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Summaries

Thoracic Society of Australia and New Zealand position statement on chronic suppurative lung disease and bronchiectasis in children, adolescents and adults: what is new and relevant to Aotearoa New Zealand?

Paul Dawkins, Betty Poot, Sarah Mooney

Bronchiectasis is a condition where the airways in the lung become enlarged and are plugged with mucus. It is a long-term condition that affects both children and adults. It can lead to daily coughing and phlegm and often leads to recurrent chest infections. This condition can get worse over time, but with proper management it can remain stable or improve. This article summarises key recommendations for the diagnosis and treatment of bronchiectasis. It highlights the importance of achieving equal outcomes for Māori and Pacific people and a team approach to care.

Trends in obesity among 4-year-old children in New Zealand—pre- and post-COVID comparison

Sheetalpreet Singh, Timothy Jelleyman

Soon after the COVID-19 lockdown there was a notable increase in obesity among 4-year-olds in New Zealand. The impact was greatest among Pacific peoples, those living in deprived areas and in the Auckland Region where there was a longer period of lockdown. Children need to be supported with a healthy lifestyle, especially during disruptions such as pandemics. Ongoing monitoring of trends can guide public health policy and action.

Te Matahouroa: a feasibility trial combining Rongoā Māori and Western medicine in a surgical outpatient setting

Jonathan Koea, Glennis Mark, Donna Kerridge, Amohia Boulton

Four patients of varying ethnicities participated in a trial combining Western medicine and Rongoā Māori in a surgical outpatient setting. Patients were seen by both a consultant surgeon and a Rongoā practitioner. Both patients and practitioners reported high levels of satisfaction in working together in a collaborative environment that provided patient- and whānau-centred care.

Changes in sodium valproate dispensing in women of childbearing age with a diagnosis of borderline personality disorder in Aotearoa New Zealand

Matthew Tennant, Chris Frampton, Roger Mulder, Kate Eggleston, Ben Beaglehole

Psychological and psychosocial interventions are the recommended treatments for borderline personality disorder. There are no licenced medications for treatment of borderline personality disorder. Sodium valproate is associated with a high risk of major congenital malformations, occurring in approximately 10% of exposed offspring. In addition, sodium valproate exposure during pregnancy is associated with increased risk of intellectual disability and neurodevelopmental disorders, reported to affect 30–40% of exposed offspring. In the past, sodium valproate has been used "off label" for mood instability in borderline personality disorder. This is no longer recommended. In 2014, 10% of women of childbearing age diagnosed with borderline personality disorder were treated with sodium valproate. This reduced to 6% of women in 2019. In 2014, there was substantial ethnic disparity with 18.1% of Māori women and 15.8% of Pacific women dispensed sodium valproate compared with 7.4% of New Zealand Europeans. This disparity reduced in 2019, with 6.4% of Māori women and 12.5% of Pacific women dispensed sodium valproate compared.

Durable ventricular assist devices for patients with advanced heart failure: the New Zealand experience

Conor W Rea, Thomas F Pasley, Peter N Ruygrok, Amul Sibal

The prevalence of heart failure in New Zealand is increasing. A small number of select patients, with predicted poor short-term survival, are candidates for advanced heart failure therapies such as transplantation and durable mechanical circulatory support (MCS). The aim of our study was to introduce left ventricular assist devices to the wider clinicians and highlight their contemporary role in managing patients with advanced heart failure in New Zealand.

Using quality indicators to assess performance of endobronchial ultrasound in the staging and diagnosis of lung cancer: a pre/post study at a New Zealand centre

Paul Griffiths, Jeong Suk Oh

Lung cancer is a major cause of illness in New Zealand, and it is vital that people are accurately diagnosed so that appropriate treatment can be given. Endobronchial ultrasound (EBUS; a camera test to look into the airways/lungs and take biopsies) is a test that can be used to diagnose and stage lung cancer; however, we do not really know how good our EBUS service is unless we look in to it. Through looking at our service, we have seen that a high-quality service is being provided when compared to international quality standards (these are statements that represent best practice), and that by monitoring performance over time we have been able to identify areas that can be changed so that the quality of EBUS can be further improved.

Concomitant septic and crystal arthropathy: a single-centre 10year retrospective observational study in New Zealand

Saptarshi Mukerji, Padraig Ryan, Harnah Simmonds, Jessica Buckley, Jane Birdling

Patients presenting to the emergency department (ED) with an infected joint (septic arthritis), or an inflamed joint due to microcrystal deposition within the joint space (crystal arthritis), are a common occurrence. The diagnosis of these conditions can be challenging for emergency physicians who must rely on clinical interpretation and examination to diagnose these conditions, and initiate early treatment prior to receiving finalised investigation results. Patients with both these conditions simultaneously are at risk of misdiagnosis of crystal arthritis alone. This study quantifies and characterises patients presenting to ED with septic arthritis, crystal arthritis, and simultaneous septic and crystal arthritis. Risk factors were identified and statistically evaluated. Traditional diagnostic criteria were evaluated and updated guidelines were recommended in keeping with study results and statistical analysis.

The long COVID conundrum from a New Zealand perspective

Angus Mackay

The prevalence of long COVID remains unclear, especially in New Zealand, where it could be considerably less, but this needs to be verified so that appropriate action can be taken by the Ministry of Health (Manatū Hauroa). Rudimentary clinical case definitions provided by the World Health Organization and others need urgent updating, as it has become increasingly clear that long COVID is much more complex than first thought, and made up of several different distinct sub-groups, including one major sub-group related to SARS-CoV-2 afflicted organ damage (primarily lungs) and another major sub-group (maybe 50%) who have post-viral fatigue syndrome, resembling myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). However, most prevalence and patient studies, crucially, have not utilised ME/CFS diagnostic criteria to help identify which sub-group patients might belong to, and without such characterisation of "patient sets" results have been difficult/impossible to interpret. In addition, a "de novo" neurological-

centred/neuroinflammatory model revolving around a dysfunctional paraventricular nucleus (PVN), the "stress centre" within the hypothalamus (the "master gland") of the brain, in genetically susceptible individuals, has been proposed for long COVID related post-viral fatigue syndrome (& ME/CFS). Thereby, a "call" is made for more "brain-focussed" research (away from traditional but, to date, largely fruitless "blood-based" research).

A case of oesophageal foreign body migration into the thyroid gland

Leon Kong, James Sanders

In this paper, we describe a patient who presented with sore throat and trouble swallowing. She denied swallowing any foreign body. Radiological imaging (X-ray and computed tomography) raised concern for a retained foreign body in the neck. Endoscopy in the gullet (oesophagoscopy) did not show a foreign body. She required multiple surgical procedures including endoscopy and removal of half the thyroid lobe before the foreign body was found. We discuss ways to manage this condition, especially when it is not a straightforward case.

Does iodised salt sold in New Zealand contain enough iodine?

Nan Xin Wang, Sheila A Skeaff, Claire Cameron, Rachael M McLean

It is important for children and people who are pregnant to have adequate iodine intakes for normal growth and development of infants and children. In New Zealand we add iodine to table salt to supplement intakes. We tested iodine levels in iodised salt and found that levels had dropped compared to previous studies. Two salts had iodine concentrations that were below required levels.

Blood pressure monitoring devices in healthcare facilities of the Manawatū-Whanganui Region

Kian Jones, Albert Robertson, Norman Panlilio, Ankur Gupta

This study looked at the devices used to measure blood pressure in healthcare facilities in the Manawatū-Whanganui Region of New Zealand. High blood pressure, which affects many adults, can lead to serious health problems if not diagnosed and treated correctly. The devices used to measure blood pressure need to be accurate, but many are not. This study found that a large number of these devices are proven to be inaccurate, which can lead to incorrect treatment. The study compared local devices to a trusted database of accurate devices to see if they meet international standards.

Thoracic Society of Australia and New Zealand position statement on chronic suppurative lung disease and bronchiectasis in children, adolescents and adults: what is new and relevant to Aotearoa New Zealand?

Paul Dawkins, Betty Poot, Sarah Mooney

The landscape of bronchiectasis management has evolved significantly since the Thoracic Society of Australia and New Zealand (TSANZ) Guidelines were last updated in 2015. An updated position paper has been developed in response to emerging evidence and the need for a comprehensive approach to bronchiectasis care. This position paper, available on the Respirology journal's open access platform and the TSANZ website, addresses the management of this complex, heterogeneous condition, particularly highlighting the importance of multidisciplinary collaboration, integration of new evidence and recognition of specific needs in the care of children and youth. Equity of care and outcomes in Indigenous and Pacific populations is of particular relevance. The position paper brings to light gaps in funding, as some recommended treatments are unavailable in Aotearoa New Zealand.

Introduction

Bronchiectasis is a chronic condition characterised by cough and sputum production, recurrent respiratory infection and bronchial dilatation on computed tomography (CT) scan.¹ Bronchiectasis continues to present significant challenges to healthcare systems and professionals. Children/youth and adults of Māori and Pacific ethnicity are over-represented in Aotearoa New Zealand, have more severe bronchiectasis independent of socio-economic status² and have higher hospitalisation rates³ and respiratoryrelated mortality.⁴ This updated position paper,⁵ developed by a multidisciplinary team including physicians, physiotherapists, a respiratory nurse, an Indigenous academic and health consumer representatives, is a comprehensive update to previous recommendations. It is the product of a collaborative approach to improving patient outcomes across diverse healthcare settings.

Methodology

This contemporary position paper updates the 2015 guidelines.⁶ Methodology, incorporating a systematic review of updated literature, was undertaken based on the TSANZ recommended process for producing position papers. Adult bronchiectasis guidelines from the European Respiratory Society in 20177 and British Thoracic Society in 20198 were used as historical references, together with the 2021 European Respiratory guidelines for the management of children and adolescents with bronchiectasis,9 with which the TSANZ position paper is compatible. A total of 32 recommendations were revisited, with 28 undergoing modifications based on new evidence and expert opinion. Additionally, one new recommendation was introduced. A Delphi process had representation from a wide range of clinicians (including a physician, paediatrician, nurse and physiotherapist from Aotearoa New Zealand), which ensured the guidelines are representative and reflective of current best practices in Aotearoa New Zealand.

Why is the position paper important?

Following guideline-concordant treatment will improve the morbidity and possibly the mortality of our bronchiectasis population¹⁰ within the unique context of Aotearoa New Zealand. There are financial implications to the health service of using treatments that are inappropriate, outdated or have little evidence base. Furthermore, there are cost implications of not providing evidence-based treatment, both to the health service in terms of dealing with the consequences of poorly controlled chronic disease and for the patients in terms of health outcomes and quality of life. Therefore, appropriate resource allocation to bronchiectasis services is essential, including adequate staffing.

Key updates and recommendations

The updated position paper introduces significant changes and additions, including:

- A refined definition of bronchiectasis and the aims of optimal management, focussing on preserving lung function, enhancing quality of life, minimising exacerbations and preventing complications. Specifically for children and youth, there are further aims of optimising lung growth and, where possible, reversing any structural injury.
- Some detailed recommendations for diagnostic investigations, distinguishing between minimal and extended tests separately for adults and children. Treatable causes such as primary ciliary dyskinesia, allergic bronchopulmonary aspergillosis, non-tuberculous mycobacteria, immunodeficiency, cystic fibrosis and alpha-1 antitrypsin deficiency are emphasised.
- An updated antibiotic selection guideline, with specific emphasis on the eradication of *Pseudomonas* on its first isolation, based on its implications for patient prognosis (exacerbations, hospitalisations and mortality) and quality of life.
- The inclusion of long-term oral macrolides, and nebulised antibiotics (in the context of chronic *Pseudomonas* infections) to decrease bacterial load and airway inflammation and reduce exacerbations.
- An emphasis on treatable traits in the management of comorbidities, both phenotypic and endotypic. This is an important change of approach, also used in other airway and pulmonary diseases, where the heterogeneity of the disease is addressed by looking separately at

aetiological, pulmonary, extrapulmonary and environmental or lifestyle factors.

• A multidisciplinary approach of individualised care is emphasised as a way to reduce barriers, improve adherence to treatment and provide culturally responsive healthcare.

Addressing equity and access

The position paper has a strong emphasis on equity, which is particularly relevant in the Aotearoa New Zealand context. Two of the statements address equity issues in Indigenous populations and hard-to-reach populations. The position paper highlights the challenges to and obligations of ensuring Māori have equitable access to healthcare resources, stressing the importance of early diagnosis, individualised management including education and resource access, and community engagement, while acknowledging more flexible and adaptive arrangements are required. This is in line with Te Tiriti o Waitangi obligations. There is a very high incidence of bronchiectasis in the New Zealand Pacific population and engaging with Pacific leaders in the community is important, as well as the provision of cultural support staff and interpreters.

Transitional care

A new statement outlines the importance of transitional care to meet the needs of adolescents with bronchiectasis. This involves engagement of paediatric and adult multidisciplinary team services, clear and documented plans for transfer of care and evidence-based guidelines on transition and bronchiectasis management.

Funding challenges

The position paper recommendations bring to light funding challenges and highlight the gap between Aotearoa New Zealand and Australia. For instance, long-term azithromycin is not funded for adults at present. Nebulised antibiotics are recommended in this position paper and other guidelines, but there is no public funding of required resources. Nebulising equipment and their servicing and monitoring are not provided, at the time of writing, for antibiotics or saline preparations. Nor are hypertonic saline nebules funded for the selected patients with tenacious

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secretions who benefit from improved sputum clearance in order to improve their quality of life. The pneumococcal vaccine is also not funded for adults with bronchiectasis outside of immunodeficiency and some specific comorbidities. The health service needs commitment to multidisciplinary clinics and resources for this chronic disease.

Implementing the recommendations

Position papers and guidelines only function if they are implemented, and there is a clear evidence-practice gap across the field of medicine.¹¹ TSANZ arranged webinars across their membership, including in Aotearoa New Zealand. A webinar was delivered via the Goodfellow Unit in order to reach the primary care community. Physiotherapy and nursing have also delivered to their respective forums. The Australian authors of the position paper have recently published a parallel perspective article in the Medical Journal of Australia.12 New information leaflets, checklists and personal management plans have been published under the joint banner of TSANZ and the Asthma and Respiratory Foundation NZ (https:// www.asthmafoundation.org.nz/health-professionals/australia-and-new-zealand-bronchiectasis-guidelines). A clinician- and patient-focussed consensus and quality standard document is planned, similar to the British Thoracic Society,13 in order to drive improvement.

Future research

Position papers and guidelines are only as good as the evidence from which they draw upon. Many statements in the current position paper still rely on expert experience and opinion. For future clinical studies, it is paramount that the right populations are studied, the right interventions are used and the right end points are measured. The heterogeneity of bronchiectasis has impeded the developments of new therapies, and the proper selection and stratification of people with bronchiectasis for clinical trials is essential for the future. This could be achieved by grouping people with bronchiectasis by shared phenotypes or endotypes. Consistent and standardised definitions of end points (particularly regarding exacerbations) are essential in this regard.¹⁴ Minimum important outcome sets (agreed on by patients and clinicians) and patient-reported outcomes need to be incorporated into trials.15

Conclusion

The updated TSANZ position paper for bronchiectasis management represents a significant step towards a more effective, equitable and patient-centred approach to care in our region. By incorporating the latest evidence, emphasising multidisciplinary collaboration and addressing the unique needs of children, adolescents and Indigenous populations, this position paper sets the current standard for the management of bronchiectasis in Aotearoa New Zealand. To meet these standards, the gap in funding the basic recommended therapies must be addressed. Future research focussed on the heterogeneity of the condition, person-centred and culturally responsive approaches and interventions. together with consistent outcomes, will be crucial for continuing to refine and improve bronchiectasis care.

COMPETING INTERESTS

Nil.

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Trends in obesity among 4-year-old children in New Zealand—pre- and post-COVID comparison

Sheetalpreet Singh, Timothy Jelleyman

ABSTRACT

AIMS: We described long-term trends in obesity using preschool data from New Zealand and compared rates pre- and post-COVID by key demographic variables.

METHODS: Growth data from the B4 School Check (B4SC) information system for the period 1 July 2012 to 30 June 2022 were used to calculate obesity rates. The date 25 March 2020 was the threshold used to compare the rates between pre- and post-COVID periods. Obesity rate ratios for these two periods were calculated for each demographic sub-group.

RESULTS: The overall obesity rate increased by 1.8% after COVID-19. Males had higher obesity rates and a greater absolute increase (2%) in the post-COVID period. The greatest absolute increase in obesity was among Pacific peoples (4.3%), followed by Māori (2.2%). Children in most deprived areas and those in the Auckland Region had greater absolute increases of 3% and 2.5% respectively, post-COVID.

CONCLUSION: The COVID-19 lockdown has had an immediate impact on obesity rates among 4-year-old children, especially for the Pacific population, those living in high deprivation areas and regions with longer periods of lockdown (Auckland). There are implications for public health policy and practice to support children in adopting a healthy lifestyle, especially during pandemics.

C hildhood obesity has considerable impacts on the physical and psychological wellbeing of children. Obesity during childhood increases the risk for metabolic, cardiovascular, orthopaedic, hepatic and renal disorders, including psychosocial issues such as poor self-esteem, vulnerability to bullying, behavioural and learning issues.¹

The prevalence of obesity among 2–14-yearolds in New Zealand increased from 9.5% in 2019/ 2020 to 12.7% in 2020/2021 (about 3% absolute increase) based on the New Zealand Health Survey.²

Similar increases in obesity rates have been seen internationally, e.g., in the UK (from 9.9% to 14.4% among 4–5-year-olds),³ USA (13.7% to 15.4% among 2–17-year-olds)⁴ and China (from 10.4% to 12.8% among 6–17-year-olds).⁵ There is evidence from international literature that COVID-19 lockdown periods have contributed to the increase in overweight/obesity rates, whereby confinement, reduced opportunities for physical activity, more screen-time and possible changes in eating habits created an obesogenic environment.

This descriptive analysis was conducted using B4 School Check (B4SC) data to see if the increase in childhood obesity rates observed in the New Zealand Health Survey also occurred in young children, and to understand the potential impact of COVID-19.

The objectives of this report are to:

- Illustrate trends in obesity over a 10-year period (2012/2013 to 2021/2022) using the B4SC data.
- Analyse differences in obesity rates pre- and post- the COVID period (between 2018/2019 and 2021/2022) and stratify results by demographic variables.

Method

Data were obtained from the B4SC database for the financial years 2012/2013 to 2021/2022 covering the period 1 July 2012 to 30 June 2022, and long-term rates in obesity were plotted.

The B4SC is a national programme that offers a free health and development check for all 4-yearolds in New Zealand to identify and address any health, behavioural, social or developmental concerns that could affect a child's ability at school.⁶ The checks are conducted by registered nurses in child health and vision and hearing technicians.

Height and weight measurements are taken based on guidelines outlined in the B4SC

practitioner's handbook.⁷ Height is measured using a portable stadiometer placed on a hard surface with the child standing upright, heels touching the base of the stadiometer and head in Frankfort plane. Weight is measured using an electronic floor scale on a hard surface. The guideline advises two readings for each anthropometric measurement, and the result is the average of the two readings reported to 0.1cm or 0.1kg.

Body mass index (BMI) is calculated by dividing the weight (in kilogrammes) by the square of the height (in metres). A child is classified as obese if their BMI is greater than the 98.0th percentile for their age and gender, as per the definition used in performance reports produced by the Ministry of Health – Manatū Hauora. The World Health Organization (WHO) standard tables are used for obtaining the growth percentile information.⁸

For pre- and post-COVID comparison by subgroups, data only for the financial years 2018/2019 to 2021/2022 were used. Records with unknown gender and missing deprivation information were excluded, amounting to less than 1% of records. Consistent with performance reporting, prioritised ethnicity was used. This refers to a method whereby individuals who identify with more than one ethnic group are assigned to a single group based on a pre-determined hierarchy. The child's prioritised ethnicity is derived by selecting the highest ranked of (up to) three distinct ethnicity classifications assigned to the child as imported from the child's record on the primary health organisation (PHO) enrolment register. Details on the rankings can be found elsewhere.⁹ Obesity rates were plotted for the financial years 2018/2019 to 2021/2022 by guarters. B4SCs done after 25 March 2020 were classified as post-COVID cohort; checks prior to this date were classified as pre-COVID. Differences in obesity rates between pre-COVID and post-COVID were compared, and results were stratified by sex, ethnicity, neighbourhood deprivation and location (i.e., Auckland and non-Auckland regions). The Auckland Region combined the results for Auckland, Counties Manukau and Waitematā districts, the remainder classified as non-Auckland Region. Depending on the completion date of the check, the New Zealand Index of Deprivation (NZDep), based on either the 2006 or 2013 Census, was used to estimate the relative socio-economic deprivation of an area. This was grouped into quintiles, where quintile 1 represents the 20% of areas with the lowest levels of deprivation and quintile 5 represents the 20% of areas with the highest level of deprivation. Rate ratios were used to compare the obesity rates between the periods. As this is a population-based study, no tests of statistical significance were conducted.

To outline longer-term trends, obesity rates at the national level were plotted from 2011 to the latest available data at the time of the analysis (as of 8 July 2022).

Results

Completed checks

The ethnic distribution of completed checks was fairly stable over the years, except for a slight increase in the last 3 years among Māori and a corresponding decrease among Pacific peoples compared to the yearly average prior to COVID-19 (Table 1). The distribution of completed checks by deprivation in the recent 3 years shows a decrease among those in the highest deprivation category. Completed checks that occurred in the Auckland Region were substantially lower in 2021/2022 compared to the yearly average prior to COVID-19. The disproportionate decrease in completed checks among certain sub-populations, such as Pacific peoples and those in the most deprived communities (quintile 5), may have an impact on our interpretation of obesity rates in the post-COVID period.

The intersectionality of ethnicity and deprivation is illustrated for the Auckland and non-Auckland regions (Figure 1, 2) below. These show that the majority of Pacific peoples live in the most deprived areas, followed by Māori, particularly in the Auckland Region.

Trends in obesity rates

The obesity rate was on average 8.9% between quarter one 2012/2013 to the quarter two 2015/2016 year (Figure 3). The rate gradually decreased to an average of 7.6% between quarter one 2015/2016 to the end of the quarter two 2019/2020 year.

The number of checks dropped to about 4,000 in the last quarter of 2019/2020 when New Zealand moved to Alert Level 4 in response to COVID-19, during which the obesity rate was 8.7%. While the number of checks increased in the first two quarters of the 2020/2021 financial year, the obesity rate continued to increase, and was on average 9.0% during 2020/2021. There was a second national lockdown in quarter three of the 2020/2021 year, but the number of checks completed was of similar magnitude relative

Table 1: Demographic characteristics of children with completed B4SC.

