captured is likely to have included the majority of symptomatic or severely affected patients and therefore this estimate remains relevant for the planning of hospital-based services.

Guidelines recommend discussion of all new cases of IPF in an ILD MDM to confirm the diagnosis. In our study only 8% of patients had been discussed in such a forum. No doubt this reflects the fact that an ILD MDM has only been available at Christchurch Hospital since 2017, though even among patients diagnosed since its inception, the rate is only 30%. The lack of uptake likely reflects capacity issues, as the ILD MDM was only held monthly initially and triage priority given to new or complex ILD cases. However, four patients were given a new diagnosis of IPF on the recommendation of the MDM, in keeping with international literature whereby changes in diagnosis and management have been shown to occur in >50% of ILD cases discussed in such a forum. Improving the capacity and uptake of this service should therefore be considered a priority, particularly as multidisciplinary discussion is a requirement for funded pirfenidone therapy in New Zealand.

In this study 25% of patients prescribed pirfenidone died during follow-up. Among those surviving, less than half achieved long-term adherence. The majority reported gastrointestinal intolerance although

Table 1: Demographics and clinical characteristics of patients who were prescribed, and were not prescribed pirfenidone during the follow-up period.

<table>
<thead>
<tr>
<th></th>
<th>Prescribed pirfenidone</th>
<th>Not prescribed pirfenidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=20</td>
<td>N=48</td>
<td></td>
</tr>
<tr>
<td>Age (years) (median, IQR)</td>
<td>79 (69.8–80.3)</td>
<td>82 (73.8–85.3)</td>
</tr>
<tr>
<td>Male (n, %)</td>
<td>16 (80)</td>
<td>34 (70.8)</td>
</tr>
<tr>
<td>FVC (L) (mean, SD)</td>
<td>2.20 (0.44)</td>
<td>2.67 (0.91) *</td>
</tr>
<tr>
<td>FVC (% Predicted) (mean, SD)</td>
<td>65.8 (10.9)</td>
<td>76.7 (24.2)</td>
</tr>
<tr>
<td>FVC &gt;50% and &lt;80% predicted (ie, eligible for treatment) (n, %)</td>
<td>18 (90)</td>
<td>18 (37.5) *</td>
</tr>
<tr>
<td>ILD MDM discussion (n, %)</td>
<td>2 (10)</td>
<td>4 (8.3)</td>
</tr>
<tr>
<td>6MWT undertaken (n, %)</td>
<td>5 (25)</td>
<td>3 (6.3) *</td>
</tr>
<tr>
<td>Resting SpO₂ documented (n, %)</td>
<td>11 (55)</td>
<td>33 (68.8)</td>
</tr>
<tr>
<td>Domiciliary O₂, discussed (n, %)</td>
<td>4 (20)</td>
<td>11 (22.9)</td>
</tr>
<tr>
<td>Prescribed (n, %)</td>
<td>6 (30)</td>
<td>7 (14.6)</td>
</tr>
<tr>
<td>End-of-life discussion or ACP documented (n, %)</td>
<td>8 (40)</td>
<td>11 (22.9)</td>
</tr>
<tr>
<td>Hospital Admission in last 12 months (n, %)</td>
<td>12 (60)</td>
<td>11 (22.9) *</td>
</tr>
<tr>
<td>Died during follow up (n, %)</td>
<td>5 (25)</td>
<td>10 (20.8)</td>
</tr>
<tr>
<td>Discontinued therapy (n, %)</td>
<td>8 (40)</td>
<td></td>
</tr>
</tbody>
</table>

* p<0.05
reasons for discontinuation were not always documented. This is in contrast to real world experience of pirfenidone elsewhere in which discontinuation rates due to adverse events are reported as between 16 and 20%. In these studies, dose adjustment was associated with improved adherence, and elsewhere dedicated close follow-up, patient support and education has been of benefit. Currently no specific protocol for treatment initiation exists in our institution, but this may be an option, incorporating the above factors, that needs to be explored to improve adherence. Alternatively, the poor tolerance may reflect the age of our patients, who had a median age of almost 10 years greater than those described elsewhere.

The provision of supportive care and end-of-life planning are important considerations in what remains a terminal condition. Fifteen (22.7%) patients in this study were prescribed either ambulatory or long-term oxygen therapy, which is comparable to data from the British Thoracic Society IPF Registry in which 26% of patients were prescribed oxygen. However, documentation of oxygen saturations was only complete in 64.7% of patients, and exertional testing was infrequent, so it is possible that patients who may benefit from this therapy are not being identified in the clinic. Meanwhile, documentation of end-of-life planning was complete in just 27.9% of patients.

It is reassuring to see that patients who died were more likely to have been prescribed oxygen and to have had end-of-life care plans made, but the overall proportion of patients receiving these interventions was low, as it was for those referred to specialist nursing services and palliative care in the Canterbury DHB region. Our rate of palliative care referrals are similar to those (13.7%) identified in one large retrospective cohort, but this would appear to be inadequate for a disease process with high mortality and symptom burden. In fact, data from the Swedish Registry of Palliative Care would suggest that patients with ILD receive poorer access to end-of-life care than patients with lung cancer. There is clearly an unmet need in this area, and it may be the case that use of a decision support tool to prompt end-of-life discussions could improve documentation of these issues and referral for appropriate supportive services where indicated.

Limitations of this study include the retrospective nature of data collection and case identification. These may have introduced a risk of ascertainment bias, or an underestimate of disease prevalence respectively. Furthermore, data on referrals to palliative care, pulmonary rehabilitation and specialist nursing was not available outside Canterbury DHB.

To our knowledge this is the first study to estimate the prevalence of IPF in New Zealand and is an important step forward in planning for the future in a disease in which worldwide incidence is increasing, therapeutic options are widening and pathways of care are becoming increasingly complex, yet standardised. Furthermore we have been able to identify limitations in current practice locally, in terms of the uptake of MDM discussion, physiological measurements and supportive care, along with high discontinuation rates of therapy. Improvements in these areas may be beneficial for patients but will also have impacts in terms of the resources required to achieve this.
Competing interests:
Nil.

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Cost and resource implications of introducing intensive nodal surveillance for sentinel node positive melanoma in provincial New Zealand

Joseph Winstanley, Emma Cervenak, Christopher Harmston

ABSTRACT

AIMS: Two randomised trials have shown that immediate completion lymphadenectomy for sentinel node positive melanoma provides no long-term survival benefit; compared with a follow up regime of intensive nodal surveillance. The aim of this study was to assess the cost and resource implications of introducing this regime for patients with sentinel node positive melanoma in a provincial New Zealand hospital.

METHODS: Patients with cutaneous melanoma presenting to Northland District Health Board between 1 January 2012 and 31 December 2014 were identified. The financial and resource burden of standard treatment was assessed, including operative, outpatient and imaging interventions. Theoretical financial and resource costs of intensive nodal observation for a theoretically equivalent cohort were calculated.

RESULTS: The cost of standard treatment was $7,147 per patient and the theoretical cost of nodal observation was $5,300 per patient. Standard treatment required more operating theatre time and inpatient treatment. Nodal observation required more outpatient appointments and imaging.

CONCLUSIONS: The cost of nodal observation was lower than standard treatment than in our study. There is a shift in resource requirements from operating theatre and inpatient care to outpatient appointment and imaging. The overall resource impact is low and introduction of nodal observation appears achievable.

New Zealand has the highest age-standardised incidence of melanoma in the world, with 2,567 new cases diagnosed in 2016. The treatment of melanoma also consumes significant healthcare resources, with the annual healthcare cost estimated to be upwards of 5.7 million dollars.

Nodal tumour burden is an important prognostic marker in patients with melanoma, and can direct adjuvant treatment. Traditionally, sentinel lymph node biopsy (SLNB) is recommended for patients with primary cutaneous melanoma with a Breslow thickness exceeding 1.0mm. In patients with thin melanomas (less than 1.0mm) with ulceration or high risk features, a discussion regarding the benefits of SLNB is recommended. Until recently, most patients in New Zealand with a positive sentinel node would be counselled to undergo immediate completion lymphadenectomy.

Two recent randomised trials have challenged this traditional approach to SLNB management. The MSLT-II and De-COG SLT trials randomised patients with a sentinel node positive melanoma to immediate completion lymphadenectomy; or intensive clinical follow-up and delayed dissection for clinically detected recurrence. Both trials showed no improvement in overall disease-free survival in the immediate completion lymphadenectomy group.
This has already led the Melanoma Multi-disciplinary group in New Zealand to recommend intensive nodal observation for certain patients with a positive SLNB. In the nodal observation arm of the MSLT-2 study, patients were monitored with clinical examination and nodal ultrasound every four months for the first two years and every six months during years 3 to 5 of follow-up.

The cost and resource implications of this change in management are not well understood, and there has been no study in Australasia assessing this. It is likely that intensive nodal observation will become standard practice and it is essential that clinicians and managers anticipate this. The aim of this study is to assess the cost and resource implications of introducing intensive nodal observation for patients with cutaneous melanoma and a positive SLNB in a provincial New Zealand hospital.

Methods

Consecutive patients with a diagnosis of primary cutaneous melanoma and melanoma in situ presenting to Northland District Health Board between 1 January 2012 and 31 December 2014 formed the primary cohort. Patients were identified by searching the Faster Cancer Treatment Registry and the NDHB databases for inpatient admissions, incoming primary care referrals and incoming referrals from other health boards were also searched for completion. Cases of ocular, intra-oral and anal melanoma were excluded. Cases of recurrent melanoma, as indicated by histopathology, were also excluded.

Patient electronic records were accessed using the electronic record and results reporting system, CONCERTO. Information collected included patient demographics and tumour characteristics, operations undertaken, outpatient clinic attendances and ultrasound attendances.

In order to reduce the effect of individual costing anomalies within our small cohort, we estimated the median cost for each type of melanoma-associated intervention from 1,012 patient episodes. This included all surgical admissions, day case procedures, outpatient clinic visits and outpatient ultrasound scans in Northland DHB from 1 July 2007 until 27 September 2018 that were associated with the primary diagnosis of melanoma. CostPro software was used to calculate in-house patient level costs for each episode and New Zealand common costing standards were used throughout. We were then able to apply these median costs to our primary cohort and a theoretical cohort undergoing intensive nodal observation in keeping with the regime outlined in the MSLT-2 trial. All patients in the intensive nodal observation group were assumed to survive three-year follow up to give a maximum estimated cost.

The primary area of interest was the additional clinical and financial resource required to introduce intensive clinical follow-up of the nodal basin for patients with positive sentinel nodes in cutaneous melanoma. Data was analysed in Microsoft Excel and presented using standard techniques.

The study was performed as part of a service review of melanoma care within NDHB. The study was reviewed by the Health and Disability Ethics Committee who issued an ‘out of scope letter’, deeming formal ethical approval unnecessary.

Results

Basic demographics and clinical outcomes

Two hundred and ninety-seven new cases of primary cutaneous melanoma were identified among 294 patients, including 82 patients with melanoma in situ. Median age at diagnosis was 69.1 years (IQR 58.9–76.5). The median length of follow-up was 1,737 days (IQR 1408–2024). Basic demographic characteristics of our primary cohort are outlined in Table 1. All patients with a positive sentinel node went forward for completion lymphadenectomy. This included three axillary, one neck and two groin dissections. Of the six patients followed up after immediate lymphadenectomy, four deviated from routine follow-up due to complications. These included seroma (N=3), wound infection (N=1), haematoma (N=1) and damage to the spinal accessory nerve (N=1). Four patients died during follow-up after immediate completion lymphadenectomy.

There were 29 patients eligible for SLNB on the basis of Breslow thickness who didn’t undertake it within Northland DHB.
Nine did not proceed due to age or existing comorbidities, one patient suffered anaphylaxis to the blue dye, four patients were confirmed as having SLNB in the private sector. Fifteen patients were lost to follow up and it is not known how many of these went on to have private surgery elsewhere.

Costs and resourcing

Costs of traditional management were calculated for patients (N=6) in our retrospective cohort with a positive sentinel node biopsy (Table 2). Median length of follow-up post-lymphadenectomy was 2.60 years (IQR 1.32–5.21); mean 3.04 +/- 0.99 years.

These were compared to a theoretical cohort undergoing intensive nodal surveillance over three years as per MSLT-2 protocol. The overall cost of traditional management in our retrospective cohort was $42,883 (mean cost per patient $7,147). All six patients undergoing intensive nodal surveillance were assumed to survive at least three years, resulting in a maximum estimated cost of $31,802 (mean cost per patient $5,300). This includes the forty-eight ultrasound scans required to follow them up over three years. A 26.1% nodal-recurrence rate over three years was predicted in this cohort, in line with the observation arm of the MSLT-2 trial. To provide context, the overall estimated cost to Northland DHB of melanoma excisions (including melanoma in situ) and inpatient admissions for SLNB and lymphadenectomy was $513,393 over the study period (Appendix).

Discussion

This study shows that in sentinel node positive melanoma, intensive observation of the lymph node basin is likely to be associated with lower costs than traditional management. However, there is a shift in resource requirements with lower operative and inpatient costs, and higher outpatient and imaging requirements.

