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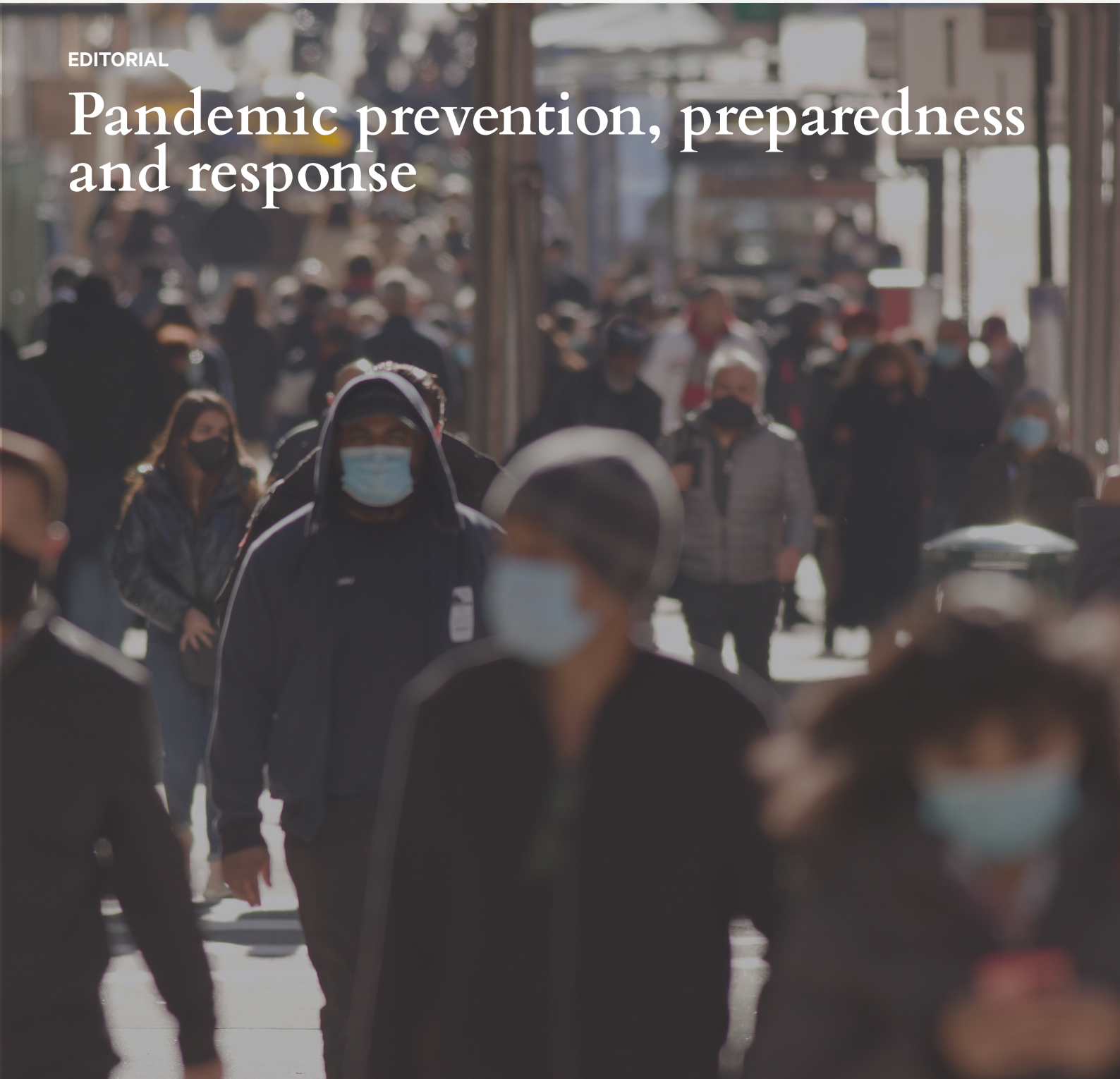

EDITORIAL

Pandemic prevention, preparedness and response

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Summaries

Pandemic prevention, preparedness and response: are we better off now than pre-COVID?

David R Murdoch, Ashley R Bloomfield

Investment in pandemic prevention, preparedness and response (PPPR) is nowhere near the scale or speed necessary globally. PPPR is a fundamental aspect of national security, demanding sustained investment and a whole-of-government approach to ensure readiness for future threats. Pandemic planning must be a living, adaptive process integrating lessons learnt from emerging evidence, the development of new technologies such as vaccines and the repeated testing of plans to ensure they actually work in practice. We need to prepare for the next (inevitable) pandemic, and that response is one of national security, not just a health issue. The updated national pandemic plan that was recently released is a start, but much more work is required.

Early pregnancy high normal HbA_{1c}: a high risk group?

Megan J Chatfield, Lisa Woods, Ella Sussock, Rosalie E Elder, Rosemary M Hall

HbA_{1c} is a blood test that reflects average blood sugar levels over the last 2–3 months, and it is routinely measured at the beginning of pregnancy. Pregnant people with elevated HbA_{1c} (in the pre-diabetes and diabetes range) are at increased risk of adverse pregnancy outcomes. This paper looked at whether pregnant people with HbA_{1c} at the upper limit of normal had an increased risk of adverse outcomes compared to those with a lower HbA_{1c}. There was no significant difference found.

Predictors of symptom recurrence and survival in patients with malignant gastric outlet obstruction treated with self-expanding metal stents

Michael Chieng, Henry Wei, Sarah Haydon, Cameron Schauer

Self-expanding metal stents (SEMS) are commonly used to ease symptoms in patients with a blockage in the upper gastrointestinal (GI) tract caused by cancer. They work well in the short term but may not last a long time. We studied a large group of patients at different hospitals to find out what factors might cause the stent to malfunction and also how we might predict the longevity of patients so we can select the best treatment for them. We found that different types of stents have different pros and cons, which can affect how often patients need additional invasive treatments. In our paper, we also discuss new treatments for this condition and how we should focus future research on working closer with patients to improve quality of life.

Quantifying cost-savings in the treatment of neovascular age-related macular degeneration in Aotearoa New Zealand

James S Lewis, Matthew Roskruge, John Ah-Chan

The study looked at whether a new drug called faricimab could save money and improve treatment for a serious eye condition called neovascular (wet) age-related macular degeneration (nAMD) in New Zealand. This condition can cause severe vision loss, especially in older adults, and is treated with eye injections. The findings suggest that using faricimab could result in national cost savings of up to NZ$139,104,706 over 10 years by reducing the number of eye injections patients need. This would lower the risk of complications and make the treatment process easier. Additionally, the time saved for doctors and nurses could be used to improve care for Māori and Pacific peoples, who often face significant barriers to accessing eye health services.

Awareness and preparedness of healthcare workers for the initial wave of COVID-19 in Aotearoa New Zealand

Thomas Pirker, Ibrahim S Al-Busaidi

A unique survey at Christchurch Hospital during the first wave of the COVID-19 pandemic in 2020 has revealed surprising gaps in healthcare worker preparedness across Aotearoa New Zealand. While frontline staff displayed strong COVID-19 awareness, their overall readiness for the pandemic was notably lower. Social media, driven by user-generated content, emerged as one of the primary sources of information. These striking findings highlight the urgent need for policy reforms, enhanced training and improved infrastructure to better equip healthcare workers for future pandemics in Aotearoa New Zealand.

Polokalama Fekumi ki he Kanisā ‘o e Halanga-me’atokoní—Ko e vakai ‘a e Tongá: Tongan New Zealanders’ views on how to ensure the National Bowel Cancer Screening Programme works well for the Tongan community

Viliami Puloka, Aivi Puloka, Michelle Lambert, Louise Signal

Many Pacific New Zealanders die unnecessarily from bowel cancer because the National Bowel Screening Programme fails to deliver screening equitably. For example, only 35% of Tongan people are screened, compared with 58% of New Zealanders overall. This new research shows there are ways of improving the system. Researchers investigated the views of Tongan New Zealanders about their experiences of the bowel screening programme and how to make it work well for Tongans. Participants argued that Tongans are very motivated to look after their health, but this programme is not designed to meet their needs. Participants overwhelmingly supported a by Tongan, for Tongan approach led by Tongan health providers. This can be done, but what is required is courage and political will to shift power and resources to ensure equitable outcomes in the National Bowel Screening Programme.

Sex-specific analysis of acute alcohol use in suicides and reporting of alcohol as a contributor to suicide deaths in New Zealand 2007–2020: a cross-sectional study of coronial data

Rose Crossin, Jaimie Dikstaal, Christina McKerchar, Lana Cleland, Annette Beautrais, Katrina Witt, Joseph M Boden

Being acutely affected by alcohol can increase suicide risk. In this study, we used coronial data to understand the characteristics associated with suicide involving alcohol. We also investigated the factors associated with whether alcohol is coded as being contributory to death. Our conclusion is that targeted public health interventions designed by and for specific demographic groups are needed, alongside universal interventions that address social and structural determinants, and reduce alcohol use.

Implementation of the Medicinal Cannabis Scheme in New Zealand: six emerging trends

Marta Rychert, Chris Wilkins

The New Zealand Medicinal Cannabis Scheme successfully established a domestic medicinal cannabis production sector, reduced prices and expanded the range of products to provide alternatives to illegal supply. However, there is increasing supply of THC-dominant and flower products, and the privatisation of prescribing via cannabis clinics, and this may have unintended negative consequences. The price of legal products has declined to a point where they are comparable to the illegal market. Inequities persist due to expense, and disproportionately affect Māori and those on lower incomes.

Adult decision-making capacity and health research in Aotearoa New Zealand

Ben Gray, Angela Ballantyne

The current Code of Rights precludes research on people who lack capacity (for example, someone unconscious) unless it is in their best interests. This means that important research to develop evidence on caring for people who lack capacity cannot be done. The National Ethics Advisory Committee (NEAC) is best placed to make the nuanced decisions balancing the societal benefits of research against the risks to the research participant. Legislation should be changed so that these decisions can be made solely by NEAC.

Persistent left superior vena cava after insertion of central venous catheter

Nandika Muruvan, Arthur Cavan, Marilyn Aday, Ankur Gupta

The superior vena cava (SVC) is a large blood vessel that drains into the heart. Normally, humans have one of these large blood vessels on the right side. The patient described on our article had a right and left SVC. This variant can be accompanied with other differences in the structure of the heart and how the blood drains into the heart. It is important for doctors to look out for these differences when we come across this unusual big vessel.

Pandemic prevention, preparedness and response: are we better off now than pre-COVID?

David R Murdoch, Ashley R Bloomfield

It is nearly 5 years since the start of the COVID-19 pandemic, and infectious disease outbreaks continue to cause international concern. Mpox in Africa was recently categorised by the World Health Organization (WHO) Director-General as a Public Health Emergency of International Concern (PHEIC),[1] while highly pathogenic avian influenza has spread to a range of non-avian species around the globe and has infected humans in several countries.[2] Yet there is a sense of "collective global amnesia" about the COVID-19 pandemic. Investment in pandemic prevention, preparedness and response (PPPR) is nowhere near the scale or speed necessary. Despite repeated warnings from experts, numerous initiatives and the direct lived experience of a major pandemic, the level of activity does not match that required to mitigate the widespread health, social and economic impacts of the next (inevitable) pandemic. The risk is that we are falling into what has been dubbed "the cycle of panic and neglect."[3]

Despite waning international political will and the relatively slow pace of progress, all countries can and should apply clear lessons from COVID-19 to their own situations and update their plans to prevent, prepare for and manage the next major infectious diseases risk. In New Zealand, the Royal Commission of Inquiry into COVID-19 – Te Tira Ārai Urutā is due to report in November 2024. The recent announcement of a second stage to that Inquiry,[4] which is not reporting until early 2026, means that many lessons from the COVID-19 pandemic may not be reflected in New Zealand's pandemic preparedness until more than 3 years after the last pandemic was considered over.

However, the COVID-19 experience here and in other countries, and work undertaken by WHO and others, provides some clear pointers about how our pandemic preparedness can be strengthened. The recent publication of an updated national pandemic plan, *New Zealand Pandemic Plan: A framework for action*,[5] is an important milestone and starting point for integrating key lessons.

Avoid reliance on an influenza-centric pandemic plan

The immediate challenge in the early stages of the COVID-19 pandemic was that existing pandemic planning, both in New Zealand and most other countries, was largely focussed on influenza. The 2017 *New Zealand Influenza Pandemic Plan: A framework for action* was designed with the expectation that a new pandemic threat would either be or behave similarly to influenza. However, it became quickly apparent in early 2020 that COVID-19 was not behaving like seasonal influenza, and a shift to the "manage it" phase of the plan would likely overwhelm the health system and result in unacceptable loss of life, as was being witnessed in many countries at the time.

A significant shift in strategy was required, making it clear that pandemic planning must incorporate the ability to adapt to the specific characteristics of the pathogen at hand. This was one of the earliest key lessons from COVID-19.

The importance of clear leadership and decision-making structures

The huge uncertainty and complexity of the COVID-19 pandemic also demonstrated the centrality of leadership and decision-making for both pandemic planning and for responding to security threats more broadly. Each country's response varied significantly, and in New Zealand it became clear early on that leadership structures envisioned in planning frameworks needed to be rethought rapidly to respond to the evolving situation and the emergence of elimination as the overall strategy. Rapid, highly co-ordinated cross-government leadership and decision-making were needed. The complexity of the situation meant that no pre-existing framework could fully account for the range of challenges the pandemic

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posed. Countries had to make decisions quickly, often with incomplete information, while co-ordinating resources, public health measures and communication strategies across multiple sectors.

Beyond a health crisis: planning for a whole-of-society response

COVID-19 did not just present a threat to public health—it was a significant threat to New Zealand's economic and social security. The pandemic disrupted supply chains and schools, closed businesses and exposed inequities. The pandemic demonstrably required a whole-of-government and whole-of-society response, confirming that pandemic planning should do so as well.

Our view, which has implications for preparedness, is that pandemics should be considered primarily as a security threat rather than simply a health threat. Pandemic preparedness and response are not for public health experts alone. Thus, planning should be "owned" and led by the country's security apparatus, currently based in the Department of the Prime Minister and Cabinet to ensure that pandemic responses are able, from the get-go, to address threats to economic and social wellbeing as well as public health.

Global preparedness strengthens collective and individual country responses

Key global frameworks, such as the legally binding International Health Regulations (IHR) have been updated to reflect the lessons learned from COVID-19.[6] Between November 2022 and June 2024, the IHR were amended by the 196 signatory countries (including New Zealand) to strengthen global cooperation on pandemic preparedness and response. A key focus of these updates was equity—ensuring that every country, regardless of their resources, has the tools and support they need for PPPR—which has benefits for all countries. At the same time, the updated IHR maintains the sovereignty of individual countries, allowing them to make their own decisions about how best to respond, while drawing on non-binding guidance from the WHO and its Director-General.

This dual emphasis on global solidarity and national autonomy is vital. Future pandemic threats are inevitable, and a co-ordinated global response can mitigate their impact. However, individual countries must also be equipped to respond in ways that reflect their unique circumstances and needs—just as New Zealand did in its response to COVID-19.

Progress in New Zealand: the updated New Zealand pandemic plan

The updated national pandemic plan,[5] published in July by the Ministry of Health – Manatū Hauora, is an important step towards strengthening New Zealand's preparedness. This plan is an interim update, with the findings of the Royal Commission of Inquiry to be incorporated in due course. More importantly, this also signals that pandemic planning is dynamic and will continue to evolve.

This reflects another valuable lesson from the COVID-19 response—planning is an ongoing process rather than just a plan per se. This planning process should regularly test and evaluate the core "pillars" of a response, including leadership, decision-making, communications and technical advice, against a range of potential pandemic pathogens on a continuous basis. The process should also regularly incorporate lessons learned.

We consider that the plan should be updated at least annually and that there are at least biannual exercises to test it against different potential pandemic pathogens (including the hypothetical unknown "pathogen X"). Currently, the plan focusses on respiratory pathogens; recent and ongoing outbreaks of mpox remind us that we need to prepare for diseases caused by pathogens predominantly spread through other routes as well.[7,8]

Additionally, there is a need to ensure the essential elements of the updated plan are easily accessible to those who need to use it. The updated plan is over 200 pages, and a helpful next step would be an easily navigable online version of the plan, broken down into accessible modules with links to key resources and tools. This would make the plan more usable both in training exercises and during an emergent pandemic, ensuring that all stakeholders—including government officials, frontline workers and communities—can easily find the information they need. It could also be more easily updated to integrate lessons learnt from emerging evidence, the development of new technologies such as vaccines and the repeated scenario testing to ensure the plan's key elements work in practice. New Zealand's pandemic planning will also be informed by the findings of projects

funded through the Te Niwha Infectious Disease Research Platform.[9]

In conclusion

Our view, borne out by the COVID-19 pandemic, is that PPPR is a fundamental aspect of national security, demanding sustained investment and a whole-of-government approach to ensure readiness for future threats.

Pandemic planning must be a living, adaptive process integrating lessons learnt from emerging evidence, the development of new technologies such as vaccines and the repeated testing of plans to ensure they actually work in practice. In doing so, countries can build a more resilient response, capable of adjusting swiftly and effectively to future threats.

As a country, we also need to ensure we have the infrastructure to underpin and support PPPR. This critical infrastructure resides not only within the healthcare and public health systems; it includes infrastructure to support government and public administration, supply chain and logistics, information and communication technology, essential services, financial systems, community services and the education system.

The lessons learned from COVID-19 should serve as a catalyst for continued improvement in pandemic planning. By embracing an iterative planning process, establishing and empowering cross-government leadership, viewing pandemics through a security lens and enhancing accessibility to planning resources, we can better prepare for future challenges. The goal is to ensure that our strategies are resilient and adaptable, ready to face whatever new threats may arise so that we are best placed to manage future pandemics—of any kind—effectively.

COMPETING INTERESTS
The views expressed do not necessarily represent the position of the Institute of Environmental Science and Research (ESR).
Ashley Bloomfield was New Zealand's Director-General of Health 2018–2022 and was Co-Chair of the World Health Organization's Working Group on Amendments to the International Health Regulations.

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Early pregnancy high normal HbA_{1c}: a high risk group?

Megan J Chatfield, Lisa Woods, Ella Sussock, Rosalie E Elder, Rosemary M Hall

ABSTRACT

AIM: To determine if high normal early pregnancy HbA_{1c} (35–40mmol/mol), in the absence of diabetes, was associated with increased risk of adverse perinatal outcomes compared to normal HbA_{1c} (<35mmol/mol).

METHOD: A retrospective chart review was carried out on all singleton births in the Wellington region from 1 July 2019 to 31 December 2019. Exclusion criteria were participants domiciled outside the Wellington region, HbA_{1c} ≥50mmol/mol, pre-existing diabetes, gestational diabetes in current pregnancy, no HbA_{1c} performed <20 weeks or the first HbA_{1c} was taken at ≥20 weeks. Baseline characteristics, HbA_{1c} and pregnancy outcomes were obtained. The primary outcome was birth weight and was analysed using multiple linear regression.

RESULTS: There were 1,067 participants in the normal HbA_{1c} ($nHbA_{1c}$) group and 186 in the high normal HbA_{1c} ($hnHbA_{1c}$) group. There was no difference in birth weight between $hnHbA_{1c}$ and $nHbA_{1c}$. $hnHbA_{1c}$ had significantly lower odds of post-partum haemorrhage and composite maternal adverse outcomes compared to $nHbA_{1c}$ (OR 0.52, 95% CI 0.35–0.76) and (OR 0.64, 95% CI 0.46–0.89).

CONCLUSION: High normal HbA_{1c} was not associated with increased risk of adverse perinatal outcomes in pregnant people who did not develop gestational diabetes.

HbA_{1c} (glycated haemoglobin) predicts pregnancy-related adverse outcomes in people with pre-diabetes and diabetes.[1–3] Aotearoa New Zealand guidelines recommend measuring HbA_{1c} with the first antenatal blood tests to identify previously undiagnosed diabetes; where HbA_{1c} ≤40mmol/mol is normal, 41–49mmol/mol suggests greater risk and ≥50mmol/mol represents probable undiagnosed diabetes.[1] HbA_{1c} ≥50mmol/mol is diagnostic of diabetes in Aotearoa New Zealand, and those meeting this criteria are referred to secondary services for specialist input during pregnancy.[1] Some people with HbA_{1c} of 41–49mmol/mol are referred, however this is dependent on local guidelines.[4]

People with pre-diabetes and gestational diabetes (GDM) are at increased risk of adverse perinatal outcomes.[2–7] The *Hyperglycemia and Adverse Pregnancy Outcome (HAPO)* study identified increasing risk of perinatal complications with increasing maternal glycaemia below the threshold for diabetes.[5] There is limited literature on pregnancy outcomes in people without diabetes with an early pregnancy HbA_{1c} at the upper limit of normal. In 466 women followed prospectively in Australia, an early pregnancy HbA_{1c} of ≥38 mmol/mol was highly predictive of developing GDM and increased risk for large for gestational age (LGA).[8] In Aotearoa New Zealand, Hughes et al. (2014) demonstrated that women with an early pregnancy HbA_{1c} in the pre-diabetes range (41–46mmol/mol) who were not treated for GDM had increased rates of major congenital anomaly, pre-eclampsia, shoulder dystocia and perinatal death compared to women with normal HbA_{1c}.[2] There is no data in Aotearoa New Zealand for people who have a booking HbA_{1c} of <41mmol/mol.

HbA_{1c} may not be a reliable predictor of glycaemic control at early gestations, falling 4–10mmol/mol by the second trimester.[8,9] Several factors contribute to this fall, including haemodilution and an increase in red cell turnover.[10] Therefore, a person with pre-diabetes based on an HbA_{1c} of 41–49mmol/mol outside of pregnancy, who has already developed a degree of glucose dysregulation, may have a normal HbA_{1c} by the time the first antenatal bloods are taken. This means these people are not identified as higher risk—either at all, or until later in pregnancy.

In Aotearoa New Zealand, routine measurement of early pregnancy HbA_{1c} has enabled identification of previously undiagnosed type 2 diabetes mellitus and more timely interventions. However, when performing screening it is vital to understand the risks associated with "high normal" results of a continuous variable. We hypothesise that women with "high normal" early pregnancy HbA_{1c} may experience higher rates of adverse perinatal outcomes. The aim of this study was to determine whether early pregnancy HbA_{1c} of 35–40mmol/mol in people without either pre-existing diabetes or a later diagnosis of GDM was associated with

an increased risk of adverse perinatal outcomes compared to people with HbA_{1c} <35mmol/mol. The second aim was to establish whether the risk of adverse outcomes increases as HbA_{1c} increases.

Method

A retrospective chart review was performed to look at the relationship between early pregnancy HbA_{1c} (<20 weeks gestation) and adverse perinatal outcomes in pregnant people from the Wellington region delivering at Wellington Regional Hospital, Kenepuru Maternity Unit or Paraparaumu Maternity Unit between 1 July 2019 to 31 December 2019. This study was approved by the Health and Disability Ethics Committee of Aotearoa New Zealand.

Baseline characteristics and pregnancy outcomes were obtained from the Capital and Coast District Health Board (CCDHB) Patient Information Management System database. HbA_{1c} results from Wellington Southern Community Laboratory were collected. HbA_{1c} was quantified using Bio-Rad Variant D-100 Ion Exchange High-performance Liquid Chromatography (HPLC). D-100 has shown reliable analytical performance with good precision and linearity and a CV of <1%.[11] Singleton pregnancies with HbA_{1c} <50mmol/mol at <20 weeks gestation were included. Exclusion criteria were pre-existing diabetes mellitus, developing GDM in the current pregnancy, missing BMI, no HbA_{1c} at <20 weeks gestation or the first HbA_{1c} was taken at ≥20 weeks gestation.

Participants were divided into groups: HbA_{1c} <35mmol/mol, ("$nHbA_{1c}$"), HbA_{1c} 35–40mmol/mol, ("$hnHbA_{1c}$") and HbA_{1c} 41–49mmol/mol ("pre-diabetes").

The primary outcome was birth weight (g). An equally important outcome was customised birth weight centiles, which were calculated using the GROW Bulk Centile Calculator version 6.7.8.3 (Perinatal Institute, Birmingham, UK), which adjusts for maternal height, weight, ethnicity, parity, sex and gestational age at delivery. LGA was defined as >90th customised centile, and small for gestational age (SGA) was defined as <10th customised centile. Secondary outcomes were mode of delivery: normal vaginal delivery, caesarean delivery, assisted vaginal delivery; shoulder dystocia; perineal tears (third and fourth degree); post-partum haemorrhage (PPH) (estimated blood loss >500ml at delivery); induction of labour; pre-term delivery (<37 weeks); neonatal hypoglycaemia requiring treatment, Neonatal Intensive Care Unit (NICU) admission requiring respiratory support; NICU admission in days and perinatal death. Perinatal death was defined according to the Perinatal and Maternal Mortality Review Committee as foetal death occurring >20 weeks gestation, or ≥400g birth weight, and included neonatal deaths occurring up to 28 days of life.[12]

Power calculations were performed prior to data collection. It was estimated that a sample size of 1,400 was achievable in the study timeframe, which would have at least 80% power to compare HbA_{1c} groups with respect to birth weight (assuming a difference of 150g, SD=580), and adverse outcomes (assuming a difference of 10% vs 20%), testing at the 5% significance level.

Baseline characteristics and adverse outcomes are presented as mean (Standard Deviation) or median (range), and n (percent) as appropriate. The $nHbA_{1c}$ and $hnHbA_{1c}$ groups were compared with respect to age (independent-samples *t*-Test), BMI (Wilcoxon Rank-Sum Test with continuity correction), ethnicity and parity (Pearson's Chi-squared test of independence). Dichotomous adverse outcomes were analysed using binomial logistic regression and birth weight was analysed with multiple linear regression. All analyses for adverse outcomes were tested for differences between the $nHbA_{1c}$ and $hnHbA_{1c}$ groups, adjusting for age, BMI and ethnicity. In addition, a further analysis was performed for vaginal birth and post-postpartum haemorrhage that controlled for parity. There were few observed events for the adverse events of shoulder dystocia and perinatal death recorded, so no analyses were run. Maternal and neonatal composite adverse outcomes were created separately. Composite outcomes were used that included clinically important outcomes; for neonatal this included birth weight >4,000g, LGA, SGA, shoulder dystocia, pre-term delivery (<37 weeks), admission to NICU, hypoglycaemia requiring treatment and perinatal death. For maternal this included delivery via caesarean section, perineal tears (third and fourth degree), PPH, induction of labour, pre-term delivery (<37 weeks). Secondary analyses were conducted with BMI as the only predictor. No correction for multiple comparisons was applied, p-values less than 0.05 were considered statistically significant and data were analysed in R version 4.2.0 for Windows (Vienna, Austria).

Results

Between 1 July 2019 and 31 December 2019

there were 1,514 singleton births in the Wellington region (Figure 1). Of these, 261 were excluded from analysis, 1,067 recorded $nHbA_{1c}$ (<35mmol/mol) and 186 recorded $hnHbA_{1c}$ (HbA_{1c} 35–40mmol/mol). One person had an HbA_{1c} in the 41–49mmol/mol range, so this group was not made. Seven people had no BMI recorded and were excluded. The mean HbA_{1c} of those who developed GDM (and were excluded) was 34.7mmol/mol (SD=6.8).

Baseline characteristics are presented in Table 1. Participants in the $hnHbA_{1c}$ group had a higher BMI (25.4kg/m^2 vs 24.4kg/m^2, p=0.023), were more likely to be Pacific peoples, Indian or Other Asian ethnicity compared to participants in the $nHbA_{1c}$ group (p <0.05) and multiparous (65.6% $hnHbA_{1c}$ vs 52.6% $nHbA_{1c}$, p=0.001).

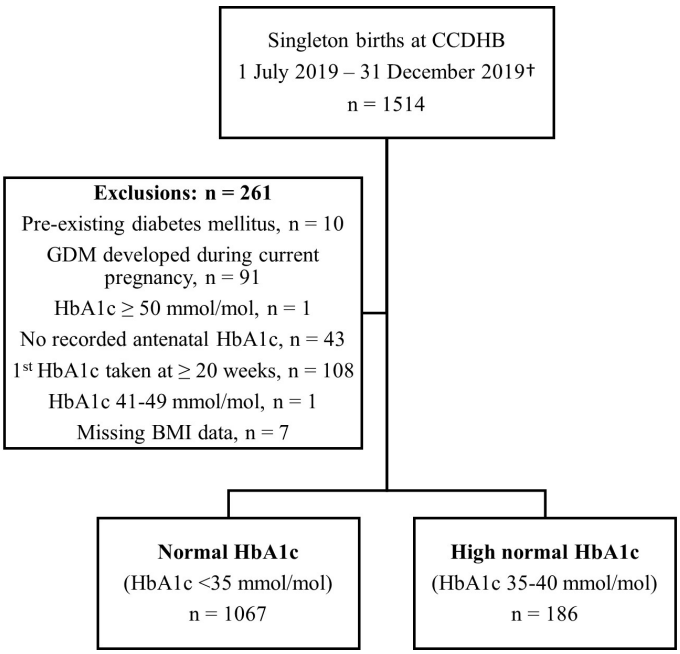
Perinatal outcomes are presented in Table 2. There was no difference in birth weight between $hnHbA_{1c}$ and $nHbA_{1c}$ groups. There was no significant relationship between pregnancy outcomes, including birth weight, and HbA_{1c} as a continuous variable. Participants with $hnHbA_{1c}$ had significantly higher odds of experiencing a normal vaginal delivery than those with $nHbA_{1c}$ (OR 1.4, 95% CI 1.01–1.97), adjusting for age, BMI and ethnicity. However, after controlling for parity, $hnHbA_{1c}$ was no longer significantly associated with a normal vaginal delivery (OR 1.33, 95% CI 0.89–1.97).

Participants with $hnHbA_{1c}$ had significantly lower odds of experiencing a PPH compared to participants with $nHbA_{1c}$ (OR 0.52, 95% CI 0.35–0.76). After controlling for parity, there was little change (OR 0.56, 95% CI 0.38–0.82). Of the people who had a PPH, 5% in the $hnHbA_{1c}$ group had a blood loss of >2,000ml compared to 1.5% of people in the $nHbA_{1c}$ group. No significant differences were found in other pregnancy outcomes, including neonatal outcomes. Five perinatal deaths occurred in the $nHbA_{1c}$ group—two stillbirths and three neonatal deaths—and none in the $hnHbA_{1c}$ group.

A statistically significant difference between the $hnHbA_{1c}$ group and the $nHbA_{1c}$ group was found in the risk of composite maternal adverse perinatal outcomes (OR 0.64, 95% CI 0.46–0.89), and remained significant after adjusting for parity (OR 0.64, 95% CI 0.45–0.91).

A secondary analysis was performed looking at BMI only as a predictor of adverse perinatal outcomes. Increasing BMI was associated with an increased likelihood of macrosomia (birth weight >4,000g) (OR 1.06, 95% CI 1.04–1.09), caesarean section compared to normal vaginal delivery (OR 1.02, 1.01–1.04), PPH (OR 1.03, 1.01–1.05) and induction of labour (OR 1.04, 1.02–1.06). Maternal and neonatal composite adverse outcomes were

Figure 1: Flow diagram of study protocol.



†Births at Wellington Regional Hospital, Kenepuru Maternity Unit or Paraparaumu Maternity Unit. Only people who domiciled to the Wellington region (CCDHB) were included.

Table 1: Baseline characteristics of participants based on early pregnancy HbA_{1c} group, excluding pre-existing diabetes and GDM in current pregnancy.

		Normal HbA_{1c} (HbA_{1c} <35mmol/mol) n = 1,067	**High normal HbA_{1c} (HbA_{1c} 35–40mmol/mol) n = 186**	**p-value**
Age, years	mean (SD)	32.1 (5.4)	32.4 (5.2)	.3929
BMI, kg/m^2	median (range)	24.4 (16.9–68.1)	25.4 (14.5–59.9)	.0263
Ethnicity	NZ European, n (%)	492 (46.1%)	55 (29.6%)	<.0001
	Māori, n (%)	125 (11.7%)	28 (15.1%)	
	Pacific peoples, n (%)	91 (8.5%)	27 (14.5%)	
	Indian, n (%)	50 (4.7%)	18 (9.7%)	
	Other Asian, n (%)	125 (11.7%)	33 (17.7%)	
	Other, n (%)	184 (17.2%)	25 (13.4%)	
Parity	Primiparous, n (%)	506 (47.4%)	64 (34.4%)	.0013
	Multiparous, n (%)	561 (52.6%)	122 (65.6%)	

Table 2: Perinatal outcomes using odds ratios comparing early pregnancy HbA_{1c} group: high normal HbA_{1c} vs normal HbA_{1c}, excluding pre-existing diabetes and GDM in current pregnancy.