Demographic characteristics	n (%)	n (%)										Yearly average prior to COVID-	Yearly average
	Total	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	19 (2012/2013– 2018/2019)	post-COVID (2019/2020- 2021/2022)
Gender													
Male	269,018 (51.3%)	26,020 (51.5%)	29,498 (51.6%)	29,091 (51.3%)	28,515 (51.2%)	29,245 (51.1%)	28,309 (51.2%)	28,232 (51.5%)	22,738 (51.4%)	27,600 (51.1%)	19,770 (50.9%)	51.3%	51.1%
Female	255,452 (48.7%)	24,492 (48.5%)	27,691 (48.4%)	27,604 (48.7%)	27,177 (48.8%)	27,937 (48.9%)	27,029 (48.8%)	26,537 (48.5%)	21,534 (48.6%)	26,397 (48.9%)	19,054 (49.1%)	48.6%	48.9%
Ethnicity													
Māori	121,188 (23.1%)	10,014 (19.8%)	11,840 (20.7%)	12,607 (22.2%)	12,888 (23.1%)	13,913 (24.3%)	13,355 (24.1%)	13,025 (23.8%)	10,404 (23.5%)	13,254 (24.5%)	9,888 (25.5%)	22.6%	24.5%
Pacific peoples	53,554 (10.2%)	4,821 (9.5%)	5,757 (10.1%)	6,227 (11.0%)	6,065 (10.9%)	6,047 (10.6%)	5,814 (10.5%)	5,557 (10.1%)	4,441 (10.0%)	5,391 (10.0%)	3,434 (8.8%)	10.4%	9.6%
Other	349,746 (66.7%)	35,686 (70.6%)	39,594 (69.2%)	37,861 (66.8%)	36,739 (66.0%)	37,223 (65.1%)	36,169 (65.4%)	36,188 (66.1%)	29,429 (66.5%)	35,353 (65.5%)	25,504 (65.7%)	67.0%	65.9%
Deprivation													
Quintile 1	101,702 (19.4%)	9,669 (19.1%)	10,886 (19.0%)	10,712 (18.9%)	10,585 (19.0%)	11,050 (19.3%)	10,719 (19.4%)	10,642 (19.4%)	9,098 (20.5%)	10,369 (19.2%)	7,972 (20.5%)	19.2%	20.1%
Quintile 2	97,222 (18.5%)	9,268 (18.3%)	10,542 (18.4%)	10,462 (18.5%)	10,359 (18.6%)	10,378 (18.1%)	10,258 (18.5%)	9,976 (18.2%)	8,508 (19.2%)	10,267 (19.0%)	7,204 (18.6%)	18.4%	18.9%
Quintile 3	96,798 (18.5%)	9,025 (17.9%)	10,551 (18.4%)	10,513 (18.5%)	10,254 (18.4%)	10,453 (18.3%)	10,259 (18.5%)	10,090 (18.4%)	8,392 (19.0%)	10,081 (18.7%)	7,180 (18.5%)	18.4%	18.7%

Quintile 4	100,152 (19.1%)	9,647 (19.1%)	11,239 (19.7%)	11,188 (19.7%)	10,403 (18.7%)	10,849 (19.0%)	10,411 (18.8%)	10,419 (19.0%)	8,204 (18.5%)	10,286 (19.0%)	7,506 (19.3%)	19.1%	19.0%
Quintile 5	125,841 (24.0%)	12,244 (24.2%)	13,560 (23.7%)	13,574 (23.9%)	13,912 (25.0%)	14,257 (24.9%)	13,539 (24.5%)	13,454 (24.6%)	9,885 (22.3%)	12,751 (23.6%)	8,665 (22.3%)	24.4%	22.8%
Location	Location												
Auckland	181,170 (34.5%)	16,982 (33.6%)	20,248 (35.4%)	20,933 (36.9%)	20,807 (37.4%)	20,831 (36.4%)	19,452 (35.2%)	19,309 (35.3%)	15,238 (34.4%)	18,549 (34.4%)	8,821 (22.7%)	35.7%	30.5%
Non-Auckland	343,318 (65.5%)	33,539 (66.4%)	36,943 (64.6%)	35,762 (63.1%)	34,885 (62.6%)	36,352 (63.6%)	35,886 (64.8%)	35,461 (64.7%)	29,036 (65.6%)	35,449 (65.6%)	30,005 (77.3%)	64.3%	69.5%

Table 1 (continued): Demographic characteristics of children with completed B4SC.

Figure 1: Intersectionality of ethnicity and deprivation quintile for completed checks in Auckland Region (2012/2013–2021/2022).

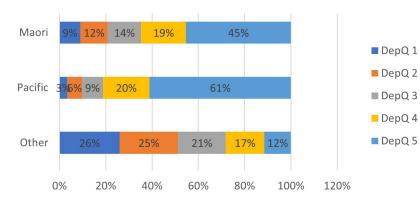


Figure 2: Intersectionality of ethnicity and deprivation quintile for completed checks in non-Auckland region (2012/2013–2021/2022).

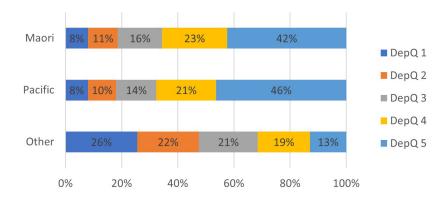


Figure 3: Obesity rates, 2012/2013-2021/2022.



Financial year quarters: q1 (Jul–Sep), q2 (Oct–Dec), q3 (Jan–Mar), q4 (Apr–Jun). National lockdown periods were between 25 March 2020 to 20 April 2020 and 17 August 2021 to 31 August 2021. For the Northland Region, the second lockdown period lasted from 17 August 2021 to 2 September 2021, while for Auckland Region it lasted from 17 August 2021 to 21 September 2021.

to similar time periods in previous years. The obesity rate dropped to 8.0% in quarters two and three of 2021/2022.

Comparison of obesity rates between pre- and post-COVID periods

A total of 188,247 children were included in the analysis from 1 July 2018 to 30 June 2022, of which 94,526 (50.2%) had their check during the post-COVID period (Figure 4). In the pre-COVID period there were on average about 14,000 checks per quarter compared to about 9,400 checks per quarter post-COVID. The overall obesity rate in the pre-COVID period was 6.9% compared to 8.7% during post-COVID period.

Gender

Males had higher obesity rates (Figure 5) and a slightly greater percentage point increase in the obesity rate post-COVID (2%) compared to females (1.6%) (Figure 6).

Ethnicity

The greatest percentage point increase in obesity rate was seen among Pacific peoples (4.3%), followed by Māori (2.2%) (Figure 8).

Deprivation

Obesity rates increased, moving from least to most deprived areas (Figure 9). The greatest percentage point increase in obesity was noted among children in quintile 5 (3%) (Figure 10).

Location—Auckland vs non-Auckland regions

During pre-COVID period, obesity rates were similar in both Auckland and non-Auckland regions (Figure 11). The increase in prevalence in Auckland Region occurred shortly after the lockdown in 2019/2020, while in non-Auckland Region a staggered increase was seen over 2020/2021. A significant increase in the rate was observed in Auckland during the last two quarters of 2021/2022 year. Children in Auckland Region had a greater percentage point increase in obesity (2.5%) post-COVID compared to those in non-Auckland Region (1.4%) (Figure 12).

Each demographic sub-group had greater obesity rates in the post-COVID period compared to the pre-COVID period, and overall, there was a 26% greater relative increase (Table 2). Similar relative increases in obesity rates were observed among Māori (21%), Pacific peoples (25%) and non-Māori non-Pacific peoples (29%). Children in the Auckland Region had a greater relative increase in obesity (37%) during the post-COVID period compared to those in the non-Auckland Region (21%). The greatest rate differences between preand post-COVID periods were observed among Pacific peoples (4.3%) and those in quintile 5 areas (3%).

Discussion

Prior to COVID-19, the B4SC data demonstrated a general decline in obesity rates among the

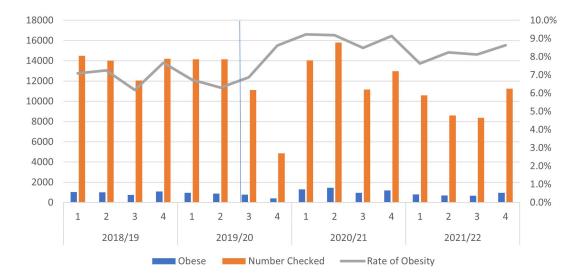


Figure 4: Trend in obesity rates, pre- and post-COVID.

Figure 5: Obesity rates by gender, 2018/2019–2021/2022.

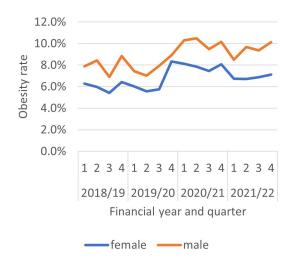
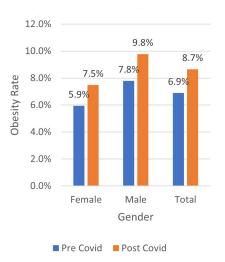


Figure 6: Obesity rates pre- and post-COVID, by gender.



4-year-old population in New Zealand. This downward trend was also reported by Daniels et al., whereby the declining prevalence was seen across all socio-demographic indicators.¹⁰ However, since the onset of COVID-19 and introduction of lockdown at the end of March 2020, obesity rates have increased by about 2% nationally, particularly in the first two quarters of 2020/2021, with variable increases among sub-populations.

Increasing rates of obesity among children and adolescents have been noted in other jurisdictions such as the UK, China, Austria and Israel. A systematic review of 12 studies from eight different countries demonstrated a significant increase in body weight gain among children (mean differences of 2.67) and rates of obesity (OR 1.23) during lockdown.¹¹ The UK's National Child Measurement Programme reported its largest increase in obesity prevalence, ranging between 3.3% and 5.6% among children in reception years and Year 6 in 2020/2021.¹² Similar rate increases of 3% and 5.5% have been observed in cohort studies in China¹³ and Austria.¹⁴ Shifts in BMI distribution are attributed to sedentary behaviour, increased screen-time, poor diet and irregular sleep patterns.¹¹ In New Zealand during the lockdown period, Early 2021/2022.

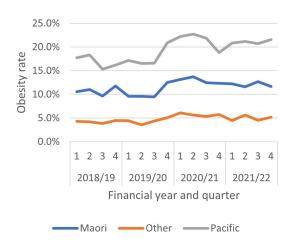
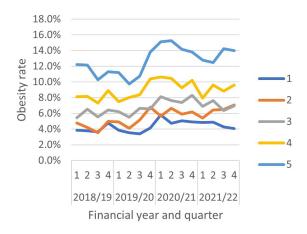
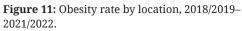


Figure 7: Obesity rate by ethnicity, 2018/2019-

Figure 9: Obesity rate by deprivation quintile, 2018/2019–2021/2022.





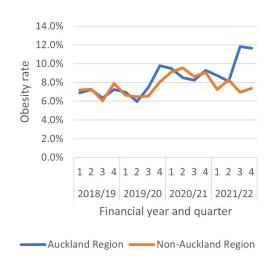


Figure 8: Obesity rates pre- and post-COVID by ethnicity.

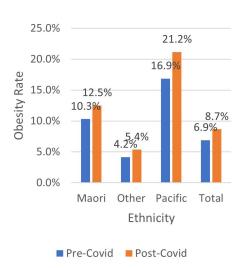


Figure 10: Obesity rates pre- and post-COVID, by deprivation quintile.

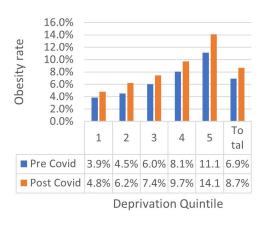
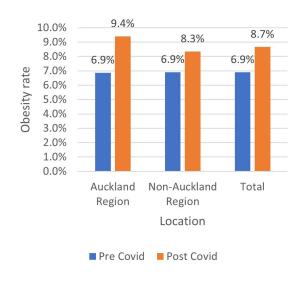


Figure 12: Obesity rates pre- and post-COVID, by location.



	Obesity rates			Rate difference
Population sub-group	Pre-COVID (%)	Post-COVID (%)	Rate ratio	(%)
Total population	6.9	8.7	1.26	1.8
Māori	10.3	12.5	1.21	2.2
Pacific peoples	16.9	21.2	1.25	4.3
Non-Māori, non-Pacific	4.2	5.4	1.29	1.2
Deprivation Quintile 1	3.9	4.8	1.25	1.0
Deprivation Quintile 2	4.5	6.2	1.37	1.7
Deprivation Quintile 3	6.0	7.4	1.23	1.4
Deprivation Quintile 4	8.1	9.7	1.20	1.6
Deprivation Quintile 5	11.1	14.1	1.27	3.0
Male	8.0	10.0	1.26	2.0
Female	5.9	7.5	1.26	1.6
Auckland Region	6.9	9.4	1.37	2.5
Non-Auckland Region	6.9	8.3	1.21	1.4

Table 2: Sub-group analysis of obesity pre- and post-COVID.

Childhood Education centres and kindergartens were mainly closed or catering for very small numbers of children. Therefore, care and learning moved to the home environment, with increased screen-time and reduced opportunity for recreational physical activity. The COVID Kai survey in New Zealand showed a general shift toward an unhealthy dietary pattern, with increases in consumption of sweet and salty snacks, including sugary drinks, during the lockdown.¹⁵

Consistent with several international studies, our analysis shows a greater absolute increase in obesity rates among boys than girls.^{13,16} One of the reasons offered is the proportionally greater impact for boys with a more physically active profile prior to COVID-19.^{13,16} Boys were found to consume more processed meat and less fruit and vegetables,¹³ and had more meals per day than girls.¹⁷ Our administrative data do not include information on potential risk factors to explain the sex differential observed.

Our analysis shows the greatest absolute increase in obesity rates were among Pacific peoples, with consistently higher prevalence followed by Māori. Insights from local research indicate significant risk factors for obesity and barriers to its prevention that affect Māori and Pacific peoples due to socio-economic disadvantage stemming from colonisation. As such, these groups have limited access to and understanding of healthcare services, lower levels of health literacy and health-seeking behaviour.¹⁸ Lifestyle differences and greater exposure to adverse marketing of unhealthy food could contribute to increased risk of obesity among Māori and Pacific children;¹⁹ for example, higher consumption of sugary drinks²⁰ and purchasing of food items high in fat and sugar.²¹

Those living in the most deprived areas faced the greatest absolute increase in obesity rates post-COVID. International studies have shown linkages between deprived communities and higher obesity rates due to the relatively low cost of energy-dense foods and the association of lower income and food insecurity with lower intakes of fruit and vegetables.²² Healthier foods are generally more expensive and less readily available in deprived communities.²³ There is also a lack of recreational facilities for children living in densely populated areas.²⁴ A survey in Western Australia during the COVID-19 pandemic showed that families with lower socio-economic backgrounds were disproportionately affected, with greater increases in unhealthy eating, lower levels of physical activity and higher increases in family sedentary behaviour.²⁵

The comparatively longer period of lockdown in Auckland during the latter half of 2021 could have contributed to the greater impact. International cohort studies have shown a similar relationship between longer duration of lockdown and greater increases in obesity, such as in the USA and Korea.^{4,26}

Limitations

The administrative data used do not compare the same cohorts of children pre- and post-COVID periods. Hence, there could be unknown biases in relation to the population included. However, the number of records pre- and post-COVID periods are of similar magnitude for balanced sampling to allow comparison. The national database provides large volumes of records, adding to the credibility of the findings.

Obesity has been determined using BMI, which may have some limitations for paediatric populations of different ethnic groups to distinguish between body fat and lean mass.²⁷ For example, Pacific peoples may inherently have a greater lean body mass than their non-Pacific counterparts and could contribute to higher obesity rates.²⁸ There is conflicting literature on the use of different BMI thresholds for overweight and obesity among different ethnic groups. Duncan et al. proposed cut-offs that were higher for Pacific and Māori girls (aged 5–16), than the figures by the International Obesity Task Force.²⁹ However, an Auckland study that used bioelectric impedance recommended one consistent standard across all ethnicities.³⁰ Our analysis has used one standard across the population, to align with national performance reporting.

The impact of COVID-19 lockdowns has been explored at the sub-group level separately, which does not account for any interactions between these demographic factors. However, we display the intersectionality between these in Figures 1 and 2 as a basis for future inferential statistics using multiple regression techniques.

There is no systematic data collected in the B4SC database on levels of physical activity, food intake or screen-time, limiting our ability to assess potential risk factors. By exploring the preand post-COVID rates by demographic parameters separately, any interactions between parameters have not been accounted for.

Conclusion

Our analysis shows that COVID-19 lockdowns were temporaneously associated with obesity rates among children having a B4SC. Pacific peoples, those living in high deprivation areas and in regions with longer periods of lockdown, such as in Auckland, have been most affected. There are implications for public health policy and practice to ensure that children are supported in adopting healthy behaviours, including being physically active, eating healthy food, having sufficient sleep and moderating screen-time appropriately. It is imperative to take innovative steps, particularly during the pandemic, when mitigating the adverse effects of unhealthy weight gain was considerably more challenging.

The results by demographics have been explored in isolation. Further work using multiple regression methods can be applied to understand these factors in concert. We have not investigated growth trends among children in the normal or lower end of the spectrum, which may be useful to provide a more holistic view of changes in growth patterns. Hence, there is scope for investigating overall shifts in mean BMI and its distribution. More data in the coming years are required to reassess the current state and determine whether the increase in obesity rates is transient or ongoing.

COMPETING INTERESTS

None. The views in this paper are of the individual authors and not necessarily representative of their affiliation.

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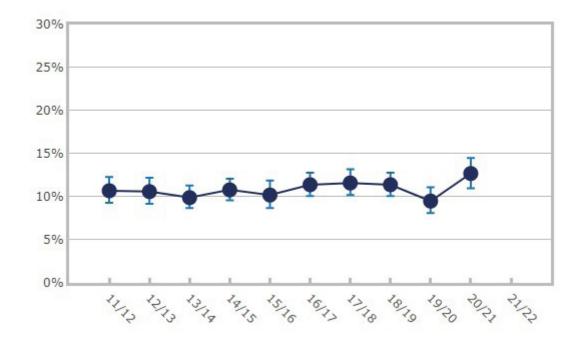
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Appendices



Appendix Figure 1: Percentage of children (aged 2–14 years) who were obese, 2011/2012–2020/2021.

 $New Zealand \ Health \ Survey, NZHS \ (2020/21) \ https://www.health.govt.nz/nz-health-statistics/surveys/new-zealand-health-survey#2020-21$

Note that the NZHS uses a different definition from that used in the methodology of this report. In the NZHS, BMI is calculated by dividing weight in kilogrammes by height in metres squared (kg/m²). For children aged 2–14 years, age- and sex-specific BMI cutoff points developed by the International Obesity Task Force (IOTF) were used to define BMI categories equivalent to those used for adults (Cole et al. 2000, 2007; Cole and Lobstein 2012). The IOTF BMI cut-off points have been designed to coincide with the WHO BMI cut-off points for adults at the age of 18 years. Children aged 2–14 years are classified as obese, with a BMI equivalent to an adult BMI of 30 (or greater). The following site provides details on the IOTF BMI cut-offs and how these align with the WHO BMI cut-off points for adults: https://www.worldobesity.org/about/about-obesity/obesity-classification

Te Matahouroa: a feasibility trial combining Rongoā Māori and Western medicine in a surgical outpatient setting

Jonathan Koea, Glennis Mark, Donna Kerridge, Amohia Boulton

ABSTRACT

AIM: This feasibility study was undertaken to implement and assess a Rongoā Māori (traditional Māori healing)/Western medicine collaboration model in a general surgical outpatient setting.

METHODS: Six patients were recruited and consulted with both a Rongoā Māori practitioner and a Western trained surgeon three times in 6 months. Appointments were an average of 45 minutes duration, patient whānau (family) were welcome and kai (food) was provided as a culturally appropriate custom. Qualitative interviews were conducted with patients, whānau and practitioners after the final appointment with practitioners. The data were thematically analysed and reviewed by the team researchers.

RESULTS: Seven themes were identified from the successful collaboration: benefits of Rongoā/medical collaboration to participants; the high value of healer/doctor relationships with participants; participants' experiences of healer/doctor collaboration; healer/doctor perceptions of the Rongoā/medical collaboration process; paying attention to the ecosystem of each participant; unanimous support for Rongoā/medical collaboration to be implemented in the health system; suggestions for Rongoā/medical collaboration improvement. **CONCLUSIONS:** Many challenges remain, but collaboration between Rongoā Māori healing and Western health professionals in public hospitals is not only possible, but also meets the need for patient-centred care.

lthough there is a current world-wide trend to integrate traditional medicine into Western medical healthcare systems driven by the World Health Organization (2019),¹ in Aotearoa New Zealand, Rongoā Māori (traditional Māori healing) is conducted mainly outside the Western medical system, with little collaboration occurring between the two. While the Aotearoa New Zealand government has made recent contributions to the funding of Rongoā service provision, particularly via the Accident Compensation Commission (ACC),² these efforts remain outside the publicly funded hospital system, which treats patients requiring inpatient care and outpatient investigation and care. In addition, efforts to standardise and regulate the Rongoā Māori sector³ runs counter to Māori healing principles, which are focussed on the needs of patients, the capacity of the healer and the traditions of the locality. Previous research has indicated support for Rongoā and Western medical collaboration,^{4,5} but the literature has noted many complex and challenging issues that need to be explored further, key among these being the relationship between traditional healers and medical practitioners.⁴

Earlier investigations have shown that instead of integration, which is the incorporation of traditional medicine into healthcare systems, there should be a mutual collaboration, where both systems work together, but remain individually intact and not changed in any way.^{4,5} Greater collaboration between Rongoā Māori and mainstream health systems could provide a number of benefits; not the least is the inclusion of Māori cultural values into healthcare, which in turn may facilitate greater Māori participation, adherence, satisfaction and an overall improvement in Māori health outcomes.6,7 One way to achieve collaboration is to provide combined holistic healing and medical health treatment for patients in a way that includes Māori cultural values and traditional healing practices.4

Given the complex nature of the issues involved with collaboration between traditional healing and Western medical health systems, the approach taken in this research was to focus on the collaborative relationships between the healer, doctor and patients using a previously published collaboration model (Figure 1).⁴ This small feasibility trial sought to establish a clinical Figure 1: Rongoā/medical collaboration model.4,5



collaboration between a surgeon and a Rongoā Māori practitioner and to explore the success factors, obstacles, collaboration benefits and drawbacks for this approach for both practitioners, patients and their whānau (family).

Methods

This trial's aim was to explore interpersonal relationships between traditional healing and Western medical practitioners in Rongoā/medical collaboration by undertaking a small collaborative trial to assess potential barriers to successful collaboration. This required both a Western medical and a Rongoā Māori practitioner to be willing to work cooperatively to treat patients. This study took a unique approach to situate the healer and doctor in the same room to treat the same patient. The healer and doctor involved in this project were Jonathan Koea (Ngāti Mutunga, Ngāti Tama), a surgeon and clinical researcher based at Waitematā District Health Board, and Donna Kerridge, a traditionally trained Rongoā Māori practitioner, registered Medical Herbalist, and at the time the study commenced, Māngai (spokesperson) for Te Kāhui Rongoā Trust (the New Zealand national collective of Rongoā Māori practitioners).

Prior to commencing the collaboration study, JK and DK participated in a mutual Rongoā Māori/medical education workshop to share the principles of Māori healing and medical practice. The workshop aimed to encourage knowledge sharing, full and equal partnership, and protection and medical acceptance of Rongoā.

Patient recruitment

Patients under the care of the upper gastrointestinal multidisciplinary clinic⁸ who had completed treatment of upper gastrointestinal disease, and who were under clinical follow-up, were considered eligible to participate in this research. While it was initially anticipated that more patients would need to be contacted to participate in the study, the first six who were approached all consented to be involved. There were three males and three females ranging in age from 31–79 years, as shown in the demographics table in Table 1.

Each patient was given the option to attend an in-person Rongoā/medical consultation three times, every 2 months, over a 6-month period, with both JK and DK. Each appointment was of at least a 45-minute duration, patient whānau were welcomed and food/refreshments were made available in alignment with culturally appropriate custom when hosting manuhiri (guests). Each medical/surgical consultation included taking a directed history, performing a clinical examination and reviewing any relevant clinical investigations, such as radiological examinations or blood tests. Patients were simultaneously seen by both practitioners and sessions ran according to patient treatment need and choice.

A treatment/management plan was discussed for each patient that included both Western medical interventions (regular blood tests, radiological monitoring), and also Rongoā Māori, which both Rongoā/medical practitioner agreed on.

Following the third session on Saturday 10 December 2022, the healer, doctor and participants who were in attendance completed a semi-structured qualitative interview conducted by GM, who had not previously been present during the clinical appointments. This involved using the interview schedule of questions and collecting open-ended data to explore participants' thoughts about their Rongoā/medical collaboration experience.⁹ These qualitative semi-structured interviews asked participants about the perspectives of collaboration between the healer and doctor, their communication and the benefits and challenges. The interviews also discussed patient consultation satisfaction, practitioner cooperation and overall perspectives of the collaboration process.