Although our population was much smaller than the MSLT-2 study, the gender and tumour site distribution were comparable. Our rate of positive SLNB was 10.2%, compared to 20.8% in the published literature. Unlike MSLT-2, we also included seven patients with thin (0.75–1.0mm) melanomas with ulceration or high mitotic rate, all of whom went on to have a negative SLNB. It is worth noting that 10 patients did not undergo SLNB on clinical grounds. We are unable to estimate the effect of these patients or those lost to follow-up on our
rate of SLNB positivity. However, we do not believe that they would alter the primary comparator of cost per patient in each cohort.

The benefits of lymphadenectomy are balanced against the risk of operative complications, which is known to be high. This is reflected in our study where patients required seroma catheter insertion, antibiotic therapy, percutaneous drainage or a prolonged course of physiotherapy. A drawback of our methodology is that these outpatient costs were not fully accounted for and the true financial burden of completion lymphadenectomy may be even higher than presented. It also demonstrates the importance of performing a true intention to treat analysis.

The higher sensitivity of ultrasound over clinical palpation in the detection of nodal recurrence is well established. However, sonographic criteria vary widely among published studies and no single feature is sufficiently specific. Ultrasound guided procedures are increasingly performed by surgeons in the clinic setting. However, the degree of interpretative experience required for ultrasound surveillance can only be expected from senior sonographers or radiologists. As a result, radiology departments will need to anticipate the increased demand that surveillance will have on their staffing and expertise.

Our primary area of interest in this study was the extra clinical and financial resource required to implement this treatment paradigm. We predicted that an extra five outpatient appointments and eight ultrasound scans would be required on average per patient over a three-year period. While this would require reallocation of resources within our hospital, the extra cost would be more than offset by the savings made from stopping immediate completion lymphadenectomy. In reality, these costs are low when considered in the context of the overall melanoma budget. Our estimated expenditure on melanoma exceeded half a million dollars over three years and didn’t take into account the countless negative excisional biopsies performed by our health board. Financial constraints should therefore pose no barrier to following new evidence-based guidelines in this setting.

The authors appreciate the limitations of this study, in particular in trying to predict cost and resource requirements from retrospective data. It is however the first study considering the resource implications of this clinical change in practice in New Zealand. Our population is small, but likely to be representative of other provincial DHBs across New Zealand. We also note that four of our completion lymphadenectomy patients died during follow-up, highlighting the poor prognosis among this group.

In short we have demonstrated that the introduction of intensive nodal observation in patients with positive SLNB in melanoma is likely to result in decreased costs, but some management or reallocation of resources will be needed. As the burden of patients with a positive SLNB is low, it is likely that the introduction of this type of regime would be achievable for provincial hospitals in New Zealand.

### Table 2: A cost and resource comparison of traditional management versus intensive nodal surveillance over three years.

<table>
<thead>
<tr>
<th></th>
<th>Traditional management (N=6)</th>
<th>Intensive nodal surveillance (N=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (range)</td>
<td>Total (N=6)</td>
</tr>
<tr>
<td>Completion lymphadenectomy</td>
<td>1 (6)</td>
<td>$33,906</td>
</tr>
<tr>
<td>Outpatient appointment</td>
<td>3 (2–14)</td>
<td>31 ($8,125)</td>
</tr>
<tr>
<td>Ultrasound scan</td>
<td>0.5 (0–2)</td>
<td>4 ($852)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$42,883</td>
<td>$31,802</td>
</tr>
</tbody>
</table>
## Appendix

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Total undertaken during study</th>
<th>Estimated median cost per procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wide local excision in minor operations clinic</td>
<td>140</td>
<td>$401 (303–521)</td>
</tr>
<tr>
<td>Wide local excision in main operating theatre</td>
<td>75</td>
<td>$1,705 (1,438–2,160)</td>
</tr>
<tr>
<td>Wide local excision and sentinel lymph node biopsy in main operating theatre</td>
<td>59</td>
<td>$5,008 (4,223–5,933)</td>
</tr>
<tr>
<td>Lymph node dissection (eg, axillary or groin) in main operating theatre</td>
<td>6</td>
<td>$5,651 (3,989–7,821)</td>
</tr>
<tr>
<td>Surgical outpatient appointment</td>
<td></td>
<td>$265 (265–265)</td>
</tr>
<tr>
<td>Superficial ultrasound scan</td>
<td></td>
<td>$213 (213–213)</td>
</tr>
</tbody>
</table>

### Competing interests:
Nil.

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### REFERENCES:


How much rehabilitation are our patients with stroke receiving?

Stephanie Thompson, Annemarei Ranta, Karen Porter, Naomi Bondi

ABSTRACT

BACKGROUND: Stroke rehabilitation often needs to continue following discharge from hospital. The New Zealand Stroke Network recommends community team review within seven calendar days of discharge and a minimum of three hours of therapy per specialty per week. International stroke guidelines make similar recommendations. The Wellington Community Older Adults, Rehabilitation and Allied Health team aimed to determine current local community stroke rehabilitation practice and compare this to guideline recommendations.

METHOD: A prospective cohort of 50 patients with a new diagnosis of stroke, referred to a community rehabilitation team in Wellington, were included in this service audit. The amount of rehabilitation patients received in the first four weeks and first three months following hospital discharge was measured, as well as time to first appointment. In addition, a service satisfaction questionnaire was sent to the patients.

RESULTS: The median (interquartile range, IQR) number of days from hospital discharge until first appointment with the community team was 10 (6.3–14.8) calendar days. In the first four weeks after hospital discharge, patients received from all health professionals an average (SD) of 1.1(0.4) rehabilitation sessions and 34.2 (43.6) minutes of rehabilitation per week. The average (SD) in the first three months or to point of discharge, whichever occurred first was 1.1 (1.1) sessions and 42.2 (49.3) minutes of rehabilitation per week.

CONCLUSION: There were delays in providing an initial community rehabilitation appointment and insufficient therapy intensity when comparing audit results to New Zealand Guideline expectations. As a result of this audit, recommendations for service improvements have been made.

Sroke affects approximately 9,000 New Zealanders annually and in 2016/2017 there was a prevalence of 1.5% or approximately 57,000 adults. Stroke is the leading cause of long-term disability in the developed world and most people surviving stroke will require rehabilitation. Stroke rehabilitation should begin the day after stroke and will often need to continue following discharge from hospital. Rehabilitation in the community can lead to improvements in recovery in terms of regaining independence and returning to activities of daily living. While research has found that rehabilitation after hospital discharge is provided in most places in New Zealand, there is great variation in treatment intensity and often a significant delay in the provision of these services. At Capital and Coast District Health Board (CCDHB) three general community teams provide community stroke rehabilitation to patients in the area. CCDHB provides services to a population of approximately 307,250 (2016/17 estimate). In the Wellington catchment area (population of approximately 131,000), the Wellington Community Older Adults, Rehabilitation and Allied Health (WCORA) team provides rehabilitation to people with stroke aged 16 years and older. Approximately 25% of stroke patients in the region are referred for community rehabilitation, and these patients make up approximately 12% of the team’s total workload. WCOR is an interdisciplinary team with allied health, nursing and medical health professionals, however it is not a stroke-specific community team.
The team delivers a five-day-a-week service during business hours, with no treatment available on weekends or public holidays, and does not provide an early supported discharge service. Rehabilitation is provided predominantly in patients’ own homes, but outpatient appointments are also available for those able to travel. The WCORA team routinely incorporates patient ‘home work’ in addition to therapy sessions, in order to increase rehabilitation intensity. However, this component of therapy time was not captured in this audit.

Guidelines vary in their recommendations for stroke rehabilitation provision in the community in terms of frequency, intensity and how soon post-hospital discharge this should commence. The New Zealand National Stroke Network published minimum recommended standards for DHBs in the delivery of community rehabilitation for patients with stroke. These recommendations included commencing a rehabilitation programme within seven calendar days of hospital discharge and providing three days a week of physiotherapy, occupational therapy and speech language therapy for the first four weeks, as clinically indicated. In 2018, the Ministry of Health (MOH) introduced a community rehabilitation indicator which states that 60% of patients referred to the community rehabilitation team should have a face-to-face contact within seven calendar days of hospital discharge. Stroke rehabilitation practice guidelines from Canada state that therapy for patients with stroke should be provided for at least 45 minutes a day per discipline required, two to five days per week for at least eight weeks. The Healthcare for London stroke rehabilitation guide recommends patients are contacted by the community team within twenty-four hours of discharge from hospital, assessed within three days of discharge and that treatment is commenced within seven days of assessment. The guideline also recommends three sessions per week of community physiotherapy, occupational therapy and speech-language therapy, as clinically indicated, for the first four weeks and suggests that rehabilitation should be provided on an ongoing basis to allow patients to meet their goals.

Aims

This service audit set out to determine the current state of stroke rehabilitation practice within the WCORA team and to compare this against best practice guidelines.

This audit aims to determine how quickly following hospital discharge patients with stroke are seen for community rehabilitation, and the amount and number of contacts of rehabilitation they receive within the first four weeks and three months of hospital discharge. In addition, patient satisfaction with the community stroke rehabilitation service will be assessed.

Methods

Study design

Fifty consecutive patients with a new diagnosis of stroke referred to the WCORA team for rehabilitation were included in this prospective audit, commencing in June 2016. Patients were identified from the team’s referral register. The paper-based data collection tool was placed in the front of the patient’s community medical file. Clinicians (including physiotherapists, occupational therapists, speech-language therapist, liaison nurses, social workers and rehabilitation assistants) documented where treatment occurred (eg, home, workplace, outpatient setting) and the amount of time spent treating each patient for the first three months they were involved or until discharge, whichever occurred first. The WCORA team is a goal-oriented service, and patients are discharged once their therapy goals are met. Clinicians were asked to only document treatment time (not assessment) during their sessions.

On completion of treatment, patients who were still alive were sent a seven-question survey to assess their satisfaction with the amount of treatment received and the location in which they received it. They were also asked to indicate whether they would come into an outpatient clinic if more treatment could be provided in that setting. The survey was designed to be aphasia-friendly so that those patients with a speech or language disorder could complete the survey if they wished. As this was a...
service audit project assessing the current state of practice, it was determined that formal ethics review was not required.

Data analysis
Simple data summaries (mean, SD, median, IQR, minimum and maximum) were calculated using Microsoft Excel.

Results
Fifty patients were included in the audit between June 2016 and March 2017. For the amount of treatment received and the treatment location, we had 46 sets of complete data at the end of the audit period. One patient died before completing the audit period and notes for three people were not able to be located. The average (SD) number of days from hospital discharge until first appointment with the community team was 11.5 (7.0) days (median 10; IQR 6.3–14.8), while the average (SD) number of days until first treatment session was 13.9 (9.1) days (median 11.5; IQR 7–20). Seventeen of the 46 patients (37%) were seen within seven calendar days of hospital discharge. Twenty-nine of 46 patients (63%) received treatment as well as an assessment at their first appointment.

Patients received in total an average (SD) of 4.3 (3.4) visits from all required disciplines combined during the first four weeks after hospital discharge (median 3; range 0 to 15) and a total of 11.6 (10.3) visits during the first three months or until discharge from the community team, whichever occurred first (median 7.5; range 1 to 38). Table 1 presents the number of rehabilitation sessions and amount of rehabilitation received per week in the first four weeks following hospital discharge and the total received throughout the audit period (three months post-hospital discharge or until the patient was discharged from the WCORA, whichever occurred first). Zero hours indicates that the patient received an assessment, but no treatment was provided. Nineteen of the 46 (41%) patients were still receiving treatment from one or more members of the WCORA team three months after hospital discharge. Sixteen of the 46 (35%) patients received only one or two sessions before being discharged, based on their clinical need.

Forty-nine patients were still alive at the end of the follow-up period and were sent a survey. Of these, 18 (37%) responded. Of the 18 patients who responded to the survey, 11 (61%) reported receiving treatment at home, one (5.5%) in the outpatient clinic only, five (28%) both at home and in the clinic and one (5.5%) did not respond to the question. Eleven of the patients (61%) who responded to the survey indicated they “completely agreed” or “mostly agreed” that their preference was to be seen at home. Two of the patients (11%) indicated that they did not have a strong preference on the location of their treatment. In contrast, 10 (55.5%) patients indicated that they “completely disagreed” or “mostly disagreed” with the statement “I would have preferred to be seen as an outpatient”. Patients who responded to the survey appeared, on the whole, satisfied with the amount of rehabilitation that they received from the community ORA team. Thirteen (72%) of the respondents completely agreed with the statement “I was happy with the amount of treatment I received”, two (11%) mostly agreed, one completely disagreed (6%) and two (11%) did not respond to the question.

Table 1: Number of rehabilitation sessions and amount of rehabilitation received per week.