Outcomes	**Normal HbA_{1c} (HbA_{1c} <35mmol/mol) n = 1,067**	**High normal HbA_{1c} (HbA_{1c} 35–40mmol/mol) n = 186**	**p-value[†]**	**Odds ratio (95% CI)[†]**
Birth weight (g)				
Mean (SD)[‡]	3,459.6 (582.1)	3,417.3 (578.8)	.6933	
Customised birth centiles				
Large for gestational age (>90th centile), n (%)	140 (13.1%)	23 (12.4%)	.7775[§]	0.934 (0.570, 1.470)[§]
Small for gestational age (<10th centile), n (%)	86 (8.1%)	23 (12.4%)	.0565[§]	1.610 (0.968, 2.584)[§]
Neonatal composite adverse outcomes,[¶] n (%)	414 (38.8%)	83 (44.6%)	.1837	1.244 (0.900, 1.713)
Maternal composite adverse outcomes,[#] n (%)	647 (60.6%)	98 (52.7%)	.0074	0.640 (0.462, 0.888)*

Table 2 (continued): Perinatal outcomes using odds ratios comparing early pregnancy HbA_{1c} group: high normal HbA_{1c} vs normal HbA_{1c}, excluding pre-existing diabetes and GDM in current pregnancy.

Components of composite outcomes			
Mode of delivery			
Normal vaginal delivery (NVD), n (%)	600 (56.2%)	118 (63.4%)*	
Caesarean section (CS)			
Total caesarean section, n (%)	362 (33.9%)	58 (31.2%)	
Emergency caesarean section, n (%)	235 (22.0%)	37 (19.9%)	
Forceps or ventouse delivery, n (%)	105 (9.8%)	10 (5.4%)	
Shoulder dystocia, n (%)	1 (0.1%)	0 (0%)	
Perineal tears (third and fourth degree), n (%)	44 (4.1%)	8 (4.3%)	
Post-postpartum haemorrhage (PPH), n (%)	342 (32.1%)	40 (21.5%)*	
Induction of labour, n (%)	235 (22.0%)	30 (16.1%)	
Pre-term delivery, <37 weeks, n (%)	63 (5.9%)	15 (8.1%)	
NICU admission, n (%)	160 (15.0%)	28 (15.1%)	
NICU admission in days, mean (SD)	12.3 (21.6)	13.6 (21.1)	
NICU requiring respiratory support, n (%)	89 (8.3%)	14 (7.5%)	
Hypoglycaemia requiring treatment, n (%)	70 (6.6%)	16 (8.6%)	
Perinatal death, n (%)	5 (0.5%)	0 (0%)	

†Adjusting for age, ethnicity and BMI.
‡Box Cox transformation applied, lambda = 1.92.
§Not adjusted for ethnicity or BMI as these are adjusted for within the GROW Calculator.
¶Neonatal composite adverse outcomes: birth weight more than 4,000g, large for gestational age, small for gestational age, shoulder dystocia, pre-term delivery (<37 weeks), admission to NICU, hypoglycaemia requiring treatment and perinatal death.
#Maternal composite adverse outcomes: caesarean section, perineal tears (third and fourth degree), post-postpartum haemorrhage, induction of labour and pre-term delivery (<37 weeks).
*Statistically significant difference. P-value = 0.05 for NVD and 0.01 for PPH.

significantly increased with increasing BMI.

Of the 91 people who developed GDM, and were excluded, 86.5% had an HbA_{1c} <41mmol/mol and 13.5% had an HbA_{1c} ≥41mmol/mol. In those who had an HbA_{1c} ≥41mmol/mol (n = 12/1,514) (excluding those with pre-existing diabetes), 91.7% went on to develop GDM (11 of 12). Of all the people with high normal HbA_{1c} (35–40mmol/mol), before excluding for GDM, 13.8% went on to develop GDM (30 of 218).

Discussion

This retrospective review demonstrated that pregnant people with an early pregnancy high normal HbA_{1c}, without pre-existing diabetes or later development of GDM, have no difference in birth weight compared to people with normal HbA_{1c}. Those in the hnHbA_{1c} group did not have an increased risk of adverse perinatal outcomes and were less likely to have a PPH or experience adverse composite outcomes, even after controlling for parity. Increasing BMI, irrespective of HbA_{1c}, significantly increased the odds of macrosomia, caesarean section, PPH and induction of labour.

There were proportionally more Indian and Pacific peoples in the high normal HbA_{1c} group compared to the normal HbA_{1c} group. These ethnicities have the highest rates of gestational diabetes and type 2 diabetes in Aotearoa New Zealand.[13,14] This may be clinically relevant, and future research could explore whether people of these ethnicities should be screened or managed at a lower HbA_{1c} threshold.

People with high normal HbA_{1c} were less likely to have a PPH compared to those with normal HbA_{1c}. The high normal group had more multiparous people and were more likely to experience a vaginal birth, which could have influenced these results. Risk factors identified from previous pregnancies may have resulted in increased use of active management of the third stage of labour, thereby reducing the risk of PPH.

We excluded participants who later developed GDM in order to report on perinatal outcomes independent of any treatment potentially received. Our findings are in keeping with those of Immanuel et al. (2020), who reported that early pregnancy HbA_{1c} ≥39mmol/mol in obese European women did not predict adverse pregnancy outcomes.[15] Likewise, a recent retrospective cohort study showed no increased risk of adverse outcomes in women with early pregnancy HbA_{1c} 38.8–46.4mmol/mol.[16] In contrast, Capula et al. (2013) demonstrated that HbA_{1c} is a strong predictor of negative outcomes in women with GDM, with HbA_{1c} >34mmol/mol associated with a two-fold increased risk of pregnancy-related hypertension, LGA and neonatal morbidity compared to HbA_{1c} <34mmol/mol.[17] Poor pregnancy outcomes related to HbA_{1c} independent of GDM, such as macrosomia, have been reported elsewhere with HbA_{1c} ≥41mmol/mol[18] and HbA_{1c} ≥39mmol/mol.[19] Our findings that BMI predicts adverse outcomes are significant in this study and are concordant with international literature.[20–22] Of concern, more people are conceiving with an increased BMI, which, independent of dysglycaemia, increases risk of both maternal and neonatal adverse outcomes.[20–22]

The relationship between perinatal outcomes and maternal glycaemia, and the associated role of HbA_{1c}, has been explored. The HAPO study demonstrated an increased risk of adverse pregnancy outcomes with increasing maternal glycaemia,[5] and in a sub-group of women, increasing HbA_{1c} was associated with increased LGA and primary caesarean section.[3] Bozkurt et al. (2020) observed beta cell dysfunction and glucose dysregulation when early pregnancy HbA_{1c} was ≥39mmol/mol and was associated with greater risk for LGA.[23] Comparably, women with pre-pregnancy impaired glucose tolerance had a two-fold increased risk of LGA, demonstrated by Wei et al. (2017).[24]

Together with the HAPO studies, this evidence supports our hypothesis that women with a degree of glucose dysregulation, below the diagnostic criteria for diabetes, are at increased risk of adverse pregnancy outcomes, including large for gestational age. Although HbA_{1c} is a useful tool to identify people with undiagnosed pre-existing diabetes, it may be that an alternative assessment for early dysglycaemia is required to reduce adverse perinatal outcomes, or as in the studies reported here, an HbA_{1c} closer to the pre-diabetes range is required to identify dysglycaemia, which influences perinatal outcomes.

Importantly, some have suggested people who receive treatment for hyperglycaemia or diabetes in early pregnancy have improved outcomes compared to those that do not.[25] The TOBOGM Research Group has recently found that early treatment of GDM before 20 weeks gestation improves composite neonatal outcomes, though conversely, treatment did not improve maternal outcomes.[25] Also of note, Rowan (2022) demonstrated early treatment of a first antenatal HbA_{1c} of 41–46 mmol/mol reduces the likelihood of LGA, pre-eclampsia and pre-term birth.[26] In contrast, the GEMS Study demonstrated that a lower diagnostic threshold for GDM (fasting plasma glucose level of ≥5.1mmol/l, 1-hour level of ≥10.0mmol/l, or a 2-hour level of ≥8.5mmol/l) did not improve pregnancy outcomes, but leads to an increased consumption of healthcare services.[27] However, their sub-group analysis showed that women who were treated for "milder" GDM based on the lower glycaemic criteria had a reduced risk of LGA and pre-eclampsia compared to women with similar

glucose test results who received no treatment.[27]

This study has reliably captured HbA_{1c} for every person who had early pregnancy blood tests during the study time period. All samples were analysed in the same laboratory, reducing potential analytical error. As testing early pregnancy HbA_{1c} is routine in Aotearoa New Zealand, no additional investigations were required. Moreover, utilising HbA_{1c}, as opposed to glucose measures, avoids pre-analytical glucose errors. The study was undertaken within the same locality; therefore, management of each person's pregnancy followed the same guidelines.

Limitations include the short time period (6 months) and the smaller than expected sample size. The difference in birth weight was much smaller than expected, only 42.3g, so we did not have sufficient power to detect the expected difference of 150g. This difference is unlikely to be clinically meaningful; therefore, a larger sample size is required to identify a difference of this magnitude. Seven people had no BMI recorded and were excluded, further reducing sample size. One person had an HbA_{1c} of 15mmol/mol due to a history of hereditary spherocytosis, so this HbA_{1c} does not accurately reflect glucose status. It is possible that there were other participants with undiagnosed haemoglobinopathies that may have influenced their HbA_{1c} results. Additionally, pre-eclampsia is an important adverse outcome associated with hyperglycaemia in pregnancy but was not included as a secondary outcome. There was an unexpectedly low number of participants recorded as having pre-eclampsia, suggesting the data may be incomplete.

In conclusion, there is no evidence of a difference in outcomes of birth weight, neonatal or maternal outcomes in pregnant people who have an early pregnancy high normal HbA_{1c} or normal HbA_{1c}. HbA_{1c}, early in pregnancy, identifies those with pre-diabetes or undiagnosed diabetes, allowing appropriate management of these higher risk groups. There is no evidence that HbA_{1c} can be used to stratify risk outside of this range. However, given the continuous nature of an HbA_{1c} measure, and the pregnancy effects on the HbA_{1c} analysis, it is possible that these diagnostic cut points are not accurate in pregnancy. Further exploration of the appropriate use of HbA_{1c} in early pregnancy is important if Aotearoa New Zealand is to continue using it as a screening tool.

COMPETING INTERESTS
The authors report no conflict of interest. This study was approved by the Health and Disability Ethics Committee of New Zealand.
LW received payment for statistical consulting hours to her institution from Capital and Coast District Health Board.

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Predictors of symptom recurrence and survival in patients with malignant gastric outlet obstruction treated with self-expanding metal stents

Michael Chieng, Henry Wei, Sarah Haydon, Cameron Schauer

ABSTRACT

BACKGROUND: Malignant gastric outlet obstruction (GOO) poses a substantial symptomatic burden. While various therapeutic options exist, self-expanding metal stents (SEMS) are a common palliative choice for patients who are ineligible for surgery. We studied SEMS outcomes to identify factors influencing stent dysfunction and patient survival.

METHODS: A multi-centre, retrospective review of 190 patients with GOO undergoing SEMS at three tertiary hospitals was performed over 2016–2022. Technical success, clinical success and adverse outcomes were recorded. Predictors of stent dysfunction and survival were evaluated using multivariate regression.

RESULTS: Technical success was achieved in 186/190 (97.9%) and clinical success in 156/186 (83.9%), defined as post-procedural gastric outlet obstruction symptom score (GOOSS) ≥2. Eighty-two (44.1%) patients experienced an adverse event with stent occlusion the most common (23.1%). Approximately one-third (32.3%) underwent a repeat intervention. Mean stent patency time was 67 days (standard deviation=76), and median post-stent survival was 95 days (37–197). Covered and partially covered SEMS carried three times the risk of stent dysfunction compared to uncovered SEMS (odds ratio 3.06, p=0.008). Mortality predictors were Eastern Cooperative Oncology Group score ≥2 (p=0.03), extrinsic outlet obstruction (p=0.05) and presence of ascites (p=<0.001).

CONCLUSION: SEMS demonstrated technical and clinical success but posed a high risk of recurrence, with stent patency time falling short of survival in our cohort. With an evolving landscape of therapeutics for GOO, appropriate patient selection is paramount. Individuals with reduced performance status, extrinsic obstruction and/or ascites may be better candidates for SEMS due to more limited life expectancy. In this setting, uncovered SEMS carry the lowest risk of reintervention.

Malignant gastric outlet obstruction (GOO) results from the growth of cancers interfering with normal gastric emptying. Patients with this condition frequently present with nausea, vomiting and inadequate oral intake. Cancers of gastric or pancreatic origin are the most common aetiologies and obstruction can be intrinsic from within the lumen, or extrinsic from external compression.[1,2] Several therapeutic modalities have been developed for treatment, including surgical gastroenterostomy (S-GE), self-expanding metal stents (SEMS) and, more recently, endoscopic ultrasound-guided gastroenterostomy (EUS-GE).[3–6]

SEMS were developed as a treatment modality in the 1990s and have been demonstrated as technically achievable, clinically successful and cost-effective tools for palliation of GOO symptoms.[7–9] They are less invasive than alternatives and do not require general anaesthesia to perform.[10,11] Prospective studies have also shown a swifter recovery time compared with surgery, and shorter length of hospital stay.[2,12] The combination of these factors together represent additive benefits in this population, who are generally in their last days of life.

However, the durability of SEMS has come into question.[13,14] Risk of symptom recurrence has been reported between 9.9 to 50.9%, with rates of re-intervention ranging from 3.8 to 38.1%.[15] Improving these metrics is important as systemic treatments, such as immunotherapy, continue to extend the lifespans of patients with advanced cancer.[16] Meta-analyses comparing symptom recurrence, reintervention and patency between S-GE, EUS-GE and SEMS have shown small differences between interventions; however, the majority of included studies are retrospective, non-randomised and involve low numbers of participants.[5,15,17] There have been no head-to-head randomised controlled trials comparing each of the available interventional treatments.[15]

Therefore, a degree of selection bias is expected and accurate conclusions are difficult.

With expanding capability of treatments for GOO, the specific patient, disease and technical characteristics that may be implicated in risk of SEMS dysfunction, reintervention and survival are of continued interest. Understanding these factors may help to predict outcomes for different patient profiles and therefore aid with better patient selection. Our study sought to evaluate the treatment and adverse outcomes of SEMS so we may identify relevant risk factors.

Methods

Participants

We retrospectively reviewed the medical records of all patients who had undergone endoscopic stenting procedures at three tertiary hospital centres in Auckland, New Zealand between August 2016 and December 2022. Patients were included if they had a gastric or duodenal SEMS placed for malignant GOO. Patients with non-malignant obstruction were excluded. A local ethics waiver was obtained.

Procedural data

Stent type, stent location and procedural adverse events were taken from endoscopy reports. Stents were categorised into covered (C-SEMS), partially covered (PC-SEMS) and uncovered (U-SEMS) according to manufacturer specifications. There were at least two independent proceduralists at each centre and all used a wire-guided, through-the-scope SEMS deployment method with adjunct fluoroscopy. For sedation, a combination of fentanyl and midazolam was considered standard practice.

Data collection

Electronic health records were reviewed for demographic information, disease-specific information such as diagnosis, performance status (Eastern Cooperative Oncology Group [ECOG] score), nature of obstruction, presence of peritoneal infiltration, ascites and adverse events. Systemic treatments such as chemotherapy and radiotherapy were recorded if received during the study period.

Outcome definitions

Technical success was defined as confirmed stent placement in the intended location across the point of obstruction. Clinical outcomes were defined using the gastric outlet obstruction symptom score (GOOSS).[18] A score of 0 was assigned for no oral intake, one for liquid diet, 2 for soft solids and 3 for low-residue or unmodified diet before and after intervention. Clinical success was defined as a post-SEMS GOOSS score of ≥2 at the time of discharge or by day 7.

Stent dysfunction was defined by occurrence of intestinal perforation, stent migration or stent occlusion. Reintervention rates were calculated from repeat procedures performed for recurring GOO symptoms. All deaths within 7 days of attempted SEMS were recorded. Stent patency time was defined by the number of days between stent placement and recurrence of GOO symptoms.

Statistical analysis

Statistical functions were performed to define relationships between demographics, disease factors, treatment factors, rates of stent dysfunction and risks of mortality. Chi-squared tests were used to define associations between variables, with significance defined by p-value ≤0.05. Grouped cohorts were created for age (<70 and ≥70 years), ethnicity (Māori and non-Māori), performance status (ECOG <2 and ≥2), and stent type (C-/PC-SEMS and U-SEMS). A purposeful selection of covariates approach was taken with univariate variables containing p-values <0.1 included in multivariate models to identify predictive factors. All statistical analyses were performed using SPSS version 29.0 for Windows (IBM, 2022).

Results

Participants

In total, 190 patients with malignant GOO were enrolled in the study. Participant characteristics are presented in Table 1. Mean age was 67 years, with 91 (47.9%) females and 99 (52.1%) males. Māori (Indigenous) ethnicity constituted 18.4% of the study population. Mean performance status was 1.44±1.1. Gastric cancer (38.9%) and pancreatic cancer (30%) were the most common diagnoses. Intrinsic obstructions (66.8%) were more common than extrinsic (33.2%). Presence of peritoneal disease and ascites were 27.4% and 17.4% respectively. Chemotherapy was received by 46.3% of participants during the study period.

Patient outcomes

Technical and clinical outcomes are presented

in Table 2. There were 186/190 (97.9%) technically successful SEMS. Mean pre-GOOSS was 0.20±0.57 and improved to a post-GOOSS of 2.03±0.84 after SEMS. A total of 156/186 (83.9%) achieved a GOOSS of ≥2 by discharge or day 7. The majority of stents were U-SEMS (73.1%), with PC-SEMS (10.8%) and C-SEMS (16.1%) the minority. Seventy-two percent of SEMS were located with the proximal flange in the stomach.

Adverse events, reinterventions and survival

Adverse event, reintervention and survival data are presented in Table 3. Adverse events were experienced by 82/186 (44.1%) patients over the study duration. Stent dysfunction was the most common (35.5%), followed by biliary obstruction (15.1%) and death (3.2%). Stent occlusion comprised 45/66 (68.2%) stent dysfunction events, with a smaller proportion of stent migrations (15/66, 22.7%) and perforation events (6/66, 9.1%).

Sixty patients who experienced stent dysfunction underwent 71 reinterventions (32.3% of the cohort). Of these interventions, 47/71 (66.2%) were a repeat stent and 7% comprised emergency surgery. The mean number of reinterventions per patient was 0.32±0.47 with a mean stent patency time of 67±76 days. Median post-stent survival was 95 days.

Predictive variables for adverse events

Univariate analysis for stent dysfunction events is presented in Table 4. Stent dysfunction was more common in the age <70 years cohort (odds ratio [OR] 2.33, 95% confidence interval [CI] 1.22–4.47, p=0.01), males (OR 1.94, 95% CI 1.05–3.58, p=0.05), Māori ethnicity (OR 2.27, 95% CI 1.08–4.79, p=0.03) and ECOG <2 performance status (OR 2.03, 95% CI 1.05–3.92, p=0.03).

Patients with gastric cancer as the underlying diagnosis (OR 3.30, 95% CI 1.76–6.17, p=<0.001) and intrinsic obstruction (OR 2.81, 95% CI 1.39–5.71, p=0.004) were more likely to experience stent dysfunction, while this was less likely in those with pancreatic cancer (OR 0.35, 95% CI 0.16–0.73, p=0.004).

In relation to treatment factors, patients treated with C-/PC-SEMS were more likely to experience stent dysfunction compared with U-SEMS (OR 4.71, 95% CI 2.37–9.37, p=<0.001). There were no significant differences with regard to stent location (p=0.09) or treatment with chemotherapy (p=0.22). Primary diagnosis of biliary cancer (p=0.06), duodenal cancer (p=0.18), metastatic disease (p=0.46) and/or neuroendocrine tumour (p=0.43) were all non-significant variables; likewise with peritoneal disease (p=0.39) and ascites (p=0.42).

Multivariate regression analysis on stent dysfunction events is presented in Table 5. Significantly greater stent dysfunction events were consistent in the C-/PC-SEMS group compared with the U-SEMS group overall (OR 3.06, 95% CI 1.35–6.95, p=<0.008). There were also significantly higher risks of stent dysfunction seen in those with ECOG <2 performance status (OR 2.32, 95% CI 1.08–4.99, p=0.03). No other significant associations were noted.

Sub-group analysis of the specific dysfunction events that contributed to differences between stent types revealed a higher migration risk in C-/PC-SEMS compared to U-SEMS, and this was statistically significant (OR 11.8, 95% CI 3.54–39.2, p=<0.001). There were no significant differences in occlusion (p=0.23) or perforation (p=0.45) events between groups.

Univariate and multivariate analyses of mortality data are presented in Table 6. Multivariate predictors of mortality were ECOG ≥2 (OR 1.47, 95% CI 1.03–2.09, p=0.03), extrinsic obstruction (OR 1.58, 95% CI 1.01–2.47, p=0.05) and presence of ascites (OR 2.23, 95% CI 1.39–3.58, p=<0.001). Average survival for high performers (ECOG <2) was 115 days, compared with 74 days for those with poor performance status (ECOG ≥2) (p=0.03).

Discussion

This large, multi-centre study has demonstrated that SEMS are technically achievable and clinically successful at resolving GOO symptoms, consistent with published literature.[1,7] However, a detailed examination of adverse events has shown limited treatment durability, with high rates of symptom recurrence up to 35% over patients' lifetimes. In our cohort, stent patency time was 67 days, yet average survival was 95 days—meaning patients frequently had to undergo further intervention in their last days of life.

In our cohort, high performers (ECOG <2) had significantly longer survival than low performers (ECOG ≥2) and were therefore exposed to higher cumulative risk of late stent dysfunction. This is consistent with findings from other researchers.[19] On the contrary, poor performance status, extrinsic obstruction and/or ascites were independent predictors of mortality. Ascites is an important consideration when

determining the best therapeutic approach for GOO due to the impact this has on likelihood of EUS-GE technical success. The European Society of Gastrointestinal Endoscopy suggests ascites interfering with lumen-apposing metal stent (LAMS) trajectory and/or tense (grade III) ascites as relevant contra-indications.[20] Ascites from heart failure, malignancy and liver disease are all also associated with increased peri-operative surgical risks.[21–23] Therefore, patients with ascites and/or one of the other mortality prognosticators may represent the most appropriate profiles for SEMS, which are the least invasive of the options and offer reduced length of hospital stay.[24] These findings may help contribute to the design of a decision-making support tool to guide clinicians and patients through the treatment selection process.

With respect to comparators, the first randomised study comparing EUS-GE with SEMS was published recently by Teoh et al. and showed significant differences in symptom recurrence at 6 months. One of the advantages of EUS-GE is in creation of a new tract distant from the malignant site, therefore lowering the risk of subsequent tumour in-growth.[25,26] Teoh et al. demonstrated a reintervention rate of 4% for EUS-GE versus 29% for SEMS (p=0.002).[25] Of note, there were no differences in quality of life scores between both groups at 1 month. Many published studies show comparable technical success of EUS-GE with SEMS; however, it is acknowledged that there is a substantial learning curve required to master EUS-GE techniques and still no universal agreement on the best technical approach.[27–29] There are also risks. EUS-GE stent maldeployment, for example, is a complication that requires recognition and expedient management, not infrequently with surgery, in up to 11%.[29] Overall, safety and optimal patient selection require further exploration. With a trend towards increasing centralisation of advanced endoscopy expertise, EUS-GE currently remains a technique practised only in expert referral centres.[30]

With regard to stent type, C-SEMS have been developed to reduce the risk of tumour in-growth, which is presented as one of the primary drivers of U-SEMS dysfunction.[31] In our cohort, there was no observed advantage to support this. Our findings are consistent with studies by Maetani and Hori et al., which showed no benefit for C-SEMS with regards to obstruction events, but contrast with systematic reviews and meta-analyses by Hamada, Minata, Pan and Tringali et al.[13,31–35] We found that not only was this hypothetical advantage negated, but C-/PC-SEMS carried 11 times the risk of migration compared to U-SEMS (p=<0.001). This was also the primary driver of more than three times risk of stent dysfunction overall (p=<0.008). Other studies have shown equivalent stent patency time and reintervention rates between SEMS types due to the balance in stated advantages and disadvantages of these.[36,37] U-SEMS performed better in our study, but were also the most common SEMS used and still carried a relatively high risk of re-intervention. This may be related to over-representation of high performers in our study population, with 60% of the cohort possessing an ECOG score of 0 or 1 (mean 1.44). In our cohort, most cases of SEMS dysfunction were managed with repeat SEMS, which is a documented safe and effective approach.[38–40]

The strengths of this study are in its large cohort size, the broad range of SEMS types used and the detailed examination we have performed of adverse events to identify predictor variables, which are practically useful for responsible clinicians treating these patients. The limitations are in the retrospective study design and the lack of a comparator cohort. As discussed previously, future prospective studies must consider quality of life. While outlet obstructive symptoms clearly drive morbidity, research has shown that despite a focus on and improvements in symptom scores, overall quality of life decreases, emphasising the importance of other factors that must be accounted for in a condition that is rapidly life limiting.[41]

Conclusion

SEMS are technically and clinically successful but pose a high risk of recurrence, with relatively short patency time. Ideal candidates are those with more limited life expectancy or where alternative procedures are contra-indicated. Predictors of mortality are reduced performance status, extrinsic obstruction and ascites. In these patients, covered SEMS offer no advantages over uncovered SEMS, which carry a lower risk of reintervention overall.

Table 1: Patient characteristics. Data are presented as mean ± standard deviation (SD), or number of participants (% of participants).

Parameter	**n (%)**
Age, years	67±12
Male gender	99 (52.1)
Ethnicity	
New Zealand European	76 (40.0)
Māori	35 (18.4)
Pacific peoples	35 (18.4)
Asian	24 (12.6)
Other ethnicity	20 (10.6)
Domicile hospital	
Auckland	61 (32.1)
Counties Manukau	86 (45.3)
Waitematā	43 (22.6)
Performance status (ECOG)	
Mean	1.44±1.1
<2	91 (60.5)
≥2	75 (39.5)
Diagnosis	
Biliary cancer	16 (8.4)
Duodenal cancer	18 (9.5)
Gastric cancer	74 (38.9)
Metastatic disease	19 (10)
Neuroendocrine tumour (NET)	6 (3.2)
Pancreatic cancer	57 (30)
Nature of obstruction	
Intrinsic	127 (66.8)
Extrinsic	63 (33.2)
Systemic disease	
Peritoneal infiltration	52 (27.4)
Ascites	33 (17.4)

Table 1 (continued): Patient characteristics. Data are presented as mean ± standard deviation (SD), or number of participants (% of participants).

Systemic treatment	
Chemotherapy	88 (46.3)
Radiotherapy	13 (6.8)

ECOG = Eastern Cooperative Oncology Group score.

Table 2: Patient outcomes after stent placement. Data are presented as mean ± standard deviation (SD), median (interquartile range [IQR]) and/or number of participants (% of participants).

Outcomes	**n (%)**
Technical success	186 (97.9)
Clinical success	156 (83.9)
Symptom scores	
Pre-GOOSS	0.20±0.57
Post-GOOSS	2.03±0.84
Type of SEMS	
Fully covered	30 (16.1)
Partially covered	20 (10.8)
Uncovered	136 (73.1)
Location of proximal stent flange	
Gastric	134 (72)
Duodenal	52 (28)

GOOSS = gastric outlet obstruction symptom score; SEMS = self-expanding metal stent.

Table 3: Adverse events, reintervention and survival after stent placement. Data are presented as mean ± standard deviation (SD), median (interquartile range [IQR]) and/or number of participants (% of participants).

Parameter	n (%)
Adverse events	
Any adverse event	82 (44.1)
Stent dysfunction	66 (35.5)
Perforation	6 (3.2)
Migration	15 (8.1)
Occlusion	45 (24.2)
Biliary obstruction	28 (15.1)
Death within 7 days	6 (3.2)
Aspiration pneumonia	2 (1.1)
GI bleeding	1 (0.5)
Disease progression	1 (0.5)
Other	2 (1.1)
Reintervention	
Participants having reintervention for GOO	60 (32.3)
Reintervention events	71
Dilatation	13 (7.0)
Repeat stent	47 (25.3)
Other endoscopic intervention[a]	6 (3.2)
Surgery	5 (2.7)
Mean reinterventions per participant	0.32±0.47
Stent patency time, days	67±76
Survival	
Post-stent survival, days	95 (37–197)
Days in hospital after stenting	4 (2–7)

[a] Includes placement of nasojejunal tube (4), endoscopic stent clearance (1), and treatment of tumour in growth (1).
GI = gastrointestinal bleeding; GOO = gastric outlet obstruction.

Table 4: Univariate analysis of stent dysfunction for grouped cohorts.

Variable		Stent dysfunction (%)	OR	95% CI	P-value
Age	<70 years	48 (42.9)	2.33	1.22–4.47	0.01
	≥70 years	18 (24.3)			
Gender	Male	41 (42.7)	1.94	1.05–3.58	0.05
	Female	25 (27.8)			
Ethnicity	Māori	18 (51.4)	2.27	1.08–4.79	0.03
	Non-Māori	48 (31.8)			
Performance status	ECOG <2	41 (45.6)	2.03	1.05–3.92	0.03
	ECOG ≥2	21 (29.2)			
Diagnosis	Biliary cancer	2 (12.5)	0.24	0.05–1.08	0.06
	Duodenal cancer	9 (52.9)	2.21	0.81–6.04	0.18
	Gastric cancer	38 (52.1)	3.30	1.76–6.17	<0.001
	Metastatic disease	5 (26.3)	0.62	0.21–1.81	0.46
	Neuroendocrine tumour	1 (16.7)	0.35	0.04–3.09	0.43
	Pancreatic cancer	11 (20)	0.35	0.16–0.73	0.004
Chemotherapy	Yes	35 (40.7)	1.53	0.84–2.79	0.22
	No	31 (31)			
Nature of obstruction	Intrinsic	53 (42.7)	2.81	1.39–5.71	0.004
	Extrinsic	13 (21)			
Peritoneal disease	Yes	21 (41.2)	1.4	0.72–2.72	0.39
	No	45 (33.3)			
Ascites	Yes	13 (41.9)	1.39	0.63–3.05	0.42
	No	53 (34.2)			
Proximal stent location	Gastric	53 (39.6)	1.96	0.96–4.02	0.09
	Duodenal	13 (25)			
Stent type	Covered/partially covered	31 (62)	4.71	2.37–9.37	<0.001

OR = odds ratio; CI = confidence interval; ECOG = Eastern Cooperative Oncology Group score.

Table 5: Multivariate logistic regression analysis for stent dysfunction within grouped cohorts.

Variable		Univariate p-value	OR	95% CI	P-value
Age	<70 years	0.01	1.64	0.73–3.72	0.23
	≥70 years				
Gender	Male	0.05	1.49	0.71–3.14	0.29
	Female				
Ethnicity	Māori	0.03	0.60	0.24–1.50	0.28
	Non- Māori				
Performance status	ECOG <2	0.03	2.32	1.08–4.99	0.03
	ECOG ≥2				
Diagnosis	Biliary cancer	0.06	0.32	0.05–1.97	0.22
	Duodenal cancer	0.18			
	Gastric cancer	<0.001	1.81	0.67–4.88	0.24
	Metastatic disease	0.46			
	Neuroendocrine tumour	0.43			
	Pancreatic cancer	0.004	0.58	0.20–.67	0.31
Chemotherapy	Yes	0.22			
	No				
Nature of obstruction	Intrinsic	0.004	0.92	0.32–2.65	0.88
	Extrinsic				
Peritoneal disease	Yes	0.39			
	No				
Ascites	Yes	0.42			
	No				
Proximal stent location	Gastric	0.09			
	Duodenal				
Stent type	Covered/partially covered	<0.001	3.06	1.35–6.95	0.008
	Uncovered				

OR = odds ratio; CI = confidence interval; ECOG = Eastern Cooperative Oncology Group score.