Thematic data analysis was conducted to ascertain collaborative principles in practice. Thematic analysis was appropriate for this study because the research was seeking to understand the experiences and thoughts of the healer, doctor and patients on Rongoā/medical collaboration.¹⁰ The thematic analysis was conducted by becoming familiar with the data, generating initial codes and searching for, reviewing, defining and naming themes.¹⁰ Once the initial codes were generated, a specialist advisor experienced in Te Ao Māori (the Māori world) research, AB, assisted in reviewing the analysis and provided valuable feedback. This ensured knowledge sharing and collaboration values between Rongoā, medical and research professionals, and resulted in the complete set of research themes.

This trial was registered by the Research Office at Waitematā District Health Board in 2021. National ethics approval was granted by the Southern Health and Disability Ethics Committee (ref: 2022 EXP 12320).

All research data are held in anonymised computer files accessible only by the investigators via password access and will be stored for 15 years.

	Gender	Age	Ethnicity	Diagnosis	ECOG	Disease stage	Occupation
1	Male	79	Māori	Cholangiocarcinoma	1	Alive with disease	Retired
2	Female	31	Pacific peoples	MEN with tumours (treated of adrenal, liver, pancreas, thyroid)	1	Free of disease	Booking clerk ACH
3	Male	68	Pākehā	Chronic liver disease, HCC	1	Free of disease	Retired
4	Male	57	Māori	Gastrointestinal stromal tumour—resected	1	Free of disease	Drainage contractor
5	Female	52	Māori	Intrapancreatic mucinous neoplasm	1	Alive with disease	Works for Rūnanga
6	Female	46	Pacific peoples	Pancreatic neuroendocrine tumour	1	Alive with disease	Teacher

Table 1: Demographic and clinical details of the patients involved in the trial.

Results

The results of the thematic analysis provided seven themes, which are provided in this section together with healer, doctor and patient participant quotes to illustrate their experiences with Rongoā/ medical collaboration. The feedback was unanimously positive, with all participants sharing that they enjoyed the experience of collaborative treatment and believed that combined Rongoā/ medical healing and healthcare would be helpful to other people as well.

Theme 1: benefits of Rongoā/medical collaboration to participants— conversation, support and culture

Participants felt comfortable being able to discuss their health issues and being able to contact Jonathan and Donna throughout the study.

"This was a really great collaboration—I think for me, it was more fellowship *if I can narrow it down, it's just that* fellowship of our stories and being open and not being vulnerable but just being open. That we're able to express our cultural practices, know where we come from and that we have people like *Jonathan and Donna able to make, or have* an understanding of, 'Yeah, I got you. I understand where you're coming from because...' and they bring up their own personal stories. That's what made the talanoa [conversation] really awesome because we were able—and that just leads you off on to different avenues of areas in our conversation really." - Pacific female and partner, 48 years, Teacher

Participants were helped to understand their medical and health needs, as well as discuss how they felt.

"I suppose just looking at different ways of being healthy. Just looking after myself really. It made me give up smoking. I've been smoke-free ever since Jonathan cut this thing out of me ... For me, definitely the smoking. That was my biggest thing. Just having to regulate my pills better. I was missing quite a few days here and there, but I'm on track now. I think I was getting a bit slack taking the pills. Definitely got me back into a routine." – This level of comfort with having both the healer and doctor in the room meant that patients were more likely to take the advice that was given and feel supported. In addition, a single health intervention in this case surgery—was an opportunity to support the patient to improve their overall and healthrelated behaviours.

"Yeah, you've got someone there to support you. We know we could ring up either one of them and they'd be there for us, and that is huge, huge. Somebody cares. This makes you feel like, yeah, life actually is worth living, because you've got people that actually care about you. It's not just an operation, it is actually people that really care, and I think that's important." – Pākehā male, 68 years, Retired

Theme 2: the high value of healer/doctor relationships with participants—being seen, heard and treated like a person

Participants repeatedly mentioned enjoying being seen and heard, rather than being treated as a patient with a list of symptoms.

"I think I've come to the stage now with the hospital system that as a patient, they talk about their medical—about your health issue but they forget, ahh there is somebody else still in this space. So, include us." – Pacific female and partner, 48 years, Teacher

"Because normally we'd go to my sister's appointments—and again, no criticism on our medical team that we have in New Zealand, they're doing what they can but it was, 'So what was the symptoms today?' When this interaction I saw this morning, all they wanted to know is, 'How are you?' but not symptom wise but, 'How are you?' So that made all the difference as far as I can see, and like you said absolutely a trust issue." – Whānau of Māori male, 79 years, Retired

Participants believed that the connection with both Jonathan and Donna facilitated a safe cultural space and allowed participants to relax and feel comfortable. "I think it's having them both there and having one-on-one with the both of them about my experiences and that sort of thing. That was the beauty of it, I think. Given the half hour that we got, we got a lot of things cleared up." – Māori female, 52 years, Rūnanga

Whānau of participants appreciated the patient-centred approach that gave the patient the autonomy of treatment choice.

"Because really, Western medicine they treat the ailment, not the person. And there's no criticism to that, merely because that's all we know; so, if that's what you know, that's what you do. But to hear that Rongoā Māori and Western medicine was being merged and blended like this in a really authentic way, where two people who have respect for each other and respect for their talents and their profession, for me, that's really important. And that for me, is Rongoā treating the body first, because it's looking at his whatumanawa [heart/emotions] and wairua [spirit] and putting that at ease first, and then let's talk about the body. So that for me, just seeing that relationship and even hearing that korero [discussion], that summed up for me exactly why it's working." - Whānau of Māori male, 79 years, Retired

Theme 3: participants' experiences of healer/doctor collaboration—the best of both worlds

Participants discussed the different perspectives provided by both Jonathan and Donna and found that each provided equal value in the treatment sessions.

"I have sort of been on the same wavelength as Donna, so that was good. That's what I loved about it, that there's a natural medicine out there, because antibiotics and everything, codeine and these sorts of things, don't work for me. So, to tap into a natural side of things and the things that I understand. I can go down to my own ngahere [forest] and get my own medicine type of thing. What I do with Jonathan is I have the MRI every year because I've got a cyst on my pancreas that is just on the dangerous of going overboard. But what happened is that after I had my first COVID-19 inoculation/vaccination, I actually broke out—my hands broke out as well. Donna was able to help me with that. It's really bad eczema that I'm getting as well. With the two of them in the end. But then also it got so bad. The medicine was keeping it at bay, the Rongoā was, but I had to go back to the Western medicine which was Prednisone. I had to go back to that and the antibiotics as well. With the two of them still working hand-in-hand that way." – Female Māori, 57 years, Rūnanga

Theme 4: healer/doctor perceptions of the Rongoā/medical collaboration process—treating patients with manaakitanga (expressing kindness and respect for others) is fun and natural

Jonathan and Donna both found the process of treating patients collaboratively to be a natural act of manaakitanga or hospitality and caring for people, where trust was an important component in each interaction.

"I think it's been overwhelmingly positive and surprisingly easy. I think all of the things that we thought might be hard or might not work, actually, none of those really kind of materialised. It's been like a conversation really. I know we spend a lot of time thinking, 'Who will go first?' 'Who will go second?' and we'll talk about a plan. But actually it's all of those things that happen, but have been quite simultaneous and kind of arriving by consensus really, at something. Some things I've been able to help with and some things you've been able to help with, but we've never argued. All of the perceived pitfalls, barriers—I don't think ever eventuated. It's actually just been a lot of fun." – Jonathan, Doctor

"The things that I thought might have been challenging for us, and I never thought about it in a great deal, but I would've thought that there would have been instances in our different ways of approaching health and wellbeing that we might have needed to talk about, but there wasn't a single thing. And there was never a sideways ... It was like you say 'easy'. It was really easy, and it was fun and it felt natural." – Donna, Rongoā practitioner

"For me. I think. we've done it much more in a manaakitanga way rather than a medical interview, a medical consultation—it's been much more about where people are from, what they do, who's in their family, what connections we have, how are they doing. We both knew the underlying medical conditions and things; we've shared that knowledge and how could we best help them, with we being the thing. I think the thing that I've learnt and not noticed before is how we treated the family not the person. So, with the primary patient, we're also sharing their thoughts about the situation but also their own health issues or challenges or life challenges, and it's definitely become a whānau visit, not a patient visit. I didn't expect that, but it just happened that way. I think I expected it to be more a Western model, where your support person joins with you, but they were equal with the patient. They weren't lesser or just somebody on the side. They were active participants for all of them that brought support people. I think there was only one who didn't bring support people. All the others brought their support people, but those people were actively involved." – Donna, Rongoā practitioner

Theme 5: paying attention to the ecosystem of each participant—for practitioners, treating patients felt like visiting whānau and facilitated deeper connection

Both Jonathan and Donna felt that inviting patient whānau to attend treatment sessions, who were the ecosystem of each patient, facilitated deeper connection and greater insight into their overall wellbeing.

"I think that we were always looking towards the patient, I was certainly able to see them in a much bigger ecosystem because you knew their connections, where they're from. All of the things that we talk about in Western medicine, knowing what the patient's home situation is, but this was seeing them in a much bigger, in their three-dimensional universe if you like—where they came from, where they were going to, who was with them ... But you're right, you end up not necessarily treating the whole whānau but you're interacting with all of them, because that person is in a whole ecosystem." – Jonathan, Doctor

"I think one of the added things that I realised really in that very first session we had with the people, was that it really wasn't the coming together of professions, it never ever felt like that. It felt like the coming together of people, rather than professions. I recall in one of the interviews with one of the people, Donna had some great news for them about some of their results and I could still sense an element of fear in them, and Jonathan just reached out and said, 'But I'll never abandon you.' It was kind of addressing it before it had even become real for those people and the relief of just hearing those words. It made me realise we were people before we were professionals. We were people talking with people who had different gifts, that's all. That's why I think it was really easy and for me as a Rongoā Māori healer, that has taught me to not look at the profession of medicine but to remember that they are people who happen to practise medicine. It was a big learning for me from this study." – Donna, Rongoā practitioner

Theme 6: unanimous support for Rongoā/medical collaboration to be implemented in the health system—it would help a lot of people

All participants believed that Rongoā/medical collaboration would be a valuable addition to the health system because it would help a lot of people.

"... Even if it just helps a handful of people, one out of ten, or six out of ten or whatever. It's worthwhile, isn't it? Because it just could be something that most people just could not handle by themselves. Whether that means they end up getting sick again or whether they end up topping themselves, you know, when there's just no support at all. The thing is, sometimes you can go to doctors and say the same thing, but they don't understand." – Pākehā male, 68 years, Retired

"... If they were given option but if they were given the choice, for some of our people like if I know if they said, 'If you don't want to take medication but there's other way of healing, would you...'. You know, and I think 'Why not?' because right now, the generations are either for medication or looking for alternatives." – Pacific female and partner, 48 years, Teacher

"We know that it'll be about the Western model of medicine and so that will be one part. The other is—because that's the whole point about the research and developing it and growing it even though we know for some of our people it works. That's what I'm seeing but I guess in an alternative world, I imagine if we had a Māori hospital, that would—and I can see it doing really well. And that model will just prove [chuckles] but because the system is set in such a way that it's all about research, it's all about—wow, prove it!" – Donna, Rongoā practitioner

Theme 7: suggestions for future Rongoā/ medical collaboration improvement more time, more often with more cultures and more people

Participants stated that they would have liked to be able to spend more time with Jonathan and Donna. Other suggestions included having a wider diversity and larger number of participants, including Samoan cultural healers.

"I think that's the only thing I have, was just more ... get to see them and discuss with them together, because it's always better to be together having this conversation, rather than talking to one then talking to the other, then those two talking together—not that they did that, but just in our experience with the other medical fields." – Māori male, 79 years, Retired

While whānau were extremely grateful that they could contact Jonathan and Donna for help outside the Rongoā/medical collaboration sessions, they also commented:

"I'd be concerned that this is not sustainable, that accessibility is not sustainable. I could see that when he's got to have a life, Whaea's [literally meaning 'mother' but contextually referring to DK] got to have a life, so how? Thousands—can you imagine this trial getting bigger, you only have six of this that's manageable, I can see that. But make this bigger, even to double that, I don't think that kind of accessibility is sustainable. Wouldn't it be great if it was, but I can't see that being sustainable." – Whānau of Māori male, 79 years, Retired

"I think part of that context will be driven by where the health system is at the moment, because sometimes they couldn't access GPs for several weeks and they knew were available but kind of, isn't that the essence of medicine—I am your doctor. I may not be able to help with the current problem that you have but I am your doctor and I'll do what I can. Again, that's less about a transaction and more about, 'Yeah, okay I'm interested, what's the problem? Let's see if we can't sort something out."" – Jonathan, Doctor

This also emphasises the unique structuring of the practitioner/healer appointments. They were much longer than the standard outpatient appointment, with time consciously put aside to find out about the individual's life and social context—even before the medical issue was brought up. A medicine/Rongoā service would focus on medium- to long-term care, rather than stand-alone care sessions and is ideally placed to manage patients with "complex" health needs across a number of domains.

Participants also suggested the inclusion of other cultures into the study as follows:

"It would have been interesting to see a Samoan-born and have that comparison of, 'Aw okay, so this is ...' because we grew up with it, but a Samoan-born, it would've been all inclusive. I guess in that sense, just to get the different comparison of the different generation gaps between us and the elders or the ones who were born in Samoa. Because I know that it can be quite similar especially in the plants that are used and also the protocols because with [partner's name] and my grandmother, it was always with the karakia [prayer] or lotu [religion] and then we ended off with a lotu. Just natural oils. Yeah, and with [partner's name] mother and my grandmother, it was very specific plants that we use for, and that's probably similar to ... That would be really interesting because our stories, our narratives would have been different to somebody that was born in Samoa." – Pacific female and partner, 48 years, Teacher

Jonathan raised a concern about the Rongoā workforce for this type of initiative, as well as the standard medical consultation time length.

"I'd say the main challenges I think are workforce particularly for Rongoā, we have to work really hard to make sure hospitals are a welcoming environment. I think the thing will be time too. Hospitals *run on time—no, they don't run efficiently* on time, but they run, and getting away from that standard medical consultation of 15 minutes and actually it takes as long as it takes. We might not even talk about actually what's wrong until we see you again next week. We might talk about everything else, because it's a completely different way of doing things, but it gets to a much deeper kind of a high-quality point I think." – Jonathan, Doctor

Discussion

To date, we believe that this is the first study to initiate collaboration between a Rongoā practitioner and a medical doctor who are both Māori in the treatment of the same patient at the same time, in the same room, at a public hospital in Aotearoa New Zealand. There was full and equal partnership, knowledge sharing and collaboration values, as well as protection and medical acceptance of Rongoā throughout the study duration.⁴ Two key groups of high-level findings may be gleaned from this study—the first is concerned with why this study was regarded by patients and practitioners as being successful and the factors contributing to that success, and the second related high-level finding is concerned with how and in what ways the collaboration was seen as being beneficial. Both patients and practitioners agreed that the collaboration was successful in three ways: shared practitioner values, the meaningful inclusion of the patient whanau and the amount of time that was spent in each collaborative session, which assisted in initiating and establishing relationships between practitioners and patients. Three specific collaboration benefits to both practitioners and patients were observed, namely: greater patient treatment adherence and understanding (both Western medicine and prescribed Rongoā), the inclusion of Māori cultural values and practices, and patient access to both practitioners at the same time and location.

The fact that both practitioners were Māori and from the same cultural background, though trained in different bases of health and healing knowledge, proved to be a significant factor in the success of the collaboration treatment. This meant that there was no need to translate or justify the use of any Māori cultural values, approach, knowledge or practice, which eliminated cultural misunderstandings. There was a shared knowledge and mutual respect for the practice of whakawhanaungatanga (connections), karakia, kai, manaakitanga and aroha (respect) towards patients that was natural for both practitioners. This created a familiar cultural atmosphere that patients may have felt if in a cultural setting such as a marae ātea (the courtyard of a Māori meeting house), or with whanau. Both practitioners were focussed on a patient-centred practice. This involved qualities of communication, accessibility, interpersonal skills, care coordination and followup, and patients have been shown to value healthcare providers who take time to listen and work with them, care about them, support them in managing their healthcare and make an effort to personalise patient care.^{11,12} This shows that as long as there is a shared cultural understanding and mutual respect between Rongoā and Western practitioners, there is a strong possibility of collaboration being successful.

In collaboration sessions, patients were encouraged to bring whānau, and all but one patient brought supporters with them. The involvement and inclusion of whānau in healthcare decision making is a known contributor to the success of any health intervention for Māori and other Indigenous peoples,¹³ and the beneficial effects of including patient whānau are seen most clearly in the quotes under pinning themes two, four and five. The inclusion of patient whanau in their health treatment mirrors the Māori cultural values of whanaungatanga (family connections), as well as the Whare Tapa Whā Māori health model of the mind, body, spirit and whānau being intrinsic to Māori health and wellbeing.14 Support has been shown for whānau-based care and involvement in the health system because family is a fundamental support structure.^{15–17} The inclusion of whanau in patient collaboration sessions was vital to the success of this study because it brought all participants together to inform and support the best health treatment for the patient, and in many instances whanau advocated for Western medical approaches with patients and supported the work of both practitioners.18

The amount of time practitioners were able to spend with patients in this study, which was an average of 45 minutes, is uncommon in Western healthcare treatment. In fact, the opposite is the norm, where prior research showed that due to scheduling and other issues consultations may last only 2 minutes, and patients are unable to fully express their symptoms, provide history and ask questions.¹⁹ Limited time correlates with patient dissatisfaction and a lower intention to comply with the doctors' recommendations. For Māori, time and the ability to organise time are ways that support people to prioritise important cultural responsibilities such as whānau. However, Western-centric notions of time are often organised around production and economic goals in ways that undermine Māori priorities.²⁰

As has already been noted, the most evident barrier to implementing collaboration efforts is the vastly different belief systems held by those trained in a Western biomedical system compared to their traditional, Indigenous healer counterparts in regards to illness, health and healing.¹⁵ Although this investigation was successful in creating a respectful relationship between the two practitioners due to shared cultural and patient-centred values, all other studies on Indigenous/Western medical collaboration have focussed solely on the challenges.^{21–23} The main barriers are defined as lack of consultation time and training, lack of clear roles, fears relating to professional identity and poor communication. The principal facilitators included tools to improve communication,

co-location and recognition of other professionals' skills and contribution.²² This includes reconciling historical relationships, differences in epistemologies and treatment approaches, and differences in knowledge acquisition and training.

This small feasibility project has been successful in establishing a Rongoā/medical collaboration by showing the factors needed for traditional healing and Western medical practitioners to work together, as well as beneficial ways to treat patients so that they feel valued and heard. While the number of patients was small, they were selected to reflect a range of ethnicities and ages, as well as different genders in order to determine whether the proposed model of care would work at an individual patient level. While the results in this small group of patients are encouraging, a larger trial involving more patients, including those presenting with new diagnoses rather than just as follow-up consultations, should be undertaken. For Māori, the inclusion of the cultural values inherent in Rongoā healing made a significant difference to patient experience and satisfaction with the healing and health collaborative treatment process. Ethnicities other than Māori were chosen to demonstrate that Rongoā has a role in the care of all New Zealanders. However, we acknowledge that the inclusion of non-Maori ethnicities in any Rongoā service may come at the expense of Māori patients. Whether or not access to such a service was restricted to Māori patients only should be debated. However, we believe that, similar to access to classes in Te Reo Māori, the benefits of Rongoā should be accessible to all New Zealanders.²⁴ However, many of the wider issues of Rongoā/ medical collaboration remain unresolved, and further research is needed, even as Rongoā undergoes continuing changes in governmental policy and funding organisations. In order to create national and organisational collaboration parameters, a major and comprehensive paradigm shift in Western healthcare system frameworks is needed about what is, and what is not, culturally appropriate for collaboration with traditional healing customs, values and practices. This must be done in full and equal partnership with Rongoā Māori practitioners, in alignment with the principles of Te Tiriti o Waitangi (the Treaty of Waitangi, Aotearoa New Zealand's founding document).

COMPETING INTERESTS

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Changes in sodium valproate dispensing in women of childbearing age with a diagnosis of borderline personality disorder in Aotearoa New Zealand

Matthew Tennant, Chris Frampton, Roger Mulder, Kate Eggleston, Ben Beaglehole

ABSTRACT

AIMS: To compare sodium valproate dispensing in women of childbearing age diagnosed with borderline personality disorder in 2014 and 2019 to discover if prescribing practices in Aotearoa New Zealand have changed in response to international recommendations. **METHODS:** National dispensing data from the Pharmaceutical Collection were linked with diagnostic data from PRIMHD (the national mental health and addiction database) to identify people diagnosed with borderline personality disorder in Aotearoa New Zealand who were dispensed psychotropic medication. Dispensing of sodium valproate for women of childbearing age was compared between 2014 and 2019. Rates of dispensing were compared between ethnicities.

RESULTS: In 2014, 10% of women of childbearing age diagnosed with borderline personality disorder were dispensed sodium valproate. This reduced to 6% of women in 2019 (p<0.001). In 2014, there was substantial ethnic disparity with 18.1% of Māori women and 15.8% of Pacific women dispensed sodium valproate compared with 7.4% of New Zealand Europeans. This disparity reduced in 2019, with 6.4% of Māori women and 12.5% of Pacific women dispensed sodium valproate compared sodium valproate compared with 5.6% of New Zealand Europeans.

CONCLUSIONS: These findings suggest that international recommendations and guidelines have been effective in changing clinical practice and reducing ethnic inequities. Given the significant risk to offspring exposed to sodium valproate, we echo warnings against off-label prescribing of sodium valproate in borderline personality disorder.

P sychological and psychosocial interventions are the recommended treatments for borderline personality disorder. There are no licenced pharmacological treatments for it.¹ Although mood stabilisers are used off-label to attempt to manage affective instability in borderline personality disorder, there is insufficient evidence for their effectiveness in this context for this to be recommended.²

We recently reported that despite the lack of evidence for pharmacological interventions for borderline personality disorder there was increasing polypharmacy between 2014 and 2019 in Aotearoa New Zealand. In particular, there was increased dispensing of mood stabilisers.³ People with borderline personality disorder have attributed excess or unnecessary prescribing to clinicians' lack of understanding and stigma regarding the diagnosis.⁴ Uncomfortable countertransference and limited access to evidence-based psychotherapy have been cited as reasons for clinicians' deviation from treatment guidelines.⁵

Historically, sodium valproate was indicated to treat two comorbidities in borderline personality disorder; mania in bipolar disorder and to prevent seizures in epilepsy. However, in 2015 the International League Against Epilepsy recommended that sodium valproate be avoided in the treatment of epilepsy in woman of childbearing age due to the high risk of teratogenicity.6 Furthermore, in 2018, the European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) made recommendations against the initiation of sodium valproate in woman of childbearing age for any health problem except for epilepsy where no other available antiepileptic agents have been effective.7 In response to these changes, major treatment guidelines for bipolar disorder no longer recommend sodium valproate in this population.8,9

In this paper we report an extension of the analysis from the original study.³ The aim is to

compare sodium valproate dispensing in woman of childbearing age with a diagnosis of borderline personality disorder in 2014 and 2019 to see if prescribing practices have changed in response to international recommendations.

Methods

Ethics approval was provided by the Otago University Ethics Committee (HD21/095), Minimal Risk Health Research Pathway. The data utilised were collected and stored within Aotearoa New Zealand national health databases. They were received and analysed in a de-identified form using unique identifiers.

National databases

The Aotearoa New Zealand Ministry of Health collects psychiatric diagnoses and demographic information for people using public sector secondary care and non-governmental organisation mental health and addiction services within the PRIMHD database. National pharmaceutical dispensing data for Aotearoa New Zealand are recorded in the Pharmaceutical Collection database. This contains all community prescriptions from public and private clinicians.