<table>
<thead>
<tr>
<th></th>
<th>During initial community rehabilitation period (weeks 1–4)</th>
<th>During entire community rehabilitation period (weeks 1–12)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rehab sessions per week (n)</strong></td>
<td><strong>Session duration (minutes)</strong></td>
<td><strong>Total rehabilitation time per week (minutes)</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>1.1 (0.4)</td>
<td>24.7 (17.5)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>0.75 (0.5–1.4)</td>
<td>23.8 (13.5–35.7)</td>
</tr>
<tr>
<td>Range</td>
<td>0.3–3.3</td>
<td>0–62.1</td>
</tr>
</tbody>
</table>

*In some cases this was <12 weeks if goals were achieved sooner.
Five (28%) of respondents specified they wanted more treatment than they received, with four of the five (80%) indicating that they would attend a group session in order to receive additional treatment.

Discussion

This service audit set out to explore current stroke rehabilitation practice within one community-based team in Wellington, New Zealand. In line with previous research the audit found that for many patients with stroke there was a delay following hospital discharge in receiving community rehabilitation. Thirty-seven percent of patients were seen within seven calendar days of hospital discharge and some waited up to one month to be seen for their first appointment. This percentage falls well short of the MOH’s indicator of 60%.

Delays in community rehabilitation commencement can be attributed to either service or patient factors. From a service perspective, all referrals for the WCORA team, including those for patients with stroke, are screened as routine. There are no urgent appointments available with allied health professionals in the team and as this service is not stroke-specific, patients with stroke are not prioritised differently to other patient groups. All patients are booked into the next available appointment with the appropriate health professional. As such, the volume of referrals received by the team will have an impact on the length of time a patient with stroke will have to wait for community rehabilitation to commence. In addition, in the WCORA there is no backfill available to cover staff leave, extreme weather may result in community staff being taken off the road due to flooding (thus requiring appointments to be cancelled) and the Christmas period where, as per organisational preference, staff are encouraged to take leave and only skeleton staffing is available. Patient factors may include other medical diagnoses or events (e.g., admission to hospital with another medical problem) precluding or contraindicating earlier commencement of rehabilitation. In addition, the patient may decline an earlier available appointment in favour for a day or time that suits them better. Neither of these issues were specifically captured in the current audit, but any future audit should do so to help clarify reasons for delays.

It is likely that both service and patient factors impacted on how quickly patients with stroke were seen in the community for rehabilitation following hospital discharge. Patient factors are largely outside the control of the service and are the reason why indicators are not set at 100%. Service factor delays, however, need to be addressed. One solution could be to make available an ‘urgent’ appointment each week for an allied health professional to see patients with stroke promptly following hospital discharge. As a general community rehabilitation team providing stroke rehabilitation, care would need to be taken not to disadvantage the timeliness of rehabilitation to other patient groups.

Previous research suggests that not only do patients with stroke often have to wait for community rehabilitation to commence, but that at the first appointment they may only receive an assessment. In this audit, nearly two-thirds of patients began their treatment in the community during their first contact with a WCORA health professional. This is important as there needs to be a seamless transition between inpatient and community services, with continuation of intensive rehabilitation for those patients with rehabilitation needs.

Group therapy sessions are one method of delivering rehabilitation post-stroke. One benefit of group therapy in the community is that sessions can be scheduled in the first week after hospital discharge. This ensures a smooth transition between inpatient and community rehabilitation services and limits the break in rehabilitation for the patient. Group therapy may be more efficient and cost-effective, as there is a lower staff-to-patient ratio compared to individual therapy. English et al (2007) demonstrated that providing inpatient physiotherapy in a group setting compared to individual therapy time with no increase in cost. However, in the community the provision of group, clinic-based therapy may be limited by difficulties with accessing the clinic due to transport requirements, or by having a low referral rate of patients with stroke at a particular time point.

This audit demonstrated that the intensity of rehabilitation, as well as the number of contacts patients had in the first four weeks after hospital discharge, fell well short of recommended practice guidelines.
Clinical Guidelines for Stroke Management (2017) recommend that “rehabilitation should be structured to provide as much scheduled therapy (occupational therapy and physiotherapy) as possible”. A study by Ryan and colleagues investigated whether more intensive home-based rehabilitation resulted in improved outcomes for patients following stroke. They found a small, but significant difference between groups in favour of the group that received the more intensive community rehabilitation. The WCORA team could consider delegating additional treatment sessions to the team’s rehabilitation assistants as a means of increasing stroke rehabilitation intensity. In this audit less than 20% of patients were seen by a rehabilitation assistant. Research has found a number of benefits from having assistants in the team, including increased intensity of clinical care.

A positive finding from this audit is that where clinically indicated, patients continued to receive rehabilitation beyond three months. The WCORA team provides a goal-focused rehabilitation service and tailors the service provided to the individual’s needs rather than working to a defined time-period consistent with best practice guidelines. However, this prolonged input may impact on the ability of the team to pick up new patients in a timely fashion.

Despite the audit showing that best practice guidelines for delivery of community stroke rehabilitation were not met by the WCORA team, the service satisfaction questionnaire demonstrated generally positive feedback from patients. Care needs to be taken when interpreting the questionnaire results, however, as the overall sample size of this project was small, leading to a small number of returned surveys. It would be useful to administer another service satisfaction questionnaire to a larger sample of patients in order to confirm the results obtained in this audit. It may also be valuable to include an option for completing the survey online in addition to mailing out surveys, as mixed mode surveys produce a higher response rate than single mode surveys.

We identified a number of limitations with the audit and the service satisfaction survey. Firstly, the findings are limited to one community team in Wellington, and may not be generalisable to the other community teams at CCDHB or in New Zealand. Secondly, while we measured the amount of rehabilitation undertaken with a health professional present, we did not make provisions for patients to record the amount of time they spent on rehabilitation outside of therapy appointments. Any future work investigating rehabilitation intensity following hospital discharge should consider applying for ethics approval to allow for the recruitment of patients to record time spent undertaking rehabilitation activities independently of their therapists. Thirdly, we had only a small sample size, therefore only a small number of patients returned the paper-based service satisfaction survey, meaning that the results need to be interpreted with caution. The use of an online survey in addition to mailing out surveys would be useful to consider for future audits. Fourthly, this audit did not specifically ask staff to document reasons for delays in service provision, however some staff did provide information on the data collection tool, and two broad categories were identified as potential reasons for delays. Future audits should include specific information on factors impacting commencement of rehabilitation. Finally, this audit did not document severity of stroke or disability, therefore it is impossible to determine whether the low number of contacts in the first four weeks following hospital discharge was clinically appropriate (at least for some patients), or whether further rehabilitation was indicated but was unable to be provided.

**Conclusion**

This prospective service audit revealed that the WCORA team is not currently meeting best practice recommendations for the provision of community stroke rehabilitation. There were delays in providing an initial appointment and the intensity of rehabilitation is lower than recommended. Suggestions for improving service responsiveness and intensity of rehabilitation have been made, as well as recommendations for future audits. Service redesign may be needed to improve community stroke rehabilitation provision against the MOH indicators, and further work is required at a team level to implement suggested changes.
Competing interests:
Nil.

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REFERENCES:


Point-of-care testing governance in New Zealand through the lens of quality: an update on a national regulatory framework
Samarina MA Musaad, Geoffrey CE Herd, on behalf of the Northern Region POCT Group

ABSTRACT
Point-of-care testing (POCT) devices are in vitro diagnostic devices used in hospitals, primary care and at home to provide rapid medical test results to support decision making. Most POCT devices are not regulated in New Zealand and there is no requirement for public or private hospital providers who use POCT devices to meet minimum accreditation standards for POCT. This article describes a regulatory framework for POCT devices, which is consistent with the principles of the draft Therapeutic Products Bill 2018. The proposed framework includes thorough evaluation, laboratory validation and approval processes for devices, improved traceability, accreditation for POCT and an adverse event management system; in the interests of patient safety.

Background
POCT devices are not subject to effective regulation in New Zealand.\(^5\) Urine pregnancy test kits are the only POCT devices that require mandatory registration in the Web Assisted Notification of Devices Database (WAND).\(^4\) This relatively ineffectual system contrasts with the regulatory framework in the UK by the Medicines and Healthcare Products Regulatory Agency.\(^5\) In New Zealand, POCT devices are not subject to thorough evaluation prior to distribution for use in the community. This is in contrast with the Scandinavian evaluation of laboratory equipment for point-of-care testing (SKUP) service in Scandinavia.\(^6\)
In 2013, the authors proposed a national regulatory and governance framework for POCT devices, as shown in Figure 1. This was the first schematic vision of a regulatory framework for POCT in New Zealand. It was born of concern over the existence of significant regulatory gaps with potential deleterious consequences. Since then Medsafe has updated its website to include a more diligent approach for the reporting of adverse events for POCT, encouraging reporting of potential adverse incidents or near misses as opposed to only definite events. The section “Information for Industry, Part 3: Regulatory requirements for medical devices” is currently under construction, implying that more changes are underway.

At the time of writing, December 2018, the Minister of Health had released a draft of the Therapeutic Products Bill 2018 and a Therapeutic Products Regulatory Scheme consultation paper. The Regulatory Scheme covers all therapeutics products used in public and private healthcare. The draft Bill defines four types of therapeutic products: medicines, active ingredients of medicines, medical devices (including in vitro tests and software) and type 4 products. The draft Bill provides for a unique device identifier to: improve identification and traceability of medical devices, the identification of adverse events, reduce error and support documentation and longitudinal capture of data in clinical registers. The draft Bill and the consultation document recognise the scale and complexity associated with the medical devices sector and that some devices are used for in vitro diagnostic medical tests in primary, secondary and home-based care. However, significant gaps remain to be addressed because, unlike devices such joint prostheses and stents, POCT devices require validation of performance by accredited medical laboratories before funding approval. This article presents a revised, regulatory framework based on the first one proposed in 2013 as shown in Figure 1.

**Regulation of POCT: a revised and updated framework**

Three pillars underpin governance and regulation of POCT, namely:

1. Selection: only approved devices, validated by accredited laboratories should be available for use by the healthcare sector;
2. Quality and Accreditation: only certified providers should use POCT in public and private hospitals, supported by quality-controlled testing services accredited by International Accreditation New Zealand (IANZ);

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

Key: MoH: Ministry of Health; IVD: In-vitro diagnostic device manufacturers; PHARMAC: Pharmaceutical Management Agency.
Figure 2: An updated framework for regulation and governance of point of care testing in New Zealand.

### Step 1

**Regulation and Clinical Governance at a National Level (Medsafe)**

- Evidence gathering by committee; a two phase process.

#### Phase 1 Scrutiny

- **Reject**: Device did not pass initial scrutiny, no further action.
- **Accept**: Device passed initial scrutiny → Phase 2

#### Phase 2 Evaluation

- **Accept**: Local evaluation: devices that are not fit for purpose, no further action.
- **No**: Devices deemed fit for purpose should be registered in the WAND database.

#### Funding Decision

- **Yes**: Final decision for funding (or not) made by PHARMAC
- **No**: Gateway 1

### Step 2

**Public & Private Hospitals, DHBs, & General Practice**

- Clinical governance at a Regional Level: e.g., Northern Region Alliance POCI
- Group to be well resourced and supported by management, and NMA and to include representation from all three disciplines of clinical pathology, scientists, Information Technology, and ACC (consumer).

1. Address clinical and operational needs, relevant to the interested provider i.e., DHB/laboratory/Hospital/ICP practice
2. Ensure and document clear lines of communication and accountability with relevant stakeholders and departments
3. Add the device to a regional register if/when decision is made to use it
4. If the decision is not to use it → document the reason

### Step 4

**The Community**

- Pharmacies/Private Hospitals
  1. Register their procurement in a registry
  2. Full training of pharmacists & providers by laboratory and/or approved suppliers.

### Gateway 2

**New Zealanders**

- Should be educated with regards to how to use their devices and to be aware of unsafe devices that are not supported by the New Zealand government or PCTI services.
- Have the right to be able to provide feedback and to seek assistance in case of unexpected results or device malfunction.

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**Key:** ACC: Accident Compensation Corporation; WAND: web assisted notification of devices; NRA: Northern Region Alliance.
3. Monitoring: including traceability of devices and the establishment of an accessible, adverse events management system (AEMS) designed to alert the regulatory agency, consumers and suppliers.

This article proposes an updated regulatory framework which is more descriptive than the 2013 framework and provides advice on how POCT devices should be approved, validated, regulated and managed in the interests of patient safety. This updated framework is summarised in Figure 2.

In the proposed regulatory framework industry and in vitro diagnostic (IVD) companies, providers—eg, clinicians, pathologists, medical scientists and consumers—must formally apply for introduction of an IVD device to the New Zealand market (Step 1) through Medsafe or an otherwise governmental regulator. (Note: Medsafe will be considered the regulator for the remainder of this article).

Medsafe would be the first of two gatekeepers and will initiate Step 2. In the initial phase of Step 2 an expert advisory committee in Medsafe would decide to support the use of a POCT device in New Zealand. Devices that have been evaluated and scrutinised and that meet predefined standards would then enter the second phase of Step 2 and be subject to local New Zealand evaluation by accredited laboratories. Any device that is approved for the local market should be registered in the WAND database which will act as a registry of all devices supported by Medsafe for use by the consumer. Decisions regarding funding can be made by PHARMAC or alternative funding body (Step 3).

Regions and district health boards (DHB) should have local clinical governance bodies to oversee local clinical needs; this would constitute the second gateway. For example, in the Northern Region this could be the Northern Region POCT (NRPOCT) Group; these groups will undertake Step 4.