Table 6: Univariate and multivariate Cox regression analysis of mortality outcomes.

Variable		Death (%)	P-value	HR	95% CI	P-value
Age	<70 years	100 (83.3)	0.14			
	≥70 years	71 (91.0)				
Gender	Male	87 (86.1)	0.92			
	Female	84 (86.6)				
Ethnicity	Māori	33 (94.3)	0.13			
	Non- Māori	138 (84.7)				
Performance status	ECOG <2	79 (80.6)	0.04	1.47	1.03–2.09	0.03
	ECOG ≥2	68 (91.9)				
Diagnosis	Biliary cancer	2 (12.5)	0.89			
	Duodenal cancer	9 (52.9)	0.81			
	Gastric cancer	36 (49.3)	0.68			
	Metastatic disease	5 (26.3)	0.68			
	Neuroendocrine tumour	6 (100)	0.60			
	Pancreatic cancer	52 (94.5)	0.04	0.96	0.61–1.51	0.86
Chemotherapy	Yes	73 (84.9)	0.60			
	No	98 (87.5)				
Nature of obstruction	Intrinsic	111 (83.5)	0.09	0.64	0.41–0.99	0.05
	Extrinsic	60 (92.3)				
Peritoneal disease	Yes	46 (90.2)	0.36			
	No	125 (85.0)				
Ascites	Yes	32 (100)	0.01	2.23	1.39–3.58	<0.001
	No	139 (83.7)				
Proximal stent location	Gastric	122 (84.7)	0.27			
	Duodenal	49 (90.7)				
Stent type	Covered/partially covered	45 (76.3)	0.012	1.45	0.98–2.14	0.06
	Uncovered	126 (90.7)				

HR = hazard ratio; CI = confidence interval.

COMPETING INTERESTS
There are no conflicts of interest to declare.

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Quantifying cost-savings in the treatment of neovascular age-related macular degeneration in Aotearoa New Zealand

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ABSTRACT

AIMS: To estimate the cost-impact if faricimab were approved for the treatment of neovascular age-related macular degeneration (nAMD) in New Zealand.

METHODS: A retrospective, single-centre cost-analysis study. Data on intravitreal agent and injection intervals were obtained and statistically compared. Cost estimates were based on internal facility and publicly available data. The current costs of care were compared to two scenarios: one where all eyes receive faricimab, and another where eyes receiving aflibercept switch to faricimab.

RESULTS: A total of 352 eyes from 292 patients were analysed. Present values locally over 10 years were estimated at -$6,776,340 for the first scenario and $5,015,922 for the second, releasing 252 and 176 hours of clinical time per year, respectively. Nationally, the savings extrapolated to -$187,925,737 and $139,104,706, respectively. The analysis indicates significant direct cost savings for the health sector and potential reductions in patient harm due to fewer injections.

CONCLUSIONS: The approval of faricimab for the treatment of nAMD could result in substantial direct cost savings for the health sector. Additional benefits include reducing patient harm and improving ophthalmic health inequalities for Māori and Pacific peoples. Further research in diverse patient populations across multiple centres is needed to estimate the magnitude of cost savings more accurately. This study highlights the potential of faricimab to alleviate the treatment burden and provide a more sustainable healthcare option for nAMD in New Zealand, especially in cases of recalcitrant nAMD, if used in a tailored and patient-specific manner alongside the existing armamentarium of treatments.

Neovascular age-related macular degeneration (nAMD) is an end-stage manifestation of age-related macular degeneration (AMD) and is a leading cause of visual impairment and blindness worldwide.[1] AMD can be divided into early and late stages. Early AMD is characterised by soft drusen and pigmentary changes at the macula, while late AMD is characterised by geographic atrophy and/or choroidal neovascularisations, the latter with retinal haemorrhage, oedema and fibrosis, ultimately leading to significant vision loss. Age is the main risk factor for nAMD, and the incidence is expected to increase with the ageing population.[1]

In New Zealand, there are no contemporary population-based studies of the prevalence of nAMD. Recent publications have extrapolated prevalence from high-quality international studies such as Wong et al.[2] A 2016 report commissioned by Blind Low Vision NZ and prepared by Deloitte estimated the prevalence of early AMD to be 199,140, and late AMD to be 19,847.[3] A 2015 study estimated that in 2026 the prevalence of early AMD would be 208,200 people and late AMD to be 8,600 people.[4] There are no recently published data on the number of intravitreal injections performed for nAMD across New Zealand. Data from our centre shows 2,277 intravitreal injections performed in 2022 for nAMD from a population of 190,000 patients. Data from Auckland suggest 17,000 injections for all indications, with a population of 1.6 million people.[5] These data give a rate of between 1.06 to 1.20 injections per 100 people, meaning the annual number of injections in New Zealand for nAMD is likely to be between 55,985 to 63,137 injections per year, with an expected increase of 15% year-on-year.[6]

Intravitreal injections for the treatment of nAMD have revolutionised the visual prognosis, with proved efficacy and safety in clinical trials.[1] However, the real-world outcomes have often fallen short of those demonstrated in the literature, with lower best-corrected visual acuity (BCVA) gains.[7] The treatment burden of injections as

frequent as every 4 weeks on the patients, caregivers and the healthcare system as a whole may result in undertreatment, and this is thought to be the reason for lower gains in the clinical setting.[8] There is, therefore, a need for treatments that are both effective and durable.

Faricimab is a dual VEGF-A and ang-2 inhibitor administered by intravitreal injection. It is a humanised, bi-specific IgG monoclonal antibody, hypothesised to provide superior durability, as well as possibly superior efficacy in the treatment of nAMD due to its dual inhibition of two key pathways in the pathogenesis of this disease. It has been approved by the US Food and Drug Administration, the European Medicines Agency and, recently, the Australian Therapeutic Goods Administration and Medsafe.[9–12] In New Zealand, bevacizumab and ranibizumab are funded by Pharmac for the treatment of nAMD.[13] A third agent, aflibercept, is funded as a second-line agent on application for Special Authority.[14] In the TENAYA and LUCERNE clinical trials, faricimab was found to be non-inferior to aflibercept in terms of preserving BCVA. In addition, at 48 weeks, 80% of patients were on dosing intervals ≥12 weeks, and approximately 45% of patients were on 16-week dosing intervals. Comparatively, 64.1% of eyes treated with aflibercept have been reported as stable on ≥12-week dosing intervals.[15]

Palmerston North Hospital Eye Department, a part of Te Pae Hauora o Ruahine o Tararua Mid-Central, provides specialist ophthalmic care to a total population of around 190,000 patients living in Palmerston North City, Manawatū, Tararua and Horowhenua districts, and the small town of Ōtaki.[16] This study was conducted to investigate the current intravitreal dosing regimens for patients with nAMD and associated costs. A secondary cost analysis was then performed to explore potential cost-savings if faricimab were to be approved and used for the treatment of nAMD.

Methods

This retrospective cost analysis evaluated 396 eyes of 326 patients who had received intravitreal injections at Palmerston North Hospital in 2023. Records from an electronic database were used to generate a list of eyes that had received intravitreal injections for nAMD during 2023. The patient's clinical records were then reviewed to confirm the eye injected, the agent used (aflibercept or bevacizumab), the total number of injections performed in that eye to date and the current interval between injections.

The study has been evaluated by the Health and Disability Ethics Committee and deemed not to require ethics approval.

When calculating the dosing intervals used for cost analysis, 44 eyes of 42 patients were rejected as they had received fewer than four injections, on the assumption that they were receiving an induction series of injections, and the appropriate treatment interval was still being evaluated.

The hospital finance department provided cost estimates for the process of intravitreal injections, nurse-led macula review clinics and consultant clinics. These were assumed to take 20 minutes, 20 minutes and 15 minutes, respectively.

The cost for an intravitreal injection of bevacizumab was calculated as $199.48, aflibercept $1,406.23 and faricimab $1,721.23. The cost for bevacizumab was based on internal data, as it is compounded by an external supplier. The cost for aflibercept is the published price on the Hospital Medicines List. The cost for faricimab is based on the published GST-exclusive list price from Roche. The cost for a nurse-led macula review clinic was $60.62 and the cost of a consultant clinic was $100.85.

For the purposes of net present value calculations, a discount rate of 3.5% was assumed with a 10-year time horizon to align with the Pharmac recommendations for pharmacoeconomics, with sensitivity analyses at 0% and 5%.[17]

Regardless of the agent used, the number of intravitreal injections received was calculated as 52 weeks divided by the dosing interval. It was assumed that in a 52-week period, an individual eye would receive two consultant reviews, and review in the hybrid clinic after every three injections for injection intervals up to 11 weeks. For injection intervals 12 weeks and greater, a review would be conducted following each injection.

The cost scenarios explored were the current treatment model, a treatment model where all eyes were treated with faricimab and a treatment model where faricimab was used instead of aflibercept. The faricimab models assumed that patients treated would achieve the results in the TENAYA and LUCERNE trials, where of 631 eyes, 134 eyes (21.3%) were maintained on an 8-weekly interval, 211 eyes (33.4%) were maintained on a 12-weekly treatment interval and 286 eyes (45.3%) were maintained on a 16-weekly treatment interval.

Microsoft Excel for Mac (Version 16.77.1) was used for data management, and R (version 4.4.1,

The R Foundation for Statistical Computing, Vienna, Austria) along with RStudio (version 2024.04.2+764, RStudio, PBC, Boston, MA) was used for statistical analysis. The "lme4" and "emmeans" packages were utilised for fitting the mixed linear models and generating estimated marginal means, respectively.[18,19] The Bonferroni correction was applied to account for the multiple statistical tests performed, reducing the likelihood of type I errors and ensuring that the overall significance level remains controlled.[20] Specifically, the original significance level ($\alpha = 0.05$) was divided by the number of tests performed (16 intervals), resulting in a corrected α of 0.003125.

Results

In total, 396 eyes representing a cohort of 326 patients receiving injections were used to perform the initial analysis. A total of 225 eyes (56.8%) received bevacizumab and 171 eyes (43.2%) received aflibercept.

Using mixed linear models to account for the correlation between measurements on two eyes of the same patient, the estimated marginal mean (EMM) weekly interval for bevacizumab was 10.46 weeks (95% CI: 9.92 to 11.01 weeks), and for aflibercept, it was 7.26 weeks (95% CI: 6.63 to 7.89 weeks).

The mean difference between the two agents was 3.2 weeks (95% CI: 2.39 to 4.02 weeks), and this difference was statistically significant ($p < 0.0001$).

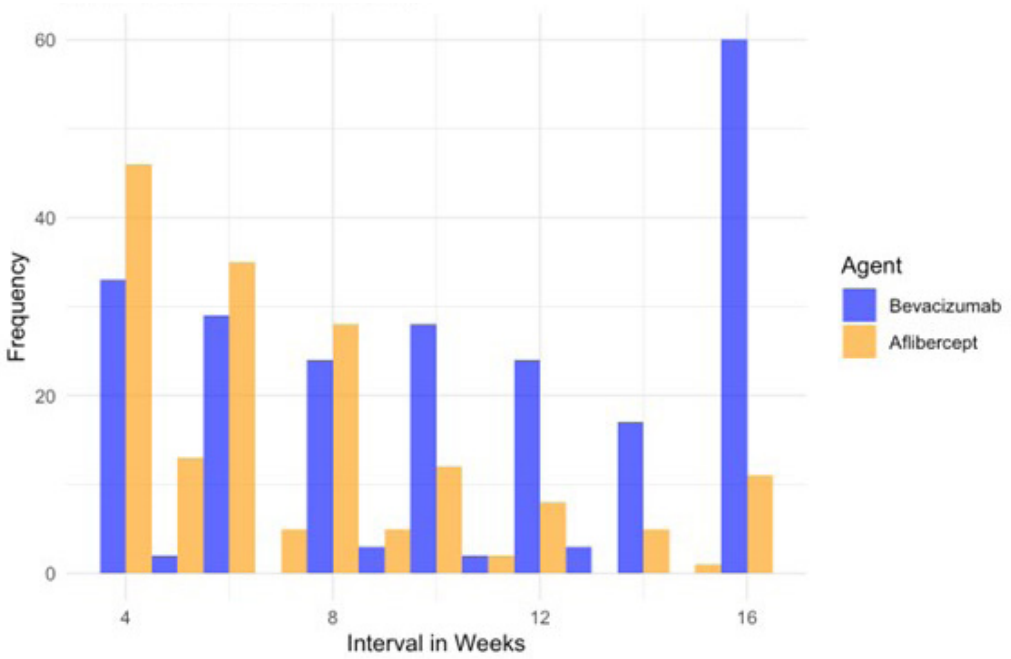
The Bonferroni-corrected p-value was 9.71e-14, which remains highly significant, indicating a robust difference in injection intervals between the two treatments.

The histogram provided shows the differences in injection intervals between the two cohorts.

Under the current treatment model, there is an estimated yearly total of 2,597 injections, with 1,265 bevacizumab injections (48.7%, estimated cost $252,293) and 1,332 aflibercept injections (51.3%, estimated cost $1,873,253). There are 1,211 nurse-led macula review clinics ($73,416) and 792 consultant clinics ($79,873). The estimated total cost is $2,278,835.

Under the option where all eyes receive faricimab, there are 1,704 injections ($2,932,567) yearly. There are 1,339 nurse-led macula review clinics ($81,191) and 792 consultant clinics ($79,873). The estimated total cost is $3,093,631, a yearly cost increase of $814,796 over the current treatment model. The net present value over the 10-year period modelled is -$6,776,340 using a discount rate of 3.5% per annum. Sensitivity testing using discount rates of 5% and 0% provide net present values of -$6,291,642 and -$8,147,964 respectively. A total of 252 hours of clinical time are saved per year.

Figure 1: Frequency distribution of injection intervals between bevacizumab and aflibercept.



Under the option where eyes receiving aflibercept instead receive faricimab, there is an estimated yearly total of 2,001 injections, with 1,265 bevacizumab injections ($252,293) and 736 faricimab injections ($1,266,336). There are 1,274 nurse-led macula review clinics ($77,212), and 792 consultant clinics ($79,873). The estimated total cost is $1,675,714, a yearly cost saving of $603,121 over the current treatment model. The net present value over the 10 years modelled is $5,015,922 using a discount rate of 3.5% per annum. The net present value is $4,657,143 using a 5% discount rate, and $6,031,213 using a 0% discount rate. A total of 176 hours of clinical time are saved per year.

The area serviced by Palmerston North Hospital accounts for 3.61% of the population of New Zealand. Without adjusting for differences such as demographic structure, the 10-year national cost impact for the first scenario can be estimated at a net present value of -$187,925,737 using a discount rate of 3.5% per annum. The national cost impact for option two can be estimated at a net present value of $139,104,706 saved using a discount rate of 3.5% per annum.

Discussion

This analysis indicates that there is the potential for significant benefits if faricimab were to be approved for the treatment options for nAMD in New Zealand. In this analysis, faricimab is demonstrated to be a strongly dominant treatment option, resulting in both improved clinical outcomes and cost savings when used in conjunction with the existing treatments rather than standalone.[21]

Clinical superiority is demonstrated in several domains. First, there is the direct harm avoided by reduced administration of intravitreal injections to patients. Endophthalmitis is a rare but devastating complication of intravitreal injections, with a reported incidence of 1 per 1,888 to 1 per 4,897 injections.[22,23] With both alternative treatment models leading to a decrease in the total number of yearly injections performed, the incidence of endophthalmitis would be expected to decrease. Other complications of intravitreal injection include corneal abrasion, subconjunctival or vitreous haemorrhage, retinal tears or detachment, uveitis, myocardial infarction and stroke.[24] The incidence of these complications could similarly be expected to lessen.

Aside from the direct cost savings demonstrated under the second scenario, further financial benefits would accrue to patients, caregivers and society from a reduced number of intravitreal injections performed. The Deloitte report highlighted the costs of reduced employment, productivity and tax revenue as a result of AMD, as well as the costs of informal care for patients receiving treatment.[3] While the calculations provided do not allow an estimate of the magnitude of this change, it is nevertheless a tangible benefit from a reduction in the burden of treatment.

The psychological impact of intravitreal injection treatments on patients also cannot be ignored. The literature suggests that patients receiving injections continue to feel anxious about treatment, including the fear of losing their vision due to complications of the injection and if they have had previous painful experiences of intravitreal injections.[25] It can be concluded that reducing the number of intravitreal injections received per year would ameliorate these feelings to some degree, decreasing the treatment burden for these patients.

Critical to the New Zealand context, a change to the current model of care also has the possibility of alleviating health inequalities between Māori, Pacific peoples and other ethnicities. While nAMD has a low prevalence among Māori and Pacific peoples and has been assumed to be zero for the purposes of prevalence estimates and forecasting,[4] the literature overwhelmingly indicates the urgent ophthalmic health inequalities faced by Māori and Pacific peoples.[26]

Our alternative treatment models indicate that between 176 and 252 hours of clinical time would be released yearly due to a reduction in the numbers of intravitreal injections and nurse-led macula review clinics. This time could then be channelled into these areas of need.

In addition, faricimab is also used for the treatment of diabetic macular oedema (DMO), a disease that disproportionately affects Māori and Pacific peoples.

Results from the YOSEMITE and RHINE clinical trials indicated that at year 1, >70% of patients in the PTI group were on ≥12-week dosing intervals, and 53% (YOSEMITE) and 51% (RHINE) received 16-week dosing intervals, compared with the standard 8-weekly intervals for patients on aflibercept.[27]

As faricimab has been approved for the treatment of nAMD and DMO in the United States, European Union and Australia,[9–11] if faricimab is funded for the treatment of nAMD in New Zealand, it will almost certainly be funded for the

treatment of DMO as well.

The benefits from reduced injection intervals with bevacizumab or aflibercept in this patient group could be expected to be broadly similar to those demonstrated in this study, including cost benefits and clinical benefits. However, we acknowledge that the increased quality of life benefits for Māori and Pacific peoples by freeing up clinical time are speculative. Although the potential for such benefits exists, it is based on the assumption that the freed-up clinical time would be effectively utilised to address these health inequalities.

Our research has several limitations. First, it is difficult to establish whether a patient has reached a treatment plateau and is being maintained on a stable dosing interval or is being moved to progressively longer treatment intervals using a "treat and extend" model to find their maximum fluid-free interval.[28]

We attempted to address this concern by excluding eyes from the calculation of dosing intervals that had received less than four injections, on the assumption that these eyes were being inducted into treatment.

Our analysis represents a snapshot of the intervals of treatment at the time the data was collected, and it is possible that this does not reflect the true underlying stable treatment patterns for our patient cohort. Further, our study draws data from a single hospital and may not generalise to other New Zealand settings.

Second, our study assumes that the treatment intervals achieved will be the same as those in the TENAYA and LUCERNE Stage 3 clinical trials. Previous experience shows real-world treatment regimens often fall short of those in clinical studies.[8]

The 6-month results of the TRUCKEE study included a majority of eyes that had been previously treated with anti-VEGF. This trial demonstrated the efficacy of faricimab in the real-world setting, although durability was not assessed.[29]

Additionally, aflibercept is used as a second-line therapy for nAMD in New Zealand. While there are still gaps in the literature regarding the durability of faricimab in treatment-resistant nAMD, emerging research suggests that faricimab offers statistically significant durability over aflibercept, even in this patient population.

One study indicates that patients attained a mean dosing interval of 7.64 weeks with faricimab compared to 5.16 weeks for aflibercept, with 10% of patients achieving dosing intervals of 12 weeks or longer.[30]

A further study found that 31.5% of patients treated with intravitreal faricimab attained a treatment interval ≥8 weeks and had a fluid-free macula on OCT at 12 months.[31] Although the emergence of reliable data on faricimab for the treatment of recalcitrant nAMD would impact the magnitude of cost-savings demonstrated by this study, the available evidence suggests that at least some of these benefits would accrue, and supports the use of faricimab as part of a tailored approach in those patients with treatment resistant nAMD on the basis of extending the injection interval and reducing the possible harm from intravitreal injections.

A final limitation of our study is the lack of a comprehensive sensitivity analysis. While we reached out to additional district health boards to obtain cost data for such an analysis, we have not received responses. We believe that an exhaustive sensitivity analysis may extend beyond the scope of this manuscript. Given that the main cost inputs, such as practitioner time and consumables, remain consistent across different types of injections, an extensive sensitivity analysis might offer limited additional value.

In conclusion, this analysis demonstrates significant differences between treatment intervals for eyes with nAMD being treated with bevacizumab and aflibercept at Palmerston North Hospital.

It highlights the possible cost impact for Health New Zealand – Te Whatu Ora if faricimab were to be funded for the treatment of nAMD, as well as considering the reduction in direct patient harms from a reduced number of injections.

Indirect benefits, from improved quality of life to increased productivity and employment, might also be expected.

There is the possibility of reduced health inequalities for Māori and Pacific peoples as clinical time is liberated, if these resources could be effectively channelled into areas of need.

Faricimab could also lead to expanded treatment options for DMO.

There is a need for further real-world research, particularly in treatment-resistant patient populations, in order to more accurately quantify the expected benefits from approving this medication.

It is hoped that this analysis will add to a body of literature informing the funding of faricimab for the treatment of nAMD in New Zealand, as part of a tailored treatment approach incorporating the existing agents and balancing the possible impacts on a patient's quality of life with our wider duty to prudently manage scarce healthcare resources.

COMPETING INTERESTS
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Awareness and preparedness of healthcare workers for the initial wave of COVID-19 in Aotearoa New Zealand

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ABSTRACT

AIMS: The TMGH-Global COVID-19 Collaborative was a multinational, multicentre, cross-sectional survey assessing the awareness and preparedness of healthcare workers (HCWs) during the first wave of the pandemic across 57 countries. Here, we report the results from Aotearoa New Zealand.

METHODS: This cross-sectional survey was conducted at Christchurch Hospital between February and May 2020. Data were collected from a convenience sample of HCWs and analysed using descriptive and multivariate regression to determine awareness (out of 40) and preparedness (out of 15) scores and influencing factors.

RESULTS: Of the 158 participants (response rate 20.8%), most were women (73%) and doctors (58%) with a median age of 38 years (interquartile range [IQR] 29–49). The median awareness and preparedness scores were 33.6 (IQR 31.1–35.1) and 8 (IQR 6–8), respectively. Mainstream media was the primary source of information on COVID-19 among HCWs. The awareness score was significantly affected by gender and profession, whereas the preparedness score was influenced by age, profession, clinical experience duration and COVID-19 training.

CONCLUSIONS: Although frontline HCWs had high awareness levels, preparedness was low. Variables influenced awareness and preparedness differently. These findings identified gaps in pandemic readiness and factors that can be leveraged to enhance future pandemic preparedness and response in New Zealand.

Coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The spread of the COVID-19 virus is attributed to waves of community transmissions.[1–3] Healthcare workers (HCWs) were at especially high risk due to their heightened exposure to individuals infected with the virus.[4,5]

During the initial wave of COVID-19 in China, around 4% of COVID-19 patients were HCWs,[6] whereas 2020 Ministry of Health data reported approximately 11% of Aotearoa New Zealand COVID-19 cases were HCWs.[6,7] The COVID-19 pandemic has contributed immensely to the physical, mental and emotional exhaustion of HCWs, placing significant strain on the New Zealand healthcare system.[8,9] The emergence of COVID-19 variants of concern has further compounded this strain.[10] The repercussions of this strain on HCWs and the healthcare system continue to be experienced 4 years after the onset of the global COVID-19 pandemic.[11]

It remains imperative to foster COVID-19 awareness and preparedness among HCWs to prevent and reduce transmission in healthcare facilities and safeguard the workforce. This continues to be important as we approach the tail-end of the COVID-19 pandemic to ensure continued vigilance and readiness for potential future infectious viral pandemics, thereby safeguarding the healthcare workforce.[12]

This study presents a sub-analysis of the TMGH-Global COVID-19 Collaborative, a multinational, multicentre, cross-sectional survey that examined COVID-19 awareness and preparedness among HCWs during the first wave of the pandemic (February–May 2020), which recruited 371 hospitals across 57 countries.[13] This study aimed to examine in detail the data collected at Christchurch Hospital, with a particular focus on early pandemic awareness and preparedness to further inform future pandemic preparedness and planning in New Zealand.[12]

Methods

Ethical approval

Māori consultation was conducted, and ethical approval was obtained from the University of Otago Human Ethics Committee (D20/063).

Study design

This was a cross-sectional, descriptive study using a questionnaire survey and convenience sampling approach. Data collection was conducted at Christchurch Hospital, New Zealand.

Data collection

Data acquisition was conducted at Christchurch Hospital as part of a multicentre, international, cross-sectional study examining COVID-19 awareness and preparedness among HCWs during the first wave.[13] Data collection spanned from February to May 2020.

All COVID-19 frontline HCWs were invited via email to participate in this study by completing an online survey. Inclusion criteria were all healthcare professionals working at Christchurch Hospital who were actively engaged in the provision of patient care and the management of individuals with suspected COVID-19 cases. Informed written consent was embedded into the initial page of the survey. Before commencing the survey, participants were provided with a description of the study. Potential participants were sent an email with a participant information sheet, and signified consent by clicking a link embedded in the document. Participants maintained the right to withdraw their consent at any point during the data collection period.

Survey

The development, testing, validation and content of the final survey questionnaire are reported in detail in the parent study.[13] In brief, the survey was divided into two sections (32 questions in total). The first section (six questions) collected data related to HCWs' demographic and professional information. The second section (26 questions) comprised items related to participant awareness and preparedness for COVID-19. The awareness and preparedness questions were based on the most up-to-date United States Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) information and checklists.[13,14,15] The last question solicited suggestions on improving overall pandemic preparedness. The awareness score represented the sum of accumulated points over four topics with a maximum of 40. The preparedness score was the number of points accumulated based on responses from 15 questions (maximum score of 15). The English version of the survey questionnaire is available here.[13]

Statistical analysis

Participants' characteristics were summarised using median and interquartile ranges (IQR) for numeric variables, and the number of participants and percentages for categorical variables were tabulated. A multilevel linear regression model was used to evaluate associations between variables that differed within the locality of this study (Christchurch Hospital). We generated a mean difference (MD) with 95% confidence intervals (95% CI) and p-values. As all questions were answered within these variables, a complete case method was used in our multilevel linear regression. MDs were compared to those from the parent study. The effect of COVID-19 training on awareness and preparedness scores was examined using a scatter plot. Data were analysed using SPSS Statistics (IBM SPSS Statistics for Windows, version 27, 2023), and R gpront (version 4.3.1) was used to produce the scatter plot.

Results

Demographics

A total of 158/761 HCWs returned completed surveys (response rate: 20.8%). Of these, 73% were women and 58% were doctors. The median (IQR) age of participating HCWs was 38 (29–49).

Workplace characteristics and sources of COVID-19 information

Participants had a median of 10 years of work experience in their respective fields (IQR 4.2–24.3 years). The largest represented hospital department among respondents was the emergency department (n=28, 17.7%). However, there was a large number of respondents from other departments including pharmacy, physiotherapy and occupational health. Around 41% (n=65) of HCWs reported prior infectious outbreak experience, and only two (1.3%) participants had experience in treating a COVID-19 case at Christchurch Hospital at the time of the survey (Table 1).

Mainstream media (n=149, 94.3%) was the primary source of COVID-19 information among respondents, followed by government organisations (n=124, 78.5%) and work colleagues (n=100, 63.3%). Nearly half (46.8%) of respondents relied on social media websites and applications as their primary sources of COVID-19 information. At the time of the survey, only 22 (13.9%) respondents had participated in a COVID-19 training course

Table 1: Socio-demographic and work characteristics of participants (n=158).

Characteristics	N (%)
Socio-demographic	
Age, years* (n=157)	38 (29–49)
Gender	
Women	116 (73.4%)
Men	42 (26.6)
Profession	
Doctor	92 (58.2%)
Nurse	33 (20.9%)
Pharmacist	7 (4.4%)
Other	26 (16.5%)
Work experience and workplace	
Work experience, years* (n=157)	10 (4.2–24.3)
Hospital department	
Emergency department	28 (17.7%)
Intensive care unit	15 (9.5%)
Outpatient clinics	18 (11.4%)
Infectious disease department	2 (1.3%)
Respiratory department	15 (9.5%)
Other	90 (57.0%)
Previous outbreak experience	
Any outbreak	65 (41.1%)
SARS	33 (20.9%)
MERS	7 (4.4%)
Bird flu	30 (19.0%)
Other outbreaks	0 (0%)
Confirmed SARS-CoV-2 cases	
No	2 (1.3%)
Yes, in my country	155 (98.1%)
Yes, in my hospital	1 (0.6%)

*Reported as median and interquartile range.

Table 2: Sources of COVID-19 information.

Variable (n=158)	N (%)
Sources of information about COVID-19	
Mainstream media (e.g., newspaper, television, radio, etc.)	149 (94.3%)
Social networks/media (e.g., Facebook, Twitter, blog, etc.)	74 (46.8%)
Academic training course	11 (7.0%)
Colleagues	100 (63.3%)
Government organisations (e.g., Ministry of Health)	124 (78.5%)
Other	5 (3.2%)
Participated in a COVID-19 course	22 (13.9%)
How satisfied you are with the medical equipment in your hospital	
Very unsatisfied	9 (5.7%)
Unsatisfied	28 (17.7%)
Neutral	57 (36.1%)
Satisfied	48 (30.4%)
Very satisfied	12 (7.6%)
To what extent do you have confidence in handling suspected COVID-19 patients?	
Not at all	17 (10.8%)
To little extent	32 (20.3%)
To some extent	80 (50.6%)
To considerable extent	23 (14.6%)
To great extent	3 (1.9%)

(Table 2). Overall, 23.4% (n=37) were unsatisfied with the availability of medical equipment required for COVID-19 management. The majority of HCWs had some degree of confidence in handling suspected COVID-19 cases while only 10.8% (n=17) had no confidence (Table 2).

COVID-19 awareness and preparedness scores

All respondents completed the questions pertaining to the COVID-19 awareness and preparedness score sections. The median awareness score was 33.6 out of a possible 40 (IQR 31.1–35.1), with a mean (standard deviation [SD]) of 32.4±4.6. The median preparedness score was 8 out of a possible 15 (IQR 6–8), with a mean of 8.4±3.4.

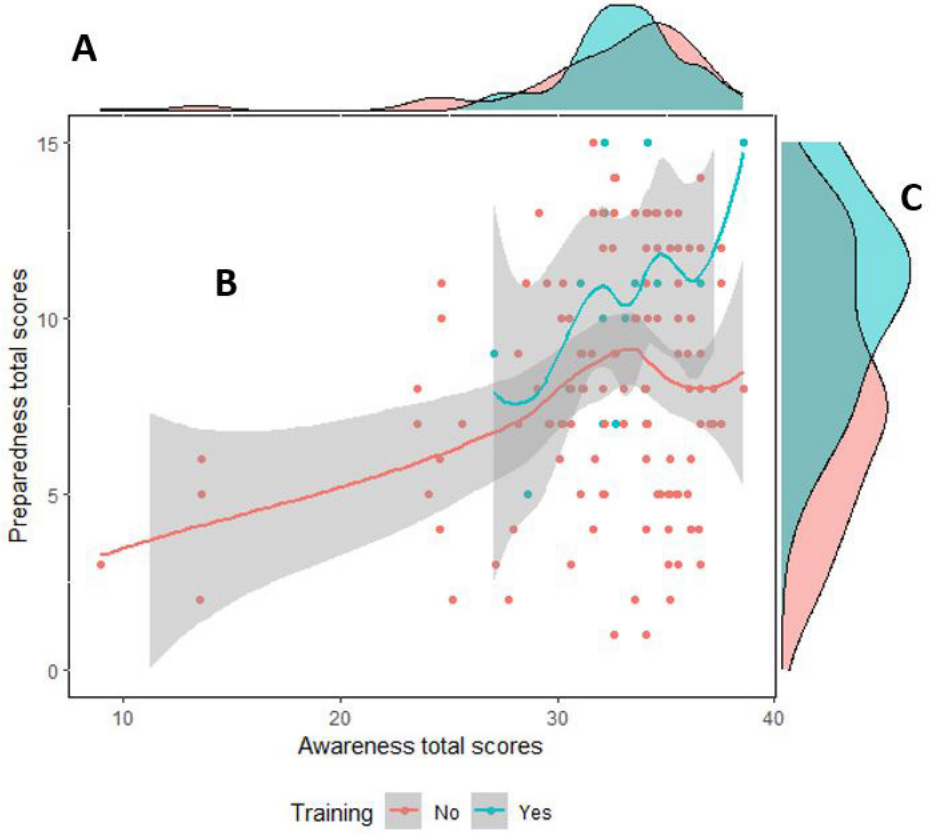
The awareness score was affected by several demographic variables (Table 3). Men had higher awareness scores compared to women, albeit with marginal statistical significance, (MD 1.645; CI=0.33–3.258; p=0.046). The other HCW category (n=26) had a significantly reduced awareness score compared to doctors (MD -5.129; -6.958–-3.229; p<0.001).