Study population

PRIMHD data were requested for all patients that received a diagnosis of borderline personality disorder in a 10-year period from 1 January 2009 until 31 December 2019. Demographic information was requested, including age, gender, ethnicity and New Zealand Index of Deprivation (NZDep). The NZDep is an area-based measure of socioeconomic status. It is expressed in deciles, where 10 indicates the highest levels of socio-economic deprivation. Ethnicity was self-identified at point of contact with health services. It has been classified into five groups: Asian, Māori, NZ European/ Pākehā, Pacific peoples and Other.

Dispensing data from the Pharmaceutical Collection database were linked to PRIMHD data using a unique identifier. For those with a diagnosis of borderline personality disorder between 2009 and 2014, annual dispensing of psychotropic medications (including sodium valproate) was requested for 2014. For those with a diagnosis of borderline personality disorder between 2015 and 2019, annual dispensing of psychotropic medications (including sodium valproate) was requested for 2019. Annual dispensing of sodium valproate was defined as being dispensed the medication at least twice within the calendar year. Sodium valproate is currently the only formulation of valproate available in Aotearoa New Zealand.

Data analysis

We report dispensing of sodium valproate to women of childbearing age with a diagnosis of borderline personality disorder in 2014 compared to 2019 in New Zealand. We considered those aged between 15 and 45 years to be of childbearing age. The age of menopause varies significantly between individuals. We chose 45 years as a conversative upper limit of childbearing age because very few women have natural menopause prior to age 45 years.¹⁰ We compared dispensing of sodium valproate (number and percentage) by ethnic group in 2014 and 2019. All women of childbearing age with a diagnosis of borderline personality disorder who were dispensed any psychotropic medication in 2014 or 2019 were used as the denominator for proportions within the relevant year. We have used women with a diagnosis of borderline personality disorder who were dispensed psychotropic medication as our denominator rather than all woman diagnosed with borderline personality disorder because some women not dispensed any psychotropic medication may have died or migrated between the time of diagnosis and the year that dispensing was requested. A full list of included medications can be found in the Appendix. The mean age and socio-economic deprivation (NZDep) were compared in those dispensed versus not dispensed sodium valproate. Chi-squared tests were used to test statistical significance between the groups.

Results

In 2014, 24% of people diagnosed with borderline personality disorder between 2009–2014 were dispensed no psychotropic medication. In 2019, 19% of people with the diagnosis between 2015–2019 were dispensed no psychotropic medications.

Table 1 reports the characteristics of the women of childbearing age diagnosed with borderline personality disorder in 2014 and 2019 who were dispensed psychotropic medication.

In 2014, there were 870 women of whom 87 (10%) were dispensed sodium valproate. Those who were dispensed sodium valproate had higher socio-economic deprivation than those not

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	2014 2019				
	2014	2019			
	(n=870)	(n=1,319)			
Mean age	31.1 years	28.4 years			
Mean age	(SD = 8.1)	(SD = 7.4)			
	6.3	6.0			
Mean NZDep	(SD = 2.7)	(SD = 2.6)			
Number of women by ethnicity					
Asian	28 (3.2%)	59 (4.5%)			
Māori	149 (17.1%)	266 (20.2%)			
NZ European	585 (67.2%)	800 (60.7%)			
Other	89 (10.2%)	154 (11.7%)			
Pacific peoples	19 (2.2%)	40 (3.0%)			

SD = standard deviation.

Table 2: Sodium valproate dispensing to women aged 15–45 with a diagnosis of borderline personality disorder.

	Number of people dispensed sodium valproate within ethnic groups			
Ethnicity	2014	2019		
Asian	2 (7.1%)	2 (3.4%)		
Māori	27 (18.1%)	17 (6.4%)		
NZ European	43 (7.4%)	45 (5.6%)		
Other	12 (13.5%)	10 (6.5%)		
Pacific peoples	3 (15.8%)	5 (12.5%)		
All ethnicities	87 (10.0%)	79 (6.0%)		

dispensed with mean NZDep scores of 7.0 and 6.2 respectively (p<0.01). The mean age for this group was 31.1 years, and there was no significant difference in the age of those dispensed sodium valproate compared with those not dispensed (p=0.35). There was significant ethnic disparity with 18.1% of Māori women dispensed sodium valproate compared with 7.4% of New Zealand Europeans (p<0.001). There was also a non-significant difference between the 15.8% of Pacific women dispensed sodium valproate and New Zealand Europeans (p=0.17).

In 2019, there were 1,319 women diagnosed

with borderline personality disorder who were of childbearing age and were dispensed psychotropic medication. There was no statistically significant difference in the socio-economic deprivation of those dispensed sodium valproate compared to those not dispensed. NZDep scores were 6.2 and 6.0 respectively (p=0.53). Women dispensed sodium valproate were slightly older, with a mean age of 30.0 years compared with 28.3 years (p=0.045). The difference between Māori (6.4%) and New Zealand Europeans (5.6%) was no longer statistically significant (p=0.64). Pacific peoples had the highest proportion of women dispensed sodium valproate (12.5%), but this was not statistically significant compared with New Zealand Europeans (p=0.082).

Compared with 2014, sodium valproate dispensing reduced from 10% to 6.0% in 2019 (p<0.001). The most significant reduction occurred in Māori woman, of whom 18.1% received sodium valproate in 2014 compared to 6.4% in 2019 (p<0.001). Dispensing across different ethnic groups is presented in Table 2.

Discussion

This study reports a reduction in the dispensing of sodium valproate to Aotearoa New Zealand women of childbearing age with borderline personality disorder between 2014 and 2019. We previously reported polypharmacy in people diagnosed with borderline personality disorder increased between 2014 and 2019, including an increase in dispensing of mood stabilisers.³ We suspect the reduction in dispensing of sodium valproate over this time is a response to recommendations against its initiation in woman of childbearing age.^{6,7,8}

In 2019, Medsafe (the body responsible for the regulation of therapeutic products in Aotearoa New Zealand) released a communication stating that sodium valproate must only be used for approved indications (epilepsy, bipolar disorder) in women of childbearing potential when other treatments have been ineffective or not tolerated, due to risks to the unborn baby.¹¹ Some of the women in our study may have been prescribed sodium valproate for these indications, rather than for borderline personality disorder. For instance, the rate of comorbid bipolar disorder in people with borderline personality disorder is 18.5%.¹² While there is limited evidence about rates of epilepsy in borderline personality disorder, the general population rate is 0.5–0.7%.¹³ Some types of epilepsy, such as temporal lobe epilepsy, may have higher rates of comorbid personality disorders.¹⁴ Given sodium valproate should only be prescribed when other treatment options have been exhausted, it is likely that a proportion of people dispensed sodium valproate were prescribed this outside of recommended use. Recent local data show poor adherence to guidelines regarding appropriate prescribing of sodium valproate to women of childbearing potential in Aotearoa New Zealand.15,16

The use of antiepileptics in pregnancy increases the risk of miscarriage, stillbirth, intra-

uterine growth restriction and major congenital malformations.¹⁷ Of the antiepileptics, sodium valproate is associated with the highest risk of major congenital malformations, occurring in approximately 10% of exposed offspring.7 In addition, sodium valproate exposure during pregnancy is associated with increased risk of intellectual disability and neurodevelopmental disorders, reported to affect 30-40% of exposed offspring.^{7,17} It is reassuring to see a change in clinical practice but we are still concerned that 6% of women with borderline personality disorder were prescribed the medication in 2019. Continued education for prescribers in primary and secondary care regarding the risks associated with sodium valproate in woman of childbearing age might vivify sensible deprescribing. Furthermore, structural changes to the prescribing of sodium valproate should be considered. For instance, if sodium valproate required written authority from a neurologist or psychiatrist this may encourage closer adherence to guidelines. Websites established to provide patient information need to be updated to reflect clinical guidelines. Healthify.nz still has mood stabilisers listed as an appropriate treatment for borderline personality disorder.¹⁸

The difference in dispensing of sodium valproate between Māori and New Zealand Europeans in 2014 was notable. This could be partially explained by the higher prevalence of bipolar disorder in Māori (4.6%) compared to New Zealand Europeans (1.8%).¹⁹ Ethnic disparities in access to quality mental healthcare have previously been highlighted and might contribute to differences in prescribing.²⁰ It was encouraging to see a reduction in the disparity in sodium valproate dispensing between 2014 and 2019.

A greater proportion of Pacific women were dispensed sodium valproate compared with New Zealand Europeans in both 2014 and 2019. These differences were non-significant and should be interpreted with caution given the small number of Pacific women impacted. Inequities in dispensing of sodium valproate are particularly important given higher rates of unplanned pregnancy in Māori and Pacific women.²¹ Ensuring that Māori and Pacific women with borderline personality disorder have access to evidence-based, culturally appropriate psychological treatments may reduce inappropriate use of sodium valproate in these groups.

The strength of this study was its use of national databases to achieve a broad overview of current clinical practice. The Pharmaceutical

Collection database captures all dispensing of prescription medications in New Zealand. In New Zealand, a maximum of 3 months of medication can be dispensed from a pharmacy. We decided to only include cases when sodium valproate was dispensed twice within the 12-month period. This may mean that our results are more conservative than actual medication use. However, we believed that picking up a second prescription was more likely to be associated with medication adherence than a single episode of dispensing.²² A limitation of this study is that we do not have data on the rates of comorbid epilepsy or bipolar disorder. We therefore have relied on general data on comorbidity to interpret our results. While we suspect that sodium valproate dispensing has reduced because of international and local recommendations, we cannot confirm causality.

In conclusion, between 2014 and 2019 there was a reduction in dispensing of sodium valproate

to women of childbearing age with a diagnosis of borderline personality disorder in Aotearoa New Zealand. This is likely to be in response to international warnings against the initiation of sodium valproate in woman of childbearing age. In 2014 there was a significant ethnic disparity with 18.1% of Māori being dispensed sodium valproate compared with only 7.4% of New Zealand Europeans. It is reassuring to see this gap has closed in 2019 with no significant difference for Māori and New Zealand Europeans. These findings suggest that international recommendations and guidelines have some effect changing clinical practice and reducing ethnic inequities. However, given the significant risk to offspring exposed to sodium valproate, and the clear guidance regarding prescribing sodium valproate in women of childbearing age, we encourage further reductions in dispensing in the years to come.

COMPETING INTERESTS

None to declare.

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Appendix

Appendix Table 1: Psychotropic medications in the national pharmaceutical dispensing data for New Zealand.

Class	Medications
Antidepressants	amitriptyline; clomipramine hydrochloride; dosulepin [dothiepin] hydrochloride; imipramine hydrochloride; maprotiline hydrochloride; nortriptyline hydrochloride; tranylcypromine sulphate; moclobemide; citalopram hydrobromide; escitalopram; fluoxetine hydrochloride; paroxetine; sertraline; mirtazapine; venlafaxine
Antipsychotics General	amisulpride; aripiprazole; chlorpromazine hydrochloride; clozapine; haloperidol; levomepromazine; levomepromazine hydrochloride; olanzapine; pericyazine; queti- apine; risperidone; ziprasidone; zuclopenthixol hydrochloride
Antipsychotics Depot injection	flupenthixol decanoate; haloperidol decanoate; olanzapine; paliperidone; risperidone; zuclopenthixol decanoate
Mood stabilisers	lithium carbonate; carbamazepine; gabapentin; lamotrigine; pregabalin; sodium valproate; topiramate
Benzodiazepines and zopiclone	temazepam; triazolam; midazolam; nitrazepam; clonazepam; diazepam; lorazepam; oxazepam; zopiclone
Other anxiolytics and hypnotics	melatonin; buspirone hydrochloride; phenobarbitone sodium
Opioids and opiates	codeine phosphate; dihydrocodeine tartrate; fentanyl; methadone hydrochloride; morphine hydrochloride; morphine sulphate; oxycodone hydrochloride; paracetamol with codeine; pethidine hydrochloride; tramadol hydrochloride
Stimulants	atomoxetine; dexamfetamine sulfate; methylphenidate hydrochloride; methylphenidate hydrochloride extended-release; modafinil
Treatments for substance dependence	buprenorphine with naloxone; bupropion hydrochloride; disulfiram; naltrexone hydrochloride; nicotine; varenicline tartrate

Durable ventricular assist devices for patients with advanced heart failure: the New Zealand experience

Conor W Rea, Thomas F Pasley, Peter N Ruygrok, Amul Sibal

ABSTRACT

AIMS: The prevalence of heart failure in New Zealand is increasing. A small number of select patients with predicted poor short-term survival are candidates for advanced heart failure therapies such as transplantation and durable mechanical circulatory support (MCS). The aim of our study was to introduce left ventricular assist devices (LVADs) to the wider clinicians and highlight their role in managing patients with advanced heart failure in New Zealand.

METHOD: A retrospective audit of all ventricular assist device (VAD) recipients from January 2005 to December 2022 was conducted. Data were collated using electronic medical and paper records. The primary outcome was survival to transplantation or successful explant of VAD.

RESULTS: Thirty-nine patients received VADs; 32 were male and seven female. Mean age was 45 years (range 10–64 years). Most recipients were NZ European (25), six were Māori, four were Pacific peoples and four were of other ethnicities. The majority of LVADs were implanted for those with dilated cardiomyopathy (67%). At the time of data collection, 24 (62%) had survived to heart transplantation, seven (18%) died while on VAD support, five from right ventricular failure and two from strokes, one patient had their VAD explanted due to recovery and seven (18%) VAD recipients continue on support awaiting transplant.

CONCLUSION: This audit has provided an opportunity to inform New Zealand clinicians of our durable MCS programme and the expanding role of VAD support in patients with advanced heart failure. The programme will need to continue to audit and report its practice in order to provide equitable allocation of this very limited resource to a growing population in need.

The prevalence of heart failure is increasing, affecting around 2% of the adult population and consuming around 1–2% of healthcare costs.^{1,2} While the overall incidence of heart failure is decreasing, as a result of improving preventative management a concerning increase in younger patients (<55 years) has been observed in New Zealand and internationally.^{3,4}

Once diagnosed with systolic heart failure the prognosis is poor, with an estimated 5-year survival of around 50%.⁵ While some patients improve and remain stable on medical therapy, most continue to experience progressive decline in their clinical course. A small number of select patients will be candidates for advanced heart failure therapy, such as cardiac transplantation and mechanical circulatory support (MCS).^{6,7}

Cardiac transplantation remains the gold standard for treatment of end-stage heart failure, despite optimal medical therapy. The median survival for patients following heart transplantation in New Zealand is around 15 years, which compares favourably to an international median survival of around 12 years.^{8,9} While donor numbers

have increased in recent years, overall donation rates are low compared to other developed countries and there remains a shortage of suitable donors in New Zealand.¹⁰ Therefore, transplantation remains a very limited treatment option due to patient suitability and organ availability, with only around 10–20 such operations performed annually in New Zealand.¹⁰

The ventricular assist device

Ventricular assist devices (VADs) are a form of durable MCS, used in patients with end-stage heart failure, refractory to medical and device therapy. Contemporary third generation VADs are centrifugal pumps that provide continuous flow, and have resulted in superior survival and have fewer device-associated complications compared to previous axial flow (second generation) or pulsatile flow devices (first generation).^{11–13} VADs have been shown to improve survival and quality of life outcomes when compared to optimal medical therapy in patients with advanced heart failure.^{11,14,15} While outcomes are not as favourable as following transplantation, the median survival for VAD patients of around 5 years is expected to improve as advances in technology and clinical expertise continue.¹⁶

The basic components of a centrifugal VAD consist of an intra-pericardial pump with an inflow cannula, an outflow graft and a percutaneous drive line that connects the pump to an external battery pack and controller (Figure 1).^{12,13,17–19} VADs can be configured to support the left ventricle (LVAD), with an inflow cannula inserted into the left ventricular apex and an outflow graft usually anastomosed to the ascending aorta surgically, usually via a mid sternotomy and using cardiopulmonary bypass. Durable VAD support for the right ventricle (RVAD) is an off-label use of the pump and requires technical modifications. The inflow cannula is usually inserted into the right atrium and outflow graft is anastomosed to the main pulmonary artery. The most common configuration is single VAD support of the left ventricle (LVAD), but if there is significant RV dysfunction then a BIVAD (LVAD and RVAD) may be required, though this comes with an increase in morbidity and mortality.²⁰

VADs in New Zealand

In New Zealand, implantation of VADs began in 2005 with the VentrAssist trial. Currently, VADs are indicated for heart transplant candidates as a "bridge to transplant" strategy and are not implanted as "destination therapy". The number of VADs implanted has increased significantly overseas, especially in the United States of America, where more than 50% of heart transplant candidates are "bridged" to transplant with a VAD.²¹ Eligibility for VAD support in New Zealand is considered by a multidisciplinary team from the New Zealand Heart and Lung Transplant Service, based at Auckland City Hospital. VADs are not suitable for the majority of patients with heart failure, and their use is limited to a small select group of patients with favourable clinical, social and anatomical characteristics. Cost has previously been a significant barrier; however, while VAD therapy is expensive (~\$100,000 per device), its cost effectiveness is similar to that of dialysis for kidney failure.22

The implanted VAD population of New Zealand is a small cohort, not previously reported, and therefore we conducted a retrospective audit, the results of which are described. The primary outcomes were to document VAD patient baseline characteristics and survival post VAD insertion. Furthermore, this paper aims to introduce VADs and their contemporary role in managing patients with advanced heart failure in New Zealand.

Methods

A retrospective audit of all VAD recipients from the programme's inception in 2005, until December of 2022, was conducted.

There were 43 patients in total. Four paediatric patients with extracorporeal Berlin Hearts were excluded, making our cohort of 39 adult patients with durable intra corporeal devices. Hospital electronic and paper records were sourced for data. Baseline demographics were gender, ethnicity, age, body mass index (BMI) and body surface area (BSA). Cardiomyopathy type was compiled into five main subcategories; dilated, ischaemic, congenital, myocarditis and restrictive/hypertrophic were recorded.

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) class was calculated for all recipients (Appendix 1).²³ The recipient's VAD type was identified and varied over time, and included VentraAssist[™] (2005– 2010), HeartWare[™] (2010–2022) and HeartMate 3[™] (2022–onwards) devices.

The primary outcome was determined to be death, transplant or explant. Competing outcomes were determined and displayed at 2-month intervals to 1-year from VAD implantation.

Results

From 2005 to 2019 VAD activity was rare, with around one to two VADs implanted per year. Since 2019 there has been a significant increase in VAD activity, with 18 patients receiving VADs in the last 3 years, five of those receiving a BIVAD (Figure 2).

Thirty-two of the 39 VAD recipients were male (82%) and seven female (18%). Age ranged from 10 to 64 years with a mean age of 45 years. Female recipients had a younger mean age (39 years) compared with males (46 years) (Table 1).

Most recipients were NZ European (n=25, 64%), six (15%) were Māori, four (10%) recipients were Pacific peoples and four were of other ethnicities (10%). The majority of LVADs were implanted for patients with dilated cardiomyopathy (67%), followed by ischaemic cardiomyopathy (28%), myocarditis (2.5%) and restrictive cardiomyopathy (2.5%). One patient had peripartum cardiomyopathy.

Sixteen recipients (41%) were classified as INTERMACS 1–2 at the time of VAD implant and 23 recipients were INTERMACS 3–5 (59%), with a

majority having a score of 3 (stable but inotrope dependent) at the time of VAD implantation. Of the 39 VAD recipients, 14 required a temporary RVAD support (tRVAD) and five patients required durable RVAD support in addition to their LVAD (BIVAD).

Primary outcome: survival to transplant

Survival to transplantation (or device explantation) was the primary outcome of interest. At the time of data collection, of the 39 VAD recipients, seven (18%) continued on VAD support awaiting heart transplant and seven (18%) had died while on VAD support. Overall, 24 patients (62%) survived to heart transplantation, and in one the VAD was explanted due to myocardial recovery without further need for advanced heart failure support. Competing outcomes as a percentage of all eligible patients up to 1 year following VAD implantation are displayed in Figure 3.

Of the patients who died awaiting transplant (n=7), the average time to death from VAD implantation was 87 days. Of the seven deaths, the majority occurred while in hospital and secondary to RV dysfunction. All deaths in hospital, and which were secondary to RV dysfunction, occurred prior to our regular use of durable RVADs. Of those who survived to heart transplantation or explant (n=25), average time to transplant or explant was 234 days.

Early vs more recent experience

Death with VAD in situ was also calculated and was reviewed in 3-yearly intervals. Over the most recent 3-year period, 18 VADs have been implanted, with one patient dying. Previous time periods have shown higher mortality rates (Figure 4), which may be related to older VAD technology and the inaccessibility of durable RVAD support prior to 2020. Comparison between devices and time periods is displayed in Table 2. VentrAssist devices were used from 2005-2010, and 50% of patients died awaiting transplant (Table 2). This compares to 16% of deaths in HeartWare recipients and no deaths thus far in HeartMate 3 recipients. HeartWare devices were used for the majority of recipients but were removed from the market in 2022, and HeartMate 3 VADs are the only devices implanted currently. Average implant rate per year of availability was 1.2, 2.1 and 8 for VentrAssist, HeartWare and HeartMate 3 respectively.

Discussion

This audit has provided an opportunity to analyse a small but previously unstudied population and

compare our results with international standards. It also allows us to inform New Zealand clinicians of our MCS programme and the expanding role for VAD support in patients with advanced heart failure.

Given this was a retrospective audit, data obtained were entirely reliant upon the accuracy and availability of clinical records. While a degree of variation is expected due to the small population number, certain differences can be distinguished when reviewing these 39 patients. More men received VAD support than women, a gender difference that is also observed in our heart transplant population, with around 68% of transplant recipients over the last 3 years being male.⁸ This gender imbalance is similar to other international centres, where around 80% of VAD patients are male,²⁴ despite the incidence and prevalence of heart failure being comparable between genders. This gender difference is not well understood and is beyond the scope of this review but may reflect the higher proportion of men with heart failure related to ischaemic heart disease,²⁵ which often makes these patients anatomically more suitable for VAD support than other types of cardiomyopathies.

In New Zealand, prevalence of heart failure is three to four times higher in Māori compared to NZ Europeans.²⁶ Noting the higher prevalence of heart failure and that Māori make up around 17% of New Zealand's population, they appear to be underrepresented in this VAD population (15%). Despite this, Māori comprise a large proportion (32%) of patients transplanted over the last 3 years.⁸ The low number of VAD implants for Māori could be explained by ethnic differences in cardiomyopathy types, especially rheumatic valvular heart disease, which disproportionately affects Māori and can be a contraindication for VAD implantation if an aortic mechanical valve is present.

While the most common aetiology of heart failure is ischaemic, the majority of LVADs were implanted for patients with a dilated cardiomyopathy. This most likely relates to the presence of common co-morbidities in ischaemic cardiomyopathy patients that make VAD support less suitable (i.e., diabetes mellitus, cerebrovascular disease, peripheral vascular disease), in addition to ischaemic cardiomyopathy being more prevalent in older patients and dilated cardiomyopathy (DCM) more common in younger patients. It also reflects that, at present, VADs in New Zealand are only implanted as a "bridge to transplant" strategy and are not used as a "destination therapy".

The mean INTERMACS score was 2.5, indicating

that the majority of VADs were implanted in critically unwell patients. This was similar to international data, with around 41% (16/39) of VADs being implanted in patients INTERMACS 1-2, though our proportion of patients who were INTERMACS 1 was around twice that of overseas reports.²⁷ While clinical decline can be unpredictable, the high percentage of INTERMACS 1 patients in our audit likely reflects our previous reliance on VAD support as salvage therapy. With increasing experience and confidence in our programme, the majority of VADs are being implanted in patients with scores of 2–4, where the best outcomes have been identified.²⁷ The higher proportion of INTER-MACS 1 patients could also reflect "late referrals" from referring centres, with some patients not referred until progressive end-organ dysfunction is occurring despite inotropic support. This emphasises the need to refer suitable patients early (INTERMACS 3-5) and before progression to cardiogenic shock.