Individuals or patients who use a POCT device at home should be fully trained and supported with advice on the limitations of the device and how to prevent common problems which may occur with these devices. Support may come from the supplier of the device, eg, pharmacist, or from delegated personnel/institution.

Discussion

Medsafe regulatory committee members with responsibility for POCT devices should include representatives from clinical pathology, medical laboratory scientists, healthcare practitioners, technical experts, and relevant allied healthcare providers.

The New Zealand Best Practice Guidelines for Point-of-Care Testing should be the primary source of guidance for setting quality standards. In the first phase, a set of predefined criteria should be the basis of initial screening for acceptance or rejection of POCT devices. Primary considerations should be given to clinical safety of the test or device, including evidence of clinical and analytical performance and history of international recalls, local needs and cost-effectiveness. Reasons for a decision should be clearly documented and defensible. Devices that are approved at the first phase would proceed to be evaluated in the second phase, the local environment. This requires a national POCT laboratory service appointed by the regulator to evaluate point-of-care (POC) tests and devices.

Evaluation of devices must be carried out locally by an accredited laboratory service. It is not sufficient to completely rely on the results of overseas validation data even though such data can add to the evidence-base. In New Zealand, medical laboratories are accredited for medical laboratory services by International Accreditation New Zealand (IANZ) against the medical testing standard ISO (International Organisation for Standardisation) 15189:2012.

Eighteen medical laboratories are accredited against the POCT standard ISO 22870:2016. Until all laboratories that offer POCT in New Zealand are required to be accredited against ISO 22870:2016, the minimum requirement to perform evaluation of devices should be accreditation against ISO 15189:2012. The criteria for scale and scope of the evaluation for each device or test will depend on the clinical utility and complexity of the device or test and on the quality of overseas evaluations if applicable. These criteria would be defined by the national POCT laboratory evaluation service. This approach is consistent with section 95 of the draft Therapeutic...
Products Bill 2018; which states the criteria for product approval and includes quality, safety and performance.\textsuperscript{7}

Traditional laboratory instruments are evaluated by experts in the medical laboratory; this is bread-and-butter of laboratory practice. Regulation is important for these instruments, and because of the detailed evaluations that they are subjected to within the laboratory, instruments that are not fit-for-purpose are not used. The same regulatory authority does not currently apply to POCT devices and tests, because they can be acquired by non-laboratory trained individuals, many of whom are not health professionals. As opposed to laboratory-based instruments, POC devices need tailor-made validation protocols that include field testing to accommodate all types of users and clinical settings.

A national evaluation laboratory service for POCT devices will prevent duplication of effort and resources between laboratories, ensure safe devices and tests are available to the New Zealand consumer, and ensure POC tests are fit for local purpose. This national evaluation laboratory service may be a standalone laboratory or a virtual laboratory made up of experts around the country who are contracted by Medsafe or the Ministry of Health. This national evaluation laboratory service is consistent with section 207 of the draft Therapeutic Products Bill 2018 which states that “the Regulator may rely on reports, assessments or decisions made by, or information received from, a recognised authority”.\textsuperscript{7}

An approved device would then be registered in the WAND database. Compulsory registration ensures traceability and effective management of recalls or adverse events. Approved devices will be available for the New Zealand consumer regardless of funding status but government funding supports equitable healthcare delivery.

When devices are approved and made available for use, the results of the evaluation or validation need to be accessible and publicly available. This aligns with the consumers’ right to be informed\textsuperscript{2} and provides a reference point on which to base decisions in case an adverse event occurs. Decisions could include repeat validation testing on a suspect device, batch or lot number of consumables, or a recall notice and substitution options. A national adverse events monitoring system (AEMS) for POCT was proposed in 2015,\textsuperscript{12} details of which are beyond the scope of this article.

The Pharmaceutical Management Agency PHARMAC decides which devices are to be publicly funded to get the best possible health outcomes.\textsuperscript{13} Each DHB in turn decides what devices to use in order to deliver local services; the choice would usually be from a national medical devices list that PHARMAC manages. It is prudent that PHARMAC have clear and functional timelines to prevent stalling of decision-making. This would avoid unnecessary delays in introducing a funded device that would benefit the New Zealand consumer. It would also allow for timely responsiveness to local needs and evolving technology. It is important to have open lines of communication between Medsafe, PHARMAC and clinical governance groups, and to avoid a silo mentality. Appointed coordinators for communication would ensure coherence of messages and a single point of contact for responses and decisions in addition to the website. Furthermore, in the unlikely event that a decision made by Medsafe or PHARMAC is deemed to disadvantage patients’ clinical needs, there should be an opportunity within a defined timeframe to appeal to the relevant body. Appointees to POCT device regulatory and governance teams need to be resourced appropriately with adequate time and travel sponsorship as required, to enable them to carry out evaluation, investigative and review functions efficiently and effectively.

Accreditation for POCT

The regulatory framework should also include provisions so that DHB contracts with contracted laboratory service providers require the provider to support and implement quality controlled, accredited POCT services where applicable within DHB hospitals.\textsuperscript{14} Many private hospitals use complex POCT devices, such as blood gas analysers, to manage patients intra-operatively and in critical care units. They may choose to maintain independent clinical governance but it is essential that the regulatory framework includes provisions for mandatory POCT accreditation against ISO 22870:2016 for these hospitals in the interests of patient safety.
Community settings should fall under the governance structure of their local DHB or regional POCT clinical governance groups. Pharmacists can be fully trained by laboratory personnel, eg, relevant DHB staff or approved suppliers; this will ensure standardised training and safe practices. An approved supplier is one that is deemed reliable and recommended by the local POCT governance group. As is the case in accredited laboratories there should be periodic recertification of pharmacists who sell POCT devices. This can be done electronically after initial face-to-face training.

Patients should be trained by the pharmacists and should have a mechanism for feedback, eg, a help-line. In the interest of traceability and patient-centred care, it may be prudent that patients or carers demonstrate their understanding of testing technique, limitations and who to contact for support. This contractual agreement co-signed by the trainer would facilitate a balance of shared responsibility.

Commercial arrangements

Commercial arrangements with suppliers need standard provisions for surety of supply and device performance. In addition, these supply agreements need to be flexible in the event that a device is found to be faulty and the decision is taken by the regulator or a provider to halt or cease the use of a device in New Zealand based on clinical evidence and risk assessment. While pre-evaluation (phase 2 of Step 2) will help avoid such a scenario, there should be safeguards for this rare, yet possible event since patient safety is the primary goal.

Education

It is the responsibility of the Ministry of Health, health providers and all healthcare personnel to educate the public regarding purchase of untested devices, eg, through the internet. While such practices cannot be stopped, our moral responsibility and duty of care cannot be disputed. This applies to patients and individuals in hospitals and in the community.

Adverse event monitoring system (AEMS)

POCT is ubiquitous and very large in scale and scope. In its own right POCT is a stand-alone virtual laboratory with a myriad of potential risky practices due to the variety of end-users who are for the most part not laboratory trained. This necessitates a dedicated national POCT AEMS, separate from traditional laboratory incident reporting.\(^\text{12}\) Such a system would consolidate evidence under one umbrella, will streamline event monitoring, allow timely dissemination of information among relevant parties, facilitate recalls and be an effective means for monitoring of (un)safe practices or devices. Medsafe has made progress towards reporting of incidents albeit not specific to POCT.\(^\text{4}\)

In the event of an adverse incident involving a device, consumers and providers will need to know that an investigation has been completed and that if the device is withdrawn, this is the advice of the regulator, the investigators and the AEMS committee. However, if the device is considered to be suitable for continued use then consumers and providers need to have confidence that the thorough validation checks have been completed and this data will again form part of the public record.

Challenges

Fiscal resources are a common limitation in all healthcare systems. Populations are expanding and aging, and patient expectations are rising while resources are not catching up. A long-term and ethical perspective would be to view people as entitled to the best healthcare possible and to invest in long-term safety; an investment that would secure the health of generations. This far-sightedness would inevitably guarantee considerable fiscal returns in terms of averting iatrogenic complications at an individual's level and increasing productivity at a population level.

Other challenges include political agendas, ineffective communication, lack of transparency, duplication of work and regulatory 'speed bumps'. Not all of these potential challenges can be avoided but a focus on the patients' wellbeing and providence is an important start.

Attitudes can also be a challenge. Some leading professionals express the lack of need for local regulation of POCT devices, stating “We are a small country. We are happy to rely on other countries' or jurisdictions' regulatory systems and transfer their framework to New Zealand” (personal communication). The authors acknowledge
that re-inventing the wheel is inefficient but complete reliance on imported ideas discredits local expertise and fosters a culture of apathy. It also defies the norm of differences; nations have different cultures and population characteristics, and therefore regulatory systems should accommodate these differences.

**Conclusion**

The authors recognise that a regulatory framework for POCT devices will be subject to political, economic and practical constraints. However, given the increasing complexity and demands of the modern medical landscape, the public has genuine rights with regards to POCT in the healthcare system. These expectations include but are not limited to, that accredited health providers use validated POCT medical devices, approved by the appropriate regulatory and funding agencies and that approved validated devices are available for home use.

We have outlined a vision for an efficient and flexible governance framework for POCT in New Zealand. It addresses regulation at a governmental level and clinical governance at a regional level. The framework presents broad principles that when embedded in the structure of healthcare delivery in New Zealand enables a robust risk-averse approach to the practice of POCT. It is focused on delivering high-quality POCT services and is aligned with the New Zealand Health and Disability Consumers Code of Rights 1996 and the draft Therapeutic Products Bill 2018. Despite potential challenges, the framework as outlined is achievable in the interests of assuring patient safety.

**Competing interests:**

Mr Herd reports affiliation with Radiometer Pacific Ltd and Roche Diagnostics NZ Ltd outside the submitted work; he is a member of the New Zealand Point of Care Testing Advisory Group and the Northern Region District Health Board Point of Care Testing Group.

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REFERENCES:
Doctors’ rights to conscientiously object to refer patients to abortion service providers

Angela Ballantyne, Colin Gavaghan, Jeanne Snelling

ABSTRACT

After five decades of restrictive laws, New Zealand is on the cusp of law reform that may result in abortion being treated as a health, rather than a criminal, matter. Given this possible liberalisation, a pressing issue is the way in which ‘conscientious objection’ (CO) will be accommodated within the new legislative landscape. In this context, CO constitutes a health provider refusing, on the grounds of personal conscience, to provide care that, although legal and potentially clinically appropriate, conflicts with their personal moral views. Currently, New Zealand law permits significant concessions for conscientious objectors. This paper argues that in the light of current reform, the justification for permitting CO should be revisited. It claims that even if it is conceded that some form of CO should be respected, a pragmatic compromise must be adopted so that both provider’s and women’s rights are sufficiently protected. We argue that the current legal situation in New Zealand is unbalanced, favouring the rights of providers at the expense of women’s timely access to abortion care. At a minimum, providers with a CO should be required to ensure an indirect referral to another provider who is willing to refer the woman to abortion services.

Abortion in New Zealand

Statistics indicate that around a fifth of New Zealand pregnancies are terminated1 and one in four women have had an abortion in their reproductive lives—more than the percentage of women who have ever used IUDs.2 Currently New Zealand women are among the 40% of women of childbearing age who live in countries that the World Health Organization refers to as having “highly restrictive laws”.3 Northern Ireland is the only other developed country with more restrictive abortion laws, while the Republic of Ireland recently liberalised its abortion law.4–5 By comparison, 61 countries, home to almost 40% of the world’s women, allow abortion upon request of the pregnant woman. A further approximately 20% of the world’s women have access to legal abortion on the grounds of social and economic circumstances.3

The Minister’s Request for Advice on Law Reform: Law Commission Briefing Paper

The vast majority of abortions in New Zealand are performed on mental health grounds (97.6% in 2013) and are performed before the end of the 10th week of pregnancy.4 In 2017, Minister of Justice Andrew Little requested that the New Zealand Law Commission (NZLC) provide advice on what alternative legal approaches could be adopted to align abortion law with a health, rather than criminal, model. Following a public consultation, the NZLC presented a range of proposals and options for reform (see Table 1).
Significantly, the NZLC posed two options in regard to CO:

Either (1) maintaining the current law regarding conscientious objection, or

(2) amending it so that health practitioners who do not wish to provide health services in relation to abortion because of a conscientious objection are required, as soon as reasonably practicable, to disclose the fact of their objection and refer the woman to another health practitioner or abortion service provider able to provide the service.7

Health providers as ‘gatekeepers’ model: what obligations regarding referral?

The NZLC paper presents two possible models: the first entails clinicians acting as gatekeepers to the abortion process; the other involves women being able to self-refer to abortion service providers. Clearly if women may self-refer for abortion, CO becomes a less significant issue. However, it is not yet clear which recommendations the government will adopt should law reform proceed. This paper considers how, if clinicians retain their role as gatekeepers to abortion services, the issue of CO should be addressed.