There was a significant increase in participant preparedness score with every 10-year increase in age (MD 0.663; CI=0.212–1.114; p=0.004) as

Table 3: Multilevel models for preparedness and awareness scores of participating healthcare workers.

Variable	Local analysis (Christchurch Hospital)			Parent study		
	MD	(95% CI)	p	MD	(95% CI)	p
Awareness						
Gender						
Women	Reference			Reference		
Men	1.645	0.33–3.258	0.046	-0.02	-0.19–0.15	0.791
Age (10-year increase)	-0.149	-0.760–0.463	0.632	-0.16	-0.34–0.01	0.068
Profession						
Doctor	Reference			Reference		
Nurse	-0.424	-2.092–1.245	0.617	-1.97	-2.16–-1.78	<0.001
Other	-5.129	-6.958–-3.229	<0.001	-2.24	-2.69–-2.19	<0.001
Experience (10-year increase)	0.016	-0.576–0.609	0.956	0.06	-0.13–0.25	0.547
Previous outbreak experience (Yes)	0.389	-1.067–1.854	0.601	0.49	0.33–0.66	<0.001
COVID-19 training (Yes)	0.888	-1.192–2.968	0.400			
Preparedness						
Gender						
Women	Reference			Reference		
Men	0.346	-0.886–1.577	0.580	0.35	0.23–0.47	<0.001
Age (10-year increase)	0.663	0.212–1.114	0.004	0.40	0.28–0.53	<0.001
Profession						
Doctor	Reference			Reference		
Nurse	0.346	-0.886–1.577	0.580	0.66	0.54–0.81	<0.001
Other	-2.388	-3.397–-0.979	0.001	-0.86	-1.13–-0.39	<0.001
Experience (10-year increase)	0.731	0.299–1.163	0.001	0.10	-0.03–0.24	0.136
Previous outbreak experience (Yes)	0.121	-0.989–1.227	0.830	0.56	0.44–0.67	<0.001
COVID-19 training (Yes)	2.66	1.146–4.177	<0.001			

Figure 1: Two multivariate cowplots illustrating the effect of training on COVID-19 preparedness and awareness. Part A illustrates the distribution of awareness scores. Part B shows individual total scores of preparedness and awareness. The centre lines were computed using LOESS method with the shadow representing their 95% confidence intervals. Part C illustrates the distribution of preparedness scores (n=158).



well as every 10-year increase in professional experience (MD 0.731; CI=0.299–1.163; p=0.001). HCW type had a significant effect on preparedness score with the Other category (n=26)—containing, for example, pharmacists, physiotherapists and other allied health professionals—and had a significantly reduced score compared to doctors (MD -2.388; CI=-3.397–-0.979; p=0.001).

Although receiving COVID-19 training was associated with higher preparedness scores (MD 2.66; CI=1.146–4.177; p<0.001), awareness scores were not influenced by COVID-19 training status (Table 3). Awareness and preparedness scores of participating HCWs were positively correlated (Figure 1; Pearson correlation r=0.254; p=0.001).

Discussion

Summary of main findings

In this study, we provide evidence pertaining to the preparedness and awareness of COVID-19 in Christchurch Hospital during the initial wave globally and before the first major New Zealand outbreak.[10] Despite the low levels of previous outbreak experience, COVID-19 training and experience in treating COVID-19 cases within the cohort, most participants had some degree of confidence in handling suspected COVID-19 patients. A large proportion of respondents were unsatisfied or neutral towards availability of COVID-19 equipment. Social media was a common source of COVID-19 information among HCWs. Among the participants the awareness score was high; however, the preparedness score was low compared with the parent study.[13] The awareness score was affected by gender and profession, whereas preparedness was influenced by age, profession, clinical experience duration and COVID-19 training.

Strengths and limitations

This study was conducted in the first international wave of COVID-19 and provides early insight from front-line staff during a novel viral pandemic. An additional strength was that this study was a part of a global multicentre study, allowing for comparison of locally collected data with other countries of varying healthcare systems and experiences.

The study's survey was developed based on CDC information on SARSCoV-2 and COVID-19 in the early stages of the pandemic. Much of the COVID-19 information and data provided then by the CDC have changed to due to new knowledge, understanding and studies. The information from the CDC was known to be true during the first wave of the pandemic.[14]

This study was also done at one single major hospital in New Zealand, with specific local demographics of both the public and HCWs. Thus, generalisability to other hospitals and healthcare settings in New Zealand is limited, especially rural areas. The single-centre nature of this study also limited the sample size to a comparably low number. Additionally, the survey may be affected by recall and selection bias, as participants might not accurately remember information and only those with the willingness and time to complete it are likely to participate. Finally, there were no follow-up studies throughout the pandemic to assess changes in awareness and preparedness levels over time.

Comparison with previous research

Our study highlighted several issues related to the general pandemic preparedness and response in New Zealand. Prior experience with infectious outbreaks and participation in COVID-19 training courses were low among participants. Additionally, most had no exposure to a COVID-19 case due to the late arrival of COVID-19 on New Zealand's shores at the time of the survey (first global wave).[6,7] Furthermore, around one quarter were unsatisfied with the equipment on hand (e.g., personal protective equipment [PPE]) for the management of COVID-19. This might partly explain the low preparedness scores (discussed below)—either HCWs did not have knowledge of existing equipment and infrastructure, or it was not available to them, thus lowering preparedness for COVID-19.[16] Despite this, most participants were confident in handling suspected COVID-19 cases. Confidence in handling COVID-19 may be a basis of awareness, as by the time of the survey COVID-19 had affected most major healthcare systems but was relatively foreign to New Zealand.

The fact that a significant portion of respondents primarily relied on mainstream media (94.3%) and social media (46.8%) for their COVID-19 information could be concerning. This is because such information may have come from non-reputable sources and may not have undergone peer review. Nevertheless, it potentially contributed to a notable elevation in awareness levels among participants and the wider community.[17–19] Misinformation, spin and falsification of COVID-related information (e.g., rumours, conspiracy theories) in digital and physical milieu were widespread during the pandemic, which was labelled the "COVID-19 infodemic" by WHO.[13,17–19] Widespread misinformation was not only circulated by the public but also by some mainstream and social media outlets, community leaders and government officials, potentially influencing HCWs' clinical practice during the pandemic.[19] Although the power and value of social media could have been leveraged to distribute COVID-19 information as it developed rapidly through the initial phase of the pandemic, it is important that HCWs verify the accuracy and credibility of information, especially in a rapidly developing pandemic.[17] Our data further support the need for a pandemic public communication and messaging strategy in addition to the training of HCWs.[11]

Local results compared to parent study (international data)

Interestingly, the cohort surveyed in our study had a higher awareness score, but a lower preparedness score, compared with the parent study.[13] This could be attributed to the low number of SARS-CoV-2 cases in New Zealand at the time of the survey, whereas COVID-19 prevalence was high in most of the other participating countries.[13] The lower COVID-19 preparedness could be due to the unknown nature of the disease in New Zealand. A lower preparedness score also might represent a lack of appropriate infrastructure or knowledge of existing infrastructure for the handling and treatment of COVID-19.[16] A sizeable proportion of participants were not satisfied with the availability of equipment required for the management of COVID-19 cases (e.g., PPE). In addition, a small proportion of participants received COVID-19 training, which might have contributed to the low

levels of preparedness. Internationally, COVID-19 preparedness would have been developed via exposure to and experience of handling COVID-19 cases, whereas awareness was developed from newly generated and growing knowledge disseminated rapidly via literature, mainstream media and social media networks at the initial stages of the pandemic, leading to this heightened awareness. The sheltered nature of New Zealand having not experienced any major COVID-19 outbreak early on in the pandemic resulted in reduced preparedness.[20]

The preparedness score largely depends on infection control protocols, procedures and infrastructure, such as PPE, isolation procedures and rooms, and hospital communication. This suggests there may be significant gaps in the resources available for managing highly infectious diseases.[16,21] This explanation is supported by findings from Howard et al., who examined gaps in COVID-19 infection control preparedness in emergency departments across New Zealand.[16] It is imperative that there are established protocols and infrastructure in place before infectious disease outbreaks. As discussed, there was a low number of participants who had undertaken an official training course on COVID-19. This could be due to the development of such a course specific to New Zealand taking place at the beginning of the pandemic or the lack of information about COVID-19 to develop such a course.

Association between awareness and preparedness scores and demographics

We found little difference in awareness scores between demographic groups.[13] The Other HCWs category (i.e., pharmacists, physiotherapists and other allied health professionals) was the only variable that was associated with a significantly reduced awareness score. This may be partly explained by the reduced pertinence for COVID-19 awareness to their professional role compared to HCWs involved in the active management of COVID-19 patients, such as doctors and nurses.

Among examined variables, age, duration of clinical experience and profession had a significant effect on preparedness. Similar to awareness levels, we found the Other HCWs category (i.e., pharmacists and physiotherapists) to be associated with a significantly reduced preparedness score. On the other hand, age and clinical experience were positively associated with preparedness scores in contrast to the parent study that found older age and not clinical experience to be associated with better preparedness.[13] Older HCWs with longer work experience are likely to have had prior experience with infectious outbreaks and to have developed management and leadership skills. Higher scores among older, more experienced HCWs are underpinned by sharing experiences between staff and hospitals, demonstrating the importance of institutional memory.[13,22,23] Previous outbreak experience did not significantly change the preparedness score, whereas previous outbreak experience increased preparedness in the parent study, and as explored in Tsuei et al.[13,23] COVID-19 training was a positive predictor of increased preparedness score, indicating that those who participated in training courses were better prepared and more equipped for dealing with COVID-19.[24]

Howard et al. found similar preparedness limitations across New Zealand, with their survey focussed on policy, training and physical resources in emergency departments across the country.[16] They found that severe under-resourcing of New Zealand emergency departments contributed to patient–clinician transmission as there was inadequate policy surrounding PPE and space for physical distancing.[16] They also suggested that New Zealand has not adapted to recent scientific advances seen in policy elsewhere (Australia) regarding PPE policy, and pandemic-specific policy.[16]

Implications for policy and practice

This TMGH-Global COVID-19 Collaborative study provided the first global insight into awareness and preparedness of COVID-19 during the initial phase of the pandemic. Utilising Christchurch Hospital data, we identified that HCWs who had undergone COVID-19 training had higher preparedness scores, with several international studies coming to the same conclusion. Localised training courses could provide better preparedness—for example, where PPE and critical isolation infrastructure is located in the facility, how to don and doff PPE, social distancing clinical requirements and, ultimately, tools and strategies to reduce the transmission of infectious diseases. This could be integrated into national- and hospital-level policies to better prepare for future pandemics. There is a heightened need for strengthened investment from the government to better prepare HCWs with a standardised training policy and reinforced infrastructure

in our already under-resourced emergency departments and hospitals.

Conclusion

This survey was conducted in the initial phase of the COVID-19 pandemic when COVID-19 disease and its effects were not fully realised in New Zealand and internationally. This study identified strengths in the local COVID-19 awareness and preparedness among frontline HCWs. It also highlighted gaps in pandemic readiness and factors (staff- and hospital-related) that can be leveraged to enhance future pandemic preparedness and response in New Zealand. Further policy, training and infrastructure improvements are required before the inevitable next infectious outbreak or pandemic to lessen the burden on HCWs.

COMPETING INTERESTS
The authors declare no conflicts of interest.

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Polokalama Fekumi ki he Kanisā ‘o e Halanga-me’atokoní—Ko e vakai ‘a e Tongá: Tongan New Zealanders’ views on how to ensure the National Bowel Cancer Screening Programme works well for the Tongan community

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ABSTRACT

AIM: The National Bowel Screening Programme (NBSP) fails to deliver screening equitably to Pacific New Zealanders. This research explored Tongan New Zealanders’ experiences of participating in the NBSP and their views on ensuring the programme works well for the Tongan community.

METHOD: In 2021, we conducted two talanoa focus groups with Tongan New Zealanders who had participated in the NBSP (n=26), recruited through a Pacific provider in Auckland. Participants were aged 60 or more and were Tongan born. Interviews with four Pacific experts working in the NBSP were also undertaken. Their views on the NBSP were explored and analysed using thematic analysis.

RESULTS: While the research participants valued the opportunity to participate in the NBSP, they had many valuable insights about strengthening it, as did the Pacific experts. Key was a by Tongan, for Tongan service run by Tongan providers, one based on Tongan models of health and health promotion, Tongan values and ways of working, and using the Tongan language, which empowers Tongans to take control of their health.

CONCLUSIONS: This research demonstrates critical elements of an effective, culturally appropriate and empowering NBSP for Tongans led by Tongan providers. If these findings are enacted, more effective delivery of bowel screening to Tongans will likely be enabled, reducing inequity in participation between Tongans and other New Zealanders. What is required is courage and political will to shift power and resources to ensure equitable outcomes in the NBSP, not only for Tongans but for all Pacific peoples.

In 2023, the National Bowel Screening Programme (NBSP) in Aotearoa New Zealand (Aotearoa) did not deliver services equitably to Pacific participants. Fifty-eight percent of New Zealanders overall were screened, but only 49% of Māori and 39% of Pacific people.[1] Pacific peoples are 60% more likely to die from bowel cancer compared to European people (HR 1.6 95% CI 1.4–1.7).[2] Screening rates also differ between Pacific communities in Aotearoa, with only 35% of Tongan New Zealanders currently screened, compared, for example, to 42% for Cook Islands Māori (In an email, the National Bowel Screening Programme, 2023). Further, the Pacific community is a significant, young and growing population in Aotearoa, which will have an increasing need for an effective NBSP.[3]

There is very little research on the views of Pacific New Zealanders exploring how the NBSP can work better for Pacific peoples, including for Tongans. Recent research by Dunlop explores the perspectives of Tongan and Samoan New Zealanders towards stool testing. Dunlop found that Pacific people *“were willing to do stool testing despite having reservations about hygiene concerns and feelings of shame or embarrassment.”*[4] Sandiford et al., identified that telephone follow-up increased participation in stool testing returns for Pacific peoples, including Tongans, by 3.6%.[5] Further, giving NBSP participants the option to return stool samples to a community laboratory rather than through the mail resulted in a small but significant increase in screening participation by Pacific peoples.[6]

The peoples of the Pacific have many different cultures and histories, including different experiences

of colonisation. As such, it is essential to recognise the needs and aspirations of the various Pacific cultures in Aotearoa. In this research, we do so by focussing on Tongan New Zealanders.

However, Pacific communities also have much in common. This includes:

> *"... shared understandings and experiences of being of Pacific Island origin with a relatively recent history of immigration to New Zealand; there are similarities in Pacific peoples' social and cultural values and views of the world."*[7]

Pacific peoples also share a history of an Aotearoa healthcare system that has been culturally inappropriate and disempowering for them[8] where they continue to encounter racism, which negatively impacts their health.[9,10] Yet there has been considerable progress in providing Pacific-led health and social services and Pacific health promotion leadership.[7]

Pacific models of health and health promotion have also emerged in Aotearoa. The Samoan Fonofale[11] and Tongan Fonua[7] and Fonua Ola[12] are commonly used models that speak to the holism of the Pacific approach. Fonua Ola includes six dimensions of Pacific health and wellbeing: spiritual, mental, physical, economic, cultural and ecological.

Tu'itahi and Lima propose the following Pacific definition of health promotion:

> *"... the empowering of Pacific people and their communities to take control of their holistic health and wellbeing and their future. It is an Indigenous approach that is inter-disciplinary and multi-dimensional."*[7]

Tongans view the world holistically and think and work collectively. Because of this, they are guided by the core values of Fefaka'apa'apa'aki (mutual respect), Feveitokai'aki (sharing, cooperating and fulfilment of mutual obligations), Lototoo (humility and generosity) and Tauhi vaha'a (loyalty and commitment). This collective approach is inconsistent with a focus on the individual, common in Western thinking and Western health systems, and a dominant value in Aotearoa.[13,14]

For Pacific peoples, healing a disease requires an internal process focussed on relationships.[14] Your response is to put things right with yourself, your relatives and your God. You are seeking the natural balance of things. At the same time, Western medicine has a strong focus on the physical healing of the individual by seeking treatment to kill the organism and get rid of the disease.

This research aims to contribute to closing the gap in knowledge on how to ensure the NBSP meets the needs of Pacific New Zealanders and, therefore, decrease the inequity in bowel screening rates. The study explored Tongan New Zealanders' experiences of participating in the NBSP and their views on ensuring the programme works well for the Tongan community. The views of key Pacific experts with knowledge of the NBSP were also sought.

Methods

We conducted two talanoa focus groups with Tongan New Zealanders who had participated in the NBSP (a women's group [n=12] and men's group [n=14]).[15] Participants were recruited among patients who had experience in the NBSP and were members of The Fono, a Pacific health provider in West Auckland. Participants were all aged 60 or more, as this was the age eligibility for participation at the time, and were all Tongan born. (Since this research was undertaken, it has been announced that the eligible start age for bowel screening will be lowered from 60 to 50 years for Māori and Pacific people. The lower age range is already in place in Te Whatu Ora Waikato and Tairāwhiti and MidCentral as part of an evaluative implementation). We also undertook four interviews with Pacific experts working in the NBSP. The talanoa and interviews were conducted by VP and AP, well-known Tongan doctors from the community. They were supported by ML. Talanoa is a conversational research method. It was guided by a semi-structured interview schedule that aimed to have a "healthy conversation" that was strengths-based. Focus group questions included "What was your experience of the bowel screening programme, what worked well, and what did not work well for you and your family, and how can the bowel screening programme be improved to meet the needs of the Tongan community?" A nurse from The Fono was present to answer any questions or provide follow-up. The talanoa and interviews were conducted in Tongan and English, audio-recorded and transcribed in English by VP and AP. Data were analysed by VP and AP using thematic analysis[16] and discussed with the wider team. When this research was conducted in 2021, the NBSP was underway. The Fono was contracted to

promote the programme and support people to participate. The University of Otago Human Ethics Committee (Health) provided ethical approval (H20/076).

Results

Experience of NBSP

Appreciation for the NBSP

All the participants highly valued participating in the NBSP. As one person said, *"I join and echo what others said about how important this programme is for our people."* One participant shared that while he was given a clean bill of health, friends of his had the test too late and had since died.

Valuing prevention

Many Tongans accept that "prevention is better than cure," which was demonstrated by the appreciation the participants revealed for the programme. One participant noted that:

> *"I was very happy when I received the letter to join the bowel screening programme because I have had other health problems back in the Island and here in New Zealand. I only found out when I was sick. This one is to find out before I am sick … Therefore, I am very happy and have done it for number of years. I do the test as soon as I received the kit."*

The participant reported that some members of the community died despite being tested because their cancer was too advanced. Others *"were lucky to find out early, and treatment helped them."* However, participants agreed that if people do not understand the service, the need for it and if it is hard to access, then the "noble saying" that prevention is better than cure will just remain a nice statement.

Fatalism

For many Tongans, there is also a strong sense of fatalism about death, as with many Pacific cultures. As one participant notes, *"at this age* [60+]*, we have reached a good age, and if we die, it's ok."* Associated with this was that people would rather not know, as one participant stated, *"what will be, will be."*

Fear of cancer

This attitude could be related to fear of cancer, as one participant said,

> *"I did not want to participate in NBSP is because I am afraid of cancer. When the pack arrives, I just put it up on the shelf, hoping to have the strength to do it later, but when Christmas cleaning came, they got dumped in the bin."*

Confidence to do the test

One participant explained the importance of people having the confidence to do the test.

> *"As mentioned by others, it will be better to have Tongan information so you can understand and have confidence that you are doing it correctly. I was fearful that if I do it wrong, my result will be bad. I do not want to have cancer and the wrong result."*

Bowel screening is a process, not a one-off event

Critical to the success of the programme is ensuring that people understand that bowel screening is a process and not a one-off event. As one expert explained, *"If the previous result was good, then when the second kit comes to them, they will start ignoring it, will have that kind of Pacific … attitude, oh well, I'm okay, I'm healthy so I'm not going to do that."*

During the talanoa, VP and AP shared a lot of information. At one point VP described the NBSP as like a *"warrant of fitness like the warrant we need for our vehicles."* The idea is that *"New vehicles require less frequent tests, but older ones like us need more frequent testing."* At the end of the talanoa, one participant commented, *"Thank you very much; this meeting helps me to understand the need to continue the screening, and I will actively participate from now onwards."*

The importance of the collective

The collective nature of Tongan society was frequently referred to by participants, including the role of women in family decision-making. As one man noted, *"This* [discussion] *has highlighted the important role women have in promoting health in the family because they can motivate the men to participate."*

Use of language and source of information

If a letter is sent, the information must be in Tongan and well explained. One person noted that *"Many people do not have a good understanding of basic English, let alone technical terms commonly used in health and medicine. It is essential to use language that people understand."* Another said, *"I am lucky I can understand English, but I know others never participate as they do not understand the communication."* As one person explained, *"It is most important to have the information leaflet in Tongan, listed in steps and using a lot of diagrams … But even in Tongan, it is not always easy to understand."*

In Tongan culture, it is essential to know who is sending the message to trust the source of the information. As one participant notes, *"When I received my pack, it did not come from Fono Henderson Clinic, and I imagined it must have come from the office of NBSP. When I looked at it, I was not motivated to touch it and did not feel I need to do anything with it."*

All the experts spoke of problems with the use of language and its meaning. As one expert explained, *"It is important for the information to be clear to our people; I know it's very clinical some of the words on the leaflet or flyer."* One participant summed up these concerns as follows:

> *"Receiving a pack from people I do not know, about a programme I have not heard about, and resources not written in Tongan, is a sure road to failure of the programme and low uptake from the Tongans. As a Tongan, it is important that for me to engage in the programme, I need to understand the value and benefits that I am investing in the programme."*

Ways to ensure the NBSP meets the needs of the Tongan community

When asked, participants and experts discussed a range of ways to ensure the NBSP meets the needs of the Tongan community. Participants were clear that the appropriate method to promote the NBSP was talanoa, healthy conversation where people are empowered to speak their minds and share their ideas. Experts advise having more talanoa time, maybe four times a year, so that relationships are built. Participants and experts emphasised using Pacific radio to promote the programme. This is particularly important because people over 60 are listeners, not readers. They are the generation who were born outside of Aotearoa.

Experts emphasised the importance of the church in the lives of Tongan New Zealanders to promote the programme. As one expert explained, *"The church is a place where people's lives are influenced … Church makes a difference in how people will listen* [where they] *are willing to make a change."*

Promoting the programme can be done effectively, as it was in the talanoa session for this research. As one participant stated,

> *"Pacific and Māori are commonly assumed and labelled as uninterested, and they do not value their health; therefore, they do not turn up to their appointment, DNA* [do not attend appointments]. *The attendance we had contradicts all that. There is something good and beautiful we are witnessing here* [referring to the talanoa focus group for this research]*."*

As one expert, The Fono Bowel Screening Coordinator, noted:

> *"I just have to remind them* [that] *doing the test is very important … And some of the people I think it's good because they know me, so they asked me if I can come and pick it up, so I can drop the test to the mailbox because they cannot drive."*

She also explained that home visiting is very valuable. She sometimes joined the community nurses on their home visits to promote the programme.

The experts agreed that it is possible to successfully run the NBSP for Tongans. People do understand the importance of prevention. However, the service must be run in a Tongan way. The experts were clear that a collective approach, working with key community leaders and the community as a whole, was critical. They also spoke of the need for relationship-building and frequent and long-term community engagement. They were clear that the idea of bowel screening needed to be socialised with the community to succeed. Further, the experts in this study clearly state that a holistic approach is required. The funding and services in the health sector are usually focussed on single health issues. What is required is a wrap-around service that addresses all their health needs.

Discussion

This research indicates that the NBSP can be better used by Tongan New Zealanders, especially if promoted by a Pacific provider, as occurred for the participants in this research. While the participants greatly appreciated the NBSP, they shared many valuable insights about how the programme could be strengthened to maximise its value to the Tongan community, as did the Pacific experts. Barriers to overcome include ensuring Tongans understand the importance of the programme to them, address any fatalism or fear associated with bowel cancer, have the confidence to do the test and recognise that screening needs to be repeated every 2 years.

In stressing the collective nature of Tongan society, participants emphasised the importance of delivering the programme to the community, not to individuals. In the Pacific culture, critical decisions lie with the community, not the individual. In Tongan society, women are recognised as the custodians of the family's health and wellbeing, and their decisions are respected by men and children. Tongans brought up in Aotearoa often play a crucial role as translators for older family members if services are not delivered in Tongan. Further, if the community understands the programme, they can support others to participate and focus on their health. These participants clearly expressed the Fonua concept of katoa or the collective.[7]

Currently, the programme has much emphasis on the invitation letter as the first point of communication. In the Tongan context, you speak to somebody. Participants were clear that for Tongans, a letter is not appropriate, especially when written in English, that they may not be able to read. Writing to people in a language they cannot understand is disrespectful and runs the risk that they will develop a negative view of the programme and not participate. Since this research was conducted, there is some information available in Tongan. People must also trust the source of the information they receive. Ideally, the message and the messenger are one and the same.

Experts and participants agreed that translation is more than just the translation of the words into Tongan. Bowel screening is a difficult medical concept with scientific terms that are complicated even in English. Translating them into a Pacific language is more than just getting a specific word; it is grasping the meaning of that word, whether written or spoken. It is important to consider how things are explained and avoid miscommunication. This is something more easily done face-to-face. Hence, the importance of talanoa and personal interactions. One concern is the concept of "testing". People may understand a test to be like a school or driving test where there is a pass/fail. Consideration could be given to renaming the "test". Perhaps the concept of "Tā e langa kei mama'o" would be better. It refers to preparation ahead of time. When stormy weather comes, you must prepare to remove the canoe from the water by putting out the log upon which to roll it. To survive, you must have the log ready ahead of time.

Promoting bowel screening is further complicated by the fact that Tongans regard the bowel as a taboo area that is not something to be spoken about in public.[4] It is a very private matter, only discussed among people of the same gender; hence, there are separate focus groups for women and men in this study. This finding supports that of Dunlop, who found that Tongan and Samoan New Zealanders *"were strongly opposed to mailing stool samples and had a preference for dropping samples at laboratories instead."*[4]

Experts agreed that the programme should be run by Tongans, for Tongans to empower the Tongan community to take control of their health[7] about bowel screening. This was supported by participants who consistently called for Tongan-based approaches in their feedback. The findings emphasise the need for a programme based on Tongan models of health and health promotion, on Tongan values and ways of working, using the Tongan language. This is best done collectively, face-to-face using talanoa, supported by Pacific radio and community networks. Careful attention is needed to use language to explain medical concepts in ways people understand. It is best delivered as part of wrap-around services, not just a programme on a single issue, in line with the Tongan holistic understanding of health.[7] Participants in the NBSP need support at all stages of the process.

Fortunately, there are Tongan providers available to undertake this work, although full coverage would require further resourcing. Pacific providers continue to demonstrate their critical role in working with their communities, particularly apparent during the COVID-19 pandemic.[17–19]

Tongan churches are an ideal setting for health promotion, as the experts in this research advised. In Aotearoa, the church is the village, the Pacific

marae. The church is a place where people feel safe. People place much trust in the church and church leaders, who can be very influential.[7,20]

Since colonisation, disease management has been primarily considered the realm of doctors and other health experts among Tongan people. This power dynamic has often made people passive healthcare recipients rather than active participants in their health. People can see screening as technical and clinical. Tongans often see the Western health system as there for treatment, not prevention. Therefore, if you do not have a problem, there is no need to look for, or accept, help. This colonisation of healthcare has distracted people from self-care to dependence on experts.

It is essential to bring back the concept of self-care to enable people to *"increase control over, and improve, their health,"*[21,7] to enable people to feel that it is all right to do self-care and that they can do it correctly, as the focus group participants in this study were able to do. COVID-19 has meant that people have undertaken self-care, e.g., using masks, staying home and testing. This has reinforced for people that self-care is an acceptable thing to do. This may have empowered people to do self-care in other areas of health.

Racism and systemic bias are key factors in the chronic inequities and poor health outcomes Pacific peoples endure in Aotearoa, as *"Ethnic inequities in health are unjust, unfair and patently avoidable."*[10] This research demonstrates the critical elements of an effective, culturally appropriate and empowering NBSP for Tongans. If these findings are enacted, it will likely ensure more effective delivery to Tongans and close the equity gap in participation between Tongans and other New Zealanders.

Effective health promotion for Tongan and other Pacific communities in Aotearoa requires Pacific leadership at national and local levels of the health system, concerted effort to build a Pacific health workforce, the grounding of programmes in Tongan models of health and health promotion and taking a strengths-based approach that builds on the enormous capacity of Pacific communities.[7]

Strengths and limitations

A key strength of this research is that it was undertaken with one Pacific community, Tongan, by leading Tongan health researchers known to the participants, using Tongan methodology, language and cultural practices. This research provides a model for high-quality research with Pacific communities, which is much needed given the scarcity of such research. As NBSP participants, the focus group members had first-hand experiences of the programme, allowing them to provide detailed insights into the programme and ways to improve it. They were also members of The Fono. It is possible that Tongans not connected to a Pacific provider, as well as those who have not participated before, may encounter further obstacles not identified by this group. While all participants were 60 plus, the views of these older Tongans may not be representative of younger generations, including those 50 plus who are now eligible for the programme and are more likely to have been New Zealand-born. Nevertheless, this research provides one of the first studies of Tongan New Zealanders' views about the NBSP. Doing so provides valuable insights from a leading Pacific community in Aotearoa and avoids conflating the views of the multiple Pacific ethnicities. However, given the common threads between Pacific communities in Aotearoa and internationally, it may provide valuable insights for others.

Implications

Many Tongans die unnecessarily from bowel cancer because the NBSP, while available, is not accessible to many Tongans. Taking a Tongan approach to the programme delivery is the solution recommended by the NBSP participants and experts in this study. Reimagining the delivery of the NBSP, starting with Tongan communities first, would create a programme much more suitable for the Tongan community. This research provides the critical elements of such a programme, as outlined above. We acknowledge that this may require resourcing. However, to develop an equitable service, this is a solution that is urgently needed. Further research is necessary to understand the views of younger Tongan NBSP participants, those who have yet to participate and the other Pacific communities of Aotearoa.

Conclusion

While the NBSP is currently available in Aotearoa, many Tongans are not aware of the service or why it is needed and cannot access it in a culturally appropriate manner. While the recently announced age reduction to 50 for Pacific peoples is an essential step in increasing accessibility, it does not take away the need to reimagine the programme from a Tongan, a

Pacific, perspective. The Tongan participants and Pacific experts in this study provide invaluable advice about how to improve the service so that it equitably meets the needs of the Tongan community, and likely that of other Pacific communities in Aotearoa and internationally. What is required is *"the courage and political will to make changes that enable power and resources to be distributed fairly and equitably for all."*[7]

COMPETING INTERESTS
None to declare.
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Sex-specific analysis of acute alcohol use in suicides and reporting of alcohol as a contributor to suicide deaths in New Zealand 2007–2020: a cross-sectional study of coronial data

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ABSTRACT

AIM: Acute alcohol use (AAU) can increase suicide risk. It is unknown if this effect differs by population sub-group in New Zealand, and what characteristics are associated with alcohol being coded as contributory to death, when AAU is identified. This study aimed to answer: 1) are the characteristics associated with suicide involving AAU different between females and males, and 2) among suicides that involved AAU, what factors are associated with alcohol being coded as a contributory factor?