Over the 18 years of our MCS programme, survival to transplant for VAD recipients is 72% and similar to other MCS centres.²⁸ As our numbers have increased, our survival to transplantation has improved, and over the last 3 years, when we have implanted around 50% of our total VADs, survival to transplant has been 94%. This includes five BIVAD patients, four of whom were successfully transplanted, with one remaining on mechanical support.

Future directions for VAD programme

The burden of heart failure in the New Zealand population is projected to grow. With a limited number of heart transplants able to be performed each year, there will be an increasing need for durable mechanical support. It is expected that VADs will continue to play a pivotal role in providing a bridge to transplantation for the New Zealand heart failure population, and in the future may even replace the need for heart transplantation in those with advanced heart failure. Timely referral of potential patients will further improve outcomes and lower costs. The VAD programme will need to continue to audit its practice in order to continue to strive to provide equitable, comprehensible and optimal care in an environment of allocating and supplying this very limited resource to a growing population of need.

Figure 1: Components of the HeartWare left ventricular assist system.

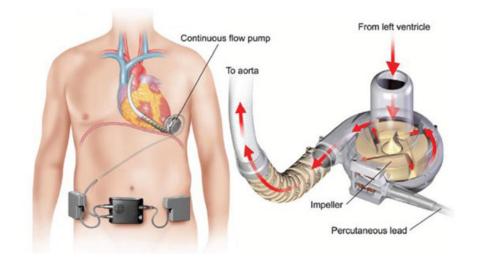
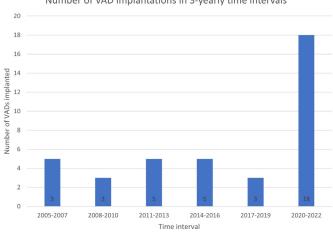


Figure 2: Number of VAD implantations in 3-yearly time intervals.



Number of VAD implantations in 3-yearly time intervals

Figure 3: Graph of competing outcomes following VAD implantation.

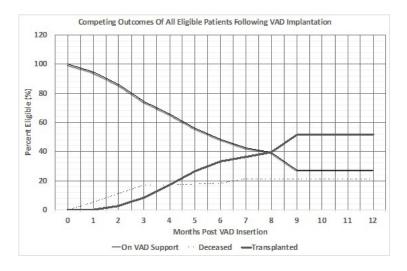


Figure 4: Number of recipients who died awaiting transplant and total number of recipients for different periods.

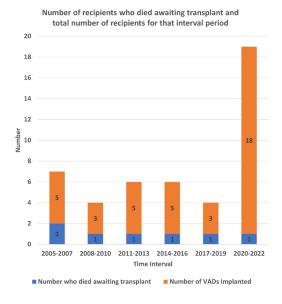


Table 1: Age and gender.

	Total population (n=39)	Male (n=32)	Female (n=7)
% total	100	82	18
Average age	45	46	41
Youngest	10	12	10
Oldest	64	64	52

 Table 2: Comparison by device type.

	VentrAssist	HeartWare	HeartMate 3	Entire population
Date of use	2005-2010	2010-2022	2022–Dec 2022	2005–Dec 2022
Number of patients	6	25	8	39
Implant rate per year of use	1.2	2.1	8	2.2
BIVAD %	0	12	25	38
Average age	33	47	47	45
% male	83	80	88	82
Average INTERMACS Score	2	2.5	3	2.5
% Death awaiting transplant	50	16	0	18

COMPETING INTERESTS

Nil.

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Appendix²³

Appendix Table 1: INTERMACS level of limitation at time of implant.

INTERMACS profile descriptions	Time frame for intervention
Profile 1: Critical cardiogenic shock	
Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels. "Crash and burn."	Definitive intervention needed within hours.
Profile 2: Progressive decline	
Patient with declining function despite intravenous inotropic support, may be manifest by worsening renal function, nutritional depletion, inability to restore volume balance "Sliding on inotropes." Also describes declining status in patients unable to tolerate inotropic therapy.	Definitive intervention needed within few days.
Profile 3: stable but inotrope dependent	
Patient with stable blood pressure, organ function, nutrition, and symptoms on continuous intravenous inotropic support (or a temporary circulatory support device or both), but demonstrating repeated failure to wean from support due to recurrent symptomatic hypotension or renal dysfunction " <i>Dependent stability</i> ."	Definitive intervention elective over a period of weeks to few months.
Profile 4: Resting symptoms	
Patient can be stabilized close to normal volume status but experiences daily symptoms of congestion at rest or during ADL. Doses of diuretics generally fluctuate at very high levels. More intensive management and surveillance strategies should be considered, which may in some cases reveal poor compliance that would compromise outcomes with any therapy. Some patients may shuttle between 4 and 5.	Definitive intervention elective over period of weeks to few months.
Profile 5: Exertion Intolerant	
Comfortable at rest and with ADL but unable to engage in any other activity, living predominantly within the house. Patients are comfortable at rest without congestive symptoms, but may have underlying refractory elevated volume status, often with renal dysfunction. If underlying nutritional status and organ function are marginal, patient may be more at risk than INTERMACS 4, and require definitive intervention.	Variable urgency, depends upon maintenance of nutrition, organ function, and activity.
Profile 6: Exertion limited	water and a second second second
Patient without evidence of fluid overload is comfortable at rest, and with activities of daily living and minor activities outside the home but fatigues after the first few minutes of any meaningful activity. Attribution to cardiac limitation requires careful measurement of peak oxygen consumption, in some cases with hemodynamic monitoring to confirm severity of cardiac impairment. "Walking wounded." Profile 7: Advanced NYHA III	Variable, depends upon maintenance of nutrition, organ function, and activity level.
A placeholder for more precise specification in future, this level includes patients who are without current or recent episodes of unstable fluid balance, living comfortably with meaningful activity limited to mild physical exertion.	Transplantation or circulatory support may not currently be indicated.
Modifiers for Profiles	Possible Profiles to Modify
TCS-Temporary Circulatory Support can modify only patients in hospital (other devices would be INTERMACS devices) Includes IABP, ECMO, TandemHeart, Levitronix ,BVS 5000 or AB5000, Impella.	1,2,3 in hospital.
A-Arrhythmia –can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to clinical compromise. This includes frequent ICD shock or requirement for external defibrillator, usually more than twice weekly.	Any profile.
FF-Frequent Flyer – can modify only outpatients, designating a patient requiring frequent emergency visits or hospitalizations for diuretics, ultrafiltration, or temporary intravenous vasoactive therapy.	3 if at home, 4,5,6. A frequent flyer would rarely be profile 7.

Using quality indicators to assess performance of endobronchial ultrasound in the staging and diagnosis of lung cancer: a pre/post study at a New Zealand centre

Paul Griffiths, Jeong Suk Oh

ABSTRACT

AIM: There are no data on the performance of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) in the staging and diagnosis of lung cancer in New Zealand. We aimed to assess the performance of EBUS-TBNA for lung cancer staging and diagnosis at our institution before and after the commencement of regular performance monitoring with comparison to published EBUS quality indicators.

METHODS: The performance of EBUS-TBNA in the staging and diagnosis of lung cancer was assessed in two phases. Phase 1 consisted of a retrospective review of all lung cancer EBUS performed over a 2-year period. Published quality indicators were determined from the literature with relevant indicators being extracted and used to determine EBUS performance. Local reporting and education were undertaken and prospective data collection was commenced. Phase 2 consisted of prospective assessment of all lung cancer EBUS over the subsequent year. Performance of EBUS was then compared between phases 1 and 2 in order to determine the effect of performance monitoring and identify areas for service improvement.

RESULTS: A total of 115 staging EBUS and 117 diagnostic EBUS were performed during the study period. Staging EBUS demonstrated good performance across phases 1 and 2 with high sensitivity and negative predictive values (NPV) for the detection of N2/3 disease, meeting published quality standards. During phase 2 there was evidence of a transition towards more guideline-concordant practice evidenced by more detailed nodal sampling during staging EBUS; however, this did not affect overall sensitivity or NPV. Diagnostic EBUS resulted in high rates of pathological confirmation meeting published quality standards across both phases. Pathway times were similar between phases 1 and 2, with reporting of molecular profiling being the predominant factor in delayed pathway times.

CONCLUSION: Monitoring and reporting of local performance allows critical assessment of practice and can identify areas for quality improvement. This review demonstrated good overall performance but prompted a move towards more guideline-concordant practice with increased mediastinal nodal sampling during staging procedures. Consideration should be given to the adoption of routine EBUS performance monitoring within local and/or regional networks, which could be incorporated alongside the newly proposed Lung Cancer Clinical Quality Registry.

Lung cancer is the leading cause of cancer-related death in New Zealand and Australia.^{1,2} Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is a bronchoscopic procedure that has become a key modality for the staging and diagnosis of lung cancer. EBUS-TBNA is generally performed by respiratory physicians in an outpatient setting and has significantly reduced the need for surgical sampling of the mediastinum, namely mediastinoscopy, and its associated risks.

At present, there is no routine requirement for the reporting of EBUS performance for lung cancer staging and diagnosis and there are no data regarding EBUS performance in New Zealand. Until recently, there have been no published quality indicators relating to EBUS performance monitoring. However, a national EBUS service specification was published in the United Kingdom (UK) in 2019, which outlines key quality indicators.³ Furthermore, care pathways and quality standards have been developed to provide a structured, multidisciplinary pathway for people with suspected lung cancer, including in New Zealand and Australia.⁴⁻⁶ These pathways highlight key performance indicators and recommended timeframes for diagnosis and treatment, and while they are not specific to EBUS,

they are clinically relevant and can be appraised when examining the use of EBUS in lung cancer.

EBUS-TBNA has a vital role in mediastinal nodal staging in people with lung cancer. Nodal stage is a predictor of prognosis, with a higher stage conveying a worse outcome.7 In cases of potentially radically treatable lung cancer, EBUS-TBNA can be performed as a *staging* procedure that improves the accuracy of mediastinal staging compared to radiological stage alone and is essential for determining optimal treatment.8 The radical management of a patient with lung cancer and mediastinal nodal involvement (N2/3 disease) requires a multimodality approach, with treatment choice being influenced by location, distribution and volume of involved nodes.9 A staging EBUS should therefore provide high sensitivity and negative predictive value (NPV) for the detection of N2/3 disease. Theoretically, sensitivity should not be dependent on prevalence of N2/3 disease; however, sensitivity and NPV have been shown to be correlated with the prevalence of N2/3 nodal disease, with prevalence being positively correlated with sensitivity and inversely correlated with NPV.8,10,11 This likely reflects biological variation between patients in higher and lower prevalence populations. For example, patients with large, morphologically malignant, positron emission tomography (PET/CT) avid mediastinal nodes will have a higher prevalence of malignant nodal involvement, and therefore a lower false negative sampling rate, compared to those with small non-avid nodes when the prevalence of malignant nodal disease is likely to be lower or microscopic in nature, with an increased false negative sampling rate.¹¹ Therefore, when assessing the performance of EBUS in lung cancer staging, it is essential to present sensitivity and NPV alongside the prevalence of N2/3 disease in those undergoing EBUS. The specificity of EBUS-TBNA is generally reported at 100%—false positive results are very rare but have been described.¹²

In cases of advanced lung cancer, when radical treatment is not possible and detailed mediastinal staging is not required, EBUS can be utilised as a *diagnostic* procedure. A diagnostic EBUS involves targeted sampling of any abnormal node or tissue in order to provide adequate material for tumour subtyping and molecular analysis. Pathological confirmation rate and adequacy of sampling for molecular analysis are therefore key performance metrics for diagnostic EBUS.

In this study, performance against EBUS quality

indicators was compared before and after the commencement of local performance monitoring in order to assess whether this resulted in improved performance of EBUS in the staging and diagnosis of lung cancer.

Methods

This performance review consisted of two phases. In September 2021, the UK EBUS service specification together with national lung cancer guidelines and clinical quality indicators from New Zealand and Australia were reviewed, with recommendations applicable to EBUS being extracted for use in this study. These recommendations and quality standards can be found in Table 1. For staging EBUS, the number of lymph node stations being sampled was also recorded, as there is evidence that this influences performance.¹³

In September 2021, a retrospective review of all lung cancer EBUS performed at our institution between September 2019 and September 2021 (phase 1) was performed. Phase 1 data were analysed and compared to the published quality standards, with findings being presented within our local lung cancer governance group, which determined the need for prospective data collection with regular reporting of performance. Prospective data collection was then performed for all lung cancer EBUS between October 2021 and October 2022 (phase 2). Performance of EBUS was then compared between phases 1 and 2 in order to determine the effect of performance monitoring and identify areas for service improvement.

Our centre has provided an EBUS service since 2014, and during the study period all procedures were performed by one of five respiratory physicians alongside a specialist trainee in respiratory medicine, using local anaesthesia with topical lignocaine to the airways and conscious sedation with intravenous fentanyl and midazolam. During the study period, patients with suspected lung cancer proceeded to EBUS following initial staging computed tomography (CT) and clinical review, with or without PET/ CT, at the discretion of the treating clinician. Lung cancer diagnosis was confirmed from a review of medical records and confirmation of clinical-pathological diagnosis at 6 months post-procedure. This 6-month follow-up period was chosen based on the recommendation from the published EBUS service specification and expert opinion.^{3, 11} Initial staging CT, or PET/CT

if performed, was reviewed to determine the radiologic stage and the American College of Chest Physicians (ACCP) radiologic group, a description of which can be found in the Appendix.⁸ Cases without evidence of metastatic disease on initial staging CT and/or PET/CT and meeting criteria for ACCP groups B, C or D were assigned to the staging EBUS group. Those with metastatic disease or those in ACCP group A were assigned to the diagnostic EBUS group.

Electronic health records were reviewed to assess demographics and lung cancer pathway metrics. EBUS-specific data were retrieved from electronic procedural reports. Final cytopathology reports were reviewed to categorise positive and negative results, adequacy of sampling for tumour subtyping and adequacy for molecular analysis. For staging EBUS, final clinical-pathological stage was reviewed at 6 months post-procedure, with procedures being classed as true positive, true negative, or false negative for N2/3 nodal involvement, with subsequent calculation of N2/3 prevalence, sensitivity and NPV. A false negative EBUS was defined as a negative EBUS-TBNA for N2/3 nodal disease that later proved positive, either at surgical resection or following 6 months of clinicalradiological follow-up, including for N2/3 nodes inaccessible by EBUS. Adverse events were categorised according to the British Thoracic Society (BTS) bronchoscopy guideline.¹⁴

Demographic and clinical characteristics were summarised using standard descriptive statistics depending on the type and distribution of data. Continuous variables were compared using an Independent Samples *t*-Test or Mann–Whitney U test, with categorical variables compared using Pearson Chi-squared test or Fisher's exact test. All tests were two-tailed and statistical significance was set at p<0.05. The SPSS Statistics package (version 26.0, 2019; IBM) was used for data analysis. The study was approved by our institutional Research and Knowledge Department, and individual patient consent was not required given the nature of the study.

Results

A total of 232 EBUS were performed for lung cancer staging and diagnosis during the study period (115 staging EBUS and 117 diagnostic EBUS). Age, sex and ethnicity were similar between groups. Demographics, clinical characteristics and procedural data are reported in Table 2.

In phase 1, four patients required a repeat

staging EBUS: two following PET/CT that showed increased metabolic activity in an N2 node that was not sampled previously (both true negative); one following a negative EBUS prior to surgery (true negative); and one due to progressive nodal enlargement following a negative EBUS (false negative). Three patients required a repeat diagnostic EBUS, one due to insufficient material for tumour subtyping, and two due to insufficient tissue for molecular analysis. In phase 2, three patients required a repeat staging EBUS: one following PET/CT showing mild avidity in a previously sampled N2 node (true negative); one due to insufficient sampling of an enlarged N2 node (true negative); and one due to insufficient tissue for molecular analysis. One patient required repeat diagnostic EBUS due to insufficient tissue for molecular analysis.

There were no significant differences in ACCP group distribution or tumour subtype between phases 1 and 2, with adenocarcinoma being the most frequent diagnosis in both the staging and diagnostic EBUS groups.

Staging EBUS performance

Table 3 summarises the performance of EBUS in the staging of lung cancer. The overall prevalence of N2/3 nodal disease in phases 1 and 2 was 55% and 57% respectively, resulting in sensitivity and NPV targets of >85%.^{3,11} Across both phases, sensitivity and NPV for the detection of N2/3 disease met the recommended targets and demonstrated a small improvement in phase 2 compared to phase 1; however, this was not statistically significant. Adequacy of sampling for molecular analysis was high across both phases, meeting recommended targets.

There were increases in the mean number of nodes sampled per procedure in phase 2 (1.9, standard deviation [SD] 0.85) compared to phase 1 (1.6, SD 0.7) (t=2.154, p=0.03), and an increase in the mean number of N2/3 nodes sampled per procedure in phase 2 (1.5, SD 0.72) compared to phase 1 (1.1, SD 0.71) (t=2.77, p=<0.01). In phase 2, patients were more likely to have two or more N2/3 nodes sampled compared to phase 1 (odds ratio [OR] 2.41, 95% confidence interval [CI] 1.1– 5.28, p=0.03).

Diagnostic EBUS performance

Table 4 summarises the performance of EBUS in the diagnosis of lung cancer. Pathological confirmation rate was high in both phases and met the recommended target, although was numer**Table 1:** Quality indicators used to assess EBUS performance in the staging and diagnosis of lung cancer.

Quality indicator	Source	Target (if stated) or for reporting only	Comments	
Staging EBUS performance	_	_	_	
Prevalence of N2/3 disease	UK service specification ³	Reporting only	For evaluation of sensitivity and NPV	
Overall sensitivity for N2/3 disease	UK service specification ³	Dependent on N2/3 prevalence		
Overall NPV for N2/3 disease	UK service specification ³	Dependent on N2/3 prevalence		
Adequate for molecular analysis (non-squa- mous NSCLC)	UK service specification ³	>90%		
Diagnostic EBUS performance				
Pathological confirmation (%)	UK service specification ³	>90%		
NSCLC-NOS (%)	UK service specification ³	<10%		
Sufficient tissue for molecular analysis (non-squamous NSCLC)	UK service specification ³	>90%		
Proportion of cases requiring repeat sampling due to insufficient tissue	UK service specification ³	<10%		
Pathway-related				
	UK service specification ³	85%		
EBUS performed ≤7 days from referral	New Zealand standards of service provision⁴	95%		
Pathology report ≤3 days from EBUS	Australian optimal care pathway ⁶	Reporting only	Target % compli- ance not stated	
Pathology report ≤5 days from EBUS	UK service specification ³	85%		
Pathology report ≤7 days from EBUS	New Zealand standards of service provision⁴	95%		
Pathology report, including molecular analysis, ≤10 days from EBUS (non-squamous NSCLC)	UK service specification ³	85%		
Pathology report, including molecular analysis, ≤14 days from EBUS (non-squamous NSCLC)	Australian optimal care pathway ⁶	Reporting only	Target % compli- ance not stated	
Total pathway time: pathology report (including molecular analysis) ≤14 days from referral (non-squamous NSCLC)	UK service specification ³	Reporting only	Target % compli- ance not stated	
Safety/adverse events				

Abbreviations: EBUS = endobronchial ultrasound; NPV = negative predictive value; NSCLC-NOS = non-small cell lung cancer not otherwise specified.

 Table 2: Characteristics of subjects undergoing staging and diagnostic EBUS for lung cancer.

	Staging EBUS			Diagnostic EBUS		
	Phase 1 n (%)	Phase 2 n (%)	p	Phase 1 n (%)	Phase 2 n (%)	р
N	69 46			76	41	
Age						
Median, years (IQR)	73 (67–80)	72 (66–79)	0.59	70 (60–75)	70 (63–80)	0.18
Sex						
Female	36 (55)	26 (60)	0.54	40 (55)	21 (52)	0.98
Ethnicity						
European	49 (75)	32 (74)		43 (59)	26 (65)	
Māori	4 (6)	4 (9)		7 (10)	5 (13)	
Pacific peoples	1 (1.5)	0		7 (10)	4 (10)	0.84
Asian	9 (14)	7 (16)	0.8	14 (19)	5 (13)	0.84
MELAA	1 (1.5)	0		2 (3)	0	
Other	1 (1.5)	0		0	0	
Status at time of EBUS		·				
Outpatient	66 (96)	43 (93)	0.68	49 (64)	25 (60)	0.71
ACCP group						
A	0	0		18 (24)	7 (17)	
В	54 (78)	38 (83)		0	0	
С	14 (20)	7 (15)	0.76	0	0	0.41
D	1 (2)	1 (2)		0	0	
Or metastatic disease	0	0		58 (76)	34 (83)	
EBUS for detection of N2/3 disease	a					
True positive for N2/3 disease	33 (48)	23 (50)		75 (99)	38 (93)	
True negative for N2/3 disease				-	-	
EBUS stage N0	20 (29)	18 (39)		-	-	
EBUS stage N1	11 (16)	2 (4)		-	-	
False negative for N2/3 disease				1 (1)	3 (7)	
EBUS stage N0 to surgical stage N2	4 (6)	2 (4)		-	-	
EBUS stage N1 to surgical stage N2	1 (1)	1 (2)		-	-	
False positive for N2/3 disease	0	0		0	0	

^a Based on further pathologic sampling or 6-month clinical-radiological follow-up. See Table 3 for associated sensitivity and negative predictive value.

Abbreviations: ACCP = American College of Chest Physicians; IQR = interquartile range; MELAA = Middle Eastern/Latin American/ African.

		Staging EBUS		
Quality indicator	Target (%)	Phase 1	Phase 2	р
		n/N (%)	n/N (%)	
Prevalence of N2/3 disease		38/69 (55)	26/46 (57)	n/a
Sensitivity for N2/3 disease	>85	33/38 (87)	23/26 (88)	>0.99
NPV for N2/3 disease	>85	31/36 (86.1)	20/23 (87)	>0.99
Adequate for molecular analysis ^a	>90	29/31 (94)	21/22 (95)	>0.99
LN sampled per procedure, mean (SD)		1.6 (0.7)	1.9 (0.85)	0.03
LN sampled per procedure				
1		36/69 (52)	17/46 (37)	0.19
2		27/69 (39)	19/46 (41)	
3 or more		6/69 (9)	10/46 (22)	
N2/3 LN sampled per procedure, mean (SD)		1.1 (0.71)	1.5 (0.72)	<0.01
N2/3 LN sampled per procedure				
0/N1 node only		13 (19)	3 (7)	
1		37 (54)	21 (46)	0.06
2		18 (27)	19 (41)	
3		1 (1)	3 (7)	

Table 3: Summary of EBUS performance metrics (per procedure) in the staging of lung cancer.

^a Only applicable to those with non-squamous non-small cell lung cancer confirmed with EBUS during the study period. Abbreviations: LN = lymph node; NPV = negative predictive value; SD = standard deviation.

Table 4: Summary of EBUS performance metrics	(per procedure) in the diagnosis of lung cancer.
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		Diagnostic EBUS		
Quality indicator	Target (%)	Phase 1	Phase 2	р
		n/N (%)	n/N (%)	
Pathological confirmation	>90	75/76 (99)	38/41 (93)	0.12
NSCLC-NOS ^a	<10	1/59 (2)	3/29 (10)	0.1
Adequate for molecular analysis ^b	>90	44/48 (92)	22/24 (92)	>0.99
Repeat sampling required due to insufficient tissue ^c	<10	3/76 (4)	1/41 (2)	>0.99

^a NSCLC-NOS rate among those with NSCLC diagnosed from EBUS.

^b Applicable to those with non-squamous NSCLC confirmed with EBUS during the study period.

^c Repeat sampling for more tissue for either immunohistochemical characterisation or molecular analysis.