The NZLC emphasises that these proposals would not remove all grounds for CO in relation to abortion. Under both options, health providers would retain their right to object to perform, or participate, in the provision of abortion.8 NZLC states that “the Government could consider changes to ensure that CO ‘does not unduly delay women’s access to abortion services’”.7 We do not engage here with the question of whether health providers should be entitled to CO. In this paper we focus on the ethical question of defining the reasonable scope of CO for abortion referrals.

The current legal position regarding CO and referral

It is clear that a physician with a CO need not perform an abortion. It is equally clear that they have a duty to inform: indeed the Health Practitioners Competence Assurance Act 2003 (HPCAA) states that in the context of reproductive health services, a health practitioner who objects on the ground of conscience to providing the service must “…inform the person who requests the service that he or she can obtain the service from another health practitioner or from a family planning clinic.”9 In addition the Code of Consumers Rights provides that patient have extensive rights, including the right to be fully informed, and providers have corresponding duties.10

The most contentious question has been around the issue of referral. The notion of ‘referral’ can relate to one of two things—referring directly to the abortion service so that the grounds for abortion can be considered by certifying consultants; or, if the clinician has a CO, referring to a colleague who is prepared to consider the matter and arrange a referral to the abortion service as indicated.7,11 The former sort of referral has been described as ‘direct referral’, the latter as ‘indirect referral’.12

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**Table 1: Law Commission Alternative Approaches to Abortion Law: Ministerial Briefing Paper options for abortion reform.7**

- Repealing the current grounds for abortion contained in the Crimes Act 1961.
- Removing the requirement for abortions to be authorised by two specially appointed doctors, called ‘certifying consultants’.
- Allowing women to access abortion services directly, or alternatively to be referred by any health practitioner they choose to consult (GP, nurse, midwife, counsellor), rather than having to get a referral from a doctor as required under the current law.
- Removing the current restrictions governing who may perform an abortion, and where abortions must be performed. Instead, the provision of abortion services would be regulated by appropriate health bodies, just like any other healthcare procedure.
- Disestablishing the Abortion Supervisory Committee.
- Assigning responsibility to the Ministry of Health for collecting statistics on abortion and overseeing the distribution of funding and abortion services.
The High Court has made it clear that both direct and indirect referrals are subject to the right of CO in New Zealand.\textsuperscript{13} In 2010, the New Zealand Medical Council sought to clarify that practitioners with a CO to providing direct referral for abortion services must arrange for the woman's case to be considered by another practitioner willing to consider and deal with the matter.\textsuperscript{14} This became the subject of a legal challenge by anti-abortion group, New Zealand Health Professionals Alliance (NZHPA).\textsuperscript{13} The High Court substantially upheld NZHPA's case, holding that, under the HPCAA, the practitioner's statutory duties extend only to informing the woman that she could be treated elsewhere, but did not extend, and importantly, could not be extended by the Medical Council, to referring the woman to another practitioner who can arrange the referral to an abortion service.

Consequently, a practitioner's duties in New Zealand are minimal. They need only inform the woman of the option of seeking out another provider, but are not required to put her in touch with an alternative provider, facilitate her transfer or even provide contact details. The NZLC clearly provides the option for changing the status quo in regards to CO and referrals, however the New Zealand Medical Association (NZMA) opposes any change to the current scope of CO.

Response to the NZLC

The response from the medical and allied health professions to the Law Commission's proposals has been mixed. The New Zealand College of Midwives, the Australian and New Zealand College of Psychiatrists and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists all considered that “conscientious objectors should either refer a woman in a timely manner to another practitioner who provides the services she seeks, or provide the woman with sufficient information about practitioners who provide the services to enable her to access those services”.\textsuperscript{7}

In contrast, the NZMA's submission to the Law Commission states that it “strongly supports the retention of the existing provisions” of CO.\textsuperscript{14} No further justification for this is offered in the submission. However, in a recent New Zealand Herald article, chairwoman Kate Baddock appeared to endorse the argument that: “For the same reason that patients have a right not to be coerced into receiving treatment, doctors and nurses have a right not to be coerced into providing it”.\textsuperscript{16}

This argument, which we call the “Argument from Symmetry”, is flawed. It fails to account for significant differences between the respective positions of patient and provider. First, it fails to account for the role-specific professional obligations of doctors. Second, it seems to misunderstand some of the core tenets of medical ethics and professionalism, such as patient autonomy and non-maleficence. As such, it cannot provide grounds for CO in general, or for the strong version that New Zealand law presently protects.

Professional autonomy: the argument from symmetry

To be clear, we are not disputing that there is a role for professional autonomy for health providers. Rather, we are arguing that the nature and scope of professional autonomy cannot be derived from, nor seen as directly analogous to, the nature and scope of patient autonomy. Medical ethics and medical law accord significant weight to the autonomous choices of adult patients. In terms of treatment refusals, a competent patient's autonomy is all but absolute. They can refuse treatment even when it is medically necessary to preserve their life or health. Furthermore, at least in theory, the patient is under no obligation to offer any justification for such a decision. It does not follow that providers have an analogous right to refuse to provide treatment or advice without justification. Rather, a doctor seeking to withhold a medically indicated and requested procedure will be required to justify their decision. (In much the same way, the fact that a defendant in a criminal trial has the right to silence does not mean that the judge can decline to offer reasons for his or her decision). Perhaps most obviously, a patient's right to refuse all medical interventions could not sensibly find its mirror in a physician's right to refuse to perform all medical procedures; such a refusal, we might think, would amount to refusing to be a doctor at all.
There are also critical differences in power, freedom and vulnerability between the patient and the doctor that the Argument from Symmetry obscures. The patient is in need of clinical care (and may well also be suffering morning sickness or other pregnancy related health issues); whereas the GP is well and working in a professional capacity. Arguably, access to medical services will have significantly greater consequences for the patient's life course than providing a referral will have on the doctor's life course. The patient cannot choose not to be pregnant, but we might think that, in undertaking a professional role, the doctor has voluntarily undertaken certain responsibilities. For these reasons, the professional responsibilities of doctors are not analogous to the moral rights of patients. The fact that patients cannot be coerced into accepting treatment is irrelevant to the question of whether doctors should be coerced/required to offer referrals (or provide other services).

Even proponents of respecting physician autonomy stop some way short of arguing for a strong autonomy right, analogous to the autonomy of an adult patient. Hence Shimon Glick and Alan Jotkowitz call for a “nuanced” and “balanced” approach, recognising that always giving CO priority over patient requests “would result in anarchy and in deprivation of services to many patients”.17

We argue, then, that support for CO cannot plausibly be derived from a putative equivalence between the autonomy rights of patients and doctors, as the NZMA has suggested. Other grounds for recognition of a right to CO have, however, been advanced.

A more plausible basis of CO: moral integrity or vocational calling

One such basis for respecting CO derives from the medical practitioner’s moral integrity. Marc Wicclair explains moral integrity element in this way:

“To claim that [the physician's] moral integrity is at stake implies that: (1) she has core ethical values (eg, principles, virtues and/or paradigm-based maxims). (2) These core ethical values are part of her understanding of who she is. That is, they are integral to her self conception or identity. (3) It would be incompatible with those core ethical values to participate in [the requested treatment].”

On Wicclair’s account, moral integrity is synonymous with one’s personal identity, hence mere distaste or disapproval of a particular procedure will not provide an adequate basis for a valid CO. Wicclair also claims that “an appeal to conscience has significant moral weight only if the core ethical values on which it is based correspond to one or more core values in medicine.”18

Christopher Cowley bases his support for CO on a similar idea, although he prefers the language of “calling” over “moral integrity”:

“Once we take seriously the idea of a calling, then we come closer to understanding the motivation of the conscientious objector; they deserve accommodation not out of respect for their integrity, but rather out of respect for their conception of medicine.”19

Like Wicclair, Cowley requires that the objection be rooted in “an understanding grounded in the role of doctor as healer”.20 If this is right, it would set an important limitation on the exercise of CO, requiring the practitioner to locate his/her position within a broader context of shared ethical values. Whether opposition to abortion would meet this standard is, presumably, arguable, but it is not a line of enquiry we pursue further here.

Freedom of conscience

A second plausible basis for CO can be found in the broad right to freedom of conscience. The New Zealand Bill of Rights Act states that “Everyone has the right to freedom of thought, conscience, religion and belief, including the right to adopt and to hold opinions without interference”.

As the NZLC noted, these rights may, however, be “subject to reasonable limits” acceptable in a free and democratic society. The right to freedom of conscience does not automatically extend to the right to act on those beliefs (we are not, for example, permitted to refuse to pay tax because we object to military spending, or because we object to funding certain health services). Further, the broad right to conscience is not equivalent to the much more circumscribed right to CO. Health providers have scope to act on conscience in many ways that do not invoke CO. They choose the area in which they practice /specialise and which patient populations to serve; they make important
contributions to academic and public debates about health policy and medical ethics; and they participate in associations aimed at political reform (eg, Doctors4Refugees, Voice for Life, Euthanasia-free New Zealand). None of these expressions of conscience invoke the right of CO.

The remainder of this article is concerned with the question of reasonable limits on the right to freedom of conscience.

**Reasonable limits**

Provision for CO at all has come in for renewed criticism in recent years. For critics like Julian Savulescu and Udo Schuklenk, providers exempting themselves from provision of healthcare is simply incompatible with the ethical demands of the medical profession. Significantly, the NZLC’s proposals do not suggest dispensing with CO altogether, nor do any of the submissions from the medical professional bodies. Moreover, recent initiatives around physician aid-in-dying make specific provision for CO. It seems unlikely, therefore, that there is much appetite for removal of CO in New Zealand medicine in the foreseeable future.

Thus the real debate is around the limits of CO, and how to balance competing interests. For most moderate commentators, this takes the form of a search for a ‘reasonable compromise’ or ‘conventional compromise’ position, which typically requires a trade-off between the doctor’s right to conscience, and other considerations. Advocating for the conventional compromise, Dan Brock states:

> “… a physician/pharmacist who has a serious moral objection to providing a service/product to a patient/customer is not required to do so only if the following three conditions are satisfied:

1. The physician/pharmacist informs the patient/customer about the service/product if it is medically relevant to their medical condition;
2. The physician/pharmacist refers the patient/customer to another professional willing and able to provide the service/product;
3. The referral does not impose an unreasonable burden on the patient/customer.”

Even Cowley, when defending the right to CO against critics, accepts that indirect referral may be a moral duty:

> “Refusing to inform a patient in such a context would not only be illegal, it could also be akin to sulking and preciousness. This is one place to draw the line, and where the conscientious objector has to accept the reality of a genuine moral pluralism, as well as her status as a minority in a reasonably democratic society.”

Even scholars defending the right of CO, then, would not support the New Zealand situation, where providers can refuse to transfer the care of the patient to another provider who will process the referral.

**Why we should be worried about (unrestricted/broad) CO and delays in access to abortion care**

We disagree with Baddock that the current CO provisions for referrals in New Zealand are reasonable and working well. Current CO provisions regarding termination referral in New Zealand impose an unreasonable burden on women. It is highly plausible that refusal to provide indirect referral can cause significant patient harms: potential inability to find another provider, delay in access to care, increased financial cost (time off work, cost of additional consultation, travel), stigma, embarrassment or loss of trust in the ‘non-judgmental’ role of providers, which may have significant implications for some patient groups that already have a tenuous relationship with the health system and the medical profession. Remarkably, when a GP refuses to even consider referral, they remain entitled to claim the cost of the consultation (prenatal care is government-funded). While the patient is left with the emotional, financial and time burden of finding another provider, the doctor can be paid for refusing on personal grounds to perform this core public service. In a health system that is supposed to be ‘patient-centred’ the current weighting of doctor and patient interests seems distorted.

Refusals to refer undeniably create some delay. The length of delay will vary; but we argue that in the context of abortion services in New Zealand, we should be concerned about all delays. Compared to other developed countries (UK, Australia,
US), abortion services in New Zealand are accessed significantly later in the first trimester. New Zealand women wait an average of 25 days between the first visit with a referring doctor and the date of their procedure.24

Timely access to abortion services is critical to women’s psychological and physical health, with earlier abortions safer.24, 25 For example, women who intend to terminate using medication (as opposed to surgical abortion) need to access services within the first 63 days of pregnancy. In general, long waiting times for elective surgery increases anxiety and have a negative impact on quality of life and psychosocial measures.26 Barriers to abortion, including delays, have disproportionate impact for rural women, minorities and less advantaged women.27 Thus the World Health Organization recommends that “Regulatory, policy and programmatic barriers that hinder access to and timely provision of safe abortion care should be removed”.28

Research shows that most of the existing delay in accessing abortions in New Zealand is at the referral stage.29 Even those GPs willing to refer sometimes require multiple consultations before they refer a woman to an abortion provider.28 It remains unclear what is causing this delay. Specifically, there is no available evidence to show that the delays in referral are the result of refusing to refer to another referrer, as opposed to simply refusing to refer to the abortion provider (while facilitating referral to another GP). This lack of specific data is not surprising; it is not known how many health providers have a CO, and conducting research with women requesting abortion is notoriously difficult given the stigma associated with abortion. We do know that New Zealand has surprising delays in the referral process relative to comparable countries and that New Zealand law currently allows for a very wide interpretation of the scope of CO. We should be especially concerned about the potential role of CO in delaying accessing to abortion referrals in New Zealand.