METHOD: Secondary analysis was conducted of suicide data from 2007–2020, from the National Coronial Information System. Binomial regression models for females and males were used to estimate sex-specific differences in risk of suicide involving AAU. Poisson regression modelling was used to estimate the relative risk of alcohol being coded as contributory where AAU was identified.

RESULTS: Suicide was more likely to involve AAU among Māori females (adjusted risk ratio [ARR] 1.35, 95% confidence interval [CI] 1.08–1.68) and Pacific females (ARR 1.75, 95% CI 1.22–2.51), compared to European females. Compared to males who were employed, all other employment statuses had significantly lower risk of suicide that involved AAU. Those who died by hanging (ARR 0.75, 95% CI 0.62–0.92) or firearms (ARR 0.55, 95% CI 0.38–0.90) were less likely to have alcohol coded as contributory, compared to those who died by poisoning.

CONCLUSION: Targeted public health interventions designed by and for specific demographic groups (particularly Māori and Pacific females) are needed, alongside universal interventions that address social and structural determinants. Data systems and coding must accurately reflect the association between AAU and suicide in New Zealand.

Suicide is a significant public health issue in New Zealand, with 557 suspected suicide deaths recorded in 2022 (giving an age-standardised rate of 10.4 per 100,000 persons).[1] This health and social burden is experienced inequitably by different population groups; suicide rates are higher in males, those who are of Māori ethnicity, and young people (particularly the 20–24 age group).[1] People with alcohol use disorder (AUD) represent another high risk group for suicide, with New Zealand cohort data providing evidence for an association between AUD and suicidal ideation in adulthood.[2] Alcohol can contribute to suicide as both a distal and proximal risk factor. Acute alcohol use (AAU) is well established as a proximal risk factor for suicidal behaviour.[3–5] This is due to the direct effects of alcohol on feelings of despair, disinhibition and impaired decision making, and its contribution to other proximal risk factors such as interpersonal conflict.[6] AAU is also associated with the use of more lethal suicide means,[7] thereby increasing the risk of a suicide attempt resulting in death. Previous international studies have found that the prevalence of AAU in suicides ranges from 10–69%, though this is moderated by population demographics including sex, ethnicity, employment status, marital status and age.[4,7,8]

A recent New Zealand study found that just over one-quarter (26.6%) of suicides in those aged 15 or older involved AAU.[9] This proportion varied by demographic characteristics including ethnicity and age group, and those of Māori or Pacific ethnicity were of increased risk of suicide involving AAU.[9] Notably, however, there were no sex differences observed in New Zealand, with males and females having equivalent risk of suicide involving AAU.[9] This is in contrast to findings from Australia[8] and the United States of America (USA),[10] which found that male suicide decedents

were significantly more likely to have AAU present. There is a trend in countries similar to New Zealand (including Australia, Canada and the USA) towards increasing suicide rates in females, particularly in those aged 10–24 years,[11,12] who are Indigenous,[11,13] and where AAU is identified,[14] which highlights that sex differences may also be impacted by other demographics such as age and ethnicity. However, in New Zealand, it is currently unknown if the characteristics associated with AAU within suicide differ between males and females. This knowledge gap on sub-group specific trends hampers the ability to develop targeted public health suicide prevention interventions for specific age, sex or ethnicity sub-groups.[7]

The World Health Organization highlights that suicides are preventable[5] and targeting alcohol use at the population level (e.g., through restricting sales or availability) has been shown to be an effective suicide prevention strategy.[15] However, to evaluate prevention efforts, including those designed for specific sub-groups, it is vital that coronial processes and cause of death (mortality) coding consistently identify where alcohol has contributed to suicide deaths. In Australia, it was found that around half (47.6%) of suicides that involved AAU (as determined by individual review of coronial records) also had alcohol recorded as a contributory cause of death, and this was associated with factors including both blood alcohol concentration (BAC) and means of death.[16] Previous New Zealand findings showed that only around one-third (33.6%) of suicides involving AAU had alcohol coded as contributory;[9] however, it is unknown what factors are associated with this. This knowledge could be used to improve coding protocols and safeguard against any potential inconsistencies.

In this study, we seek to inform and support suicide prevention efforts in New Zealand by both enhancing knowledge of AAU within suicide, and providing data that may be used to improve reporting and coding processes. Specifically, this study aimed to answer the following questions: 1) are the characteristics associated with suicide involving AAU different between females and males, and 2) among suicides that involved AAU, what factors are associated with alcohol being coded as a contributory factor?

Method

This study is a secondary analysis of an existing dataset extracted from the National Coronial Information System (NCIS), which compiles cases from the Coronial Service of New Zealand, and Australian state and territory coroners' courts.[9] This project was approved by the University of Otago Human Research Ethics Committee (HD20/102), with a second level of review and approval by NCIS (NZ019).

Case identification and coding

The full methods for the creation of this dataset have been previously reported[9] and are summarised here. Eligible closed cases were extracted from the NCIS dataset for the full available time period, which was 2007–2020. This included all deaths with a coronial finding of "Intentional self-harm" in those aged 15 or over in New Zealand. Cases were included in the dataset if eligibility criteria were met that allowed for identification of whether alcohol was present at the time of death. It is important to note from the original study that 23.3% of cases were excluded because acute alcohol use could not be ascertained, primarily due to lack of toxicology data.[9] The following characteristics were extracted and subsequently coded for all eligible cases:

- Age: age in years at death, subsequently grouped into 10-year intervals. Given the heterogeneity of 15–24-year-olds (especially regarding the legal purchasing of alcohol—the age of purchasing alcohol in New Zealand is 18 years), this age group was further split into two 5-year age groups (15–19 years; 20–24 years). Although the 5-year age groups do not align perfectly with the legal alcohol purchasing age, this categorisation enabled comparison with other studies.
- Sex: female, male.
- Employment status: employed, unemployed, student, retired/pensioner, other (including categories of home duties, prisoner, still enquiring, child not at school), unknown.
- Marital status: never married, widowed, divorced/separated, married/de facto, unknown.
- Ethnicity: initial coding was consistent with the 2018 Census ethnic group summaries of European, Māori, Pacific peoples, Asian, Middle Eastern/Latin American/African (MELAA), and other ethnicity;[17] however, due to low numbers, Asian, MELAA and other were subsequently combined into a single group named "other ethnicity".

- Method of death (based on International Classification of Diseases ICD-10-AM code): poisoning, hanging, drowning, firearm, sharp object, falls, other.

Post-mortem BAC was manually extracted from toxicological and coronial reports, recorded in mg/100mL and then dichotomised as:

- No acute alcohol use: BAC ≤50 milligrams/100mL of blood
- Acute alcohol use: BAC >50 milligrams/100mL of blood

To investigate the extent to which a suicide involving AAU is coded as having alcohol as a contributory factor, where BAC was >50mg/100mL, this variable was further categorised into 51–100, 101–150, 151–200, 201–250 and >250mg/100mL. Proportions of cases within each of these categories were previously reported.[9]

Whether alcohol was identified in NCIS records as a contributory cause of death was determined by use of ICD-10-AM codes (F10.0, F10.1–10.9, R78.0, T51, X45 or X65) and searching for the word "alcohol" at all levels of the cause of death fields. If any one of these codes was identified, we deemed alcohol had been identified as a contributory cause of death. This was then dichotomised as:

- Alcohol not coded as a contributory cause of death
- Alcohol coded as a contributory cause of death.

Sample population

The total number of eligible cases was 6,072, of which 4,658 (76.7%) met inclusion criteria. A total of 1,238 of included cases (26.6%) involved AAU. The characteristics of this sample have been previously reported,[9] and the proportions of cases that involved AAU, and where alcohol was coded as contributory, are shown in Table 1.

Statistical analysis

Statistical analysis was conducted in Stata (StataCorp, Stata Statistical Software: version 16.1 for Windows). To investigate sex-specific differences in risk, binomial regression models for females and males were used to assess the relative risk that different demographic groups had for their suicide to have involved AAU. Univariate models were firstly conducted to examine the effects of individual explanatory variables (unadjusted results). Next, we used a multivariable model adjusting for ethnicity, age group, employment status and marital status. To investigate the extent to which a suicide involving AAU was coded as having alcohol as a contributory factor, Poisson regression was used to assess the relative risk of alcohol being coded as contributory in suicides where AAU was identified. The multivariate model was adjusted for sex, ethnicity, age group, employment status, marital status, method of death and BAC category.

Results

There were 1,211 females in the 4,658 included cases (representing 26.0% of the total). Of these 1,211 females, just over one-quarter (n=323, 26.6%) had AAU identified. Of characteristics that predicted the risk of suicide involving AAU, ethnicity was the most significant variable for females (Table 2). Compared with European females, Māori females had a 35% greater risk of their suicide involving AAU, after adjusting for age group, marital status and employment status (adjusted risk ratio [ARR] 1.35, 95% confidence interval [CI] 1.08–1.68). Pacific females also had a 75% increased risk (ARR 1.75, 95% CI 1.22–2.51) compared with European females. Females

Table 1: Proportions of sample for acute alcohol use (AAU) and coding of alcohol as a contributory cause of death.

Alcohol coded as contributory	AAU identified (i.e., BAC >50mg/100mL)	
	No	Yes
No	3,266 (95.5%)	822 (66.4%)
Yes	154 (4.5%)	416 (33.6%)
Total	3,420	1,238

Table 2: Results of binomial regression modelling for risk of suicide death involving acute alcohol use for females, by case characteristics.

Characteristic		RR	95% CI	P-value	ARR	95% CI	P-value
Ethnicity	European	REF					
	Māori	1.50	1.24–1.83	<0.000	1.35	1.08–1.68	0.008
	Pacific peoples	1.85	1.29–2.65	0.001	1.75	1.22–2.51	0.002
	Other	0.45	0.25–0.82	0.009	0.47	0.26–0.86	0.015
Age group	25–34	REF					
	15–19	0.76	0.55–1.04	0.085	0.85	0.59–1.21	0.359
	20–24	1.01	0.75–1.36	0.971	0.95	0.70–1.27	0.722
	35–44	0.82	0.61–1.10	0.180	0.87	0.64–1.17	0.347
	45–54	0.81	0.61–1.07	0.144	0.87	0.65–1.18	0.374
	55–64	0.56	0.38–0.82	0.003	0.63	0.43–0.94	0.024
	65–74	0.35	0.17–0.71	0.004	0.55	0.22–1.36	0.194
	75+	0.25	0.12–0.59	0.002	0.39	0.12–1.28	0.120
Employment	Employed	REF					
	Unemployed	1.12	0.90–1.39	0.320	1.01	0.81–1.25	0.954
	Student	0.69	0.49–0.99	0.042	0.58	0.38–0.87	0.009
	Retired/pensioner	0.35	0.21–0.59	<0.000	0.61	0.28–1.32	0.205
	Other	0.94	0.67–1.30	0.696	0.93	0.67–1.29	0.666
	Unknown	1.03	0.68–1.57	0.879	0.95	0.63–1.44	0.824
Marital status	Never married	REF					
	Widowed	0.64	0.38–1.06	0.082	1.27	0.74–2.18	0.383
	Divorced/separated	0.75	0.54–1.03	0.079	0.83	0.59–1.17	0.299
	Married/de facto	0.84	0.68–1.04	0.115	0.89	0.71–1.11	0.297
	Unknown	1.28	0.88–1.88	0.195	1.40	0.96–2.04	0.082

Adjusted results are adjusted for age group, ethnicity, marital status and employment status. Values are rounded to 2.d.p (except for p-value, which is rounded to 3.d.p).
Adjusted risk ratio = ARR; confidence interval = CI; risk ratio = RR; reference category = REF.

Table 3: Results of binomial regression modelling for risk of suicide death involving acute alcohol use for males, by case characteristics.

Characteristic		RR	95% CI	P-value	ARR	95% CI	P-value
Ethnicity	European	REF					
	Māori	1.19	1.04–1.35	0.011	1.11	0.96–1.27	0.146
	Pacific peoples	1.27	1.01–1.60	0.043	1.21	0.95–1.52	0.117
	Other	0.62	0.45–0.85	0.003	0.62	0.45–0.85	0.003
Age group	25–34	REF					
	15–19	0.68	0.54–0.87	0.002	0.71	0.54–0.93	0.014
	20–24	1.09	0.91–1.30	0.347	1.08	0.90–1.28	0.413
	35–44	1.04	0.88–1.23	0.623	1.05	0.89–1.24	0.567
	45–54	0.86	0.73–1.03	0.094	0.86	0.72–1.03	0.106
	55–64	0.73	0.59–0.90	0.004	0.74	0.59–0.92	0.007
	65–74	0.46	0.32–0.68	<0.000	0.59	0.37–0.95	0.029
	75+	0.26	0.15–0.43	<0.000	0.31	0.16–0.60	<0.000
Employment	Employed	REF					
	Unemployed	0.77	0.67–0.88	<0.000	0.74	0.65–0.85	<0.000
	Student	0.64	0.49–0.84	0.001	0.76	0.56–1.03	0.072
	Retired/pensioner	0.36	0.27–0.48	<0.000	0.61	0.41–0.92	0.020
	Other	0.40	0.25–0.66	<0.000	0.40	0.24–0.65	<0.000
	Unknown	0.91	0.70–1.19	0.510	0.88	0.67–1.16	0.370
Marital status	Never married	REF					
	Widowed	0.79	0.53–1.19	0.265	1.72	1.16–2.55	0.007
	Divorced/separated	1.08	0.92–1.27	0.325	1.07	0.90–1.27	0.455
	Married/de facto	0.92	0.81–1.04	0.185	0.94	0.81–1.08	0.377
	Unknown	0.98	0.76–1.27	0.876	1.05	0.81–1.36	0.694

Adjusted results are adjusted for age group, ethnicity, marital status and employment status. Values are rounded to 2.d.p (except for p-value, which is rounded to 3.d.p).
Adjusted risk ratio = ARR; confidence interval = CI; risk ratio = RR; reference category = REF.

Table 4: Proportion coded with alcohol as a contributory cause of death by BAC.

BAC category (mg/100mL)	Alcohol not coded as contributory	Alcohol coded as contributory
51–100	234 (81.0%)	55 (19.0%)
101–150	277 (76.3%)	86 (23.7%)
151–200	209 (64.9%)	113 (35.1%)
201–250	68 (38.9%)	107 (61.1%)
>250	34 (38.2%)	55 (61.8%)
Total	822 (66.4%)	416 (33.6%)

of other ethnicities had less than half the risk of their suicide involving AAU (ARR 0.47, 95% CI 0.26–0.86). Being a student was also associated with a decreased risk compared to those females who were employed (ARR 0.58, 95% CI 0.38–0.87).

There were 3,447 males in the 4,658 included cases (representing 74.0% of the total). Of these 3,447 males, just over one-quarter (n=915, 26.5%) had AAU identified. When considering characteristics that predicted the risk of suicide involving AAU, employment status was the most significant variable for males (Table 3). Compared to males who were employed, all other employment statuses (unemployed, student, retired and other) had a significantly reduced risk of suicide involving AAU. Being widowed was associated with increased risk (ARR 1.72, 95% CI 1.16–2.55) compared to males who were never married. Regarding ethnicity, while males of other ethnicities had a reduced risk of suicide involving AAU compared to European males (ARR 0.62, 95% CI 0.45–0.85), there was no significant elevation in risk for Māori or Pacific males. Regarding age group, males aged 15–19, and those aged 55 and over, had reduced risk compared to the 25–34-year-old age group.

Of the 1,238 cases that involved AAU, the proportion that then had alcohol coded as a contributory cause of death increased with increasing BAC (Table 4).

When considering the characteristics that were associated with whether a suicide involving AAU was coded with alcohol as being contributory, the two most significant variables were BAC category and method of death (Table 5). Cases with BAC over 200mg/100mL were three times more likely to have alcohol coded as contributory, compared to cases with BAC 51–100mg/100mL. Those who had died by hanging (ARR 0.75, 95% CI 0.62–0.92) or firearms (ARR 0.55, 95% CI 0.38–0.90) were less likely to have alcohol coded as contributory compared to those who died by poisoning.

Discussion

We conducted sex-specific analyses to identify characteristics associated with suicide involving AAU separately for females and males. Additionally, we quantified which characteristics were associated with alcohol being coded as contributing to death. In relation to the sex-specific analyses, we found distinct differences between females and males. For females, ethnicity was the most significant characteristic, with increased risk of suicide involving AAU observed for females of Māori and Pacific ethnicity as compared with European ethnicity. No relationship between ethnicity and suicide risk involving AAU was observed in males. Previous New Zealand findings had suggested that Māori and Pacific peoples had an increased risk of suicide involving AAU;[9] the findings of this study suggest that these ethnic inequities may be due to increased risk in females only.

Population-level data on hazardous drinking in New Zealand also confirm a sex and ethnicity disparity. While males have an increased prevalence of hazardous drinking compared to females overall, the prevalence for non-Māori men is comparable to that of Māori women.[18] An established body of literature highlights the harms associated with coping motivations for alcohol consumption, including increased hazardous drinking.[19–21] Being of Māori ethnicity is not a risk factor per se. Rather it reflects cumulative risk (both historic and current), including racism, socio-economic disadvantage, trauma, discrimination and cultural disconnection, which may impact Māori women.[22–24]

Table 5: Results of regression modelling showing the risk (likelihood) of BAC+ suicides having an alcohol code assigned as a contributory or underlying cause of death.

Characteristic		RR	95% CI	P-value	ARR	95% CI	P-value
Sex	Male	REF					
	Female	1.30	1.11–1.53	0.002	1.11	0.94–1.32	0.218
Ethnicity	European	REF					
	Māori	0.81	0.67–0.98	0.034	0.93	0.76–1.13	0.459
	Pacific peoples	0.61	0.39–0.95	0.030	0.73	0.47–1.15	0.173
	Other	0.57	0.32–1.03	0.061	0.70	0.39–1.25	0.233
Age group	25–34	REF					
	15–19	0.85	0.60–1.20	0.347	1.03	0.73–1.47	0.852
	20–24	0.88	0.67–1.17	0.384	0.96	0.73–1.25	0.752
	35–44	1.12	0.89–1.42	0.343	1.16	0.92–1.47	0.216
	45–54	1.10	0.86–1.39	0.458	1.09	0.86–1.39	0.461
	55–64	1.04	0.77–1.40	0.816	1.07	0.78–1.46	0.692
	65–74	1.14	0.70–1.84	0.597	1.10	0.60–2.02	0.762
	75+	1.12	0.61–2.06	0.722	1.35	0.55–3.29	0.516
Employment	Employed	REF					
	Unemployed	1.14	0.95–1.37	0.152	1.08	0.91–1.30	0.371
	Student	0.83	0.56–1.23	0.351	1.03	0.69–1.52	0.888
	Retired/pensioner	1.29	0.93–1.81	0.129	1.46	0.87–2.47	0.154
	Other	1.58	1.16–2.14	0.003	1.30	0.94–1.79	0.113
	Unknown	0.91	0.60–1.38	0.651	0.94	0.63–1.40	0.768
Marital status	Never married	REF					
	Widowed	0.96	0.59–1.57	0.876	0.58	0.32–1.03	0.064
	Divorced/separated	0.91	0.71–1.15	0.422	0.81	0.64–1.04	0.096
	Married/de facto	0.85	0.71–1.02	0.089	0.81	0.67–0.98	0.031
	Unknown	1.09	0.79–1.50	0.618	0.98	0.72–1.34	0.917
Method of death	Poisoning	REF					
	Hanging	0.72	0.60–0.86	<0.000	0.75	0.62–0.92	0.005
	Drowning	1.23	0.75–2.03	0.414	0.98	0.61–1.58	0.938

Table 5 (continued): Results of regression modelling showing the risk (likelihood) of BAC+ suicides having an alcohol code assigned as a contributory or underlying cause of death.

Method of death (continued)	Firearm	0.56	0.38–0.84	0.005	0.55	0.38–0.80	0.002
	Sharp object	0.89	0.44–1.80	0.740	0.93	0.51–1.69	0.802
	Falls	1.09	0.66–1.80	0.726	0.82	0.48–1.38	0.454
	Other	1.07	0.70–1.64	0.752	1.05	0.68–1.62	0.816
BAC category	51–100	REF					
	101–150	1.24	0.92–1.68	0.154	1.32	0.98–1.77	0.070
	151–200	1.84	1.39–2.44	<0.000	1.90	1.44–2.50	<0.000
	201–250	3.21	2.46–4.19	<0.000	3.32	2.55–4.34	<0.000
	>250	3.23	2.43–4.33	<0.000	2.99	2.22–4.01	<0.000

Adjusted results adjusted for sex, ethnicity, age group, employment, marital status, cause of death and BAC category. Values are rounded to 2.d.p (except for p-value, which is rounded to 3.d.p).
Adjusted risk ratio = ARR; confidence interval = CI; risk ratio = RR; reference category = REF.

We hypothesise that females of Māori and Pacific ethnicity may be disproportionately impacted by these risk factors. In turn, this may then influence alcohol motivations, alcohol consumption and suicidal behaviour. This hypothesis suggests the need for research to elucidate this association in greater detail, and for studies to evaluate whether population-level universal alcohol interventions are effective for all population groups.

For males, employment status was a significant variable in the association between AAU and suicide. Males in employment had a higher risk of suicide involving AAU when compared to males in all other employment categories, including unemployment, being retired and being a student. While employment has historically been conceptualised as a protective factor against suicide, there is increasing recognition that the association may be more complex.[25] There are numerous ways in which employment can contribute to increased risks of suicide via a number of different potential mechanisms, including exposure to adverse psychosocial conditions at work[26] and access to potential suicide means (e.g., firearms, certain medicines).[27,28] Many of these factors have been more strongly associated with suicide deaths in employed males as compared with females,[26] although not consistently so. While this association would benefit from future research to identify potential causal pathways, it nevertheless highlights the value of workplace suicide prevention programmes for males,[29] which should include elements specifically targeted towards the harmful use of alcohol.

Consistent with Australian findings, we found that increased BAC was associated with an increased likelihood of alcohol being coded as contributory to death.[16] We note, however, that there was still a significant proportion of cases with a very high BAC identified in toxicology that did not have alcohol coded as being contributory. While we acknowledge the complexity that mortality coders must address when assigning codes, this finding does have important implications. Our study demonstrates that ICD-10 code results cannot be used to accurately report the contribution of alcohol to suicide in New Zealand. Accurate ascertainment of alcohol involvement in suicide deaths in New Zealand at the present time therefore must rely on case-by-case extraction of toxicology data, which is not feasible for routine reporting nor for ongoing evaluation of the impact of alcohol policy on suicide rates. Coronial data is an important source of knowledge to inform health policy; therefore, both suicide prevention and alcohol-related policy in New Zealand would benefit from a consistent protocol for reporting and coding the presence of AAU within suicides. Even after controlling for BAC, we found that cases where the method of death was hanging or firearms were less likely to have alcohol coded as contributory when AAU was

identified. This exclusion may occur because the cause of death is considered to be more obvious in these cases, or because it is more difficult to assess what, if any, role AAU may have played. However, given that AAU is associated with more lethal means of suicide,[7,30,31] including both hanging and firearms, it is important that the presence of AAU is recorded in these cases.

The limitations of this study reflect those of the source dataset, particularly that not all relevant variables are consistently available within the NCIS data, e.g., socio-economic status, co-morbid mental disorders, or acute stressors prior to death.[9] It is also important to note that almost a quarter of cases had to be excluded from the source dataset as the presence or absence of AAU could not be ascertained, and these data, had they been available, could have potentially impacted the findings. Additionally, there are relatively small numbers in some population sub-groups (e.g., females of Pacific ethnicity), resulting in wide confidence intervals, which should be interpreted cautiously for these populations. The findings for these population sub-groups warrant additional research to be able to reach stronger conclusions. However, a strength of this study is that it utilises a novel dataset for New Zealand, based on extracted toxicological data, which enables a more accurate understanding of the association between AAU and suicide.

Alcohol use is a modifiable risk factor for suicide and interventions targeted at alcohol should be a cornerstone of New Zealand's suicide prevention strategy.[5,15] While international population-level alcohol interventions have shown efficacy in reducing suicide, the effectiveness of these may be moderated by age, sex and ethnicity.[15] Our study highlights the need for both interventions at a population-level that address determinants of alcohol use, and to also consider public health interventions that are designed by and for specific demographic groups (in particular for Māori and Pacific females), informed by Kaupapa Māori and Indigenous theory. It is also important for research to identify causal pathways and social/structural determinants for alcohol use and suicide that may differ between females and males, and this should include Kaupapa Māori-led research. To support research, monitoring and evaluation, it is vitally important that data systems and coding accurately reflect the association between AAU and suicide in New Zealand.

COMPETING INTERESTS
Nil.

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Implementation of the Medicinal Cannabis Scheme in New Zealand: six emerging trends

Marta Rychert, Chris Wilkins

ABSTRACT

AIM: To evaluate the implementation of the New Zealand Medicinal Cannabis Scheme (MCS), including how products, prices, prescribing and patient access have evolved since 2020.

METHOD: Analysis of administrative data obtained via Official Information Act (OIA) requests and publicly available information on products and prices.

RESULTS: Six emerging trends were identified: 1) quarterly supply of medicinal cannabis products has increased fourteenfold since the implementation of the Scheme in early 2020, 2) most products are now THC-dominant rather than CBD, 3) most products are in the form of dried cannabis flower rather than oral liquids/oils, 4) prices of products have declined to be comparable to the illegal market, 5) specialised private cannabis clinics have expanded patient access, and 6) inequities persist due to expense, and disproportionately affect Māori and those on lower incomes.

CONCLUSIONS: The New Zealand MCS successfully established a domestic medicinal cannabis production sector, reduced prices and expanded the range of products to provide alternatives to illegal supply. It has also inadvertently created the conditions for the emergence of specialised cannabis clinics that have enhanced access. However, the increasing supply of THC-dominant and flower products, and the privatisation of prescribing via cannabis clinics, may have unintended negative consequences.

Since the establishment of the first medicinal cannabis schemes in California and Israel in the 1990s, a growing number of countries have legalised access to cannabis-based products for medicinal use.[1,2] Aotearoa New Zealand is one of the latest countries to implement a regulatory framework for prescribed cannabis, known as the Medicinal Cannabis Scheme (MCS), and develop a local production sector to improve patients' access. The reform was driven by high profile cases of cancer and palliative care patients, and media reports about children and teenagers without access to cannabidiol therapy.[3]

When the New Zealand Parliament debated the *Misuse of Drugs (Medicinal Cannabis) Amendment Act* in 2018, the then Minister of Health described it as "*a bill about cultivation, cannabidiol and compassion.*"[4] Six years later, patient access to cannabis-based products for therapeutic uses has undoubtedly improved: there are now over 40 cannabis oral liquid and flower products authorised for sale under the MCS that can be prescribed by any registered doctor.[5] Although many doctors remain concerned about prescribing cannabis due to limited scientific evidence of its efficacy,[6] private cannabis clinics have filled this gap, facilitating patients' access to prescribed products.

There is no shortage of anecdotal evidence for medicinal cannabis, but the scientific evidence for specific conditions remains scarce. Clinical trials confirm that cannabis improves chemotherapy-induced nausea and vomiting, may reduce symptoms of multiple sclerosis, and that cannabidiol (CBD) is useful in reducing seizures in two childhood epilepsy syndromes (Dravet and Lennox–Gastaut syndrome).[7–9] The efficacy of cannabinoids in the treatment of chronic non-cancer pain remains debated, with conflicting findings in reviews of clinical trials and methodological limitations noted.[10,11] For many other conditions for which patients seek cannabis, from social anxiety and PTSD to sleeping problems and gastrological conditions, the clinical trial evidence remains limited. Lower-quality observational studies demonstrated improvements in patient-reported quality of life and symptoms.[12]

With New Zealand's MCS now operational for over 4 years (regulations finalised in April 2020), it is timely to evaluate its achievements to date and discuss developing trends. We analyse the evolution of the legal medicinal cannabis market

in New Zealand, including how products, prices, prescribing and patient access have evolved. Findings will inform discussion of equity of access under the New Zealand MCS and provide learnings for other countries developing similar frameworks.

Methods

Our analysis draws on administrative data obtained through multiple Official Information Act (OIA) requests, information obtained via New Zealand cannabis clinics and pharmacy price lists, and a review of studies of medicinal cannabis use in New Zealand. We made multiple OIA requests from September 2020 to May 2024 to various health agencies (Medicinal Cannabis Agency, Medsafe, Te Whatu Ora – Health New Zealand and the Ministry of Health – Manatū Hauora [MOH]) for information on several aspects of the MCS, including the number of medicinal cannabis license holders, the total licensed cultivation area and the estimated medicinal cannabis production output, prescriptions (number of prescriptions and demographics of recipients) and the volume of supplied medicinal cannabis products. We reviewed the MOH website where OIA responses with information considered of public interest are posted, searching for those relevant to the MCS implementation.[13] We also searched the MOH website for information on products available under the MCS.[5] Finally, we requested the cannabis products price lists from two pharmacies (located in Auckland and Taranaki) and an online cannabis clinic, and consulted an online price list managed by a patients' advocacy group,[14] to estimate average medicinal cannabis product prices as of mid-2024.

Data on products (current as of 19 September 2024), prescriptions and demographics of patients who received prescriptions in the past 12 months (from 1 May 2023 to 30 April 2024) is reported descriptively. As past 12-month prescribing data was a bespoke dataset provided in response to our OIA, it has not undergone full data quality assurance by Te Whatu Ora – Health New Zealand. The past 12-month prescribing data and information on products under the MCS was categorised as follows: THC-dominant, CBD-dominant and balanced THC/CBD products. Age of patients who received prescriptions was categorised into 10-year age brackets. Prescription data where age, gender or ethnicity was unknown were removed as appropriate for relevant calculations. Note that one prescription may contain more than one medicinal cannabis product. Data on supply of medicinal cannabis products (from 2020 to 2023) were initially collated from multiple OIA requests,[15–17] and subsequently updated in September 2024 following MOH release of an amended dataset on its website.[18] Data on the supply of medicinal cannabis products were collated into quarters to illustrate developments with the MCS over time.

Results

We identify six developing trends that are shaping the current regime and are key to discussions about its future direction.

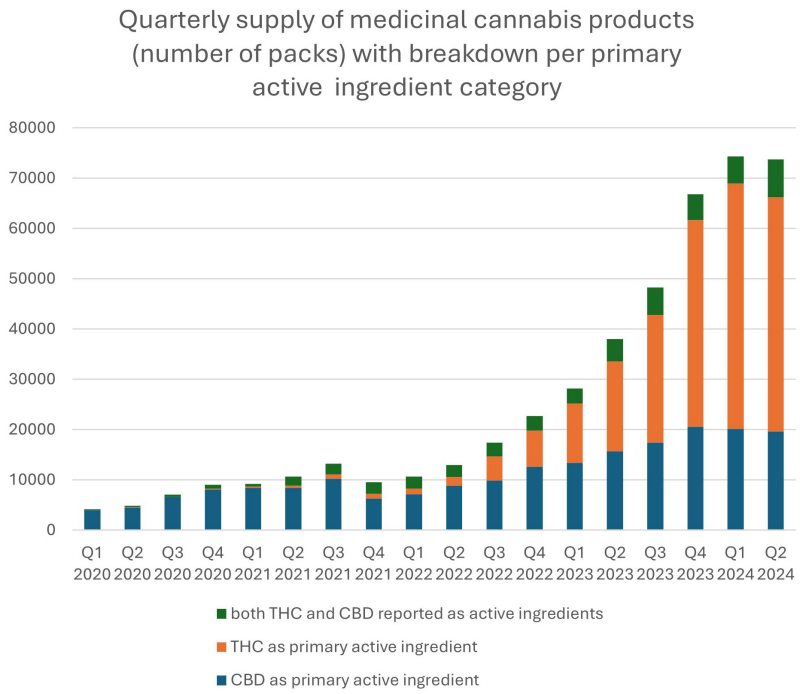
Quarterly supply of medicinal cannabis products increased fourteenfold since early 2020, and the supply of products containing THC overtook CBD-only products in early 2023

Medicinal cannabis products can be prescribed for any condition or symptom by any doctor registered to practice in New Zealand. While there is currently no publicly available database on cannabis prescribing, importers and manufacturers regularly notify and report to Medsafe (the national medicines regulatory authority) on the number of packs sold or supplied under the MCS (a requirement for all "unapproved medicines" under s29 of the *Medicines Act*).