Abbreviations: NSCLC-NOS = non-small cell lung cancer not otherwise specified.

ically lower in phase 2. The rate of non-small cell lung cancer not otherwise specified (NSCLC-NOS) was higher in phase 2 compared to phase 1, falling above the recommended target. Adequate tissue for molecular analysis was obtained in 92% of procedures during both phases. The rate of repeat sampling was low, noting that not all patients with inadequate tissue for molecular analysis underwent repeat testing (due to declining performance status or patient wishes).

Lung cancer pathway performance indicators and safety data

Table 5 shows performance indicators for EBUS-specific lung cancer pathway metrics and associated targets. Waiting time from referral to staging EBUS was longer during phase 2 with an increase in median wait time from 4 to 5 days, associated with a decrease from 93% to 83% 7-day completion during phase 2-falling short of the New Zealand quality standard of 95% compliance. Time from EBUS to initial pathology reporting (excluding molecular analysis) was above the target set by both the UK EBUS service specification and the New Zealand quality standard. With reference to the Australian optimal care pathway, between 42% and 57% of cases had a pathology result available within 3 days of EBUS, which can act as a comparator for other services as there is no published compliance target for this metric. The time interval from EBUS to receipt of final pathology, including molecular analysis, did not meet the target set by the UK service specification. During the study period, this was only applicable to those patients with non-squamous NSCLC when testing for anaplastic lymphoma kinase (ALK) rearrangement and common mutations were required. In phase 2, the proportion of cases having final pathology results available within 10 or 14 days from staging EBUS improved by 17% and 12%, and for diagnostic EBUS by 18% and 9%, respectively, although these differences did not reach statistical significance. There was a move towards reduction in total pathway time (all results available within 14 days from referral) in both cohorts, not meeting statistical significance.

There was one serious adverse event resulting in a hospital admission due to presumed EBUSrelated chest infection requiring a 3-day inpatient stay. Four procedures resulted in moderate bleeding requiring the endobronchial administration of cold saline or adrenaline, with all patients being discharged the same day with no further bleeding complications.

Discussion

This single-centre review of EBUS performance in the staging and diagnosis of lung cancer has provided evidence of a high-quality service across a number of quality indicators. While there was no significant improvement in the majority of quality indicators between phases 1 and 2, overall EBUS performance was generally excellent with both sensitivity and NPV for staging EBUS being above the targets set out in published quality standards, and pathological confirmation rate for diagnostic EBUS being high across both phases. Adequacy of material for molecular profiling was also above the published standards in both the staging and diagnostic cohorts. Pathway times varied across phases 1 and 2, with small improvements in time to final pathology reported being seen in phase 2. Importantly, there is evidence of a transition towards more guideline-concordant care evidenced by more detailed nodal sampling during staging EBUS, which is worthy of further discussion.

With regards to staging EBUS, thoracic surgical guidelines for mediastinal staging define a staging EBUS as either selective, with sampling of suspicious/radiologically abnormal nodes only, or systematic, involving assessment of all nodal stations aiming for sampling from ≥3 mediastinal nodal stations.^{8,11,15–17} Hypothesising that the number of N2/3 nodes sampled is a surrogate for selective versus systematic staging, our data suggest that a selective staging approach was favoured with an average of 1.1 mediastinal nodal stations being sampled during phase 1, increasing to 1.5 mediastinal nodal stations during phase 2. In phase 2, fewer cases had only N1 nodes sampled compared to during phase 1 (7% versus 19%), and more cases had ≥ 2 mediastinal nodes sampled (48% versus 27%). Only a small number of cases had three mediastinal nodes sampled: one case in phase 1 and three cases in phase 2. While the average number of mediastinal nodes sampled per procedure increased between the two phases, this resulted in only small improvements in sensitivity and NPV in phase 2 (1.7% and 0.9%, respectively). However, there are data to support systematic rather than selective mediastinal sampling for lung cancer staging, with a randomised control trial comparing selective EBUS, systematic EBUS and systematic EBUS plus EUS-B (endoscopic ultrasound-guided sampling using the EBUS scope in the oesophagus) showing a 4% increase in sensitivity with systematic compared to selective EBUS,

Table 5: Pathway times for EBUS and pathology results, and safety data (per procedure).

	Target	Staging EBUS			Diagnostic EBUS		
	(%)	Phase 1	Phase 2	p	Phase 1	Phase 2	p
Overall wait time, median (IQR)			·		·		
Referral to EBUS		4 (2–6)	5 (3–7)	0.04	2 (1–3)	3 (1-6)	0.14
EBUS to pathology report ^a		4 (2–5)	3 (2–4)	0.05	4 (2–5)	3 (2–5)	0.34
Referral to pathology report ^a		8 (6–9)	8 (6–11)	0.44	6 (4–8)	7 (5–9)	0.33
Performance indicator, % (n/N)							
EBUS ≤7 days from referral	85-95	93 (64/69)	83 (38/46)	0.09	93 (71/76)	93 (38/41)	>0.99
Pathology report ≤3 days from EBUS ^a	ns	42 (29/69)	57 (26/46)	0.13	42 (32/76)	51 (21/41)	0.35
Pathology report ≤5 days from EBUS ^a	85	90 (62/69)	98 (45/46)	0.14	89 (68/76)	85 (35/41)	0.56
Pathology report ≤7 days from EBUS ^a	95	100 (69/69)	100 (46/46)	>0.99	99 (75/76)	100 (76/76)	>0.99
Pathology (including molecular analysis) ≤10 days from EBUS ^b	85	21 (6/29)	38 (8/21)	0.18	18 (8/44)	36 (8/22)	0.10
Pathology (including molecular analysis) ≤14 days from EBUS ^b	ns	69 (20/29)	81 (17/21)	0.34	73 (32/44)	82 (18/22)	0.41
Total pathway time: pathology (including molecular analysis) ≤14 days from referral ^b	ns	34 (10/29)	38 (8/21)	0.79	34 (15/44)	45 (10/22)	0.37
Safety data, % (n/N)							
Serious adverse events	<3	1.4 (1/69)	0	>0.99	1.3 (1/76)	0	>0.99

Table 5 (continued): Pathway times for EBUS and pathology results, and safety data (per procedure).

Bleeding							
Mild		0	2 (1/46)		0	2 (1/41)	
Moderate	ns	3 (2/69)	0	0.24	3 (2/76)	0	0.23
Severe		0	0		0	0	

Serious adverse events: severe bleeding, cardiac arrhythmia, seizure, myocardial infarct/pulmonary oedema, pneumothorax requiring intervention, over-sedation requiring reversal agent, unplanned hospitalisation, admission to critical care unit, death.

Bleeding classification: mild = continued suctioning, bleeding stops spontaneously; moderate = requiring adrenaline or cold saline; severe = requiring bronchus blocker, fibrin sealant, resuscitation, blood products.

^a Pathology report including tumour subtyping and relevant immunohistochemistry.

^b Molecular analysis performed in those with non-squamous NSCLC during this study period, and with sufficient sample.

Abbreviations: EBUS = endobronchial ultrasound; NSCLC = non-small cell lung cancer; ns = not stated; PET/CT = positron emission tomography.

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and an additional 5% improvement when EUS-B was added.¹³ A large meta-analysis by Korevaar et al. further demonstrated improved sensitivity when EUS-B is used alongside EBUS; however, the routine use of EUS-B is not commonplace due to lack of availability and expertise, and is not in use at our centre.^{13,18} The meta-analysis reported a sensitivity of 72% for the detection of N2/3 nodal disease with EBUS across all available studies; however, direct comparison with our cohort is not possible given the varying prevalence of N2/3 disease in the meta-analysis population.¹⁸

Rapid onsite evaluation (ROSE) is utilised alongside EBUS at our centre as it can provide real-time feedback regarding the cellularity of a nodal specimen, having also been shown to increase the rate of successful lung cancer genotyping when compared with standard care, and this may influence sampling strategy.¹⁹ However, the benefits of ROSE alongside EBUS remain the subject of debate.¹⁹⁻²¹ The use of ROSE may explain the relatively low number of N2/3 nodes being sampled in our staging cohort when compared to guideline recommendations, as the bronchoscopist may choose to stop sampling once adequate material has been obtained from an N2/3 node if it provides sufficient staging information to inform treatment. However, there are potential downsides to a ROSE-guided sampling approach, as there is evidence to suggest that the total number rather than just anatomical location of malignant nodes influences prognosis.²² Additionally, precise nodal characterisation aids in the planning of radical radiotherapy for those patients who do not undergo surgery.²³ Overall, despite a more selective staging approach being favoured at our centre, we provide assurance of high-quality mediastinal nodal staging evidenced by high sensitivity and NPV for the detection of N2/3 disease that meets published quality standards.

Importantly, across both phases, only around 20% of patients undergoing staging EBUS were clinical stage N0/N1 (ACCP groups C and D, or a radiologically normal mediastinum). A meta-analysis evaluating EBUS-TBNA for systematic mediastinal staging in clinical N0/N1 lung cancer demonstrated a mean prevalence of occult N2/3 disease of 15%, with a number needed to test to detect occult N2/3 disease of 14 (95% CI 10.8–16.3).²⁴ We may be missing opportunities to identify patients with occult mediastinal nodal involvement in patients with a radiologically normal mediastinum. This is particularly relevant

in those who may receive ablative radiotherapy rather than surgical resection and lymph node dissection for complete pathologic staging. Further, the CheckMate 816 trial has shown significant improvements in outcomes following neoadjuvant chemotherapy-immunotherapy followed by surgery in those with lymph node metastases, with the National Institute for Health and Care Excellence (NICE) now recommending this treatment for patients with tumour size >4cm or nodal metastases at diagnosis.^{25,26} While this treatment is not currently available in New Zealand, this study highlights the importance of precise mediastinal staging in order to optimise treatment.

During this study, the timing of PET/CT and staging EBUS was at the discretion of the treating clinician; however, the UK NICE lung cancer guideline recommends that PET/CT be performed prior to staging EBUS.²⁷ PET/CT was available for 45% and 46% of staging procedures in phases 1 and 2 respectively. Sensitivity for the detection of N2/3 disease was lower in those who underwent PET/CT prior to EBUS (83% versus 89%, p=0.68) and NPV was higher in those who underwent PET/CT prior to EBUS (92% versus 77%, p=0.14). However, the prevalence of N2/3 disease in those with and without prior PET/CT was significantly different, being 35% and 73% respectively. This reflects the relationship between N2/3 disease prevalence and sensitivity (positive correlation) and NPV (negative correlation), as described earlier.8,11

Lung cancer pathways and service standards are endorsed in both Australia and New Zealand.^{4,6} While cancer pathways aid in mapping the patient journey from diagnosis to treatment, the focus mainly relates to the overall timeliness of care, and many do not provide explicit recommendations regarding EBUS. Delays can occur at any part of the lung cancer pathway, so critical appraisal of each step may identify areas for improvement.

Access to EBUS was better during phase 1 compared to phase 2 (93% performed within 7 days of referral versus 83%). This is likely to be multifactorial, but increased demand on lung cancer services coupled with the effects of the SARS-CoV-2 pandemic on EBUS utilisation, particularly during phase 1, are likely to be contributory. Time to initial pathology reporting is excellent (98% reported in \leq 5 days in Phase 2), but time to molecular pathology reporting is prolonged. The mean turnaround times from

initial pathology report to final molecular pathology (for non-squamous NSCLC) in the staging and diagnostic groups across both phases were 8.4 and 9.0 days respectively. Total pathway time (from EBUS referral to receipt of all pathology results) was prolonged with <40% of patients receiving all results within 14 days. This may have a greater impact on those patients with more advanced disease, as delays in the reporting of a potential targetable oncogenic driver would influence first-line treatment. In our region, molecular pathology testing is outsourced to a regional provider, with inherent delays involved in the transport and processing of samples and publishing of results. During phase 1, mutation analysis was performed upfront, followed by ALK rearrangement by fluorescence in situ hybridisation (FISH) if the initial mutation panel was negative (limited to epidermal growth factor receptor mutations during this study period). During phase 2, ALK FISH was replaced by ALK immunohistochemistry (IHC), which can be performed upfront alongside standard IHC, and likely contributed to the reduction in time to final molecular diagnosis seen in phase 2.

While this performance review provides important data regarding the performance of EBUS-TBNA in a New Zealand context, there are important limitations to acknowledge. Given the retrospective data collection during phase 1, there is risk of investigator bias in the allocation of patients to either the staging or diagnostic EBUS groups. Based on the index CT scan of the chest, those with ACCP group B, C or D were automatically assumed to have undergone a staging EBUS. However, this does not take into account the likely treatment intent for individual patients, as some patients with ACCP group B, for instance, may not have been suitable for radical treatment and may have undergone a targeted EBUS procedure only. However, the same group allocation criteria were used during phase 2 in order to allow direct comparison. Further, this study does not account for potential variability in practice between different bronchoscopists, which may influence overall performance. Although procedures were performed by a group of five operators, over 85% of all procedures were performed by three of the group. For diagnostic EBUS, diagnostic

confirmation rate and adequacy for molecular analysis were similar across all operators despite the differences in volume, being over 90% for both quality indicators. For staging EBUS, overall sensitivity and NPV ranged from 84% to 100% and 67% to 100%, respectively. Paradoxically, the highest sensitivity and NPV were from operators who performed the fewest number of cases (fewer than seven staging EBUS per year per operator). While it is reassuring that high sensitivity and NPV are provided by those performing low numbers of procedures, this may represent differing case selection and caution should be used when appraising these values. It is important to note, however, that procedural competence is not necessarily related to the overall number of cases performed,²⁸ and monitoring of procedural volume per clinician may form a useful part of a quality assurance process.

Importantly, since completion of this study, an international expert consensus statement on proposed EBUS quality indicators and recommended reporting has been published.²⁹ The statement expands on the quality indicators reported in our review, and may form the basis of local EBUS quality assurance programmes going forward.

Conclusion

EBUS-TBNA is an essential part of the lung cancer pathway and can be provided in a timely and safe manner. Monitoring and reporting of local performance allow critical assessment of current practice and can identify areas for quality improvement with a view to improving care. This review demonstrated good initial performance, but prompted a move towards more guidelineconcordant practice with increased mediastinal nodal sampling during staging procedures. In an Australasian context, consideration should be given to the adoption of routine EBUS performance monitoring within local and/or regional networks, which could be incorporated alongside the newly proposed Lung Cancer Clinical Quality Registry and would allow EBUS centres to benchmark current practice and act as a driver for quality improvement.³⁰

COMPETING INTERESTS

None.

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Appendix

Group	Description	CT features	Invasive mediastinal staging?	N2/3 prevalence
A	Mediastinal infiltration	Conglomerate mediastinal nodal involve- ment, individual lymph nodes cannot be distinguished or measured.	No Diagnostic procedure only	100%
В	Enlarged discrete mediastinal node involvement	Nodes ≥1cm short-axis diameter on CT.	Yes Staging EBUS in the first instance	60%
С	Abnormal hilar node or central tumour, normal mediastinum	Normal mediastinum (nodes <1cm) but enlarged hilar (N1) nodes (≥1cm), or central tumour.ª	Yes Staging EBUS in the first instance	20-25%
D	Peripheral stage I tumour	Normal mediastinum, normal N1 nodes (<1cm). Peripheral tumour. ^b	No Proceed to treatment if no nodal involve- ment on PET	5–10%

 Table 1: ACCP radiologic group descriptors and indications for pathological nodal staging.

^a Central tumour defined as being within proximal one third of the hemithorax on transverse CT image. ^b Peripheral tumour defined as being within outer two thirds of the hemithorax on transverse CT image. Abbreviations: ACCP = American College of Chest Physicians; CT = computed tomography. Adapted from Silvestri et al.¹ and Evison et al.²

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Concomitant septic and crystal arthropathy: a single-centre 10-year retrospective observational study in New Zealand

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ABSTRACT

AIM: To quantify and characterise patients with coexistent septic arthritis (SA) and crystal arthritis (CA) (SACA) in an emergency department (ED) setting.

METHODS: A single-centre, retrospective, 10-year observational study was conducted at a major referral centre. Patients with a positive joint aspirate for CA or SA carried out in ED, were included. The Newman criteria were utilised to define SA.

RESULTS: Of the 567 patients included in the final analysis, 427 had CA and 140 had a final diagnosis of SA. Twenty-three point six percent of patients diagnosed with SA had concomitant CA, while 7.2% of patients diagnosed with CA had concomitant SA. The greatest predisposing factors for SACA were previous history of gout, rheumatoid arthritis, being immunocompromised or having joint metalware. Synovial fluid (SF) white cell count (WCC) showed excellent predictive capability for joint infection with the area under the receiver operating characteristic curves (AUROCs) of 0.81 and 0.87 for SA and SACA respectively. The receiver operating characteristic curves (AUROCs) of patients at risk of misdiagnosis of CA alone. SF WCC of 32,000/mm³ may be a better cutoff than the traditionally accepted 50,000/mm³, possibly warranting inpatient admission for investigation and management of presumed SA.

M onoarticular arthritis is a common presentation in the emergency department (ED) and has a broad differential diagnosis, including autoimmune arthritis, septic arthritis (SA) and crystal arthritis (CA). Missing SA can have devastating consequences with a mortality rate ranging from 4–42%,¹⁻³ and can cause joint destruction with long-term joint dysfunction in 30% of patients.^{4,5} Diagnosing septic joint can be challenging in the ED, with clinicians having to rely on interpretation of clinical features and joint aspirate samples.

Additionally, some patients can have dual pathology of concomitant SA and CA (SACA).¹ CA is a risk factor for SA, and, contrarily, a joint infection may produce conditions where urate or calcium pyrophosphate crystals can precipitate into the synovium.^{6,7} Reported incidence of SACA ranges from 1.5–25% of patients with proven SA.^{8–10} However, there is a paucity of data regarding SACA, with much of the data in the form of case reports or series. Indeed, in New Zealand adults, there is only one single-centre study that reports the presence of SACA.⁸

The diagnosis of SACA is often confirmed in retrospect once the aspirate or blood culture show a positive culture growth, up to 48 hours after the aspirate was carried out in the ED. The ED physician can incorrectly give a diagnosis of CA from the initial aspirate results and discharge the patient, thus delaying diagnosis and treatment of the concomitant SA. This makes SACA a particularly difficult diagnosis to make in the ED and requires a high index of suspicion.

The aim of this retrospective study was to quantify and characterise SACA in an ED setting in New Zealand, to compare this group against CA and SA alone and to add to the data for this uncommon but critical clinical presentation.

Methods

Study design and population

A single-centre, retrospective observational study was conducted at a major referral centre in New Zealand between December 2010 and December 2020. ICD-10 search codes were used to identify all adult patients presenting to the ED with an initial diagnosis of gout, pseudogout or SA. Of these patients, those with a joint aspiration in ED were assessed for inclusion in the study. Patients were excluded if they did not have a joint aspirate in ED or their joint aspiration sample was negative for crystals and did not have a microbe isolated.

Of the included patients, the Newman criteria were utilised to define the final diagnosis of SA.⁷ A final clinical diagnosis of SA was defined as presence of one of the following:

- Microbial pathogen isolated from synovial fluid (SF) either in the ED or in the theatre
- Microbial pathogen isolated from joint tissue in theatre
- Microbial pathogen isolated in other source, such as blood or swabs
- Radiological evidence of SA

SF aspirate turbidity was not included as part of the diagnostic criteria due to the subjectivity of this factor.

A patient was deemed to have gout or pseudogout if a deposition of uric acid (UA) or calcium pyrophosphate dihydrate crystals (CPPD) was identified in their SF aspirates. Data were collected on a wide range of variables including patient demographics, patient risk factors and comorbidities, joints affected, SF aspirate results, final management and outcome. Comorbidities and risk factors for SA identified in this study were based on previous large prospective and retrospective studies.^{8,11-13}

We defined immunodeficiency as any patient with the following at the time of diagnosis:

- Solid organ transplant patients on antirejection medications
- Neutropenic chemotherapy for cancer treatment
- Immunotherapy for an inflammatory arthropathy
- End-stage renal or liver failure^{8,11–13}

Renal failure was described as any patient with a stage 3a or higher chronic renal impairment.^{8,11–13}

Data handling

A data collection form was developed by the principal investigator of the study. This form was initially piloted on 10% of the patients by study investigators. Feedback from investigators was obtained and the form was improved and standardised by the principal investigator. A data dictionary was devised and, where appropriate, incorporated within the standardised data collection form to help improve accuracy and ensure uniform handling of data that were conflicting or ambiguous. The data were all clinical information mandatory normally recorded as part of standard clinical care. Data were collected by ED research nurses, who were trained in accurate data collection and the processing of conflicting, ambiguous or missing data. Data were de-identified as soon as viable and were sent to the principal investigator for further analysis.

Data management and accuracy checks were conducted by the principal investigator with a manual check on a random portion of the data. For a 10% sample of the total cohort, the interinvestigator agreement was 96.8%. A kappa statistic of 0.93 (95% confidence interval [CI] 0.89–0.95) was calculated for 12 categorical variables, indicating an almost perfect agreement for interinvestigator reliability.

Statistical analysis

Data were analysed using MedCalc Statistical Software (version 17.8.6, Ostend, Belgium; http:// www.medcalc.org). Descriptive statistics were used to convey baseline characteristics. Chisquared testing was used for categorical variables and ANOVA was used for comparing multiple means. Simple logistical regression was used to investigate the association between outcomes various factors. Receiver operating and characteristic curves (ROCs) were plotted for several factors to test the diagnostic ability of that factor to predict either SA or SACA. An area under the ROC (AUROC) of 0.8 or higher is accepted as the cutoff for a strong model.^{14,15}

Ethics approval

This was a retrospective non-interventional study utilising clinical data that were already collected as standard clinical care. Hence, it was deemed by Health and Disability Ethics Committees to not require approval. Locality approval was gained, and approval was provided by Research Advisory Group – Māori (RAG-M).

Results

Patient demographics

Overall, 2,335 patients were identified in the initial search using ICD-10 codes. Of these, 862

patients had SF aspirates and were assessed. There were 295 patients excluded because their SF aspirate was neither positive for CA nor SA. A total of 567 patients were included in the final analysis. Patient demographics for the different groups are detailed in Table 1.

A large majority (n=427) had a crystal arthropathy with either UA (n=319) or CPPD (n=108) crystal deposition and 140 patients had a final diagnosis of SA. Thirty-three of the 140 patients (23.6%) with a final diagnosis of SA had concomitant gout or pseudogout, while 7.2% of all patients with a CA had a concomitant SA. Of the 33 SACA patients, 16 had gout and 17 had pseudogout.

Patients with an infection were more likely to have at least one comorbidity compared to those with CA only (54.55% vs 35.9%, p<0.001). Knees and ankles were the most common joints affected in all groups (Appendix 1). Thirty-five patients had polyarticular CA, four patients had polyarticular SA and two patients had polyarticular SACA.

Out of the 140 patients with SA, 102 patients had a positive SF aspirate culture from the ED. Three patients had a positive aspirate culture from theatre joint washout. Out of the remaining 35 patients, 32 had positive blood culture results and three patients had positive culture results from purulent swabs from the affected joints.

Aspirate gram stain and cell count

Gram stain was positive in one patient with CA only, while it was positive in 33% and 21% of SA and SACA patients respectively (p<0.001). The median white cell count (WCC) was also significantly higher in SA and SACA compared to CA only (Table 2). When using the WCC cutoffs, a significantly higher proportion of patients with an infection had a WCC of greater than 50,000/mm³ (CA only: 39.5%, SA: 74.5%, SACA: 83.3%, p<0.001). Mean percentage polymorphonuclear leucocytes (PMN) was not significantly different in all groups. This was also the case when comparing a cutoff of greater than 75% PMNs in each group.

The pathogens causing SA in our cohort are detailed in Appendix 2.

Differentiating between CA and SACA

Patients with a history of rheumatoid arthritis or immunocompromise had a greater risk of having SACA (Table 3). Risk factors such as previous SA and existing joint metalware were most likely to predispose a patient to have SACA (Table 3). Patients presenting with a temperature of greater than 38.5 degrees Celsius had an odds ratio of 2.67 (1.76–3.98, p=0.001).