Conclusion

The State is responsible for ensuring the provision of core health services.29 Arguably, CO provisions need to be considered at a system level—balancing the harm to potential objectors of compelling action contrary to their conscience, against the harm to patients of delaying or barring access to care.

The NZLC’s modest proposal would recognise the right to CO, and would safeguard the right of objectors to be employed in roles even where they have no intention of providing all the services that role would usually require, even where those roles are in remote areas with few other doctors. These are significant concessions to those holding a minority view.

The current legal situation in New Zealand is unbalanced, favouring the rights of providers at the expense of women’s timely access to abortion care. We endorse the position of the New Zealand College of Midwives, the Australian and New Zealand College of Psychiatrists, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists that providers should directly refer to abortion services, or facilitate transfer to another provider who can do the referral. Allowing providers to object to direct referrals, when one of their core professional obligations is to navigate patients through the health system, is one thing. But providers objecting to making indirect referrals, and thereby failing to ensure the safe transfer the patient to the care of a colleague, amounts to abandoning the patient. This takes CO too far.
Competing interests:
Nil.

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Resistant iron-induced hypophosphatemia following colorectal surgery

Yu-Jen Chen, Christopher Lim, Jacob McCormick

ABSTRACT

Iron-induced hypophosphatemia represents an increasingly recognised complication of iron infusion. A 34-year-old woman presented for surgical management of her colorectal cancer. Post-operative blood tests revealed severe hypophosphatemia, resistant to oral phosphate supplementation and large volumes of intravenous phosphate replacement. Further questioning and biochemical investigation led to the recognition of iron-induced hypophosphatemia as a contributory cause, secondary to iron infusion administered as part of pre-operative optimisation. Early consideration, diagnosis and management of this complication has the potential to reduce fluid burden associated with intravenous phosphate supplementation and optimise post-operative care.

Iron-deficiency anaemia is the most common form of anaemia worldwide. The incidence is particularly high in patients with colorectal cancer, as unexplained iron deficiency anaemia often prompts further investigation for malignancy. Intravenous iron supplementation is frequently used for pre-operative optimisation, as it offers superior bioavailability and convenience compared to oral supplementation. Among available preparations, ferric carboxymaltose (FCM) is a common choice due to accessibility, a low incidence of allergic reaction, and fast infusion time. Hypophosphatemia is an increasingly recognised adverse effect of FCM infusion, and delays in recognition, diagnosis and management may lead to sub-optimal clinical outcomes. Consequently, clinicians must consider the adverse effects of FCM infusion when caring for patients undergoing colorectal surgery.

Clinical record

A 34-year-old woman with a new diagnosis of transverse colon adenocarcinoma presented for elective laparoscopic subtotal colectomy. Although the procedure was performed without intra-operative complication, post-operative investigations revealed significant hypophosphatemia of 0.31mmol/L, decreased from a pre-operative level of 0.60mmol/L (Table 1). Despite aggressive oral and intravenous replacement of phosphate over the following 72 hours, serum phosphate levels remained low between 0.37–0.58mmol/L (Table 2). Throughout this time, the patient was asymptomatic of hypophosphataemia. The patient’s renal function and other electrolyte levels remained within normal limits.

On further questioning, the patient reported recent ferric carboxymaltose (FCM) infusion for iron-deficiency anaemia. Two infusions of FCM were administered one week apart, with the second infusion administered six days prior to her operation. Subsequent biochemical investigations demonstrated low levels of 25-hydroxyvitamin D, calcitriol and a significantly raised urinary fractional excretion of phosphate of 29.8%, suggestive of renal phosphate wasting secondary to fibroblast growth factor 23 (FGF-23) excess. Differential diagnoses included prolonged poor phosphate intake, post-operative ileus, refeeding syndrome and Fanconi syndrome.

The patient was commenced on additional oral 25-hydroxyvitamin D and calcitriol replacement, with gradual
Table 1: Blood test results with reference ranges. The pre-operative blood tests were taken six days before the day of operation.

<table>
<thead>
<tr>
<th>Blood test result (ref. range)</th>
<th>Pre-operative</th>
<th>Day 1 post-op</th>
<th>Day 6 post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin (115–155g/L)</td>
<td>96</td>
<td>98</td>
<td>109</td>
</tr>
<tr>
<td>WCC (4.0–12.0x10^9/L)</td>
<td>5.5</td>
<td>10.9</td>
<td>5</td>
</tr>
<tr>
<td>Platelet (150–400x10^9/L)</td>
<td>357</td>
<td>243</td>
<td>321</td>
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<tr>
<td>Sodium (135–145mmol/L)</td>
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<td>139</td>
<td>138</td>
</tr>
<tr>
<td>Potassium (3.5–5.2mmol/L)</td>
<td>4.8</td>
<td>3.8</td>
<td>3.9</td>
</tr>
<tr>
<td>Chloride (95–110mmol/L)</td>
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<td>108</td>
<td>112</td>
</tr>
<tr>
<td>Bicarbonate (22–32mmol/L)</td>
<td>26</td>
<td>23</td>
<td>20</td>
</tr>
<tr>
<td>Urea (3.0–8.0mmol/L)</td>
<td>2.6</td>
<td>2.3</td>
<td>0.6</td>
</tr>
<tr>
<td>Creatinine (45–90umol/L)</td>
<td>56</td>
<td>53</td>
<td>41</td>
</tr>
<tr>
<td>eGFR (&gt;90)</td>
<td>&gt;90</td>
<td>&gt;90</td>
<td>&gt;90</td>
</tr>
<tr>
<td>Calcium (2.10–2.60mmol/L)</td>
<td>2.3</td>
<td>2.06</td>
<td>1.98</td>
</tr>
<tr>
<td>Magnesium (0.70–1.10mmol/L)</td>
<td>0.86</td>
<td>0.72</td>
<td>0.8</td>
</tr>
<tr>
<td>Phosphate (0.75–1.50mmol/L)</td>
<td>0.6</td>
<td>0.31</td>
<td>0.43</td>
</tr>
<tr>
<td>Albumin (35–50g/L)</td>
<td>36</td>
<td>31</td>
<td>30</td>
</tr>
<tr>
<td>CRP (&lt;5.0mg/L)</td>
<td>1</td>
<td>72</td>
<td>3</td>
</tr>
<tr>
<td>25-hydroxyvitamin D (&gt;50nmol/L)</td>
<td>/uni00A0</td>
<td>19</td>
<td>/uni00A0</td>
</tr>
<tr>
<td>1,25-dihydroxyvitamin D (1.7–10.0 pmol/L)</td>
<td>/uni00A0</td>
<td>8.9</td>
<td>/uni00A0</td>
</tr>
<tr>
<td>PTH</td>
<td>/uni00A0</td>
<td>36</td>
<td>/uni00A0</td>
</tr>
<tr>
<td>Iron studies</td>
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<td></td>
</tr>
<tr>
<td>Ferritin (20–204ug/L)</td>
<td>591</td>
<td>633</td>
<td>/uni00A0</td>
</tr>
<tr>
<td>Iron (9–30umol/L)</td>
<td>185</td>
<td>10</td>
<td>/uni00A0</td>
</tr>
<tr>
<td>Transferrin (2.0–3.6g/L)</td>
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<td>1.6</td>
<td>/uni00A0</td>
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<tr>
<td>Transferrin saturation (15–45%)</td>
<td>&gt;100</td>
<td>25</td>
<td>/uni00A0</td>
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<tr>
<td>Random urinary sample</td>
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<tr>
<td>Creatinine (3.0–24.0mmol/L)</td>
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<td>/uni00A0</td>
</tr>
<tr>
<td>Albumin (&lt;3.5mg/L)</td>
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<td>&lt;5.0</td>
<td>/uni00A0</td>
</tr>
<tr>
<td>Glucose (mmol/L)</td>
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<td>/uni00A0</td>
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<tr>
<td>Phosphate (mmol/L)</td>
<td>/uni00A0</td>
<td>5</td>
<td>/uni00A0</td>
</tr>
<tr>
<td>Fractional excretion of phosphate (15–20%)</td>
<td>/uni00A0</td>
<td>29.8</td>
<td>/uni00A0</td>
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</tbody>
</table>
improvement of serum phosphate levels. Management of hypophosphataemia prolonged her hospital stay to eight days. The patient's phosphate levels normalised within one week of discharge.

Discussion

Hypophosphatemia is an increasingly recognised adverse effect of FCM infusion. A recent randomised trial by Wolf et al reported an incidence of 50% in patients receiving FCM. This is likely mediated by an increase in FGF-23 concentration following FCM infusion. As one of the main regulators of plasma phosphate concentration, FGF-23 suppresses renal tubular phosphate reabsorption, increasing urinary excretion of phosphate. FGF-23 also suppresses renal production of 1,25-dihydroxyvitamin D (calcitriol), which further acts to reduce intestinal uptake of dietary phosphate. While FCM-induced hypophosphatemia is usually asymptomatic, cases with classical symptoms of tiredness, diffuse muscle pain and weakness have been described in the literature.

Appropriate fluid balance is a vital component of post-operative management. ‘Enhanced Recovery After Surgery’ (ERAS) protocols recommend discontinuing or restricting intravenous fluids following colorectal surgery. In such patients, excess intravenous fluid administration is associated with a higher incidence of complications, including anastomotic leakage and wound dehiscence. Fortunately, our patient's post-operative course remained uncomplicated due to her age and otherwise good health. The risk of complications from excessive intravenous fluid administration may be higher in an elderly population, or in those with significant comorbidity.

Patients undergoing colorectal surgery may develop hypophosphatemia through other mechanisms affecting phosphate uptake and regulation. These commonly include poor oral intake, post-operative ileus and refeeding syndrome. Delays in recognising the contribution of FCM infusion to hypophosphatemia in this patient were likely precipitated by its multifactorial nature, in addition to a lack of awareness surrounding FCM-induced hypophosphatemia.

This case highlights the potential impact of delayed recognition of FCM-induced hypophosphatemia in the post-operative period. These delays led to a deviation from standard ERAS protocol, resulting in suboptimal fluid management and increased length of hospital stay. Early consideration, diagnosis and management of iron-induced hypophosphatemia may act to optimise patient recovery and reduce the risk of post-operative complication.

Table 2: Trend of the patient's phosphate level along with the total amount, in mmol, of supplemental phosphate given to the patient.

<table>
<thead>
<tr>
<th>Day</th>
<th>Serum PO4 (mmol/L)</th>
<th>Total IV replacement (mmol)</th>
<th>Total PO replacement (mmol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.31</td>
<td>40</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>0.28</td>
<td>70</td>
<td>64</td>
</tr>
<tr>
<td>4</td>
<td>0.54</td>
<td>50</td>
<td>64</td>
</tr>
<tr>
<td>5</td>
<td>0.37</td>
<td>60</td>
<td>64</td>
</tr>
<tr>
<td>6</td>
<td>0.43</td>
<td>60</td>
<td>144</td>
</tr>
<tr>
<td>7</td>
<td>0.57</td>
<td>-</td>
<td>144</td>
</tr>
<tr>
<td>8</td>
<td>0.66</td>
<td>-</td>
<td>144</td>
</tr>
</tbody>
</table>

*25-hydroxyvitamin D and 1,25-dihydroxyvitamin D (calcitriol) supplements were started.
Competing interests:
Nil.

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REFERENCES:
What we know, and don’t know, about cannabis, psychosis and violence

Joseph M Boden, Janet K Spittlehouse

In May 2019 the advocacy group Family First produced a press release expressing concern about the upcoming cannabis referendum in New Zealand in 2020. The primary focus of the press release was to argue for possible links between the use of cannabis and violent behaviour, apparently mediated via increases in psychotic symptomatology/psychotic illness following cannabis use. Finally, the press release cited a number of studies and sets of statistics as evidence for their position. In our view, the attempt to link cannabis use to violence via psychotic illness is tenuous at best, for several reasons.

The first major reason is the nature of the evidence linking cannabis use to increases in psychosis. While the link has been well-established for a number of years, the extent to which cannabis leads to an increase in psychotic illness, rather than merely increasing symptoms, is less well understood, primarily due to heterogeneity in study outcomes. For example, the Dunedin Multidisciplinary Health and Development Study reported an increase in schizophrenia symptoms and schizophreniform disorder associated with early cannabis use (prior to age 15), while our own study (the Christchurch Health and Development Study) reported an increase in psychotic symptomatology as measured by the SCL-90 in more frequent users of cannabis to age 25. It is important to note that psychotic symptomatology, while relatively uncommon, comprises a variety of symptoms ranging from relatively mild (“believing others can hear your thoughts”) to severe (“believing that a... force could control your movements or thoughts against your will”), with mild symptoms being more commonly reported. The heterogeneity between studies makes it difficult to ascertain precisely which ‘psychosis’ is being increased as a result of cannabis exposure.