The data collated from importers and manufacturers' reports indicate that the number of medicinal cannabis product packs supplied under the MCS has increased 14 times since Q2 of 2020 when the Scheme became operational, from 4,827 packs supplied in the second quarter of 2020 (mostly CBD-only products) to 73,725 packs supplied in the second quarter of 2024 (mostly THC-dominant products) (Figure 1). In early 2023, the supply of medicinal cannabis products containing THC surpassed the supply of products containing CBD as the main active ingredient for the first time.

The reports do not include data on the form of supplied products (e.g., oral liquid vs cannabis herb). Given that most THC-containing products are currently flower formulations (Table 1), the trend to sell and supply more THC-containing products may be driven by an increased supply of cannabis flower.

Figure 1: Quarterly supply of medicinal cannabis products (number of packs) per active ingredient category.



Source: collated from data submitted to Medsafe and published by MOH.[18]

Table 1: Products meeting Minimum Quality Standard under the Medicinal Cannabis Scheme per formulation and dominant active ingredient (as of 19 September 2024) (excludes two products consented for distribution as medicines: Sativex and Epidyolex).

	CBD-only	**CBD-dominant**	**Balanced CBD:THC**	**THC-dominant**	**THC-only**
Oral liquids and sublingual solutions (pack sizes from 25 to 50mL)	**Seven products**	**Six products**	**Three products**	**Three products**	**One product**
	Available concentrations:	Available concentrations:	Available concentrations:	Available concentrations:	Available concentrations:
	CBD 25mg/mL	CBD 120mg/mL + THC <0.6mg/mL	CBD 10mg/mL + THC 10mg/mL	CBD <1mg/mL + THC 10mg/mL	THC 25mg/mL
	CBD 100mg/mL	CBD 30mg/mL + THC <0.6mg/mL	CBD 15mg/mL + THC 10mg/m	CBD <2mg/mL + THC 25mg/mL	
		CBD 20mg/mL + THC <1mg/mL		CBD <1mg/mL + THC 30mg/mL	
		CBD 20mg/mL + THC 5mg/mL			
		CBD 50mg/mL + THC <2mg/mL			

Table 1 (continued): Products meeting Minimum Quality Standard under the Medicinal Cannabis Scheme per formulation and dominant active ingredient (as of 19 September 2024) (excludes two products consented for distribution as medicines: Sativex and Epidyolex).

Dried flower for inhalation via a vaporiser (pack sizes from 10 to 15 gram)			**One product**	**12 products**	
			Available potencies:	Available potencies:	
			9% THC + 8.3% CBD	26% THC + <1% CBD	
				25.5% THC + <1% CBD	
				25% THC + <1% CBD	
				22.5% THC + <1% CBD	
				22% THC + <1% CBD	
				21.3% THC + <1% CBD	
				22% THC + <1% CBD	
				20% THC + <1% CBD	
				19% THC + <1% CBD	
				18% THC + <1% CBD	
Dried flower for preparation of tea (pack sizes from 10 to 35 gram)		**One product**		**13 products**	
		Available potency:		Available potencies:	
		12.5% CBD + <1% THC		25% THC + <1% CBD	
				24% THC + <1% CBD	
				23% THC + <1% CBD	
				22% THC + <1% CBD	
				21% THC + <1% CBD	

Table 1 (continued): Products meeting Minimum Quality Standard under the Medicinal Cannabis Scheme per formulation and dominant active ingredient (as of 19 September 2024) (excludes two products consented for distribution as medicines: Sativex and Epidyolex).

				13 products	
				Available potencies:	
				20% THC + <1% CBD	
				17% THC + <2% CBD	
				16% THC + <1% CBD	
				15.25% THC + <0.5% CBD	
				13.5% THC + <1% CBD	

Data source: MOH.[5]

Most products under the Scheme are now THC-dominant

Unlike standard medicines and prescribed pharmaceuticals, medicinal cannabis products under the MCS do not need to undergo clinical trials to prove their efficacy and evaluate side effects prior to market authorisation. Instead, the Medicinal Cannabis Agency verifies product compliance with the Minimum Quality Standards (MQS) to ensure product quality (e.g., contaminant-free), stability and consistency. Both cannabidiol (CBD) and tetrahydrocannabinol (Delta-9 THC) products are allowed under the Scheme.

The first products to be verified under the MCS in March 2021 were two CBD-dominant oral liquid solutions from Canadian-based Tilray. Since then, the number of products "approved" under the MCS has increased to 47 (as of 19 September 2024). (Additionally, two products [Sativex and Epidyolex] are exempt from the requirement to assess compliance with Minimum Quality Standards, because they are consented for distribution under the *Medicines Act* [i.e., they meet recognised standards for quality, safety and efficacy for medicines]). The early producer focus on cannabidiol (CBD) and balanced THC:CBD product formulations has increasingly shifted to THC products. Most products are now THC-dominant (i.e., 62% of the 47 verified products contain more THC than CBD). One oral liquid contains THC as the sole active ingredient. The market shift towards THC-dominant products is driven by the dry flower product category. Some dry flower products are as potent as 25–26% THC per weight. Nine out of 13 dry flower products for use in a vaporiser are high potency (i.e., ≥20 THC). These products are similar to cannabis sold in legal recreational cannabis markets in jurisdictions in the United States of America (USA) and Canada. They appear to be more potent than the average cannabis flower available in the New Zealand illegal market. For example, a recent analysis of 12 police-seized cannabis samples reported THC potencies between 1% to 13.4%.[19]

The increased availability of THC products is reflected in recent prescribing patterns. In the past year, approximately 45% of prescriptions were for THC-dominant and THC-only products (Table 2). THC-dominant products are now more prescribed than balanced or CBD-dominant products.

Most medicinal cannabis products are now dried flower rather than oral liquid formulations

Patient access to dried cannabis flower has been one of the key controversies in legal

Table 2: Number of prescriptions for medicinal cannabis products in the past year (1 May 2023–30 April 2024) per active ingredient and dosage form.

	CBD-dominant and CBD only	Balanced THC:CBD	THC dominant and THC only
Flower for vaporising	0	0	29,318
Flower (tea)	1,741	0	35,757
Oral oil/liquid/spray	68,055	20,062	10,046
Total	69,796	20,062	75,121

Source: collated from data obtained through Official Information Act request.[20]

medicinal cannabis schemes around the world. While smoking is an efficient way to deliver the active ingredients in cannabis, regular smoking is associated with increased respiratory symptoms (e.g., cough, wheeze) and risk of chronic bronchitis (the association between regular smoking cannabis and lung cancer is unproven).[9,21] Smoking is the dominant route of administration for many consumers who self-medicate with cannabis, including in New Zealand.[22] The inclusion of dry herb products in the legal MCS is seen as a way to facilitate the transitioning of existing consumers to the prescribed quality-controlled channel.[23]

The MCS adopted a compromise approach by allowing prescribing of flower products as long as they are not "in a form intended for smoking." Consequently, flower products "approved" under MCS include tea preparations (14 products) and flower for inhalation via a vaporiser (13 products) (Table 1). Compared to smoking, vaporising cannabis can reduce exposure to several toxins, but the exact extent of this reduced harm and long-term effects of cannabis vaping remain unknown.[24]

Most products under the MCS (i.e., 27 out of 47) are now in a flower form, a shift from the early market focus on oral liquid formulations. The increased amount of flower product on offer is reflected in recent prescribing trends (Table 2). Although cannabis oil and liquid formulation are still dominant, 40% of prescriptions in the past 12-months were for a flower product.

Prices for some medicinal cannabis products are now equivalent with the illegal market

The high prices of imported cannabis products were one of the key reasons for the establishment of the local cannabis production sector under the MCS. As of May 2024, there were 48 medicinal cannabis license holders, including 36 licenses for cultivation activity (up from only three licenses to cultivate in August 2020).[25,26] A total of 53 hectares of land was reportedly used for licensed cannabis cultivation in New Zealand in 2023, up from 1.3 hectares of cannabis cultivation in 2020. Furthermore, the annual production of cannabis cultivated in 2023 was estimated at 71.3 tonnes, up from an estimated 8.3–14.9 tonnes in 2020.[25,26] However, not all the domestically grown cannabis is destined for sale in New Zealand; several companies report that they export cannabis overseas. Similarly, several New Zealand licensed distributors source cannabis and cannabis-based ingredients from overseas. More information is needed to fully understand the market dynamics and profit margins along the supply chain, but the development of a new cannabis production and distribution sector appear to have contributed to a decrease in the prices of both imported and locally manufactured products.

Prior to the MCS, medicinal cannabis users who accessed prescribed cannabis reported an average monthly spend of NZ$656.[22] For example, in 2019, the price of imported CBD oil from Tilray ranged from NZ$150–350 per 25mL bottle, depending on the CBD concentration, and excluding pharmacy-dependent markups.[27] We reviewed prices at three popular medicinal cannabis retailers around the country (two pharmacies and a cannabis clinic dispensary), as well as price lists collated by patients.[14] We found that the above Tilray products can now be purchased at somewhat lower prices (e.g., approximately NZ$300 for the most concentrated CBD Tilray 25mL bottle) (an approximately 15% price drop). Importantly, comparable oral liquid formulations marketed by new licensed

producers and distributors can be purchased at half the price or less. For example, one comparable CBD product "approved" under the MCS marketed by a local company is priced at NZ$100–120 (30mL bottle).

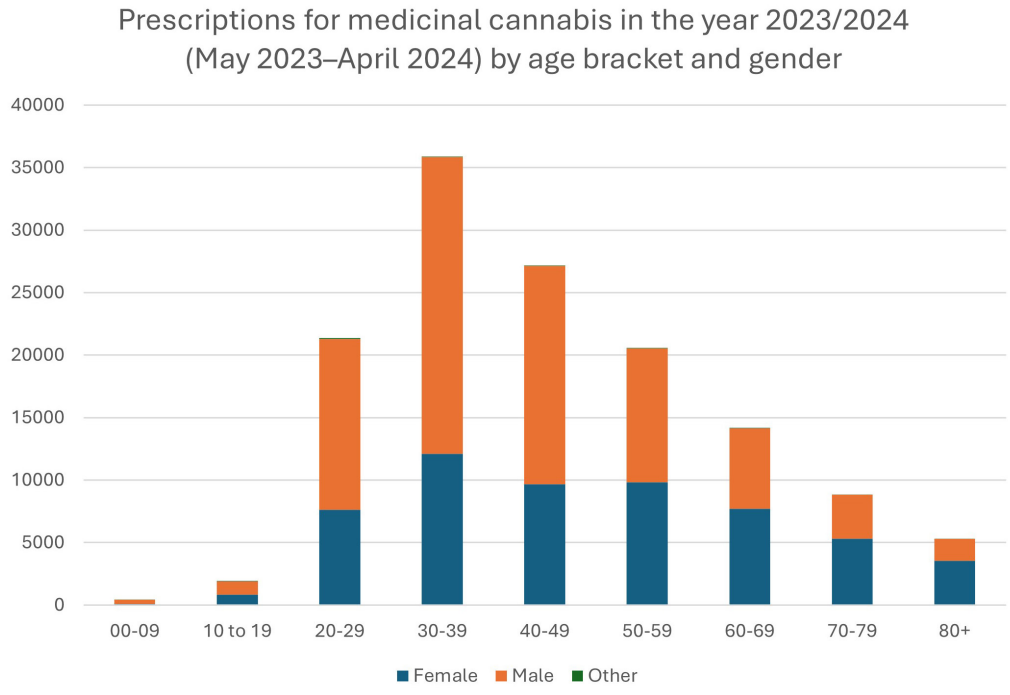
Dried flower medicinal cannabis products can be purchased for an average of NZ$15 per gram, with the lowest priced THC flower approximately NZ$11 per gram and the most expensive CBD-rich flower retailing at around NZ$20 per gram.[14] Some of the most potent THC flowers (25–26% THC) retail at NZ$12–14 per gram. This is comparable to the average dry herb prices on the illegal market in New Zealand. The latest New Zealand Drug Trends Survey, an annual snapshot of drug market trends, found consumers of illegal cannabis paid an average price of NZ$12 per gram for an ounce of flower (approximately 28 grams) of unspecified potency and quality.[28]

Cannabis clinics and online delivery have transformed patient access

The first private cannabis clinics opened in Auckland in 2018 and they appear to have become a major source of prescriptions and patient access. Cannabis clinics were not an intentionally planned part of the MCS. They emerged in response to a gap left by many doctors who were reluctant to prescribe cannabis due to limited clinical trial evidence of its efficacy.[29] One study of general medical practitioners in New Zealand found that approximately two in three did not prescribe cannabis at a patient's request,[30] and a survey of medicinal cannabis users found only one in three requests for a cannabis prescription were successful.[22]

The specialised cannabis clinics are commonly staffed with registered doctors and nurses with a special interest in cannabis and can be accessed privately without a referral.[29] Initially limited to New Zealand's biggest cities, Auckland and Wellington, a few clinics now operate in other major cities (e.g., Dunedin, Christchurch, Tauranga) and smaller centres (e.g., Nelson, Hastings), and several clinics offer telehealth services. An online search in mid-2022 found there were approximately 40 physicians with a special interest in cannabis therapy practicing across 11 cannabis clinics.[29] Some clinics run their own dispensaries, sometimes offering distance delivery services. This new development means that medicinal cannabis products can now be accessed without leaving

Figure 2: Distribution of prescriptions for medicinal cannabis products by age and gender in the past 12 months (May 2023–April 2024).



Source: collated from data obtained through Official Information Act request.[20]

one's home. With consultation prices ranging from NZ$50–150 at most clinics, they offer an alternative prescription pathway to traditional doctor practices, with the added benefit of advice from more experienced cannabis prescribers.

This unplanned "privatisation" of cannabis prescribing comes with some drawbacks, including the increased financial burden on patients due to private consultation fees and the compartmentalisation of patients' healthcare by separating health advice and treatment from patients' usual health service providers.[29] There is also a risk that financial conflicts of interests may blur the clinical judgement of doctors employed in cannabis clinics, due to their focus on a single treatment option. Clinic business partnerships and commercial arrangements may amplify concerns over this new model of care. For example, one cannabis clinic operates as a subsidiary of a company licensed to produce cannabis.[31]

Justice and the equity of access to medicinal cannabis

Although cannabis clinics have facilitated access to legal medicinal cannabis products, most people self-medicating with cannabis do not engage with the prescription scheme. According to the 2022/2023 New Zealand Drug Trends Survey, 45% of medicinal cannabis users (i.e., defined as those who use cannabis "only" or "mostly" for medicinal reasons, N=1,833) reported that legal cannabis products were "very difficult" to access, and only about one in ten had a medicinal cannabis prescription.[32] Another survey found that those on lower incomes, Māori and consumers who grow their own cannabis are less likely to transition to the prescription scheme.[23] The inequity in access to prescriptions means that the MCS may unintentionally exacerbate discriminatory criminal justice and health outcomes under the *Misuse of Drugs Act*, which prohibits the possession of non-prescribed cannabis and its use for any reason. For example, Māori have higher prevalence of using cannabis for medicinal purposes,[33] yet they are less likely to transition to the legal prescription scheme.[23] This is possibly due to stigma, income inadequacy and systemic barriers in access to healthcare, for example living in a rural area with poor access to a doctor. At the same time, Māori are more likely to be arrested or prosecuted for cannabis-related offences under the *Misuse of Drugs Act*.[34]

Prescription data for the past year (May 2023–April 2024) indicates that patients identifying as Māori (prioritised ethnicity) were under-represented, given they are more likely than other ethnicities to use cannabis medicinally. They received 12.9% of prescriptions over the past 12 months (for context, 17.4% of the New Zealand population identifies as Māori[35]). Interestingly, in younger age groups (0–9 and 10–19 years old), the proportion of prescriptions for patients identifying as Māori was higher (29% and 23% respectively).

Patients aged 30–39 received most prescriptions of all age groups (i.e., 26%), and males received more prescriptions than female patients (58%) in the past year. However, from age 60 females received more prescriptions, suggesting older women may be a key demographic for the MCS (Figure 2).

Discussion

There has been a noticeable improvement in access to medicinal cannabis products and prescriptions since the MCS came into effect over 4 years ago. For example, in the past year (May 2023–April 2024), more than 160,000 prescriptions for medicinal cannabis products have been written, and the supply of products to patients increased 14 times since the introduction of the MCS (up from 4,827 packs supplied in the second quarter of 2020 [mostly CBD-only products] to 73,725 packs supplied in Q2 of 2024 [mostly THC-dominant products]). Although cannabis oil and cannabis liquid products still dominate prescriptions, 40% of prescriptions in the past 12 months were for a flower product.

The medicinal cannabis market appears to be shifting to high THC and dry flower products. THC has recognised analgesic, anti-inflammatory and anti-emetic properties, and many patients prefer THC formulations to CBD-only products.[36] However, high potency THC cannabis also increases the risk of negative side effects, including impacts on cognition, memory, consumers' ability to complete daily activities (e.g., driving, work, parenting), risks of developing psychosis and cannabis dependency (cannabis use disorder).[37,38] Note, under the medical cannabis system, doctors are tasked with minimising these risks via detailed patient assessment, prescribing and monitoring. Frequent cannabis consumers may also develop a level of tolerance to THC intoxicating effects, and some studies suggested that CBD may counteract the acute side effects of THC, although evidence remains mixed.[39,40] A few small-scale clinical trials

report that low-THC dose cannabis products may be as effective in therapeutic applications as higher-THC potency products. For example, a small double-blind placebo-controlled study compared the effects of vaporising medium (3.53% THC) to low-dose (1.29% THC) cannabis and found equivalent analgesia in neuropathic pain patients, but less side effects.[41] It has been suggested there may be a therapeutic window for analgesic effects from herbal cannabis, with greater symptom relief at low and mid-range THC doses.[42]

While the relationship between THC potency, THC:CBD ratio, dosage and symptom relief requires further research, the market shift towards THC-dominant, high-THC potency and flower products may indicate a drift away from the original therapeutic focus of the medicinal cannabis regime. The harm reduction potential of vaporised cannabis means that theoretically, regular recreational cannabis smokers could access prescriptions as a way to reduce pulmonary harms, somewhat similar to how the Australian regime for prescribed nicotine e-cigarettes functions. The transitioning of cannabis consumers from the unregulated market with unknown product potencies, contaminants and lack of quality control[43] to a prescription regime may offer further benefits. Introduction of new non-flower product forms (e.g., chewable tables, topicals, edibles) could also facilitate the transitioning of patients from the unregulated cannabis market to the quality-assured prescribed products. Although prescribed cannabis flower products are supposed to be vaporised or brewed (for consumption as a tea), they may also be administered by patients via smoking. To our knowledge, there have been no studies investigating this potential risk with the MCS. The market shift towards products in a flower form and those with high concentrations of THC may also have unintended consequences for patients' access to medicinal cannabis. New Zealand studies have found that general practitioners (GPs) unfamiliar with medicinal cannabis are more reluctant to prescribe products in a dosage form other than pharmaceutical formulations and those containing THC, primarily due to concerns about side effects and lack of clear clinical guidelines on dosing.[6,44] If GPs are not confident prescribing the majority of products, it may contribute to further privatisation of cannabis prescribing through cannabis clinics.

Cannabis clinics have undoubtedly improved patients' access to medicinal cannabis prescriptions and products, but there are also concerns around the new model of care. In Australia, where cannabis clinics have also become a feature of the medicinal cannabis scheme, the Australian Health Practitioner Regulation Agency (APHRA) recently released a statement that such business models focussed on a single medicine "*may take advantage of consumer demand*" and "*may be putting profit ahead of patient welfare.*"[45] In New Zealand, advertising medicinal cannabis products is prohibited (as they are "unconsented medicines"), but cannabis clinics appear to be able to advertise their services under general rules in the *Medicines Act* and the *Fair Trading Act*. The increasing commercialisation of the medicinal cannabis sector is an unintended consequence of the MCS, although the same consequence has been observed in other similar medicinal cannabis schemes overseas.[46]

According to cannabis clinic pricing information, the cost of monthly medicinal cannabis therapy in New Zealand may range from NZ$120 to NZ$400, depending on the dosage and products prescribed. While the product price decreases over the past 4 years are welcomed by many patients, affordability remains an issue for those on lower incomes. Some patients may be able to receive support through the Disability Allowance if their GP verifies that medicinal cannabis is essential, directly related to their disability and there are no suitable subsidised or partly subsidised alternatives (the last criteria being the main reason for declined applications, as the patients would need to have trialled an extensive range of medications and therapies prior to medicinal cannabis).[47]

Cannabis is the most widely consumed illegal drug in New Zealand (i.e., 14.2% last year prevalence based on the latest New Zealand Health Survey). According to the 2012/2013 New Zealand Health Survey, 42% of cannabis consumers used it for medicinal reasons,[48] and large proportions of medicinal cannabis users (69%) also consumed cannabis for non-medical reasons.[33] These findings illustrate the blurred boundary between therapeutic and recreational cannabis use, with many consumers using cannabis to help relax, sleep or improve overall wellbeing—motivations reminiscent of dietary supplement use rather than prescribed pharmaceutical medicines, or alternatively strictly recreational use.

Under the current law, consumers can access high potency cannabis flower through private clinics for any health-related reason, yet possession of non-prescribed cannabis and home growing of cannabis for therapeutic use remain criminal offences. Although convictions for cannabis

possession in New Zealand have fallen significantly, particularly after the 2019 amendment to the *Misuse of Drugs Act*, which legislated a public interest test for any prosecution for personal drug possession,[49] the MCS may unintentionally exacerbate discriminatory criminal justice and health outcomes, particularly for Māori, who are more likely to be arrested for cannabis-related offences.

The increasing use of legal cannabis products via the MCS has implications for the implementation of public safety legislation beyond the *Misuse of Drugs Act*. For example, the random roadside oral fluid screening regime for drugs (other than alcohol) may disadvantage patients who use prescribed medicinal cannabis products, as they can test positive for THC even when the impairment effect has passed. Some studies have found that frequent users of cannabis (a typical consumption pattern for medicinal cannabis patients) show less impairment than infrequent users at the same dose.[50] Patients should be advised against driving after use of THC-containing products, particularly during initiation of therapy and following each dose.[51] Exemption from legal sanctions for drivers who test positive for THC but who can prove they were prescribed medicinal cannabis and demonstrate that they are not impaired at the time of driving is a much needed amendment to this scheme, as is likely to be the case for other legal medicines that have the potential to impair driving.[52]

As part of medicinal cannabis legalisation, people in palliative care (legally defined as those who, in the opinion of a medical or nurse practitioner, have "an advanced progressive life-limiting condition and nearing the end of life") were granted a statutory defence against prosecution for possession and use of illegal cannabis, and possession of a cannabis utensil. However, this did not extend to growing cannabis at home for medicinal reasons, and anyone aiding or helping a palliative care patient in using and accessing medicinal cannabis remains vulnerable to prosecution. The existing exemption was implemented as an interim compassionate measure while regulations and a product assessment scheme were developed, but following ministerial review it was retained in the law.[53] To our knowledge, there is no data on the level of public knowledge about the exemption for palliative care patients, and whether it is used in practice, i.e., if eligible patients request support documents from their doctors. The legal definition of palliative care under the *Misuse of Drugs Act* is challenging to operate in practice, e.g., in the case of a fluctuating condition, change in prognosis or recovery, when does a patient become a criminal again? Extension of the palliative care provisions to include personal home cultivation could address some of the inequities, but political and community concerns about diversion would need to be debated.

Conclusions

Our review of the implementation of the New Zealand MCS to date has identified a number of important achievements, including the establishment of a licensed medicinal cannabis cultivation and production sector, a fall in the retail prices of prescribed medicinal cannabis products, expansion of the legal medicinal cannabis product range to attract patients away from the illegal market and albeit unintentionally, the establishment of private cannabis clinics that have improved patient access and care. However, there are signs of a shift towards THC-dominant and flower products, and a move away from the original focus on therapeutic applications of cannabidiol. There has also been some increase in the privatisation via private cannabis clinics, and the emergence of new business models, including some signs of vertical integration along the supply chain. While this may have improved the efficiency of the new medicinal cannabis sector and access to medicinal cannabis therapies and products, the unintended consequence is greater commercialisation of the health service and narrowing of patient care. If patients seeking prescriptions through cannabis clinics are not presented with a range of treatment options (beyond cannabis therapy), prescribers may be reduced to providing an administrative function for those willing to pay for cannabis.[45]

Despite the decrease in legal product prices, some patients continue to voice concerns about the cost of accessing legal prescribed medicinal cannabis products that are not subsidised by the government, unlike many prescribed medicines in the New Zealand public health system. Government funding of cannabis products that do not have clinical trial evidence to support their efficacy would be hard to justify given the competing funding priorities for Pharmac (New Zealand government medicines buying agency). Those who choose to grow medicinal cannabis at home remain vulnerable to prosecution for cultivation, and possession of non-prescribed cannabis remains a criminal offence, with the sole exemption of

people in palliative care. At the same time, there are anecdotal reports that some consumers may be accessing prescribed products as a legal pathway to cannabis used for non-medical purposes. Current health inequities would be exacerbated for Māori if they face greater barriers to access (e.g., financial, obtaining a prescription, distance from a cannabis clinic) while also facing a greater risk of arrest and prosecution. A number of immediate extensions to the MCS could be considered to enhance equity, including the extension of palliative care provisions to patients with non-terminal conditions and allowance for home cultivation of a limited number of plants for personal medicinal supply.

COMPETING INTERESTS
None.

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Adult decision-making capacity and health research in Aotearoa New Zealand

Ben Gray, Angela Ballantyne

ABSTRACT

The *Code of Health and Disability Services Consumers' Rights* (the Code)[1] and the *Health and Disability Commissioner Act* (the Act)[2] are up for review. The *Code* currently applies to clinical care, teaching and research. When it was introduced, there were no national mechanisms to govern research, but since then the National Ethics Advisory Committee (NEAC) has developed detailed guidelines and established a network of ethics committees at various institutional levels. As currently written, the *Code* prohibits research on a patient who lacks capacity unless it is in their "best interests." This precludes some important research. The NEAC guidelines are more nuanced and measured, designed to balance the risks to the patient with the benefits to the community. We argue that the *Code* and the *Act* should be amended to allow decisions about research proposals on people who lack capacity to be made by an ethics committee set up by NEAC.

The Health and Disability Commissioner is currently conducting a review of the *Code of Health and Disability Services Consumers' Rights* (the *Code*)[1] and the *Health and Disability Commissioner Act* (the *Act*).[2] We are concerned about the role of the *Code* in limiting research with adults who lack the capacity to consent.

Judge Silvia Cartwright led an inquiry into allegations concerning the treatment of cervical cancer at National Women's Hospital and released her report in 1988.[3] The *Act*[2] was passed in 1994, reflecting recommendation 5b(iv)(3). The *Code*[1] was introduced in 1996, reflecting recommendations 6b(iv) and 5b(iv)(3). The National Ethics Advisory Committee (NEAC) was established in 2001 under the *New Zealand Public Health and Disability Act 2000*, now under the amended *Act 2010*,[4] reflecting recommendation 5b(i)(3). The *Act* was groundbreaking legislation, in regulating for a code that for the first time provided normative standards for clinical care, research and teaching, quality improvement obligations and a complaints mechanism. The *Code* was introduced 5 years before NEAC was established and 16 years before NEAC's first research guidelines were released. For the period 1996–2012, the *Code* was an important safeguard to support ethical research. NEAC set up a comprehensive structure of ethics review committees, and in 2012 their guidance standards on ethical research came into effect. A major revision was released in 2019, and those standards are currently under review. The current standards run to 250 pages.[5]

The application of the *Code* to clinical care has been the subject of many complaints and findings by the Health and Disability Commissioner. This has given greater clarity to providers on the Commissioner's interpretation of the *Code* in relation to clinical care—for example, in relation to when the qualifications included in section 3 are relevant. The Commissioner has noted that there have been few complaints in relation to research[6] and so there has been no similar development of the ways in which the *Code* applies to research.

Research is a more complex and multidimensional practice than the provision of clinical care. The goal of clinical care is to benefit the patient. While there may be disagreement as to which course of action is in the patient's best interests, both clinicians and patients are typically aligned in their intent. By comparison, the goal of research is to produce generalisable knowledge to benefit future patients—specifically to provide new knowledge to prevent, identify and treat illness and disease.[5] Therefore, in research, the goals of the researchers may differ from the goals of the research participants, who are often motivated by the prospect of personal benefit, access to otherwise unavailable procedures or drugs or last-ditch attempts at potentially life-saving interventions.[7] A decision to proceed with clinical care involves the patient and clinician balancing risks and benefits for the specific patient. A decision to proceed with research requires research teams, research ethics committees and clinical governance groups to assess and weigh the risks to the participants against the potential benefits to the population.

Once approved, research then requires each individual potential participant to consider, based on the information provided, whether they wish to participate. Given that, generally, the goals of patient and doctor in clinical care are congruent and that there are often conflicting goals in research, exploitation is a greater threat in research than in clinical care.

The application of the concept of informed consent to research has changed over time. While informed consent is always sought, it is common that participants make decisions to participate in research based on a relationship with or trust in the researcher,[8] and many cannot recall the details of the information provided after having signed consent.[9] *Te Ara Tika*[10] described ethical standards for research with Māori from the viewpoint of Māori researchers. The framework they proposed saw informed consent as a necessary but not sufficient requirement of ethical research, and they placed more emphasis on meaningful collaboration between researchers and participants at all phases of the research, from choosing the research topic, designing the study, implementing the study and reporting the results. The latest edition of the NEAC guidelines has these concepts embedded within. So, while the Health and Disability Commissioner sees informed consent at the heart of the *Code,*[6] NEAC has a wider focus. In discussing research on peoples with disability the main focus is on co-design and collaboration:

> *Their primary aim should be co-design; that is, research that is designed in collaboration with disabled people themselves. Co-design fosters trust and builds relationships with participants, which is a fundamental part of ethical research.*
>
> *5.2 Researchers should strongly consider a participatory approach when conducting disability research, whereby appropriate engagement with prospective participants and relevant stakeholders helps them frame research questions, devise methodology, interpret findings, avoid an 'ableist' bias, and improve the overall efficacy of the study.*[5]

There is an extensive section in the NEAC guidelines on supported decision making for those with limitations to their capacity, suggesting (in the context of people with disabilities) "*that almost any person, with the right support, is capable of providing informed consent*."[5] Informed consent remains at the heart of clinical practice. For research, it is one of several safeguards aimed to protect patients. The NEAC guidelines do an effective job of providing guidance on these safeguards.