In the SF aspirate results, a WCC cutoff of greater than 50,000/mm³ and percentage PMN of greater than 75% were significantly associated with a SACA (Table 3).

SF aspirate WCC seemed the most accurate in predicting SA and SACA compared to CA only. AUROC for SF WCC comparing SA versus CA only and SACA versus CA only were 0.81 (0.77–0.84, p<0.0001) and 0.87 (95% CI 0.84–0.91, p<0.0001) respectively (Figure 1). A SF WCC of greater than 32,250/mm³ cutoff provided a sensitivity of 95.83% and a specificity of 57.02% to diagnose SACA compared to CA only. However, a slightly lower cutoff of 32,000X10^6/L allowed a sensitivity of 100%, albeit with a poorer specificity of 49.57%.

Management and outcomes in patients with SA/ SACA

In the cohort with SA, the mortality was 3.6% (five patients), while seven patients (5%) were admitted to the intensive care unit (ICU). Total mean length of stay was 13.4 (14.9) days. Most patients (134, 95.71%) with a final diagnosis of SA were admitted to an inpatient location from ED. All patients were given intravenous antibiotics and 118 patients (84.29%) underwent a joint washout.

Six patients were discharged from ED with an initial diagnosis of CA. Four of those patients were recalled after positive SF culture results 24 hours after the aspirate was done. Two of those patients underwent a joint washout and antibiotics while two patients were managed conservatively. None of these patients needed an ICU admission and their length of stay was similar to the rest of the cohort. There were no deaths in these four patients.

The remaining two patients were transiting through the local port on a cruise ship. They self-discharged against medical advice and boarded their ship with oral antibiotics. Their outcome is unknown.

The 27 patients with SACA who were admitted from ED were admitted due to a conglomerate of reasons including clinical gestalt, patient comorbidities, high temperatures of greater than 38.5 degrees Celsius and SF WCC >50,000/mm³.

Discussion

This was a 10-year retrospective observational study to quantify and characterise patients with SACA presenting to an ED setting and to compare this group against CA and SA alone. In our cohort, Table 1: Baseline characteristics.

Characteristic	CA only		SA		SACA		P-value	
	N=427	%	N=140	%	N=33	%		
Age, mean (SD) years	58 (18)		57 (23)		65 (19)		0.662	
Female gender	79	18.5	45	32.1	9	27.3	0.003	
Ethnicity								
Māori	90	21.1	20	14.3	7	21.2		
NZ European	189	44.2	86	61.4	17	51.5		
Pacific	111	26.0	20	14.3	5	15.2		
Asian	10	2.3	4	2.9	1	3.0		
Other	22	5.2	8	5.7	3	9.1		
Unknown	5	1.2	2	1.4	-			
Comorbidities								
Diabetes history	80	18.7	25	17.9	10	30.3		
Chronic renal failure	63	14.8	14	10.0	9	27.3		
Rheumatoid arthritis	9	2.1	7	5.0	1	3.0		
Immunocompromise	41	9.6	22	15.7	5	15.2		
Number of comorbidities								
1	113	26.5	41	29.3	10	30.3		
2	32	7.5	22	15.7	5	15.2		
3	8	1.9	5	3.6	3	9.1		
4	0	0.0	1	0.7	0	0.0		
Other risk factors								
Previous gout	257	60.2	17	12.1	9	27.3	<0.001	
Previous pseudogout	17	4.0	3	2.1	1	3.0	0.375	
Previous SA	9	2.1	14	10.0	3	9.1	<0.001	
Native joint/no metalware	419	98.1	104	74.3	29	87.9	<0.0001	
Observations								
Heart rate, mean (SD)	85 (16)		89 (17)		88 (15)		0.076	
Temperature, mean (SD)	37.1 (0.9)		37.5 (0.9)		37.4 (1.0)		0.001	
Temperature >38.5 degrees Celsius (total cohort)	15 (312)	4.8	13 (103)	12.6	3 (21)	14.3	<0.001	

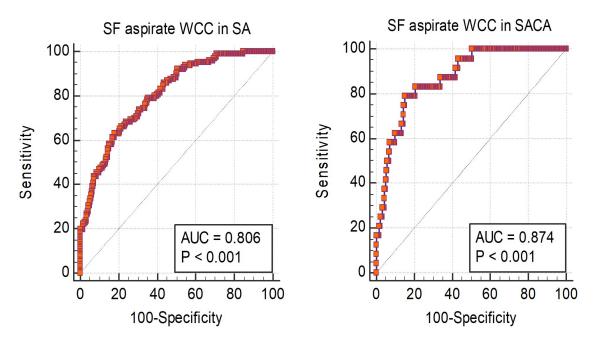
CA = crystal arthritis; SA = septic arthritis; SACA = septic arthritis and crystal arthritis.

Aspirate characteristics	CA only		SA		SACA		P-value		
	Frequencies	%	Frequencies	%	Frequencies	%			
Gram stain positive	1/426	0.2	45/136	33.1	7/33	21.2	<0.001		
Mean WCC (cells/ mm³) (SD)	49,767 (49,345)		154,858 (172,424)		174,591 (140,481)		<0.001		
Median WCC (cells/ mm³)	33,110		97,555		144,000		<0.001		
WCC (cells/mm ³) cutof	WCC (cells/mm ³) cutoffs								
<2,000	15	4.3	0	0	0	0	-		
2,000–50,000	211	60.5	24	22.6	3	16.5	<0.001		
>50,000	123	35.2	82	77.4	21	83.5	<0.001		
Mean % PMN	87 (14)		89 (11)		90 (7)		0.131		
% PMN >75%	311	90.7	96	91.4	24	96.0	0.580		

Table 2: Synovial fluid aspirate results.

CA = crystal arthritis; SA = septic arthritis; SACA = septic arthritis and crystal arthritis; WCC = white cell count; SD = standard deviation; PMN = polymorphonuclear leucocytes.

Figure 1: Showing ROCs and AUROC scores for SF aspirate white cell count in SA and SACA.



Factors	OR (95% CI)	P-value		
Male gender	1.94 (0.80–4.67)	0.157		
Ethnicity				
Māori	0.99 (0.42–2.36)	0.988		
Pacific	0.11 (0.04–0.26)	<0.0001		
NZ European	1.31 (0.65–2.66)	0.456		
Asian	0.30 (0.04–2.37)	0.254		
Medical comorbidities				
Age	1.01 (0.99–1.03)	0.364		
Diabetes	1.79 (0.72–4.47)	0.230		
Chronic renal failure	1.66 (0.60–4.65)	0.353		
Rheumatoid arthritis	2.27 (0.86–5.97)	<0.0001		
Immunocompromised	1.74 (1.03–2.93)	0.037		
Number of comorbidities	1.50 (0.92–2.55)	0.127		
Other risk factors				
Previous gout	0.22 (0.09–0.57)	0.001		
Previous pseudogout	1.18 (0.15–9.49)	0.876		
Previous SA	6.05 (1.11–32.91)	0.040		
Metalware present	5.03 (0.96–26.32)	0.095		
Large vs small joint	1.31 (0.47–3.64)	0.616		
Highest heart rate	1.01 (0.98–1.05)	0.508		
~				
Temperature >38.5 degrees Celsius	2.67 (1.76–3.98)	0.001		
		0.001		
Temperature >38.5 degrees Celsius		0.001 <0.0001		
Temperature >38.5 degrees Celsius SF aspirate results	2.67 (1.76–3.98)			
Temperature >38.5 degrees Celsius SF aspirate results WCC	2.67 (1.76–3.98) 1.5 (1.01–1.95)	<0.0001		

Table 3: Showing odds ratios for SACA versus CA only.

SACA = septic arthritis and crystal arthritis; CA = crystal arthritis; OR = odds ratio; CI = confidence interval; SA = septic arthritis; SF = synovial fluid; WCC = white cell count; PMN = polymorphonuclear leucocytes.

23.6% of patients with a final diagnosis of SA had concomitant gout or pseudogout, while 7.2% of all patients with a CA had a concomitant SA. This was similar to the only other recent study in New Zealand that reported on the presence of SACA (33 out of 128 septic arthritis patients, 25.8%) and slightly lower than other studies reported internationally (27%).^{8,16}

Our study showed several clinical patterns of SA that fit with current understanding internationally. Patients who were immunocompromised or had rheumatoid arthritis, multiple comorbidities, previous septic arthritis history or joint metalware were at greater risk of SA and SACA.^{5,7,8,11–13} Gram stain's poor performance at predicting an infected joint mirrored several adult and paediatric studies.^{16–18} The traditionally accepted SF PMN % cutoff of greater than 75% as an indicator of SA was not mirrored in our cohort and hence not useful in differentiating between CA alone and an infected joint.¹²

The most striking factor to note was the potential use of SF WCC in predicting SACA. Previously, studies have reported wide variability of mean and median aspirate WCCs for SACA, ranging from 23,057 to 113,000.8,10,19-21 One previous study indicated that the traditional SF WCC cutoff should be lowered in the setting of immunocompromised patients.³¹ However, these studies were small and there is a paucity of larger multicentred data. In our study, the SF WCC showed excellent predictive capability for joint infection with AUROCs of 0.81 and 0.87 for SA and SACA respectively. The ROCs reported a SF WCC cutoff of 32,000/mm³ that allowed for a sensitivity of 100% and a specificity of approximately 50%. Our cutoff of 32,000/mm³ is much lower than a cutoff of 50,000/mm³ that is traditionally thought to suggest a septic joint—although there are limited good-quality, large-scale studies to support this cutoff.^{17,22–25} The positive likelihood ratio for a SF WCC of greater than 50,000 and 100,000 were reported as 4.7 and 13.2.¹¹ However, in culture-proven SA, the white blood cell count only reached this level in 50-75% of cases.^{26,27}

In our cohort, most patients with SACA were admitted as possible SA. Those who were discharged initially from ED were called back within 36 hours once the SF aspirate grew a pathogen. Our samples were too small to ascertain statistically if there were any differences in outcomes in these patients, although length of stay was comparable to those admitted and there were no ICU admissions or deaths in these

handful of patients.

Traditional dictum is that rapid diagnosis and prompt management reduce the risk of significant mortality and morbidity from SA.^{24,28} However, more recent studies dispute this, with no difference in outcome (mortality, morbidity, functional outcome and quality of life) with at least a 4-day delay in presentation post-onset of symptoms or a delay of 42 hours between clinical diagnosis and arthroscopic joint lavage.^{5,29,30} Clearly, larger studies focussing on SACA are needed to assess how many SACA patients are being misdiagnosed initially and what the outcome burden is for these patients who have a delay of up to 48 hours until a positive sample culture proves the joint infection.

Limitations

There are inherent biases in retrospective studies. Selection bias was reduced by having strict inclusion and exclusion criteria. A comprehensive list of ICD-10 codes were used to standardise the search terms to identify patients. However, the search was over a 10-year period and some coding terms may have changed over that time. The total number of patients with SACA in this study was small and as a result outcome assessment and ethnicity subgroup analyses were limited. Given the paucity of data, it was unclear what the frequency of SACA was in an ED setting and the duration over which we needed to collect data from. Our study also did not look at a several aspects that in retrospect would have been beneficial to assess:

- A wider range of comorbidities
- Other risk factors, such as overlying cellulitis and local trauma
- Time of onset of symptoms to presentation
- Longer-term outcomes

Attempts were made to identify patients who were already on antibiotic treatment prior to or at time of diagnosis with an infected joint. However, given the retrospective data set over a 10-year period, these data were challenging to accurately collect from clinicians' notes. There were significant gaps in that data and they were not included in the final analysis.

Conclusions

This study added to the small amount of data available for SACA in New Zealand, as well as globally. SACA remains a small but important subgroup of patients at risk of misdiagnosis in the ED as having a CA alone. SF WCC of 32,000/mm³ may be a better cutoff than the traditionally accepted 50,000/mm³, possibly warranting inpatient admission for investigation and management of presumed SA with the lower cutoff. Clearly more data are needed across sites in New Zealand to confirm the findings of this study and to confirm whether there is any actual difference in outcome caused by treatment delays in patients with SACA being discharged with a misdiagnosis of CA.

COMPETING INTERESTS

We declare that there exist no conflicts of interest for this study.

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Appendices

Appendix 1: Showing the percentage distribution of joints affected in the SA, CA and SACA groups

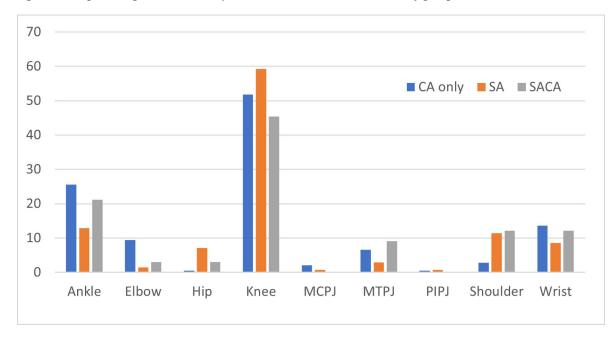


Figure 2: The percentage distribution of joints affected in SA, SACA and CA only groups.

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Appendix 2: Showing the frequencies of the various pathogens causing an infected joint in this cohort

Table 4: Frequencies of the various pathogens causing SA and SACA.

Pathogen	Frequencies	%
Staphylococcus aureus	36	25.7
Streptococcus pyogenes	14	10.0
Streptococcus dysgalactiae	8	5.7
Group A Streptococcus	7	5.0
Staphylococcus lugdunensis	7	5.0
Staphylococcus epidermis	6	4.3
E.coli	4	2.9
Group B Streptococcus	3	2.1
Bacillus cereus	2	1.4
Klebsiella pneumoniae	2	1.4
Methicillin-resistant <i>Staphylococcus aureus</i>	2	1.4
Neisseria meningitides	2	1.4
Pseudomonas aeruginosa	2	1.4
Coagulase-negative Staphylococcus	1	0.7
Enterobacter aerogenes	1	0.7
Kingella kingae	1	0.7
Neisseria gonorrhoeae	1	0.7
Staph warneri	1	0.7
Streptococcus intermedius	1	0.7
Streptococcus pneumoniae	1	0.7

The long COVID conundrum from a New Zealand perspective

Angus Mackay

n important consequence of the SARS-CoV-2 (COVID-19) pandemic is that a significant proportion of patients infected by severe acute respiratory COVID-19 have ongoing long-term effects, termed long COVID.¹ This condition may affect between 10 and 20% of those infected by COVID-19.¹⁻³ This means up to 500,000 people in New Zealand may have experienced some form of long COVID, and for some patients this may persist.^{1,4} The New Zealand Ministry of Health – Manatū Hauroa has established a long COVID programme with the goal of supporting long COVID patients, and has compiled a comprehensive evidence brief, informing ongoing work into the disease.⁵ This condition may be important for Māori, who may have an increased risk of developing long COVID, together with higher rates of COVID-19 and lower vaccination rates. The Health Services Research Centre, Victoria University of Wellington (New Zealand) recommended the establishment of a national long COVID centre to support local clinics, with a proposal for case managers to work with the community to support the health and wellbeing of those with long COVID.6 The Ministry of Health – Manatū Hauora has also provided funding to establish a long COVID registry in collaboration with The University of Auckland.⁷ This may improve knowledge about its prevalence in New Zealand, better understanding of its impact on individuals and society, and insights into its complex symptomology. The registry was established in July 2023 and by January 2024 had data on 1,030 participants, with a final report imminent. A nation-wide study of the impact of COVID-19 on those infected before December 2021, before the onset of the Omicron variant, reported that 220/990 (22%) of those who tested positive met the World Health Organization (WHO) clinical case definition for long COVID.⁸

The effect of COVID-19 infections in relation to long COVID may be more complex in New Zealand, which, because of early lockdowns and an initial phase of vaccination, has lower rates of hospitalisations and deaths per capita than other countries.^{9,10} Only around 5,500 people have died from COVID-19 in New Zealand, one of the lowest pandemic mortality rates of any country in the world. A study reporting mathematical modelling, and allowing for the use of antiviral drugs, showed that vaccines probably saved around 7,500 lives and prevented around 46,000 hospitalisations in the first 18 months of widespread community transmission.¹⁰ This may mean that the prevalence of long COVID in New Zealand could be considerably lower than the estimates discussed above. International studies support the view that vaccinated individuals,¹¹ infected by the less pathogenic variants of COVID-19, and especially if non-hospitalised, are less likely to develop long COVID.^{1,3} However, it remains unclear, both internationally and in New Zealand, whether the risk of developing long COVID increases with each subsequent COVID-19 re-infection or not. A large study of United States of America (USA) veterans compared those who had one COVID-19 infection with a group that had two or more re-infections.¹² They reported that reinfection was associated with an increased risk of a wide range of long COVID-associated outcomes, regardless of vaccination status, and suggested increased immune evasiveness by progressively mutated variants of COVID-19 could partially explain their findings. Older patients, such as the majority of USA veterans, and more vulnerable patients may then be predisposed to long COVID, with subsequent re-infections due to cumulative actions.^{12,13} Nevertheless, for younger patients with generally milder infections and, therefore, those re-infected within a post-Omicron environment, the risk of long COVID may be lower than for older patients.13 This is important because the safeguards to protect older adults and other vulnerable groups, such as mask-wearing and visitor regulations to aged care facilities in New Zealand, have become increasingly relaxed over time.^{13,14} Later and likely less pathogenic variants of COVID-19 are also more transmissible than the earlier ones, vaccine efficacy has been diminished by a faster mutating virus and it has also become evident that long COVID can develop from even mild or non-hospitalised cases of COVID-19.^{1,4} Consequently, the actual numbers

of long COVID cases in New Zealand could still be large. $^{\rm 5,14}$

The consequences of outdated WHO/USA CDC long COVID definitions

In October 2021, the WHO provided a rudimentary clinical case definition for long COVID, subsequently adopted by the Ministry of Health – Manatū Hauora, for what was then termed post-COVID condition.² In 2022, the USA Centres for Disease Control and Prevention (CDC) provided an updated definition expanding the WHO version, but with only a very general description and without further detailed criteria.¹⁵ Internationally there are other definitions.³ However, no universal definition for long COVID exists. It is increasingly evident that long COVID is much more diverse than originally conceptualised and may be made up of several major sub-groups. For example, there is a sub-group of patients who have been severely affected by COVID-19 infection, with frequent hospitalisations, who appear to suffer from long-term damage to various organs, particularly the lungs as the primary site of infection, but also other organs including brain, heart, kidneys, liver, spleen, gut and pancreas.¹ Infection also may trigger a variety of autoimmune diseases, cardiovascular diseases and diabetes.^{1,4} Another major sub-group is that of long COVID patients who have debilitating post-viral fatigue syndrome (PVFS) symptoms, resembling myalgic encephalomyelitis/chronic fatigue syndrome (ME/ CFS).^{1,4} ME/CFS is essentially the same disease as PVFS, except ME/CFS can be triggered by viral as well as non-viral agents. An estimate is that half of individuals with long COVID meet the criteria for ME/CFS.1 The absence of an evidence-based definition of long COVID means that interpretation of prevalence studies, patient studies and its pathophysiology intertwined within a mix of different sub-groups is very difficult. Due to the increasing complexity of long COVID, a unifying hypothesis to explain its pathogensesis would appear unlikely. Nevertheless, a diverse range of pathophysiological mechanisms have been postulated, including persistent reservoirs of COVID-19 in tissues, immune dysregulation with or without reactivation of Epstein-Barr virus (EBV) and micro-clotting.^{1,3}

Table 1 shows commonalities and differences between different definitions relevant to long COVID and ME/CFS diagnosis.¹⁶

As summarised in Table 1, there is considerable overlap between the core symptoms reported by the WHO and the USA CDC, and as listed by the Ministry of Health - Manatū Hauora, but also important differences. For example, the USA CDC includes congestion or runny nose, rashes and changes in menstrual cycle as core symptoms. Otherwise, the core symptoms listed by the WHO and USA CDC are mainly generic and ambiguous in nature without being assigned to any pathophysiological outcome or sub-group with relevant clinical manifestation. Consequently, many of these common core symptoms could be interpreted as being clinical manifestations related to COVID-19 afflicted organ damage, long COVID-related PVFS, or both. For example, a persistent cough accompanied by dyspnoea (breathlessness) and chest pain or tightness could be related to COVID-afflicted long-term lung damage, although it could also be confused with laboured breathing, which is a symptom commonly experienced by ME/CFS sufferers.¹⁶ The latter has been proposed to occur due to a dysfunctional autonomic nervous system, rather than lung inflammation. Several of these symptoms, such as chronic fatigue, sleep problems including insomnia and cognitive dysfunction, would likely be clinical manifestations commonly shared across long COVID sub-groups. Along with unrefreshing sleep, myalgia, orthostatic intolerance and postexertional malaise (PEM) they are also key symptoms used in the diagnosis of ME/CFS.¹⁶ In fact, PEM is the pathognomonic symptom of ME/ CFS, whereby patients experience an increase in the severity of their symptoms and possibly the appearance of new symptoms after physical or cognitive exertion, often manifesting itself after a characteristic 12- to 48-hour delay. However, although both the WHO and USA CDC include PEM as core symptoms, ME/CFS diagnostic criteria have not been recommended for use in their definition descriptions. Consequently, patient cohorts selected for long COVID studies have been heterogeneous and poorly characterised, without differentiation according to the severity of the initial infection, or to which long COVID pathophysiological sub-group they might belong, making their results much more difficult to interpret. As a rare exception, a German study reported that 19/42 (45%) of long COVID patients, with either only mild infection, or moderate illness with accompanying pneumonia but no evidence of long-term damage to organs, met multiple criteria for the clinical diagnostic criteria

WHO ¹	CDC ²	New Zealand MoH ³	ME/CFS ⁴	
Chronic fatigue	Chronic fatigue	Fatigue	Chronic fatigue	
Myalgia	Myalgia	Myalgia	Myalgia	
PEM⁵	PEM⁵	Reduced exercise capacity and general malaise	PEM⁵	
Cognitive dysfunction	Cognitive dysfunction	Cognitive dysfunction	Cognitive dysfunction	
Sleep problems, e.g., insomnia	Sleep problems	Sleep problems Sleep problems awakenings, unrefrest sleep		
Altered smell or taste	ed smell or taste Altered smell or taste		Altered smell or taste, sensitivity to light and noise	
Dyspnoea	Dyspnoea	Dyspnoea	Laboured breathing	
Persistent cough	Cough	Cough		
Chest pain or tightness	Chest pain	Chest pain or tightness		
	Headache	Headache	Headache	
	Sore throat	Sore throat	Sore throat	
	Stomach pain, diarrhoea	Abdominal pain, diarrhoea, nausea	Irritable bowel syndrome, nausea, bloating	
Heart palpitations	Heart palpitations, orthostatic intolerance		Heart palpitations, orthostatic intolerance	
	Fever or chills	Fever	Fever or chills	
	Anxiety, depression	Anxiety, depression		
	Rash	Rash		
	Congestion or runny nose			
	Changes in menstrual cycle			

Table 1: Long COVID (and ME/CFS) core symptoms.

- ¹World Health Organization ²USA Centers for Disease Control and Prevention ³New Zealand Ministry of Health – Manatū Hauora ⁴Myalgic encephalomyelitis/chronic fatigue syndrome
- ⁵Post-exertional malaise

of ME/CFS, alongside a cohort of ME/CFS patients.¹⁷ The remainder of the patients also met ME/CFS diagnostic criteria, except their illness was milder and the PEM duration was shorter.