The second major reason for the tenuousness of the Family First argument is related to the nature of the studies linking psychosis with violence. Most of the research linking increased risk of violence to psychosis have examined patients with a diagnosis of a psychotic disorder, rather than those with reported symptoms. The magnitude of the elevated risk among those diagnosed with a psychotic disorder is relatively small, but greater than among those who report symptoms but do not meet criteria for disorder, and it is relatively rare for psychosis to precede violent behaviour. In addition, many of these studies examined violence among psychiatric inpatients who have been involuntarily committed to hospital due to risk of harm to self or others, suggesting that sample selection may play a strong role in the observation of violent behaviour among these individuals. Furthermore, earlier studies that have examined the links between psychotic symptomatology and violence have found that there were a specific subset of symptoms, related to perceived threat and internal control-override that were related to violent behaviour, rather than psychotic symptomatology more generally. Therefore, while the risk of violence is elevated among individuals diagnosed with psychosis, the nature of the links between specific features of psychosis and violence is not well understood.

A further concern with the press release by Family First is that several studies have been cited, but none of them directly link cannabis exposure, psychosis and violence. In addition, many of the studies have been undertaken with selective samples (eg, men convicted of intimate partner violence), from which conclusions about
these linkages in the general population cannot be drawn. It should also be noted that some studies conflate “substance use disorder” with alcohol use disorder, which has been shown to have an unequivocal link to increased risk of violent behaviour. Further, the press release fails to note methodological weaknesses in the cited studies (eg, failing to control for anti-social personality disorder), as well as cautious interpretations made by the original authors. Finally, however, the press release also quotes statistics from various jurisdictions in which the influence of cannabis is inferred by the authors of the release, but clearly cannot be shown to be causal.

We agree with Family First on one important point; more research is needed on the possible linkages between cannabis exposure and violence. However, the use of tendentious arguments, and failing to properly report on the strengths and weaknesses of the research literature is not the way to move forward in our discussions concerning the best way to regulate the consumption of cannabis. Furthermore, such commentary serves to perpetuate the stigmatisation of persons with serious mental illness. The New Zealand public deserves a good-faith approach by all involved in the debates.

Competing interests:
Nil.

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REFERENCES:
Sun protection policy in New Zealand

Ben Gray

McNoe and Reeder's paper on sun protection policy in New Zealand has an important flaw. Although data was collected on ethnicity the paper did not include ethnicity in the analysis of the data. While it is accepted that New Zealand as a whole has a high incidence of melanoma, this is largely within the New Zealand European population that account for 79.9% of cases with low levels reported in Māori 0.7% and Pacific 0.2%, and probably even lower levels in people from Africa and the Indian subcontinent (5.7% other and 13.5% unknown). Even these statistics in New Zealand are difficult to interpret. As Callister noted “In New Zealand, where there is a high rate of ethnic intermarriage and ethnicity is culturally constructed, there is likely to have been a weakening of the relationship between ethnicity and skin colour”. It is entirely possible that the 0.7% Māori who get melanoma are all fair skinned.

Adherence to the sun protection policy is more important in schools with large proportions of New Zealand European children, and of less importance in schools with a high proportion of dark-skinned children. They did not use the ethnicity data to test the hypothesis that adherence to the sun protection policy was lower in schools with a high proportion of children with dark skin.

The sun protection policies advocated in this paper are essential for children with fair skin, and of diminishing benefit as the child's skin gets darker, to the point where for very dark-skinned children they provide no demonstrated benefit. However, such policies will have an unmeasured adverse effect by promoting vitamin D deficiency. In a study at our practice (enrolled population around 7,000) on pregnant women, 87% of women were deficient in vitamin D and a review of records found 10 children under five years old having been diagnosed with rickets in the previous three years. The practice has just 18% New Zealand European. It seems counter-intuitive to walk past Newtown School to see the Somali children with sun hats on. For more detail on effects of sun exposure and vitamin D deficiency, see New Zealand policy statement. Protecting children at low risk of developing melanoma from the sunlight that will increase their vitamin D levels risks causing harm. The logistics and costs of arranging supplementation make it unlikely to be effectively implemented. We could learn the lesson from the Sudden Unexpected Death in Infants (SUDI) experience. The initial public health response was effective in dropping the rate in the New Zealand European population, but for 10 years Māori had a rate twice that of the non-Māori population. A team of researchers addressed the problem from a Māori perspective and devised the ‘pepe pod’ that led to a dramatic reduction of SUDI in Māori. An earlier appreciation that a different public health approach was needed for Māori could have saved lives.

We are an increasingly multicultural society. We need to be more sophisticated in our health promotion policy and take care not to use a one-size-fits-all.
Competing interests:
Nil.

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REFERENCES:


The thorny issue of alcohol control in Aotearoa/New Zealand: developments in Ireland

Frank Houghton

Ford et al recently discussed the ongoing and problematic nature of alcohol misuse in New Zealand.1 Like many other Western countries, New Zealand liberalised its sale and supply of liquor legislation towards the end of the 20th Century, starting with the 1989 Sale of Liquor Act.2–3 Over time this legislation and subsequent amendments permitted a significant expansion in the number and types of premises permitted to sell alcohol, a reduction in the age to legally purchase alcohol from 20 to 18, and allowed Sunday trading in alcohol.2–3 The outcome of this deregulation has included an increase of more than 100% in the number of alcohol outlets in New Zealand, increasing from 6,000 to 14,000 over a decade, and a growing state of widespread unease concerning the negative impact of alcohol on society in New Zealand.4

The adverse global impact of alcohol is significant,5 and New Zealand is no exception.4,6,7 It must be remembered that any routine assessments of the impact of alcohol on morbidity and mortality may overlook the role of alcohol as a facilitator and risk factor for both domestic violence and suicide. The inequitable negative impact of alcohol-related morbidity and mortality among Māori is also a particular issue of concern.8–10

Ireland has an equally problematic relationship with alcohol,11–17 and has traditionally been subject to a host of negative stereotypes and caricatures internationally around this issue.17–19 Per capita alcohol consumption in Ireland is a significant issue of concern.11–16 However, the beginning of a turning point towards a more responsible approach to alcohol may be seen with the explicit inclusion of alcohol in Ireland’s Drug strategy in 2009.25

More recently, after more than 1,000 days of debate and in the face of significant opposition from representatives from rural constituencies, Ireland’s parliament (the Dáil) has just passed a new alcohol Bill which paved the way for a range of more stringent control measures.26–27 These include minimum unit pricing, mandatory cancer warnings and the spatial segregation of alcohol sales in shops.26

Given both the negative impact on morbidity and mortality attributable to alcohol and the high level of public unease about this issue, it may be an opportune
time for New Zealand to once again seriously reconsider similar initiatives. New Zealand’s Sale and Supply of Alcohol Act 2012 enacted some, but not all of the impressively comprehensive Law Commission report Alcohol in Our Lives: Curbing the Harm. Thus former opportunities for more stringent protections may have been wasted, however now is the time for action. Recent research in New Zealand has highlighted the failure of a voluntary code of warnings on alcohol. Additionally, despite a reluctance in government circles, there appears to be growing pressure to push for legislation to introduce a minimum unit price initiative. Support for such a measure may also be seen in a recent Ministry of Justice report. In relation to the segregation of alcohol sales, it should be noted that the New Zealand Medical Association (NZMA) has already called for a ban on the sale of alcohol from supermarkets. In addition, research from New Zealand has amply demonstrated the high level of exposure of children to alcohol in everyday environments that only serves to normalise alcohol, a product that is ‘no ordinary commodity’.

Competing interests:
Nil.

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REFERENCES:


A randomised trial of prophylactic antibiotics for miscarriage surgery

Surgical intervention is needed in some cases of spontaneous abortion to remove retained products of conception. Antibiotic prophylaxis may reduce the risk of pelvic infection.

This trial was devised to throw some light on this issue. Three thousand four hundred and twelve patients from Malawi, Pakistan, Tanzania and Uganda were enrolled. Half of them received a single preoperative dose of 400mg of oral doxycycline and 400mg of oral metronidazole, and the other half received identical placebos. Pelvic infection was defined as two or more of four clinical features—purulent vaginal discharge, pyrexia, uterine tenderness and leucocytosis.

The conclusion reached was that antibiotic prophylaxis before miscarriage surgery did not result in a significantly lower risk of pelvic infection, as defined by pragmatic broad criteria, than placebo.


Management of atrial fibrillation after cardiac surgery

Is atrial fibrillation (AF) that occurs after cardiac surgery best controlled by rhythm or rate control? This is questioned in this study.

After reviewing more than 2,000 relevant papers the authors of this study identified five reports that they considered to provide the best evidence—four were reports of randomised trials and one was a retrospective cohort study. Hospital length of stay were approximately equal in the two management protocols. Freedom from AF at follow-up was found to be similar. Minimal adverse effects were seen in both groups.

It appears that rate and rhythm control are equally good in the management of AF after cardiac surgery.

Internal Medicine Journal 2019; 49:656–658

Use of hormone replacement therapy and risk of venous thromboembolism

The aim of this nested case-control study was to assess the association between risk of venous thromboembolism and use of different types of hormone replacement therapy.

80,396 women with a diagnosis of venous thromboembolism were compared with 391,494 matched female controls. The researchers found a significantly increased risk of venous thromboembolism in those taking oral contraceptives compared with the subjects with no exposure. Equine oestrogen with medroxyprogesterone had the highest risk (2.10) and estradiol with dydrogesterone had the lowest risk (1.18). Transdermal preparations were not associated with risk of venous thromboembolism.

In the present study, transdermal treatment was the safest type of hormone replacement therapy when risk of venous thromboembolism was assessed. Transdermal treatment appears to be underused, with the overwhelming preference still for oral preparations.

BMJ 2019; 364:k4810

URL:
Myositis Ossificans

By GORDON MACDONALD, M.D., Dunedin

On several occasions during the past few years I have sent notes to the NEW ZEALAND MEDICAL JOURNAL regarding the progress of this disease in a girl whose case I first reported in the JOURNAL of 29th August, 1891. In October last she died suddenly from heart failure and general weakness. No post-mortem examination was permitted, and thus a most unusual and interesting case has passed out of all further observation. As the younger generation of practitioners may not have access to the JOURNAL of 29th August, 1891, I may recapitulate the principal points in the case. The disease was first observed when the child was two years of age. It showed itself as a hard lump about the middle of the left sterno-mastoid muscle. After this a series of lumps appeared, disappeared, and reappeared in various positions upon the head and trunk. The disease steadily progressed in spite of all treatment, and has now ended fatally. In some remarks I made in the original paper I have noted that Dr. Lendon, of Adelaide, who reported a case to the first Intercolonial Congress in 1887, says: “In my own case, and I think, also, in that of William Clark, the case in the Museum of the Royal College of Surgeons, London, it is a noted fact that the disease is mainly situated in the muscles of the appendicular skeleton and has spared those of the axial skeleton.”

Now, in my case the reverse is the fact. The occurrence of nodes in this case, their appearance, disappearance, and reappearance, lends some colour to the theory that it may have had its origin in some syphilitic taint. Nothing, however, has been detected in the family history to warrant any such conclusion. In a note I sent to the JOURNAL in August, 1905, I stated: “The internal organs are apparently healthy and seemingly not involved in the general degeneration going on in the external
“In 1905 the muscles of the legs were not very much involved, but since then they also became involved, so that the whole of the external muscular system latterly became more or less diseased. She was able to move about in a more or less helpless manner until some twelve months ago, but since then she has been entirely confined to home and to bed, her whole frame being quite rigid. She had entirely lost all power of expanding her chest and movement in the muscles of the abdomen. Strange, too, she could neither smile nor laugh, so her face always held one fixed gaze as if dead. She could neither feed herself, nor dress herself, nor wash herself, nor lie down, nor rise up—in short, she became a helpless infant. She also suffered from bradycardia and slow, irregular respiration. Her mental faculties were very feeble, but she developed a species of cunning which served her purposes to some extent. Her left sterno-mastoid muscle, completely ossified, was removed whilst she was an inmate of the Dunedin Hospital in 1891.”

URL:
The proceedings of the 243rd and 244th meetings of the OMSRS

A digital method for estimating orthodontic treatment need
C Cai, S Olliver, L Mei, J Broadbent
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Dental malocclusions refer to the misalignment of teeth and may range from trivial to debili-tating. The Dental Aesthetic Index (DAI) is commonly used to identify individuals with very severe malocclusions who may qualify for publicly funded care, but estimation of DAI scores may vary between referring dentists. The 3Shape Trios intra-oral scanner generates accurate three-dimensional digital images of the oral cavity, enabling the calculation of DAI digitally. However, no published reports have described such a method. We aimed to determine whether a modern digital imaging technique may enable more reliable estimation of DAI scores and allow its use in the Dunedin Multidisciplinary Health and Development Study (DMHDS).

World Health Organization criteria were used for estimating clinical DAI scores and were adapted to our digital method where necessary. DAI was measured both clinically and digitally by two examiners on a sample of 16 individuals presented with varying occlusal traits: a total of four times for eight participants and eight times for the remaining eight participants. After examiner calibration was complete, DAI was then collected for DMHDS calibration was complete, DAI participants. After examiner times for the remaining eight participants and eight traits: a total of four times for presenting with varying occlusal

DAI scores obtained digitally ranged from 19 to 35 (mean 26.8, sd 4.6) and test-retest scores varied by a mean of only 0.1 points (sd 1.1). Both individual and average intra-class correlations based on consistency agreement and two-way mixed effects model were high, at >0.95 for all measurements of intra- and inter-examiner reliability. DAI scores in the Dunedin Study were strongly associated with self-perceived dental appearance, reaffirming the validity of the index.