Tensions between the application of the *Code* to clinical care versus research are most notable in relation to Right 7(4), which requires that when the consumer (patient or research participant) is not competent to make decisions for themselves, services can be provided if it is in the best interests of the consumer.[1] The 2019 report that was instigated by the Commissioner in response to the last review of the *Code* describes this issue succinctly:

> *When someone is unable to give informed consent, in certain limited circumstances, including that the research will be in the person's "best interests", Right 7(4) of the Code allows the person to be enrolled as a research participant. The "best interests" test does not provide for any consideration of the potential for advances in knowledge that may benefit people other than the participant.*[6]

Right 7(4) is particularly problematic for research with adults who are unable to give consent.[11] A person with capacity can choose to be part of a research study because they value contributing to knowledge that will benefit other patients. But for a patient lacking capacity, the "best interests" test in Right 7(4) applies and research cannot proceed unless it is deemed by the responsible doctor to be in the best interests of the patient. In a letter from NEAC to Associate Minister of Health Jenny Salesa on this topic they described a study that could be affected by these constraints:

> *Among patients who are hospitalised with severe traumatic brain injury, 60 percent either die or survive with severe disability. One treatment—a decompressive craniectomy—showed promise in reducing deaths caused by traumatic brain injuries. To see whether this treatment that had started to become commonplace was the best approach, a study was conducted in 2011. This study showed that what appeared to be a treatment with good outcomes, in fact*

> *ended up being worse for patients. The study's results, by changing standard practice, also saved an estimated 20 million dollars a year for New Zealand.*[12]

As a matter of justice, all classes of patients deserve good evidence to inform their clinical care; this includes patients with conditions that impair their capacity to consent either permanently or for a critical period of time (e.g., congenital intellectual disability, dementia or lack of consciousness with a critical injury). If clinical care is offered during this period, we need evidence to inform this care. Inevitably, this will entail some form of research. Conservative research ethics paradigms that restrict research with these groups may further entrench their vulnerability by denying them access to the standard of evidence-based clinical care that other, non-vulnerable groups expect. This is unjust.[13]

Balancing these competing interests and adequately protecting patients who cannot consent themselves from exploitation in research requires detail and nuance that is beyond the scope of the *Code*. NEAC has developed considerable expertise in setting pragmatic standards that carefully navigate the complex interests at play in research. NEAC has supported the development of a network of ethics committees at various institutional levels to provide guidance and review of specific research studies.

By comparison, the Health and Disability Commission has developed into an agency whose expertise is receiving and resolving complaints and advocating for improvements in individual-level clinical care. A search of Health and Disability Commission decisions for "research" locates just three cases of decisions relating to research. The Health and Disability Commission has limited expertise in considering the balance between patient rights and population benefits in health research.

The 2019 report from the Commissioner on this issue[6] recommended changing the "best interests" test in Right 7(4) in relation to research to "*no more than minimal foreseeable risk and no more than minimal foreseeable burden*." The report notes that there are two places where decisions are made—at the level of an ethics committee approving a study, and then at the level of potential participants agreeing to participate in the study. The report was concerned about additional safeguards and suggested involving a wider group in the decision making on participation. No changes have occurred as a result of this report.

The latest NEAC guidelines propose a two-step test in relation to patients who lack capacity:

> *Where the research imposes only minimal risk, it should have the prospect of providing benefits to the participants or the group to which they belong. Where the research exposes participants to greater than minimal risk, it should have the prospect of benefit for the individual participant. Benefits should be commensurate with the level of foreseeable risk. In balancing benefit to risk, the risk/benefit ratio should be 'at least as favourable to the participants' as alternative approaches.*[5]

Our proposal is that this test be used to determine whether a research proposal can be approved by a health and disability ethics committee. This provides safeguards at the level of study design. We agree with the Commissioner's suggestion that involving a wider group in the decision making on participation would be an appropriate safeguard at the level of individual participation

For these changes to be implemented, legislation would need to be amended. At the least, the *Act*, the *Code* and the *Protection of Personal Property Rights* (PPPR) *Act*, to which the *Code* aligns, will require amendment. We note that the Law Commission is currently investigating proposals for a replacement to the PPPR *Act*.[14]

It is redundant, confusing and constraining to have two bodies in Aotearoa New Zealand setting normative standards for health research.

The Medical Council of New Zealand is also responsible, on authority from the *Health Practitioners Competence Assurance Act,*[15] for setting standards for the ethical conduct of doctors in Aotearoa New Zealand. But the Medical Council has largely delegated the task of balancing the benefits of the research with the risks to the participant to the NEAC ethics approval process[16]—and we argue that the Health and Disability Commission should do the same. The Health and Disability Commission is under considerable resource pressure because of rising complaints;[17] it would be sensible to focus their resources on advocacy and complaint resolution in relation to clinical care. In relation to research, the *Code* should be aligned with NEAC guidelines so that ethical control of research is assured through NEAC processes

COMPETING INTERESTS
Ben Gray and Angela Ballantyne are not and have not been members of the National Ethics Advisory Committee.

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Persistent left superior vena cava after insertion of central venous catheter

Nandika Muruvan, Arthur Cavan, Marilyn Aday, Ankur Gupta

Central venous catheter (CVC) insertion for haemodialysis (HD) is a regularly performed procedure.[1] Usually, it is easily accomplished by a well-trained hand; however, it does not come without risk of complications. Infection, arrythmia, thrombosis, bleeding, pneumothorax and malposition of the catheter tip are among these.[2,3] The preferred access site for a non-tunnelled catheter is the right internal jugular vein due to its direct path to the superior vena cava (SVC) and right atrium. The second choice would be the left internal jugular vein. Femoral placement is an additional option but has high rates of infection and may cause loss of ambulation.[4]

The National Kidney Foundation recommends using arteriovenous (AV) access fistulas/grafts for HD. Eighty percent of incident HD patients still initiate dialysis with a CVC due to its ability to be used promptly in emergency situations.[1,5,6] The incidence of CVC tip malposition is up to 7%. Venous anatomy variation is a contributing factor to tip malposition.[7] Although persistent left superior vena cava (PLSVC) is the commonest anomaly of the thoracic venous system, it remains a rare congenital variant overall. It can, however, have a significant clinical impact.[8]

Case report

A 60-year-old male with chronic kidney disease stage 5 due to type 2 diabetes mellitus was seen in the outpatient dialysis unit for insertion of a non-tunnelled CVC. This was a temporary access site for HD while awaiting his left brachiocephalic AV fistula to mature. A double lumen non-cuffed HD catheter was inserted into the left internal jugular vein as the right internal jugular was found to be thrombosed on ultrasound. This was a likely outcome due to multiple previous tunnelled HD catheter placements. An uncomplicated procedure was followed by aspiration of dark red, non-pulsatile blood from the lumen. There were no signs of cyanosis, bleeding or hypotension after insertion. A routine post-procedure chest X-ray (CXR) showed an atypical position of the tip of the catheter in the left mediastinum (see Figure 1).

The patient was sent for an urgent computed tomography (CT) of the chest that revealed a catheter tip placed in a PLSVC, the drainage of which was into the right atrium via the coronary sinus, which was deemed safe for use for the purpose of HD by the radiologist on duty (see Figure 2a and 2b).

The catheter was used successfully for HD sessions until the AV fistula had reached maturity. The patient was closely monitored during HD sessions, which remained uneventful. The CVC was removed once the AV fistula was mature and successfully cannulated. With follow-up of the patient, there was no impaired venous flow to the left upper limb, and HD sessions carried out via the mature fistula remained uneventful.

Discussion

PLSVC is the most common congenital venous anomaly of the thoracic systemic venous return. The incidence is 0.3–0.5% of individuals in the general population and up to 12% in individuals with other documented congenital heart abnormalities.[3] PLSVC results from when the left superior cardinal vein caudal to the innominate vein fails to regress[8] (see Figure 3). There are several anatomical variations that occur in PLSVC. Most commonly, a PLSVC can coexist with a right SVC in 80–90% of cases. Bilateral SVCs can also vary in size to different degrees. In 65% of bilateral SVC cases, a left innominate vein is absent.[3] In 80–92% of cases, the PLSVC drains into the right atrium via the coronary sinus with no resultant change in haemodynamic state, as is the case with our patient. Conversely, 10–20% of cases of PLSVC can drain into the left atrium either through the coronary sinus, the roof of the left atrium or the left superior pulmonary vein.[3] Other abnormalities found concomitantly with PLSVC are atrial septal defect, ventricular septal defect, bicuspid aortic valve and aortic coarctation.[9,10]

There are important implications of PLSVC as it applies to cardiac venous return. Particularly, a venous return pattern where the PLSVC drains to the left atrium, and any cardiac

abnormality resulting in right-to-left cardiac shunting can place patients at risk for embolic complications to the arterial system.[3] Cases of supraventricular arrythmias, cardiac arrest and coronary sinus thrombosis have been reported in PLSVC after CVC.[11] Therefore, one needs to characterise the venous return in a patient with known PLSVC prior to initiating use of the CVC placed within it.[3]

Based on the anatomical variations and the risk associated with catheterisation of a PLSVC, its safety for long-term HD use has not been accurately evaluated.[11] PLSVC is, however, rarely reported, as it can go undiscovered since most dialysis catheters are inserted into the right internal jugular and venous system imaging is not routinely done prior to catheter insertion.

Although not utilised in this case, echocardiography can provide a non-invasive diagnosis of PLSVC.[12] A lateral CXR can differentiate cannulation of the hemizygous or superior intercostal vein, as this has a similar presentation on antero-posterior CXR as cannulation of the PLSVC.[10,12] In our case, the CVC was safely used after confirmation via CT scan that the catheter tip was in the PLSVC, and its drainage was into the right atrium.

Conclusion

Venous imaging should be considered in patients with known congenital cardiac abnormalities prior to insertion of HD catheter to confirm the presence or absence of a PLSVC. Conversely, patients that were discovered to have a PLSVC should be investigated for other cardiac anomalies. We have arranged for an outpatient echocardiogram for our case. PLSVC can be used safely for short-term HD with careful monitoring.[11] Physicians placing HD catheters should be aware of the potential of a PLSVC, its diagnosis and its complications. When dealing with the accidental placement of a central catheter into a PLSVC, one should consider the reason for insertion and the condition of the patient. The risks and benefits to allow HD through a PLSVC should be considered on a patient-to-patient basis.[7] In our case, access for HD was imperative and without prompt access his condition would worsen. The venous drainage of the PLSVC was confirmed via CT. Although rare, by increasing our awareness around this condition we can minimise complications and improve patient safety overall.

Figure 1: Antero-posterior sitting chest radiograph demonstrating the left internal jugular vein (IJV) catheter tip overlying the left aspect of the mediastinum at the level of the pulmonary outflow tract.

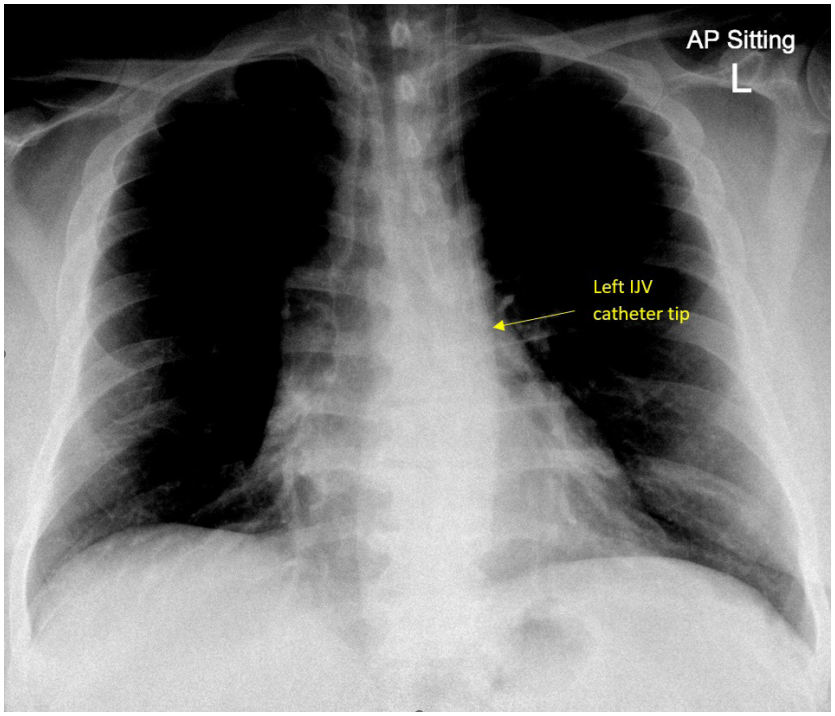


Figure 2a: An obliqued coronal reconstruction of a performed computed tomography venogram demonstrating the left internal jugular catheter with tip positioned within the variant left-sided superior vena cava and the drainage of this venous anomaly into the coronary sinus, which is enlarged at 12mm (indicating increased flow). The left brachiocephalic vein is also imaged in segments and is seen joining the right brachiocephalic vein to form the right superior vena cava.

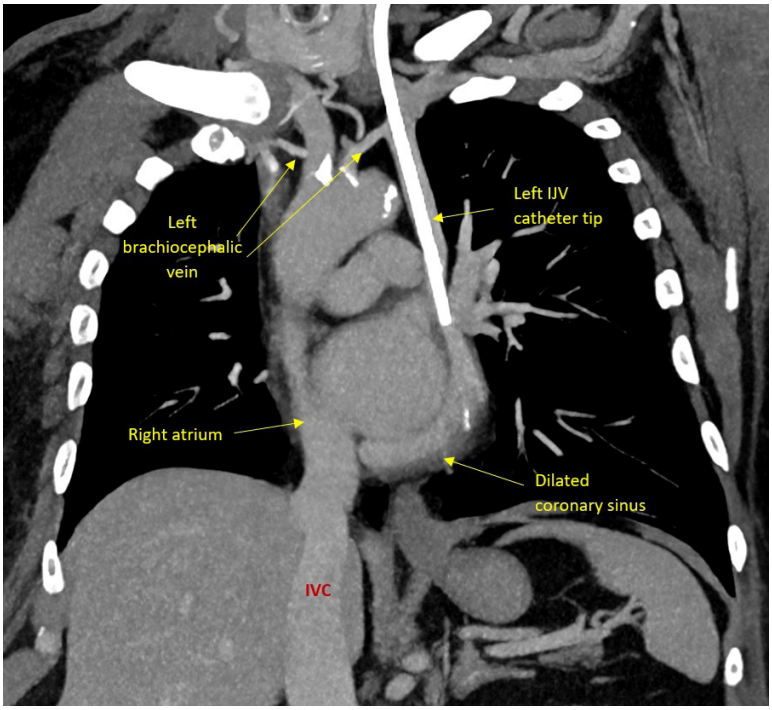


Figure 2b: An axial slice of the performed computed tomography venogram demonstrating continuation of the coronary sinus draining into the right atrium.

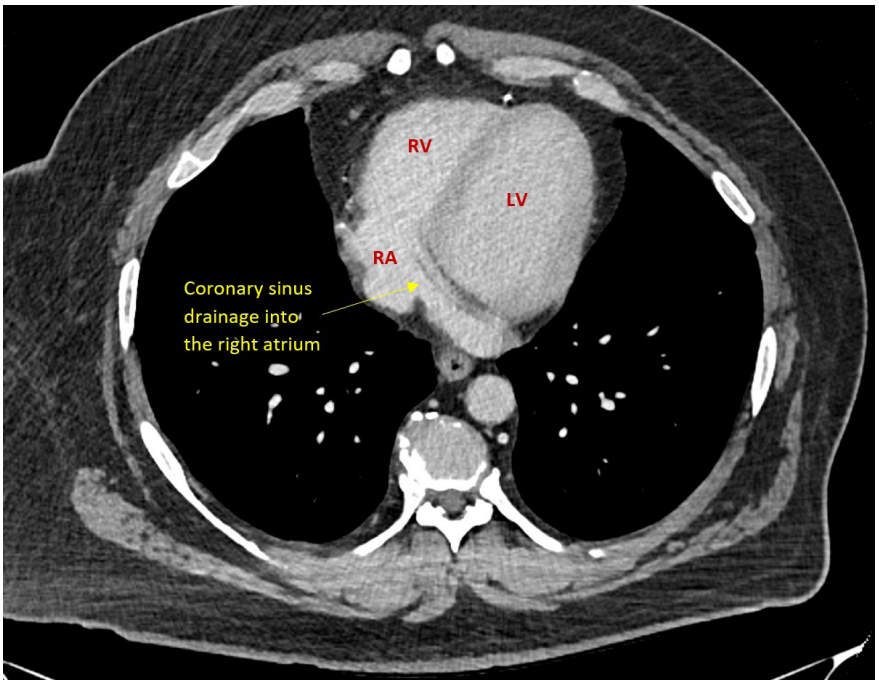
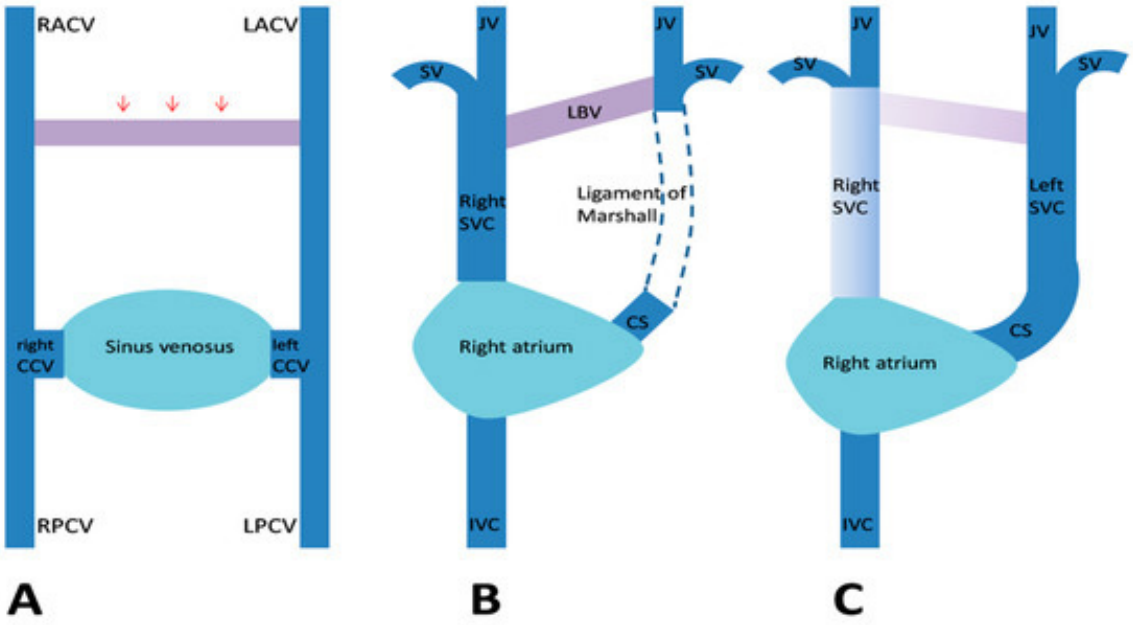


Figure 3: Embryological development of a persistent left SVC. A) The venous drainage system of the embryo, with transverse anastomosis (red arrows) forming between the anterior cardinal veins. B) Normal regression of the proximal segment of the LACV and the formation of the ligament of Marshall. C) When this obliteration fails to occur, a left SVC develops.



Abbreviations: CCV = common cardinal vein; CS = coronary sinus; IVC = inferior vena cava; IJV = internal jugular vein; LACV = left anterior cardinal vein; LBV = left brachiocephalic vein; LPCV = left posterior cardinal vein; RACV = right anterior cardinal vein; RPCV = right posterior cardinal vein; SV = subclavian vein; SVC = superior vena cava.
Adapted from: Demșa I, Crișu D, Haba CMȘ, et al.[13] Open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (http://creativecommons.org/licenses/by/4.0/).

COMPETING INTERESTS
Nil.

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Towards equitable access in bowel screening

Susan Parry, Cathy Whiteside, John McMenamin, Bronwyn Rendle

We acknowledge Dearing et al.'s[1] contribution to bowel screening research, highlighting that the programme is not achieving equitable access to screening. The National Bowel Screening Programme (NBSP) routinely monitors spoilt kit and definitive spoilt kit rates as programme indicators. Since 2020, with a peak in spoilt kits associated with COVID-19, there has been a steady decrease in the rate of spoilt kits for all population groups. There have been a number of initiatives undertaken to support this. The kit sent to participants has been redesigned with clearer instructions on how to do the test and prompts to put the supplied barcode on the sample tube and to write in the date the test was performed. Māori and Pacific participants who return a kit without a date, or a clearly incorrect date, are called on the day to get a correct date so that the kit can be processed. Information resources have been published in multiple languages.

Despite reducing the rate of spoilt kits, the definitive spoilt kit rate remains a challenge for the programme. This is where a participant does not get a definitive screening result within 6 months of a spoilt kit result. This is a failure of the programme, not the individual. Internal analysis shows that there is no pattern by the reason a kit is spoilt, i.e., a delay in transit compared to a sample with no barcode. We are currently improving the way we provide information to providers to identify participants who may need additional support to successfully complete screening.

Action on spoilt kits sits within a wider set of activities in the programme to equitably increase participation in screening. These include advice from our Māori and Pacific networks, culturally appropriate local outreach programmes, lab drop-off available in the Northern Region, national awareness-raising campaigns, education for healthcare providers and primary care engagement.

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COMPETING INTERESTS
None declared.

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Re: Towards equitable access in bowel screening

Chey G Dearing, Georgia C Dearing

Tēnā koe,

We appreciate the engagement[1] generated by our recently published research and this opportunity for robust conversation to improve the National Bowel Screening Programme (NBSP). We acknowledge the NBSP for efforts made in reducing the spoilt kit rate. We would like to highlight that the spoilt kit rate was not an indictor we sought to examine in our recent research. The spoilt kit rate considers the proportion of kits spoilt to total kits received for all participants, while our research focussed on a sub-group of participants, not kits. The NBSP initiatives listed are encouraging for Māori and Pacific people participants. However, our research suggests Asian participants, those living in high-deprivation areas and men may also require incentives.

We speculate that the spoilt kit rate may be a flawed indicator for the population highlighted by our research. The attempted but failed (ABF) to be screened population we examined is unique because despite being sent one or more replacement kits, this population does not re-attempt screening, or they send multiple kits that are spoilt. This is not similar to the large majority of participants, who after spoiling a kit successfully complete a replacement kit and are then screened. The spoilt kit rate includes data from this second and considerably larger population. Thus, a decreasing spoilt kit rate and an increasing ABF participant rate as highlighted by our research may co-exist, and are not inconsistent data. It is critical that bowel screening is transparent and able to be scrutinised. We suggest that the spoilt kit rate and the ABF proportions/NBSP definitive spoil kit proportions should be published as outcome measures at regular intervals for scrutiny.

COMPETING INTERESTS
None declared.

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The Work of the British Medical Association on the Problem of Reducing Maternal Mortality

NZMJ, 1924

As it has been assumed in some quarters that the New Zealand Branch of the British Medical Association has been supine in the matter of dealing with maternal mortality, the Executive considers a statement advisable on what actually has been done. The question was first raised in May, 1921, by the publication of certain statistics by the Children's Bureau of the United States Department of Labour.

It was at once discussed by the Council of the British Medical Association in New Zealand, and it was considered of such importance that a special section should be devoted to it at the Annual Conference of members of the Branch due to be held in Wellington in February, 1922. It was accordingly referred to all the Divisions of the Branch and was discussed by them as a preliminary to final consideration by the General Conference in February. The following is an extract from a notification to members which appeared in the New Zealand Medical Journal (the official organ of the British Medical Association), of August, 1921:—

> "One important feature of the Annual Meeting will be a discussion on the mortality and morbidity resulting from childbirth. The whole of Wednesday morning will be devoted to this, and the opening paper will be given by *Dr. Henry Jellett*, of Christchurch, formerly master of the Rotunda Hospital, Dublin. He will be followed by others closely connected with the subject, and *Dr. D. S. Wylie, C.M.G.*, who will present the Public Health Aspect."

In the meantime the Director-General of Health advised that the matter should be referred for the consideration of the Board of Health, of which the Minister of Health is chairman and on which the British Medical Association is represented—a Board which works in close co-operation with the British Medical Association. The report of the Board of Health appeared towards the end of the year and was referred to a meeting of the council of the British Medical Association on 3rd December, 1921. As, however, the whole question was then under consideration by the Divisions of the British Medical Association, and members had been asked to prepare for the full discussion at the Annual Conference, 1922, it was decided to defer consideration by the Branch as a whole until the Conference, at which all members in New Zealand would be represented. During all this time the question was being actively discussed by the Divisions throughout New Zealand, and by members generally, in order that some definite data might be forthcoming in view of the general discussion at the Annual Conference, and the editorial of the February (1922) Journal was devoted to the subject of "Maternal Mortality." At the Annual Conference, which was held in Wellington in February, 1922, papers were read by *Drs. Jellett*, *Wylie*, and *Tracy Inglis* (Medical Officer of St. Helens Hospital, Auckland). A discussion followed, which was continued throughout the second day of the Conference, and late into the evening. Reference to the N.Z. Medical Journal of April, 1922, will show that the greater part of that issue was devoted to the subject. A sub-committee consisting of *Drs. Tracy Inglis*, *Jellett*, *Agnes Bennett*, *E. Rawson*, and *Pottinger*, was set up by the Conference to go further into the subject and, the report of the sub-committee having been unanimously adopted by the Conference, was by resolution referred to the Board of Health, and a copy was sent to every member of the Branch. The following is a copy of the report:—

> "1. This meeting of the British Medical Association, while it recognises that maternal mortality in New Zealand and elsewhere is greater than it should be, deplores the undue publicity which has been given to the subject in the lay

press, and expresses the opinion that more harm than good has been done by creating a feeling of apprehension among prospective mothers and the women of the country generally.

2. In view of the statements recently made in Parliament, steps should be taken to restore confidence in the State Maternity Hospitals in which the maternal mortality, despite the many serious cases they admit, compares very favourably with that of New Zealand as a whole.

3. In the statistics of the country there appear to be two possible sources of error tending to reflect unjustly on the medical profession: —

(*a*) The inclusion of deaths from criminal abortion. In this respect it should be noted that many abortions are criminal in origin, that the number of these that prove septic is considerable, and that the death-rate amongst these is very high. The medical profession has no responsibility for such cases.

(*b*) The inclusion under the head of maternal mortality of deaths due to intercurrent diseases in pregnancy, labour or puerperium. If these deaths are included with the international standard, then they do not prejudice the statistics, but if they are not included in other countries, then it is unjust to the profession to include them in New Zealand.

4. The practical teaching of midwifery in New Zealand as regards both nurses and students, requires to be placed on a more satisfactory basis. Further, the provision of post-graduate courses for medical practitioners and nurses is also very badly needed.

5. That greater facility be given for hospital nurses receiving training in midwifery either at their own hospitals or at the various St. Helens hospitals in New Zealand.

6. The causation of puerperal sepsis remains largely obscure and rests probably on the varying resistance of individual patients.

There is no doubt as to the contributing causes; for instance, lack of antenatal hygiene and treatment, excessive vaginal manipulations, careless asepsis and antisepsis, and unfavourable surroundings and the meeting is alive to the necessity of avoiding or removing these conditions, and recommends that a circular embodying this should be sent to all medical men in the Dominion.

7. Facilities should be provided whereby sterilised maternity outfits should be easily obtainable.

8. In the event of puerperal sepsis, a confidential report should be asked for from the medical man before any further steps are taken by the Health Department.

9. Private hospitals which are too small to be run efficiently and profitably are a danger to the welfare of parturient women and should be replaced as is found possible, by private maternity hospitals attached to public hospitals, or to the St. Helens hospitals or by properly equipped hospitals built for the purpose, and State-aided where necessary."

The above report was acknowledged by the Secretary of the Board of Health in the following communication, dated 11th July, 1922:—

"In March last your Association was good enough to forward to the Board of Health a number of copies of the report of the sub-committee which was set up to consider the question of Maternal Mortality in New Zealand. I am now directed to thank you for forwarding the report and to say that the various recommendations contained therein have had the consideration of the Board, which is negotiating with the Department of Health in respect thereto."

In February, 1923, at the request of the Board of Health, the New Zealand Branch of the British

Medical Association sent a copy of the following resolution to all its members:—

> "That with a view to the reduction of maternal mortality the Board recommends medical practitioners to use every endeavour to ensure that their midwifery cases shall be attended by registered midwives wherever practicable."

Since that time greater prominence had been given to the subject of maternal mortality by the regrettable outbreak at the Kelvin Maternity Hospital, Auckland. The Royal Commission appointed to inquire and report upon the circumstances surrounding the Kelvin outbreak included in its *personnel* two members of the British Medical Association.

Prior to the Kelvin Commission the New Zealand Board of Health appointed a Select Committee to advise on regulations for private maternity hospitals, etc. All nurse injectors appeared before the Committee, and a very important report on the regulations necessary for private maternity hospitals was submitted to the Health Department; and when regulations were published later they were approved by the New Zealand Branch of the British Medical Association. The members of this Special Committee of the Board of Health are all members of the British Medical Association. The New Zealand Branch of the British Medical Association, in addition to its own JOURNAL, supplies to every member the *British Medical Journal*, which in nearly every number contains reports and discussions on midwifery. The regulation now to be enforced in New Zealand of submitting morbidity returns of maternity hospitals to the Health Department was first suggested by the British Medical Association. To show that the British Medical Association acts in a public-spirited way when the interests of its individual members are implicated, recently the Executive of the British Medical Association approved a proposal of the Director-General of Health to suspend from practice for a suitable period any doctor who had a septic puerperal case in his practice if there was a reasonable suspicion that the doctor was likely to spread the infection.

This statement might be further extended and amplified, and is not by any means a complete record of the work of the British Medical Association in the last few years in the direction of helping to lessen maternal mortality and morbidity. The Inspector of Maternity Hospitals, the Director-General of Health, the Director of Child Welfare, medical advisors of the Plunket Society, etc., are all members of the British Medical Association.

Proceedings of the Health New Zealand Te Whatu Ora Waitematā, University of Auckland and AUT Collaborative Research Symposium 2024

Oral presentations

Evaluating the appropriateness of the Dynamic Appraisal of Situational Aggression for Māori in forensic mental health services in New Zealand: participatory action research

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BACKGROUND

In New Zealand, tāngata whai I te ora Māori, who constitute roughly half of the population in forensic mental health services (FMHSs), are provided with interventions to target mental illness and mitigate the risk of inpatient aggression (McKenna, 2020). Yet, these interventions are oriented towards Western care practices (Wratten-Stone, 2016). The Auckland Regional Forensic Psychiatry Service introduced the Dynamic Appraisal of Situational Aggression (DASA), a risk assessment instrument developed to assess imminent risk of aggression (Ogloff & Daffern, 2006).

AIMS

This study aims to assess the appropriateness of the DASA for Māori in FMHSs in New Zealand.

METHODS

Participatory action research involved seven Māori nurses and a Māori cultural advisor in two hui. The first hui (N=7) explored Māori perspectives on the value of the DASA, while the second hui (N=6) discussed potential adaptations to the measures. Discussions were digitally recorded and thematically analysed.

RESULTS

The findings confirmed support for using the DASA with Māori but identified limitations in measuring cultural elements specifically relevant to Māori. Five adaptation options for cultural enhancement were suggested.

DISCUSSION

Cultural enhancement of the DASA is necessary for its appropriate use with Māori, requiring consultation with Māori cultural expertise and psychometric testing for validity and reliability.

CONCLUSION

For the DASA to be safely used with Māori, there is a need for the current content and process of the DASA to be refined locally within a cultural context and validated with Māori. Consultation with Māori cultural expertise is crucial for informed decisions on cultural enhancement.

Platelet rich plasma for benign vocal pathology

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BACKGROUND

There are few options for treatment of dysphonia secondary to vocal pathology related to lamina propria scar, atrophy, sulcus or inflammatory disorders. Platelet rich plasma (PRP) may provide anti-inflammatory and regenerative properties seen with other tissue engineering therapies without the risks associated with these treatments. We evaluated vocal fold (VF) injection of PRP for feasibility, phonatory effects, patient satisfaction and durability.

METHODS

Patients with dysphonia secondary to vocal fold scar, atrophy, sulcus and inflammatory lesions were included. PRP injections were administered in-office to bilateral vocal folds. Patients were followed up at 1 week, 1, 3, 6, 12 months

RESULTS

Seventy-five intracordal PRP injections were administered to 48 patients. Improvements in VHI-10 scores at 1, 3, 6 months were seen (mean VHI 21.73 at baseline, 15.62 at 6 months, $p<0.001$).

A total of 72.3% rated improvement at 7 or above on Likert scale and 95.7% of patients would consider a future PRP injection. Secondary outcomes VFI, MPT and GRBAS also demonstrated significant improvements over time. Patients receiving a single PRP injection (n=26) still demonstrated significant VHI-10 improvements at 1, 3 and 6 months.

DISCUSSION/CONCLUSION

VF office PRP injections are feasible and safe and can provide phonatory benefit and reduce vocal effort in benign VF disorders. A single PRP injection is sufficient to provide sustained benefit in some cases.