This study demonstrating digital measurement of DAI scores allows reliable, rapid and accurate estimation of orthodontic treatment need outside the clinical setting.

Supported by a grant from the Auckland Dental Association Summer Scholarship.

The role of macrophages in allogenic skin graft rejection in murine models
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An allograft is transplantation of skin from a genetically unrelated donor to a victim with a large area of uncovered trauma. While an allograft can restore organ function, rejection is a frequent problem due to the cellular destruction instigated by immune cells, such as macrophages. Immunosuppressants delay but do not prevent rejection, suggesting certain immune cells may be critical to graft integration. Macrophages can be categorised into two generalised subsets: M1, which are pro-inflammatory and M2, which promote tissue repair. We aimed to define the role of M1 and M2 macrophages in allograft rejection and integration in a murine model.

C57BL/6 and BALB/c mice were used as they have distinct immune responses. Full-thickness skin punch biopsies were taken from a donor C57BL/6 mouse, transplanted into full-thickness wounds on BALB/c mice and vice versa. Three C57BL/6 and four BALB/c mice received grafts. Mice were euthanised and the wound harvested on the day of estimated 50% rejection, C57BL/6 mice were euthanised one day prior to BALB/c mice. Immune cells within the grafts were identified using flow cytometry and immunofluorescent histochemistry; statistical significance was assessed with an unpaired t-test.

Two C57BL/6 and three BALB/c mice retained grafts. When the graft remained, tissue showed greater viability and integration in wounds of BALB/c mice. C57BL/6 and BALB/c mice had higher frequencies of M1 macrophages within wounds with grafts (mean ± SEM, C57BL/6 75.94±11.12%, BALB/c 22.85±6.74%, P<0.05); BALB/c mice displayed higher frequencies of M2 macrophages (BALB/c 10.67±1.61%, C57BL/6 5.35±2.24%, P<0.05).

This study implicates M1 cells with a role in allograft skin rejection and M2 cells in skin graft integration, both are therefore a possible drug target.

Supported by a School of Biomedical Sciences Summer Research Scholarship.
Aortic size index to predict risk in coronary artery disease patients

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Cardiovascular disease is one of the leading causes of death and disability worldwide. Current risk stratification and classification of coronary artery disease (CAD) can be performed using coronary angiography. However, significant risk is not accounted for with this approach. We investigated the use of aortic size index (ASI, abdominal aortic diameter divided by body surface area) as a means of more accurate prognostication.

The cohort consisted of a consecutive series of patients undergoing coronary angiography due to suspicion of stable or unstable CAD. ASI was calculated based on an abdominal ultrasound. Standard demographic variables were obtained, and patients were stratified based on severity of their disease (obstructive, non-obstructive or no luminal disease). Adverse events were defined as myocardial infarction, hospitalisation due to unstable angina, unplanned revascularisation procedure or death due to any cause. ASI was analysed as a continuous measure as a predictor of events using logistic regression, and then as a categorical measure (extreme ASI, referring to the largest and smallest ASI groups based on predefined cut points (lower <0.835cm/m² and upper >1.2cm/m²) using Cox proportional hazards regression.

Data from 867 patients were analysed (mean age 68 years, 65% male). ASI showed a U shape relationship with outcomes where extremes of ASI had a higher risk of a subsequent event. Survival analysis revealed a 40% increase in event rate for those with ASI extremes (hazard ratio 1.40, 95% confidence interval 1.07–1.84, P=0.02), which remained significant when adjusted for age and sex. However, no significant relationship was seen with ASI when history of diabetes and overall CAD classification were included in the model (hazard ratio 1.21, 95% CI 0.92–1.59, P=0.18).

In conclusion, ASI is predictive of adverse events in patients undergoing coronary angiography, but does not add significant information over traditional predictors of adverse outcome.

Supported by a Division of Health Sciences Summer Student Research Scholarship.

Assessing the efficacy of a novel adeno-associated viral capsid in targeting the brain

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One barrier to the treatment of Alzheimer’s disease is a lack of effective methods to deliver therapeutics to the brain, particularly by non-invasive routes. Adeno-associated viral (AAV) vectors used for gene therapy may provide a solution as some serotypes can cross the blood brain barrier, allowing for minimally non-invasive administration. A novel AAV capsid, AAV-PHP.eB, was recently reported to produce high transgene expression in mouse brain after intravenous administration. The present study compared the efficiency of two AAV vectors in targeting the brain after intravenous administration: AAV-PHP.eB, and a similar widely used viral vector, AAV9.

C57Bl/6 mice were administered either AAV-PHP.eB (n=5) or AAV9 (n=4) carrying the transgene for green fluorescent protein (GFP) via tail vein injection (100µL). Four weeks after vector administration, brain sections were immunolabelled for GFP and cell-type specific markers. Liver sections were also examined for GFP expression. The small number of cells expressing GFP in both vector groups meant results were limited to qualitative observations.

Like AA9, AAV-PHP.eB produced GFP expression in both neurons and glia. However, GFP expression in the brain produced by AAV-PHP.eB was not as high as reported. Despite transduction being sparse, AAV-PHP.eB was more effective than AA9 at transducing cells across the whole brain. AAV-PHP.eB also produced much lower GFP expression in the liver than AA9, which suggests that AAV-PHP.eB has high tropism for brain cells. The low liver transduction may mean more of the vector is available to reach the brain.

The higher efficacy of AAV-PHP.eB compared to AA9 at transducing brain cells following intravenous delivery is encouraging when considering translation of this approach to humans. After additional work to evaluate the effectiveness of AAV-PHP.eB, it is planned to test this vector in future preclinical studies involving animal models of Alzheimer’s disease.

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Nanosilver as an antimicrobial for grafting materials and its cytotoxicity on human gingival fibroblasts in vitro

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Moa Bone® is a deproteinated bovine bone product which increases clinically important bone regeneration in dental procedures. However, graft sites are often associated with infections. Silver nanoparticles (AgNP) represent a promising antimicrobial, yet limited infor-
mation is available on their safety profile.

We investigated the cytotoxicity of AgNP on human gingival fibroblasts (HGF; N=3) using both in vitro cell viability and caspase 3/7 apoptosis assays. Chlorhexidine (CHX), silver nitrate (AgNO3) and silver diamine fluoride (SDF) were tested as widely accepted licensed clinical controls. Data was calculated as a mean ± SD of pairwise comparisons where controls of untreated cells were set to 100%. Paired t-tests were used for comparisons and IC50 regression analysis conducted in GraphPad PRISM7.

AgNP (22.5µg/mL for 4h) resulted in significant cytotoxicity to HGF with only 8.42±14.58% (P=0.0083) of cells being viable as compared to control (100%). However, no significant cytotoxic effect was seen at doses below 5µg/mL. CHX was used clinically at 0.2% and was cytotoxic at 0.02% after 4h (9.80±10.96%, P=0.0049). AgNO3 was cytotoxic at 50µg/mL after 4h (0.43±0.75%, P=0.00002). SDF had an IC50 of 10.2µg/mL at 4h and 10.6µg/mL at 96h, indicating minimal cumulative effect. Additionally, AgNP showed a statistically significant anti-apoptotic effect at 22.5µg/mL (39.78±5.74%, P=0.0031) and 50µg/mL (62.93±3.56%, P=0.002).

The cytotoxic effect of AgNP on HGF was similar to or less than that of CHX, AgNO3, and SDF and it was anti-apoptotic. Overall, AgNP showed a promising cytotoxicity profile which warrants its investigation as an adjunct to Moa Bone.

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Elucidating the effect of prenatal androgen excess on male reproductive function and metabolism

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Elevated maternal androgen levels are associated with the development of polycystic ovary syndrome (PCOS, a prevalent metabolic/infertility disorder) in females. Emerging clinical research has recently postulated the existence of a male PCOS phenotype, as it has been observed that the male relatives of women with PCOS manifest an array of similar reproductive and metabolic abnormalities. Therefore, this project aimed to elucidate the reproductive and metabolic phenotype of prenatally androgenised mice (PNAM).

Pregnant mouse dams were subcutaneously injected with either 250µg of dihydrotestosterone (DHT) (eliciting PNAM offspring) or a control oil vehicle solution (200µL) (vehicle control offspring) on gestational days 16, 17 and 18. Pubertal onset and fertility was analysed by determining the age of the first successful mating (resulting in conception) and daily anogenital distance (the distance between the glans penis and anus) measurements from postnatal day 35 onwards. Body weight measurements were recorded every five days throughout puberty and then every 10 days throughout early adulthood. Testes and seminal vesicles weight was additionally measured.

Overall, this project found no statistically significant differences between PNAM and vehicle controls in terms of body weight, age of first successful mating and seminal vesicles weight. However, the normalised anogenital distance measurement by body weight of PNAM (n=20) mice was significantly shorter (ie, female-like and suggestive decreased circulating androgens) at postnatal day 40 in comparison to vehicle controls (n=15) (P=0.01). Additionally, the normalised testes to body weight ratio was significantly lower in PNAM mice (Mann Whitney U test, P=0.0152).

Therefore, this study has illustrated males exposed to elevated prenatal androgens manifest small changes in external genitalia and gonadal weight, but are still fertile and exhibit no overt metabolic phenotype. It remains to be determined whether men exposed to elevated maternal androgens manifest any reproductive abnormalities.

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Folia-specific vulnerability of the cerebellar climbing fibre synapse in a mouse model of human spinocerebellar ataxia type 1

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Ataxia, or loss of movement control, is caused by disrupted cerebellar synaptic connections. The cerebellar cortex exhibits a foliated anatomical structure (undergoes repeated folding) that is largely conserved between mice and humans. All folia contain Purkinje neurons (PNs) that receive strong excitatory climbing fibre (CF) synaptic connections that

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modulate their output, but how this CF synaptic organisation differs in health and disease remains unknown. PNs can be sub-grouped based on molecular markers they express, such as excitatory amino acid transporter, EAAT4, which varies across folia. Furthermore, reduced EAAT4 expression and disrupted CF morphology both occur in the early stages of spinocerebellar ataxia type 1 (SCA1). Here, we test the hypothesis that CF disruption in SCA1 is greatest in cerebellar folia where EAAT4 is normally expressed.

Sagittal cerebellar sections (30µm) were collected from 15-week-old ataxic SCA1 and non-atactic wild-type (WT) mice for fluorescence immunohistochemistry and confocal microscopy. Double-labelling with EAAT4 and calbindin ensured co-localisation at PNs, while calbindin and vesicular glutamate transporter 2 were used to assess PN and CF morphology, respectively.

In WT mice we observed higher EAAT4 expression in posterior versus anterior cerebellar folia (P<0.01, one-way ANOVA, n=4). CF morphology also varied across folia in WT mice (anterior versus posterior, P<0.001, two-way ANOVA, Tukey’s multiple comparisons), but CF morphology in SCA1 mice was only disrupted in posterior folia (interaction P<0.001, two-way ANOVA, n=6 WT, SCA1). However, SCA1 mice showed PN atrophy throughout the cerebellum, compared to WT mice (P<0.001, two-way ANOVA, n=6 WT, SCA1).

Results indicate that CF synapses located in the posterior cerebellum are more vulnerable to loss of EAAT4 expression in SCA1 mice. Our findings suggest the need for folia-specific therapeutic targeting for early treatment of SCA1. Supported by a Division of Health Sciences Summer Research Scholarship.

Do online resources foster self-management support in people with persistent pain?

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Persistent non-cancer pain affects one in five New Zealanders. Online resources such as smartphone applications (apps) and websites are a potential solution for fostering self-management skills such as self-reflection and active goal setting in people with persistent pain. The aim of our review was to evaluate the contents of online resources (apps and websites) for people with persistent pain facilitating self-management support.

A systematic search was performed in the New Zealand App Store and Google Play Store and major search engines Google, Bing and Yahoo. Online resources were included if they were designed for people with persistent pain, provided information on pain management strategies and available in English. The contents were evaluated using an a priori 14-item self-management support checklist. The 23-item Mobile Apps Rating Scale (MARS) and HONcode certification was used to appraise app and website quality respectively.

Eighteen apps and 27 websites met inclusion criteria. Overall, the included apps and websites met a median of 3 (range 1–8) and 5 (range 1–8) of the 14-item self-management checklist. For both apps and websites, self-monitoring of symptoms and self-tailoring of strategies were frequently featured functions, while few online resources had features facilitating social support and communicating with clinicians. None provided information tailored to cultural needs of the user. The app quality mean scores using MARS ranged from 2.7 to 4.5 (out of 5.0). HONcode certification was present in six of the 27 websites. Only two apps and two websites underwent scientific evaluation supporting their clinical efficacy.

Although pain management apps and websites provide information to develop self-efficacy, none provided culturally appropriate information. While few apps and websites were validated to show improved health outcomes, none were tested in people with persistent pain. Both users and clinicians have to be aware of such limitations and make informed choices in using and recommending online resources as a self-management tool.

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