Acceptability of co-located health interventions within an AAA pilot screening programme for Māori: a mixed method study of patient, family/whānau and community views

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Health New Zealand Te Whatu Ora – Waitematā, Māori Health Pipeline

BACKGROUND

Co-located health interventions within screening programmes are gaining recognition as a strategy to increase access and health benefits for populations experiencing access barriers to healthcare.

AIMS

To evaluate the acceptability of accessing co-located health interventions within an Abdominal Aortic Aneurysm (AAA)/Atrial Fibrillation (AF) screening programme in Te Tai Tokerau as a method to reduce inequities in healthcare for Māori.

METHODS

Surveys of screening participants and whānau, interviews with screening participants and community hui were conducted. Descriptive statistics describe quantitative survey responses. Survey free-text responses, interviews and community hui were thematically analysed.

RESULTS

Ninety-five screening participants and 31 whānau completed the survey; 15 screening participants interviewed and 24 people participated in community hui. Screening participants (81%), whānau (81%) and the community valued co-located interventions as part of AAA/AF screening. Reasons were convenience, "could see the value" to improve their health, satisfied with AAA/AF screening and perceived limited time in GP appointments for prevention. Following Māori tikanga and engagement with skilled and pleasant staff were the main factors influencing satisfaction. Blood tests for heart and other diseases (e.g., diabetes, renal) were the most supported type of test due to family history of heart disease; blood testing was highly valued and provided reassurance about health status.

DISCUSSION

Participants identified significant advantages to additional health checks for improving access and health status. Fostering culturally appropriate, positive and high-quality interactions with Māori within the healthcare system were shown to be essential.

CONCLUSION

Proposed additional health checks included in AAA/AF screening programmes were acceptable and advantageous to health.

ACKNOWLEDGEMENTS

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Whakawhiti Ora Pai Community Health and Social Services at Te Hapua and Te Kao, Whānau Ora Community Clinic – Kaeo, Te Rūnanga o Whaingaroa, Dargaville Medical Centre, Te Hā Oranga.

Service evaluation of a novel combined physiotherapy and dietetics services for people with osteoarthritic knees

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BACKGROUND

Osteoarthritis (OA) is a highly prevalent disabling condition that is expected to rise. Arthritis New Zealand estimates the cost of managing OA in 2018 was NZ$12.2 billion. Surgical and pharmacological interventions appear to supersede evidence-based guidelines advocating conservative options.

AIMS

An initial 6-month pilot was implemented to optimise conservative treatment for moderate–severe OA knee patients referred to the Waitematā orthopaedic service via physiotherapy and dietetic input.

METHODS

From July 2021–June 2023, 439 patients were referred to the OA knee pathway and engaged in one-on-one and group intervention sessions involving education, nutritional advice and exercise prescription.

RESULTS

Of the patients who completed the KOAK survey post-pathway, 82% demonstrated an improvement in their knowledge of OA. Over 39% of patients completing KOOS reported improved quality of life. Of those who completed the eating habits questionnaire, 66% improved their nutrition knowledge, and 64% improved their diet. Twenty-five patients who did not complete the PROMs reported having changed their diet. In total, 54% improved their diet and 17.5% reported lost weight.

DISCUSSION

The findings from this OA pathway demonstrate that with the inclusion of a physiotherapist and dietitian in delivery of osteoarthritis care to patients with moderate to severe OA, patients improved their knowledge, function and symptom management.

CONCLUSION

The results from the pathway show that optimising conservative management, even in moderate to severe OA, can improve function and symptoms. A multi-disciplinary model should be considered a first-line treatment offered to all patients before surgery is considered an option.

ACKNOWLEDGEMENTS

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"I think everyone should be doing it": a preliminary mixed-methods analysis of DBT STEPS-A, a universal coping skills programme from rangatahi

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BACKGROUND

Dialectical Behaviour Therapy – Skills Training for Emotional Problem Solving for Adolescents (DBT STEPS-A) is a 30-week programme developed from the comprehensive DBT protocol to be delivered in schools as an early intervention programme. This approach takes a preventative position wherein rangatahi are taught skills from DBT for managing challenging situations, with the premise that this may prevent the development of more severe psychological difficulties.

AIMS

To explore the outcomes of DBT STEPS-A based on psychometric data and the views of rangatahi who participated in the programme.

METHODS

This research will use a mixed-methods approach including the analysis of pre- and post-psychometric data and thematic analysis of focus groups completed with rangatahi at five schools that have completed the DBT STEPS-A programme.

RESULTS

Positive improvements were seen across all psychometrics and indicated clinically meaningful change in behaviours and psychological wellbeing. Rangatahi valued the programme, with key themes indicating a positive change in behaviour and coping at school, at home and with friendship groups. All rangatahi endorsed the programme and reported that the programme should be offered universally in schools to all students.

DISCUSSION

DBT STEPS-A appears to be well accepted by rangatahi and produces clinically meaningful change. Although feedback was positive overall, there were also some recommendations for improvement and a karanga from rangatahi to continue to offer the programme to other students due to the positive impact.

CONCLUSION

Overall, DBT STEPS-A appeared to be well accepted by the rangatahi, and shows promising outcomes based on psychometric scores.

ACKNOWLEDGEMENTS

We also wish to acknowledge the rangatahi for their willingness and candidness to share their views with the research team and the schools for supporting STEPS-A and this research project. The Well Foundation with support from Rotary Club of Downtown Auckland, The Trusts, Lottery Community Grants, ProCare and Henderson Rotary has provided NZ$275,000 of funding for the salaries of Marinoto Child and Adolescent Mental Health Service staff to deliver STEPS-A. The following clinicians facilitated the STEPS-A programme: Lauren Glass, Jessica Klippenstein, Katie Lancaster, Amy Wilson Hughes, Susannah Limbrick, Kirstin O'Connor, Evie Andres, Selena Griffith and Shelly Hindle.

Co-design of a pharmacist-led mental health intervention for long-term condition patients

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BACKGROUND

Subthreshold depression and anxiety are common conditions that are associated with significant suffering, impaired functioning, increased healthcare utilisation and economic costs. If unmanaged, it may progress to clinical depression and anxiety in up to 35% of people. Subthreshold conditions are often associated with long-term conditions (LTCs). Community pharmacists have a pre-existing relationship with people with LTCs and offer an opportunity to address their unmet mental health needs.

AIMS

To design a pharmacist-delivered mental health brief intervention for LTC patients with subthreshold depression and anxiety.

METHODS

Semi-structured qualitative interviews with community pharmacists, consumers and key stakeholders exploring their perspectives on a proposed service were conducted. Interviews were transcribed and analysed using a general inductive approach and NVIVO software.

RESULTS

Participants of varying backgrounds, ages, ethnicities and geographical locations were interviewed. Five main themes were identified: current practice, attitudes towards the service, advantages/disadvantages of community pharmacy, barriers/facilitators to implementation and service characteristics.

DISCUSSION

Most participants saw the value of such a service delivered via community pharmacy and intervening early. Community pharmacists were seen as accessible and approachable. Barriers included lack of resources, business outlook, pharmacist characteristics and public/patient-related factors, but participants discussed ways to mitigate these barriers. Service characteristics of in-person delivery and flexibility were emphasised. Interventions ranged from signposting and giving resources to "CBT-like" interventions.

CONCLUSION

Respondents believe there is potential to address subthreshold depression and anxiety in a community pharmacy setting, but further studies are needed to determine the feasibility and effectiveness of interventions in a community pharmacy setting.

ACKNOWLEDGEMENTS

Health Research Council of New Zealand – Clinical Research Training Fellowship; The University of Auckland.

Oritetanga paerewa: culturally safe communication and de-escalation practices/strategies for clinicians working with tangata whaiora Māori in acute adult mental health inpatient units

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BACKGROUND

Seclusion is the process where mental health consumers who are considered high risk to others are locked in a room alone against their will. This is a traumatising practice, and Māori consumers are five times more likely to be secluded than non-Māori. Concerns have been raised as to whether unconscious bias and racism may play a part in this. The elimination of seclusion has been identified as a national priority, however there is very limited evidence regarding alternatives to seclusion for Māori, such as culturally safe de-escalation practices.

AIMS

The aim was to identify what culturally safe communication and de-escalation strategies are effective for staff working with Māori who acutely distressed or agitated within adult mental health inpatient units.

METHODS

This was a kaupapa Māori, qualitative study. Nine semi-structured interviews were undertaken with experienced Māori inpatient staff across four adult mental health units. A focus group hui was then held with seven of the original participants.

RESULTS

Five main themes were identified: mana enhancing (personal power), whakawhanaungatanga (relationships), pono (honesty), kanohi ki te kanohi (communication) and huarahi (approaches).

DISCUSSION

Participants felt that there was a better way to work with Māori, however they are hampered by existing attitudes, ward cultures and environments that support the use of restrictive practices.

CONCLUSION

This study contributes new evidence on culturally safe de-escalation strategies for Māori who are experiencing agitation or distress within inpatient mental health settings. The use of such strategies may contribute to reducing the high seclusion rates for Māori.

ACKNOWLEDGEMENTS

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Satisfaction with retirement village living in the context of frailty

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BACKGROUND

Retirement villages are promoted as offering age-friendly environments to support older people. Overall, there are high rates of satisfaction with village-living reported by residents. There is no data on how satisfied people living with frailty are with the village lifestyle.

AIMS

To investigate the association between frailty and residents' satisfaction with village-living.

METHODS

Villages and residents from Auckland and Waitematā districts were recruited. Demographic, health and social data were collected from participants, including satisfaction with aspects of village-life. Frailty was calculated by frailty index constructed from baseline data. Multivariable regression was used to analyse frailty between levels of satisfaction.

RESULTS

A total of 578 residents were recruited from 33 villages. Median (interquartile range) age was 82 (76–87), and 73% were female. Overall, 93% report being "very satisfied"/"satisfied" with village-living. Residents reporting being "neutral" to "very dissatisfied" with overall satisfaction, satisfaction with social activities, opportunities to be active, affordability and with services had significantly higher frailty scores compared to those "very satisfied".

DISCUSSION

Despite living in an age-friendly and resource-rich environment, those reporting dissatisfaction have higher frailty, suggesting villages may not adequately support those with frailty. While expectations around purchasing this lifestyle may influence satisfaction, this does raise the query of how those living with frailty in the wider community have their needs met to satisfactory levels.

CONCLUSION

Further research is required to explore reasons for less satisfaction in those with higher frailty in order to inform how best to support people living with frailty, whether in villages or the wider community.

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National Science Challenges: Ageing Well; Waitematā DHB; HOPE Foundation for Research on Ageing (sponsored Rosa Griffith's summer studentship).

Participating retirement village managers and residents.

Microbial resistance patterns in periprosthetic joint infection of the knee—a 20-year longitudinal study

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BACKGROUND

Understanding the causative micro-organisms and initiating early appropriate empirical antibiotics is imperative in the management of periprosthetic joint infections (PJI).

AIMS

To identify patterns of micro-organism and antibiotic resistance profile in early and late PJIs and analyse changes in profile over the last 2 decades. This information is crucial for guiding empiric antibiotic selection.

METHODS

PJI data from three tertiary centres from 2000–2023 were identified and reviewed. First episode of PJIs were classified using the Auckland classification into early (<1 year since primary) and late (>1 year since primary) PJIs. For each case, the causative organism(s) and antibiotic sensitivity were recorded and analysed.

RESULTS

A total of 539 PJI cases with 606 cultures were included. Early PJIs were significantly more likely to involve resistant micro-organisms (OR 2.85, CI 1.71–4.76, P<0.05) and be polymicrobial (OR 8.714, CI 3.95–19.22, P<0.05). The predominant organisms for both early and late PJIs were *Staphylococci Aureus*,

with gram-negative micro-organisms contributing to 20% of cases in both early and late PJIs. Flucloxacillin monotherapy provided sufficient coverage for 54% of early PJI cases and 74% of late PJI cases. In comparison, Vancomycin monotherapy provided sufficient coverage of 82% in both early and late PJI cases. The number of resistant cases remained unchanged across the 23-year period, involving approximately 1 in 6 PJIs (P>0.05).

DISCUSSION/CONCLUSION

Despite significant usage of empiric antibiotics for PJIs, the primary causative micro-organisms have remained the same, with no notable increase in resistance cases over the past 2 decades. In early PJIs, Vancomycin with the consideration of Gram-negative agent should be considered as the choice of empirical antibiotic, given the high proportion of polymicrobial and resistant cases.

ACKNOWLEDGEMENTS

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A comic book for information prior to coronary angiography

Newcombe R, Reynolds J, Armstrong G, El Jack S

Health New Zealand Te Whatu Ora – Waitematā Cardiovascular Unit

BACKGROUND

Levels of education and literacy influence patients' understanding of informed consent.

AIMS

We produced information for coronary angiography in comic book format. It was designed to be easier to comprehend than the Heart Foundation booklet but narrower in scope. Before distribution we needed to ensure the comic booklet was going to be accepted by patients.

METHODS

A questionnaire was administered to evaluate perceptions of the comic book (CB) compared with the existing Heart Foundation (HF) pamphlet. Twelve nurses and 15 patients were surveyed.

RESULTS

There was no difference in the perception of completeness of information: CB 41%, HF 56%, both 4%. No respondent felt CB contained unnecessary detail, but 22% felt it was present in HF (p<0.001). Fifty-nine percent felt neither format had unnecessary detail.

All respondents felt CB was best for those who struggle with understanding (p<0.001). No respondents felt CB was too long or too wordy, whereas 41% felt HF was (p<0.001). Thirty-seven percent felt neither was. If having a coronary angiogram, CB was preferred by 67%, HF by 22% and either by 11% (p=0.002).

Compared with patients, nurses were significantly more likely to view HF as too wordy (p=0.003) and containing unnecessary information (p=0.005).

DISCUSSION

The comic book format was more succinct and understandable. It was preferred by the majority of respondents. However, some patients do prefer more detailed information. Clinical staff may not always recognise this.

CONCLUSION

As a result of our survey, we provide the comic booklet in addition to the current pre-angiography education to all patients before the consent process.

The use of the graphic comic booklet can be seen as an important educational tool to aid patient understanding of angiography and risks involved prior to the angiogram consent process.

ACKNOWLEDGEMENTS

Dr Guy Armstrong; Graphic Design team AUT.

Implicit factors overwhelm patient informed consent

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BACKGROUND

Informed consent and education are the explicit manifestations of patient-centred healthcare. However, patient understanding is not always increased following informed consent.

AIMS

We aimed to assess how patients' understanding alters following informed consent and education for outpatient elective coronary artery stenting.

METHODS

A questionnaire on beliefs about stents was administered to: 1) patients after elective outpatient stenting for stable angina, 2) a reference group of lay people with no history of stenting in themselves or their first-degree relatives, and 3) five interventional cardiologists, two non-interventional cardiologists, three cardiology trainees and 15 nurses.

Patients (n=110) and lay persons (n=118) differed in sex but not age, deprivation or ethnicity.

RESULTS

As expected, patients' views moved closer to those of doctors and nurses for belief in the relief of stable angina by stents (p<0.001). Patients' views did

not differ significantly from lay persons for symptomatic and prognostic benefits of stents in acute heart attack.

Paradoxically, patients' views diverged further from those of doctors and nurses with regard to the prognostic benefit of stents in stable angina ($p<0.040$) and for the general question of whether stents or "healthy lifestyle and medicines" have the most prognostic impact ($p<0.041$).

DISCUSSION

The implicit factors causing paradoxical divergence of patient views from that of the doctors and nurses are unknown. Patient-related factors could include self-education and cognitive biases such as choice-supportive bias and the narrative fallacy.

CONCLUSION

Explicit informed consent and education may be overwhelmed by implicit factors.

Characteristics, transmissibility and outcome of healthcare associated COVID-19 (HA-COVID) in the initial Omicron era—Waitematā experience

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BACKGROUND

Healthcare associated (HA) COVID-19 poses a significant challenge in terms of infection prevention/control measures and excessive morbidity affecting the duration of hospitalisation.

METHOD

We performed a retrospective review of all HA-COVID acquisitions at Waitematā Health from 1 May till 1 August 2022 in order to understand the clinical characteristics, transmission rate, treatment and outcomes of these patients. A unique case definition and surveillance plan for those exposed was implemented.

RESULTS

Analysis of 198 healthcare associated COVID-19 acquisitions revealed an average duration of illness 8.7 days, average length of stay 24.2 days and 30-day mortality rate of 6.1%, which is significantly higher compared to patients with community-acquired COVID-19 in New Zealand as shown in COHESION-2 study. The average age of the study population was 76 years old. This population was 50% male and female. Predominant comorbidities include chronic lung (30%), heart disease (35%), hypertension (53%) and CVA (30%). COVID-19 was mild in 86% of cases, moderate in 8% and severe in 6%. Specific treatment included paxlovid in 18% and remdesivir in (11%), dexamethasone or equivalent (14%), supplemental oxygen therapy (18%) and antibiotics (25%). Almost all HA-COVID events occurred in a multi-bed environment in selected wards with suboptimal engineered bedspace (95%).

CONCLUSION & DISCUSSION

We have demonstrated high transmission of COVID-19 in multi-bedded rooms in certain wards with poor airflow, unique clinical characteristics, suboptimal utilisation of antivirals, and higher morbidity and mortality rate.

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Infectious Diseases Waitematā District Health Board.

How do mental health nurse practitioners work to improve access to healthcare services?

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BACKGROUND

The prevalence of mental health and addiction disorders in New Zealand is growing, with access to services a major challenge for individuals and communities. Nurse practitioners (NPs) have the potential to improve this access, addressing health inequities and poor health outcomes. However, little is known about how they work, and the models of care used.

AIM

To outline the variety of roles, positions and differing models of care held by mental health nurse practitioners (MHNP), and identify how they improve access, health inequities and outcomes for people accessing mental health and addiction services.

METHODS

Descriptive qualitative methods were applied in this study. Ten MHNP, across a variety of national clinical settings, participated in individual face-to-face or Zoom interviews.

RESULTS

Three exemplars demonstrated the unique models of care established by NPs. Thematic analysis identified three key themes: the unique role of the MHNP; enabling access; collegial relationships, ambiguity and challenges.

DISCUSSION

Three main themes and six sub themes were

identified in the findings. The three themes are discussed in conjunction with the research question, aims of the research and the literature review.

CONCLUSION

MHNP are uniquely placed to improve access to healthcare services through flexible patient-centred care. They are leaders in healthcare, address health inequities and improve patient outcomes through innovative integrated models of care. They are adept at improving access to healthcare services for all New Zealanders by bridging nursing and biomedicine disciplines, with their advanced scope of practice offering a solution to transforming mental health service delivery to reach all New Zealanders.

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Dr Sue Adams, Helen Butler – The University of Auckland.

Posters

Opportunistic HPV self-testing in ethnically diverse GP clinics

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Health New Zealand – Te Whatu Ora Māori Health Pipeline

BACKGROUND

The introduction of human papillomavirus (HPV) self-testing in September 2023 has potential to transform access to cervical screening.

AIMS

This study tested implementation of opportunistic s elf-testing in six culturally diverse GP clinics for 20 months prior to the programme change. Along with HPV type prevalence, real-world challenges and enablers to offer, and uptake of the self-test were explored to provide policy-relevant findings for the national screening programme.

METHODS

We trained 40 clinicians in offering the self-test to women eligible for screening who attended a participating clinic for any reason. Women had the option to take a kit home. HPV results were followed up by specialist study nurses. Feedback surveys with participants and post-study interviews with clinicians were thematically analysed.

RESULTS

HPV test results were received from 3,922 participants (Māori 14%, Pacific 39%, Asian 38%, Other 9%).

Of the 16% of participants who took kits home, the return rate was 63%.

Ten percent of samples tested positive for HPV (HPV 16/18 2%, HPV other 8%). Follow-up cytology was achieved for 96% of participants with HPV other detected

Survey responses were highly positive and indicated a preference for mailed kits when next due.

DISCUSSION

Women were receptive to opportunistic offer of self-testing in clinic. Supportive practice systems, good communication and centralised follow-up are facilitators, as is the option to take kits home; however, resourced active follow-up is required to ensure good sample return rates.

CONCLUSION

Opportunistic offer of HPV self-test in GP clinics is an important component of a multipronged strategy to increase equitable participation in cervical screening.

ACKNOWLEDGEMENTS

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Change: addressing youth addiction via digital innovation

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BACKGROUND

Addiction in young people is a global concern; however, access to treatment is poor. Specifically, there are few options addressing behavioural addictions such as gambling and social media. Digital interventions focussed on addiction can meet this treatment gap; however, few of these are designed for young people.

AIMS

To create a digital intervention for youth addiction treatment.

METHODS

We consulted with young people and addiction clinicians to develop a framework for digital addiction treatment. We collaborated with software and design experts to incorporate this into "Headstrong", a rule-based chatbot accessible via a native app. We created scripts that were adapted and inputted into

the chatbot software system. Feedback from youth consumers was sought.

RESULTS

Beta versions of preliminary modules have been developed and released on the Headstrong app and platform. Youth consumer feedback has been positive and has been used to refine and improve the modules.

DISCUSSION

Change is designed as three courses based on psychoeducation and harm minimisation (Get Smart), motivational interviewing (Explore It) and cognitive behavioural therapy (Make tracks). Each course contains five to eight modules covering information (e.g., Safe Partying, Porn) or adapted psychological interventions (e.g., values activity, coping with cravings). Badges, memes, GIFs, audio clips and interactive quizzes are used to engage and entertain users.

CONCLUSION

The Headstrong digital app is an ideal platform upon which to provide addiction interventions. As digital youth addiction treatment options are scarce, the Change Headstrong course has the potential to fill a key treatment gap.

ACKNOWLEDGEMENTS

Health New Zealand – Te Whatu Ora.

Intensive care unit staff perceptions of redeployment to other clinical areas: a mixed method approach

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Health New Zealand Te Whatu Ora – Waitematā ICU

BACKGROUND

Nurse redeployment is not a new practice in the intensive care unit (ICU) and high dependency unit (HDU); it has become much more significant during the COVID-19 pandemic to address the staffing deficit in other clinical areas. Redeployment helps in controlling varying patient acuity and census. In 2022, around 5,537 nursing hours of redeployment occurred for registered nurses and healthcare assistants in the study ICU/HDU. According to the available statistics from the study ICU, when there are extra staff in the unit, managers send staff to another unit where there is a shortage. However, deployment from another unit to study ICU is never practiced.

AIMS

To explore the perceptions of intensive care unit staff deployed to other clinical areas and identify challenges that the staff face during redeployment.

METHODS

Forty nurses and HCAs completed an anonymous online questionnaire, and five nurses participated in one-to-one semi-structured interviews. Participants were recruited through purposive sampling from the selected ICU/HDU.

RESULTS

Content analysis of the data revealed three major themes: "Negative feelings of redeployment", "Positive feelings of redeployment" and "Visible and structured leadership interventions".

DISCUSSION

Our results showed that ICU nurses reported an increased level of stress, anxiety, feelings of unsafe, low morale and dissatisfaction. Positive perceptions include friendliness and warm welcome by ward nurses. Participants suggested redeploying ICU nurses in the specialised area, discussing redeployment in the interview and redeployment allowances would boost nurses' morale.

CONCLUSION

This research will create insight into the redeployment of intensive care unit staff to other clinical areas. It will add value to patient safety and improve institutional healthcare policies.

ACKNOWLEDGEMENTS

Researchers appreciate Ms Kathryn Tennant, an external qualitative researcher, for conducting the face-to-face interviews. We also would like to thank all the study participants.

Immunoglobulin A vasculitis in Aotearoa: incidence, clinical features, treatment and outcomes

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Health New Zealand Te Whatu Ora – Waitematā Renal, The University of Auckland Department of Medicine

BACKGROUND

Immunoglobulin A vasculitis (IgAV) is a small vessel vasculitis. Few studies describe outcomes in adults.

AIMS

To describe the incidence, clinical features and outcomes in adult patients, with renal biopsy proven IgAV over an 18-year period.

METHODS

Ethical approval was obtained (AHREC 25461). Potential cases were identified, in patients over the age of 16 years, who underwent renal biopsy between 2003–2020. A retrospective review was performed. Data were analysed using SPSS 29.

RESULTS

The incidence was 2.09 cases per 100,000 patient-yrs with no excess by ethnicity. Mean age at presentation was 42.8 yrs (range 16.4–70.5 yrs). Mean creatinine at presentation was 118µmol/L (range 51–410µmol/L).

Twenty-six patients received corticosteroids (CS), with two patients also receiving cyclophosphamide and five patients also receiving azathioprine.

Six patients (17.6%) needed dialysis, with four patients going on to receive a renal transplant. At end of study, 12 (35.3%) patients had chronic kidney disease (CKD). Four patients (11.8%) died.

DISCUSSION

We saw an incidence of renal biopsy proven IgAV of 2.09 per 100,000 patient-years, greater than the incidence of historic hospital-based cohorts in adults (0.8–1.1 per 100,000 patient-years).

The majority of patients (76.5%) received CS, with a fifth of patients (20.6%) receiving concurrent therapy with azathioprine or cyclophosphamide. Use of these medications did not impact on the future need for RRT.

CONCLUSION

We see an incidence of IgAV of 2.09 cases per 100,000 patient-years. Morbidity was high, with 17.6% needing RRT and 35.5% having CKD with 11.8% mortality.

Te Oranga Pūkahukahu: Māori participant experiences of the first lung cancer screening study in New Zealand

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Health New Zealand Te Whatu Ora – Waitematā, Te Toka Tumai and Māori Health
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BACKGROUND

In Aotearoa, lung cancer (LC) is the greatest contributor to inequity in mortality for Māori. Lung cancer screening (LCS) using low dose CT demonstrates significant mortality reduction; however, no population-based testing has been conducted in Aotearoa, and internationally no studies have focussed on equity or Indigenous people.

AIMS

The effectiveness of LCS has not been determined for any Indigenous population, hence we tested the assumptions and study processes relevant to the implementation of LCS in Aotearoa.

METHODS

We assessed our approach using established implementation frameworks. Whānau support was welcome across the process. Participants and whānau were invited to provide feedback through post participation surveys regarding:

- Their experience of LCS
- The acceptability of the shared decision-making/results management processes
- Participant burden.

RESULTS

Survey participation rates were 55% for participants having a CT scan, 29% for those undergoing risk assessment but who were not eligible for a CT scan and 27% for those eligible for CT who decided not to proceed. Most participants were happy to take part, while some felt anxious. Ninety-seven percent of participants remembered the study nurse explaining the risks and benefits when deciding whether to have a CT scan, and 87% of participants felt that this discussion helped them to take part.

DISCUSSION

Respondents were positive regarding their experience, with some suggestions for improvement.

CONCLUSION

Developing LCS acceptable to Māori participants will be essential to ensuring equitable uptake of a future national programme. This study provides important implementation context for LCS in Aotearoa.

ACKNOWLEDGEMENTS

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Systemic lupus erythematosus (SLE) patients in Auckland, New Zealand: attainment of lupus low disease activity (LLDAS), prevalence and ethnic differences in renal disease

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BACKGROUND

Systemic lupus erythematosus (SLE) is a multi-system autoimmune disorder with diverse clinical manifestations. There is a lack of SLE research in New Zealand.

AIMS

To assess attainment of lupus low disease activity state (LLDAS) in the Auckland cohort of Asia Pacific Lupus Collaboration Treat to Target study. Additional aims include examining clinical features, prevalence and understanding lupus nephritis outcomes in different ethnic groups.

METHODS

All patients fulfilled either 1997 ACR or 2012 SLICC SLE classification criteria. At each study visit (3 to 6 monthly), patients were assessed prospectively for flares using SLEDAI-2K. Information on demographics and clinical data were collected. Patients were assessed annually for SLE damage.

RESULTS

A total of 144 patients from three Auckland hospitals (Waitematā, Auckland and Middlemore) were recruited during 2018–2020. Seventy-six percent (n=109) of patients achieved LLDAS at least once. Lupus patients in Middlemore Hospital had lower LLDAS attainment (40%) compared to the other two hospitals (88–90%; p<0.001).

Arthritis (n=115, 80%), was the most common clinical feature. Asian (n=23/60, 38%) and Pacific people (n=9/28, 32%) had more renal disease (p=0.03). Pacific people had proportionally more proliferative (Class III/IV) lupus nephritis (n=8/9, 89%; p=0.046). The prevalence of SLE in Auckland is 56.9 per 100,000.

DISCUSSION

The differences in LLDAS attainment and ethnic disparities in lupus nephritis highlight the need for access to funded targeted SLE drugs in New Zealand.

CONCLUSION

This is the first New Zealand study to provide prospective data on SLE disease activity and damage. There are ethnic differences in the ability to achieve LLDAS and lupus nephritis outcomes.

ACKNOWLEDGEMENTS

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Review of quality of smoking data in primary care practices comparing to smoking data from the New Zealand Māori and Pacific Abdominal Aortic Aneurysm screening programme.

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BACKGROUND

Accurate smoking data is essential for assessing smoking-related health risk and eligibility for interventions based on smoking status. Smoking information collected in primary care practices (PCPs) is widely used as a major data source.

AIMS

To assess PCP smoking data quality comparing to the data from the Māori and Pacific Abdominal Aortic Aneurysm (AAA) screening programme.

METHODS

The PCP smoking data was extracted and compared with the smoking data collected from participants at the AAA screening session. The concordance was assessed using kappa scores. For a subset of participants who had discordant smoking status, their longitudinal PCP smoking records were reviewed. Data was compared in three groups: current smoker (smoke at least monthly), ex-smoker (stopped >1 month ago) and never smoker (smoked <100 cigarettes in lifetime).

RESULTS

Of the 1,841 people who underwent AAA screening, 1,716 (93%) had PCP smoking data recorded. PCP smoking data showed 82% concordance with the AAA data (adjusted kappa 0.76). Fewer current or ex-smokers were recorded in the PCP data. Among 93 participants still enrolled in the participating PCPs, 43% had their smoking status updated. Details on quantity, duration or quit date of smoking were largely missing in PCP records.

DISCUSSION

PCP smoking data quality is consistent with international findings. Given the misclassification and missing detail on quantity and duration, smoking status-based intervention programmes (e.g., lung cancer screening, AAA screening, cardiovascular risk assessment) should consider complementary mechanisms to ensure eligible individuals are appropriately invited to the programme.

CONCLUSION

Ongoing quality improvement of PCP smoking data is important, alongside alternative mechanisms to identify smokers for programmes based on smoking-related risk.

ACKNOWLEDGEMENTS

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participating PCPs and the primary care leadership who supported this audit during a period of ongoing COVID-19 related disruption. KP is supported by a New Zealand Heart Foundation Heart Health Research Trust fellowship.

Refeeding hypophosphataemia and syndrome in parenteral nutrition: a single centre experience

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Health New Zealand Te Whatu Ora – Waitematā

BACKGROUND

Refeeding syndrome (RFS) is a potential complication of restarting nutrition. NICE guidelines assess the risk of developing RFS. No consensus exists currently within the proposed definitions of RFS and refeeding hypophosphataemia.

AIMS

Assess prevalence of RFS within patients receiving parenteral nutrition (PN). Identify risk factors, where possible.

METHODS

Included were patients receiving PN for ≥48 hours (October 2017–February 2022). Electrolyte abnormalities were corrected prior to initiating PN, with initial half macronutrient provision for those at risk. Data were collected from nutrition and laboratory databases. Clinical records of cases meeting biochemical criteria for RFHP/RFS were reviewed. Risk factor analyses were performed using logistic regression. Explanatory variables investigated included patient age, period NBM, BMI, recent weight loss, baseline magnesium and potassium levels.

RESULTS

A total of 354 cases received PN for at least 48 hours. According to NICE criteria: 199 were high risk (1 risk factor), 123 were moderate risk (2+ risk factors) and 32 were minimal risk. Seventy-one cases met criteria for RFS/RFHP (all asymptomatic). Logistic regression using the combined set of criteria identified baseline potassium and weight loss as being the only explanatory variables that reached statistical significance (p=0.047, p=0.0157). The predictive model generated failed to predict development of RFS when tested against the patient dataset.

DISCUSSION

Clinically significant RFHP/RFS is avoided with correction of electrolytes prior to, and reduced macronutrient provision upon starting PN. No contributory factors were identified that could predict development of RFS.

CONCLUSION

Current practice mitigates risk of developing symptomatic RFS in our patient group.