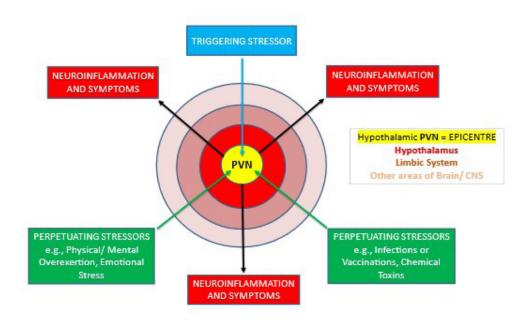
The emerging role of neuroinflammation in long COVID

A pathophysiological mechanism of interest for long COVID is the potential role of neuroinflammation related to over-activated glial-cells, the innate immune cells of the brain.¹⁸ Microglial activation as part of a neuroinflammatory response could occur as a response to a direct insult to the brain, such as a viral infection, but could also occur following respiratory inflammation, leading to the development of neuro-cognitive problems, including cognitive dysfunction and other ME/CFS-like symptoms. However, there are few neuroimaging studies using sensitive enough technology to detect chronic but low-level neuroinflammation that may be present within the brains of long COVID patients. For example, a positron emission tomography/magnetic resonance imaging (PET/MRI) study reported hypometabolism in the cerebellum and brainstem of 143 long COVID patients,19 which could be related to neuroinflammation. Other studies have reported PET/MRI detection of extensive neuroinflammation

throughout the brain in two long COVID patients concentrated in the thalamus;²⁰ an association, using diffusion MRI, between structural imaging changes in the thalamus and basal ganglia, and persistent fatigue in 47 patients with long COVID;²¹ and, finally, a PET/MRI study identifying changes consistent with neuroinflammation in the ventral striatum and dorsal putamen of 20 patients reporting persistent depressive and cognitive symptoms, after initially mild to moderate COVID-19 infection.²² However, as with other long COVID studies, patient differentiation was lacking, and apart from one study, ME/CFS diagnostic criteria were not used.

A New Zealand author had already proposed a neuroinflammatory model, particularly involving the limbic system (highlighted in the studies above), for long COVID-related PVFS,²³ but also applicable to ME/CFS.^{24,25} The paradigm proposes a common triggering mechanism, whereby both the primary trigger for long COVID-related PVFS (COVID-19 infection), and the multiple triggers of ME/CFS that can be viral or non-viral, including emotional trauma, chemical toxin shock and menopause are all designated as severe physiological stressors or traumas.²³ A triggering stressor (COVID-19 induced cytokine storm, in the case of long COVID-related PVFS) is proposed to target the paraventricular nucleus (PVN), a

Figure 1: A neuroinflammatory model for long COVID-related post-viral fatigue syndrome²³ and myalgic encephalitis/chronic fatigue syndrome.^{24,25}



Paraventricular nucleus of the hypothalamus = PVN.

stress-centre within the hypothalamus, causing it to physiologically "switch" into a dysfunctional PVFS "on" mode, if an intrinsic stress threshold within genetically susceptible patients is exceeded. A dysfunctional PVN then targeted by life's perpetuating stressors, which act as the "drivers" of an ongoing neuroinflammatory process inducing either post-exertional malaise (PEM) episodes or longer-lasting relapses depending on the intensity and duration of the incoming stressor(s), could be the epicentre of long COVID-related PVFS and ME/ CFS pathophysiology. Figure 1 shows a schematic outline of this proposal.

Resultant inflammation and dysfunction to the hypothalamus and limbic system could explain most symptoms experienced by sufferers. Long COVID-related PVFS and ME/CFS could be neurologically centred diseases and this may explain why blood-biomarkers have been difficult to find for these diseases. Ongoing EBV reactivation is also a plausible factor, acting as a perpetuating stressor in a subset of patients.

Another New Zealand author²⁶ has also developed an overlapping model for ME/CFS, which is applicable to long COVID-related PVFS, incorporating key components of neuroinflammation and a dysfunctional hypothalamic PVN. However, the main focus of the triggering event is on a different kind of physiological switch leading to a chronically activated immune/inflammatory response of the peripheral system, a fundamental shift away from Mackay's neurologically centred model. Following the initial triggering event, those authors propose that subsequent systemic pathology is transmitted to the brain via neurovascular pathways, or via a porous blood-brain barrier, resulting in chronic neuroinflammation and leading to a sustained illness with chronic relapse-recovery cycles.²⁶ That research group has also reported a mass spectrometry study comparing immune-cell protein profiles from the blood of six long COVID patients with nine ME/CFS patients.²⁷ Both long COVID and ME/CFS patients had "classical" symptoms that were consistent with the clinical case definitions of ME/CFS. The approach of examining immune-related proteins in those who have long COVID and ME/CFS has also been reported by other authors, identifying dysregulation of these proteins in a complex way consistent with ongoing dysfunction that may be different for ME/CFS compared to COVID-19 infection.²⁶ Ongoing research in New Zealand may clarify these patterns.²⁸

Conclusion

The prevalence of long COVID may not be so high in New Zealand as globally but could affect at least 10% of those who have had COVID-19 infection. A more accurate assessment of the disease prevalence is important to plan services, which may have particular relevance to important groups in New Zealand such as Māori and Pacific peoples. There has been a call for ongoing monitoring of this situation, particularly as New Zealand has experienced continued waves of infections.¹⁴ A key recommendation that arises from this call is to expand vaccination to encompass younger children.

An empirical research-based, universal and detailed definition of long COVID would enhance understanding and research to reflect composition and characteristics of this heterogeneous patient group.^{3,29} Integration with the now increasingly refined ME/CFS diagnostic criteria¹⁶ will allow for characterisation of long COVID-related PVFS patients, particularly from the milder or moderate cases where longer-lasting organ or system damage would be less likely.¹⁷

New Zealand research is needed to complement international research efforts such as the USA National Institutes of Health *Researching COVID to Enhance Recovery (RECOVER)* initiative. A fresh initiative would be highly recommended, involving longitudinal studies tracking long COVID-related PVFS and ME/CFS patients through relapse–recovery cycles, making comparative studies of their symptoms, with simultaneous data retrieved from sensitive neuroimaging technology (such as PET/MRI), cerebral spinal fluid biomarkers related to neuroinflammation and blood-biomarkers including proteomics.³⁰

COMPETING INTERESTS

None.

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A case of oesophageal foreign body migration into the thyroid gland

Leon Kong, James Sanders

P oreign body (FB) impaction in the throat is a common medical emergency. The majority (>80%) of these will spontaneously pass or be amenable to removal under direct vision with endoscopy.¹

Failure to remove the FB promptly can lead to complications including visceral perforation, deep neck abscess, aortoesophageal fistula and mediastinitis.^{1,2} We present a case of FB migration into the thyroid gland.

Case report

A 71-year-old female presented to hospital with a 4-day history of left-sided sore throat, odynophagia and dysphagia. She reported onset after eating Shepherd's Pie (mince and potato). She denied ingestion of bone or solid FB. Her medical background included hypertension.

On examination, she was afebrile. There was no subcutaneous emphysema. There was no FB seen on flexible nasendoscopy. Blood tests showed white blood cell (WBC) 15 and c-reactive protein (CRP) 45. A lateral neck X-ray showed a radiopacity in the prevertebral soft tissues (Figure 1).

She proceeded promptly to rigid oesophagoscopy under general anaesthesia. This found localised purulent exudate and mucosal laceration in the posterior wall of the upper oesophagus without obvious FB. The patient was woken up and had an urgent computed tomography (CT) of the neck, which showed a 20x5mm hyperdense FB in the paraesophageal soft tissue that was penetrating the left thyroid lobe with associated abscess 23x20x10mm (Figure 2).

The next day, she returned to theatre for rigid oesophagoscopy and neck exploration. Further attempts to retrieve the FB during pharyngooesophagoscopy and subsequent neck exploration via mid-line thyroidectomy incision failed, therefore a left hemithyroidectomy was performed. Only after this was the FB (a piece of glass) found dislodged from its position within the superior thyroid.

Post-operation, she remained on augmentin 1.2g IV Q8hr and NG feeding for 1 week before

resuming oral intake after a normal contrast swallow study. She was reviewed in the outpatient clinic 2 weeks later and reported a full recovery.

Discussion

This case illustrates a patient with an impacted oesophageal FB that migrated into the thyroid gland. The diagnosis is challenging in patients without subjective history of FB ingestion. FB impaction >24 hours increases the risk of complication by 14 times.¹ Thus, the European Society of Gastrointestinal Endoscopy recommends emergent endoscopy (within 6 hours) when patients present with a history of sharp FB ingestion.¹ Risk factors for FB impaction in adults include older age, pre-existing oesophageal pathology and neurological disease.³

Radiological imaging is a useful supplement to workup. Initial screening with a lateral neck X-ray can identify radio-opaque FB including metals, glass and animal bones.⁴ However, there is a high rate of false negatives. In patients with suspected complications, CT is the gold standard with its superior sensitivity and specificity (>90%).^{3,4}

When FB impaction is suspected, endoscopic examination of the upper aerodigestive tract, either rigid or flexible, can be both diagnostic and therapeutic. Around 10% of cases will require endoscopy.^{1,5} Surgical intervention such as open neck exploration is necessary in complicated cases where the FB is not identified or not able to be removed via the endoscopic route.

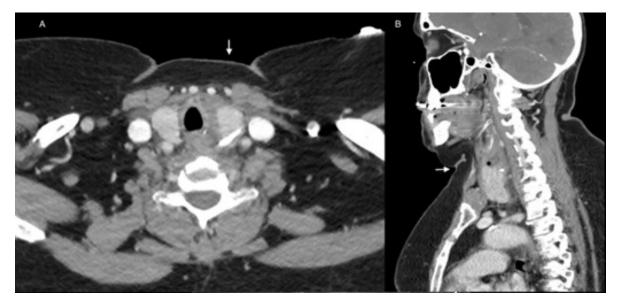
Conclusion

Extraluminal migration of impacted oesophageal FB is a rare phenomenon. A high index of suspicion for retained FB is required. Atypical factors in this case included delayed presentation and no subjective history of FB ingestion. In atypical cases, radiological imaging is crucial for diagnosing the presence of FB and complications. Failure to remove the FB via oesophagoscopy warrants consideration of an external approach.

Figure 1: Lateral neck X-ray showing radio-opacity with gas bubbles in the prevertebral soft tissues at C5/6 level (white arrow).



Figure 2: a) Axial CT showing hyperdense FB penetrating the left thyroid lobe (white arrow); b) sagittal CT showing FB in thyroid lobe with associated fluid collection and gas bubble superiorly (white arrow).



COMPETING INTERESTS

None.

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Screening for anal cancer in New Zealand

Mary Birdsall

ear Editor. Anal cancer is a preventable cancer with the knowledge and tools we currently have, but these tools are not being used.

Anal cancer is mostly caused by the human papillomavirus (HPV)—like cervical cancer—and anal cancer is increasing in New Zealand by about 3% per year. Each year around 100 New Zealanders are diagnosed with anal cancer and one third will die from their disease. The average age at diagnosis is 60 and two thirds of those affected are women. The average size of the cancer at diagnosis is 3.3cm, so anal cancer in 2024 is presenting at an advanced stage similar to where cervical cancer was in the 1980s before effective cervical screening was introduced.

Vaccination against high-risk HPV is effective at preventing HPV-related cancers; however, immunisation rates in New Zealand are falling, and among Māori youth the rates are now below 50%. It is important that vaccination rates are improved to prevent HPV-related cancers.

Anal cancer arises from high-grade squamous intraepithelial lesions (HSIL) and the ANCHOR study has shown that treatment of HSIL significantly reduces the incidence of anal cancer by 57%.¹

Screening guidelines for anal cancer have just been published by the International Anal Neoplasia Society.² These guidelines recommend that high-risk populations undergo screening for anal cancer guided by risk thresholds, with screening initiation at age 35 in men who have sex with men and transwomen living with HIV. For other people living with HIV and men having sex with men and transwomen, screening should commence at age 45. For solid organ recipients, screening should commence at 10 years posttransplant. For persons with a history of vulval precancer or cancer, screening should commence within 1 year of diagnosis. Persons aged 45 or older with a history of HSIL of the cervix or vagina, or cancer, perianal warts, persistent cervical HPV-16 or autoimmune diseases could also be considered for screening.

An anal cancer screening programme can use either anal cytology or high-risk HPV testing. The development of an anal cancer screening programme is also dependent on skilled clinicians being able to perform high-resolution anoscopy (HRA) and treat lesions when found.

There is no screening programme for anal cancer in New Zealand. Some people know they are at high risk for anal cancer; however, others are not aware of their increased risk and there are no clinical services for these people, and few clinicians trained in HRA. Offshore, various specialties have upskilled in HRA including sexual health physicians, gynaecologists, colorectal surgeons, infectious disease physicians and gastroenterologists.

I am writing this letter to raise the awareness of anal cancer in New Zealand and to encourage the development of a screening programme. Anal cancer may soon kill more New Zealanders than cervical cancer because of the effectiveness of the cervical screening programme. One of the challenges of the HPV primary screening programme is what to do with people over 45 with persisting HPV-16 disease, who would benefit from screening for anal cancer.

Yours sincerely, Mary Birdsall

COMPETING INTERESTS

Nil.

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Does iodised salt sold in New Zealand contain enough iodine?

Nan Xin Wang, Sheila A Skeaff, Claire Cameron, Rachael M McLean

odine is an essential component of thyroid hormones, which are required for regulation of metabolism, temperature control, normal growth and brain development in humans.^{1,2} The World Health Organization (WHO) recommends the use of iodised salt as a key strategy to prevent iodine deficiency in populations living in areas at risk of low iodine intakes.³ The soil in New Zealand is low in iodine, and salt iodisation has been the primary strategy to prevent iodine deficiency since the 1920s.⁴ After the re-emergence of mild iodine deficiency in New Zealand in the 1990s,⁴ a series of reviews by Food Standards Australia New Zealand (FSANZ) resulted in a legislative change in the Food Standards Code, and the fortification of bread with iodised salt became mandatory in 2009.^{5,6} Since the fortification of bread, the iodine status of children and adult men have improved. However, in the 2014/2015 New Zealand Health Survey, median urinary iodine concentration (UIC) showed women aged 25 years and older were still classified as mildly iodine deficient.⁷ For example, in women between 25 to 34 years old and 35 to 44 years old, their median UIC was 96ug/L (a population with a median UIC of 100ug/L is considered iodine sufficient) and their prevalence of UIC less than 100ug/L is 51.5% and 50.7% respectively. It is important for women of reproductive age, in particular, to consume an adequate amount of iodine, as during pregnancy the foetus is dependent on the mother to provide thyroid hormones for the development of their central nervous system.8 Currently, New Zealand's legislation allows voluntary iodisation of salt at 25-65mg iodine/kg salt.6 Compliance with the standard was previously assessed in 2009 by the Institute of Environmental

Product	Туре	Form	Packaging	lodised	Sales volumeª (%)	Price/100g (NZD)
1	Table salt	Fine	High-density polyethylene	Yes	20.1	0.55
2	Table salt	Fine	High-density polyethylene	Yes	34.3	0.42
3	Table salt	Fine	Cardboard	Yes	3.7	0.27
4	Sea salt	Coarse	Home compostable film	Yes	4.2	0.49
5	Low-sodium salt	Fine	Aluminium can	Yes	0.1	1.77
6	Himalayan pink salt	Coarse	Home compostable film	No	14.3	0.72
7	Sea salt	Coarse	Home compostable film	No	4.2	0.49
8	Sea salt	Coarse	Soft plastic	No	3.3	0.42
9	Table salt	Fine	Soft plastic	No	7.1	0.22
10	Table salt	Fine	Soft plastic	No	6.0	0.12

Table 1: Description of selected retail.

^aThe sales volume is based on all salt sales in New Zealand.

Science and Research,⁹ which found that the median iodine content of iodised salt was 47mg/ kg. Similarly, the New Zealand Food Composition Database lists iodised salt at 49mg iodine/kg of salt;¹⁰ however, the data on which this estimate is based are more than 20 years old (in an email from Subathira Sivakumara, Plant & Food Research, 26 May 2022). This study aimed to assess the current concentration of iodine in retail salt in New Zealand.

Methods

The Nielsen Homescan consumer panel (in an email from NielsenIQ, 26 May 2022) provided salt sales data by brand in New Zealand between April 2021–2022 (NielsenIQ, personal communication, 26 May 2022). Salts that exceeded 3% of total salt sales volume were included in the analysis (Table 1). An additional reduced-sodium iodised salt that did not meet the sales volume criterion was also analysed because the introduction of reducedsodium salt substitutes is a relatively new strategy in New Zealand to reduce sodium intake. In total, 10 salt samples were selected for analysis of iodine content.

Table 2: Iodine content of retail salt in New Zealand.

The Food and Agriculture Organization of the United Nations (FAO) recommends having at least 10 food samples collected from multiple regions in a country to obtain representative nutrient values for a food.¹¹ Salt was purchased from supermarket outlets in five cities (Auckland, Rotorua, Wellington, Christchurch and Dunedin) in New Zealand. Two packets of each salt sample were bought from each city. However, Product 3 (iodised table salt) could not be obtained in Dunedin. In total, 98 packets of the salt samples were purchased and analysed for iodine content.

All the salt samples were bought in June 2022 and analysed in July 2022. Each salt was made into a salt solution individually. The entire content of each package of salt was emptied into a volumetric flask and weighed on a Sartorius CPA12001S scale (Sartorius AG, Göttingen, Germany) to measure all the iodine in the salt package. Then, the salt was dissolved in distilled deionised water. Once the salt had dissolved and water added up to volume of the flask (i.e., 2 or 5 litres), the full flask was weighed again. A 50mL sample of each salt solution was analysed for iodine content using inductively coupled plasma mass spectrometry

	n lodised lodine in salt (mg/kg)				
Product			Median	25 th , 75 th percentile	Range ^a
1	10	Yes	37	31, 42	23-43
2	10	Yes	36	27, 44	26-54
3	8	Yes	29	24, 31	23-33
4	10	Yes	37	33, 38	29-43
5	10	Yes	35	29, 38	27-40
Total (iodised)	48		35	29, 38	23-54
6	10	No	<3	<2, <3	<2-<3
7	10	No	<2	<2, <2	<2
8	10	No	<2	<2, <2	<2
9	10	No	<1	<1,1	<1-3.5
10	10	No	<1	<1, <1	<1
Total (non-iodised)	50		<2	<1, <2	<1-3.5

^aThe concentration of iodine in non-iodised salt is too low and the ICP-MS is only able to determine up to a value of less than 1–3.

(ICP-MS) in the Department of Chemistry, University of Otago. Five pooled samples were used to conduct precision checks of instrument. The mean iodine concentration of the pooled samples was 35.1ng/ml and a standard deviation of ±0.19.

The iodine content of the salts (mg/kg) are reported as a median, 25^{th} , 75^{th} percentile and range.

Results

The median iodine content of iodised salt was 35mg iodine/kg salt (Table 2), with a range between 23–54mg iodine/kg salt. In contrast, the five non-iodised salts that were analysed had a median of less than 2mg iodine/kg salt, with a range of less than 1–3.5mg iodine/kg salt.

Discussion

This study provides up-to-date information on the iodine concentration of retail salt in New Zealand. Our study shows that the current median salt iodisation level is 35mg/kg, which is substantially lower than the iodine content assessed in 2009 (47mg/kg)⁹ and that listed in the New Zealand Food Composition Database (49mg/kg). Additionally, there were two products (Products 1 and 3) with samples that fell below the minimum regulated iodine level of 25mg/kg salt.⁶ The iodine content in salt is not regularly monitored in New Zealand. The WHO recommends that the monitoring of iodised salt occur regularly on-site, at least once in every batch of iodised salt and periodic external monitoring by factory inspections and government audits.12

Product 3 had the lowest iodine content and was packed in cardboard. The low iodine content could be due to the more permeable material of the cardboard, which might make the iodine compounds added to salt become less stable, compared to other packaging such as the high-density polyethylene.¹³ The International Council for Control of Iodine Deficiency Disorders recommends an airtight packaging made out of high-density polyethylene or low-density polyethylene to prevent losses of iodine in salt.¹⁴

Our analysis shows that non-iodised salt contains very little iodine (less than 1–3.5mg iodine/kg salt). The consumption of non-iodised salt will not add to iodine intake and will not help women in New Zealand to achieve iodine sufficient status. Of particular concern is the increased popularity of specialty salts such as the pink Himalayan salt, which made up 14% of the total salt sales volume in the last year and are usually not iodised. Iodine fortification of salt is an effective tool to prevent iodine deficiency. However, a previous study simulating the iodine concentration of salt in New Zealand to meet recommended iodine intake for women of reproductive age found that the median salt iodisation level (35mg/kg) observed in our study will result in 29% of women consuming less than the estimated average requirement of $100\mu g$ of iodine a day.¹⁵ Inadequate iodine intake prior to pregnancy can lead to irreversible detrimental effects on cognitive development for the foetus in the early stages of pregnancy.¹⁶

Given the finding of iodine concentration at the lower level allowed in New Zealand, the mild iodine deficiency in all women above the age of 25 and the effects of iodine deficiency on the population, it is imperative that New Zealand explores other ways to increase iodine intake in the population. Expanding the number of foods where it is mandatory to add iodised salt would be an option. Currently, FSANZ only requires iodised salt to be added to bread. An electronic survey sent out to food processors (n=800) in 16 countries, including Australia, assessed the challenges that they faced in using iodised salt in processed foods.17 The Australian food manufacturers reported not using iodised salt in processed foods due to several challenges. These included the higher costs of iodised salt, the effect of iodised salt on product quality, consumers not being concerned about the addition of iodised salt and iodine nutrition not being a priority for the company. These were similar challenges expressed by bread manufacturers in Australia and New Zealand when iodised salt was proposed to be added to bread.¹⁸ Nevertheless, the legislation to add iodised salt to bread was successfully implemented in both countries. Indeed, the Iodine Global Network encourages governments to mandate the use of iodised salt in industrially processed foods.¹⁹ In addition, a systematic review examining the sensory effects of adding iodised salt to processed foods found that there is little change to the physical or chemical properties of a range of products, including cheese, processed meats, french fries, cereals, baked goods and pickled vegetables.²⁰ This shows that there is scope in New Zealand to extend the use of iodised salt to all, or other, processed foods in a mandatory approach.

The strengths of our study were the salt sample collection across the North and South Island of New Zealand and the use of the gold standard analytical method (ICP-MS). Our study was limited to a 1-month window when purchasing the salts and there could be differences in iodine content due to storage time and conditions.¹³

COMPETING INTERESTS

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Blood pressure monitoring devices in healthcare facilities of the Manawatū-Whanganui Region

Kian Jones, Albert Robertson, Norman Panlilio, Ankur Gupta

ypertension (HT) affects almost one third of the world's adults and 31% of New Zealand adults respectively,¹ and is a leading global, potentially preventable risk factor for death and disability.² Appropriate diagnosis and treatment of HT reduces the risk of cardiovascular and chronic kidney disease. HT is often asymptomatic and about 25% of those with HT are undiagnosed.3 Measurement of blood pressure (BP) must precede HT. It is crucial in clinical medicine, yet it remains one of the most inaccurately performed measurements. International guidelines recommend that devices to measure BP should be validated for accuracy.⁴ Failure of validation leads to inaccurate assessment of BP and incorrect treatment decisions. A study investigating the validation of 870 automated BP monitoring devices (BPMD) reported that validated devices provided readings within 4mmHg of manual auscultatory BP 68% of the time, compared to only 15% of the time for non-validated devices.⁵ This finding has been reported in a number of other studies.^{5,6} Ideally, validation of BPMD should be independent of the manufacturer, and follow international validation protocols, such as the 2018 International Organization for Standardization protocol.⁷ Unfortunately, between 75 and 80% of automated BPMD sold world-wide have no evidence of clinical validation for accuracy.^{5,8} The purpose of this study was to review BPMD used in the Manawatū-Whanganui Region and compare these with those listed in a recognised database of validated devices.

The catchment patient population for the region of Manawatū-Whanganui in New Zealand is 191,100. Most of the information was gathered from the MidCentral District Health Board bio-medical department, which services and repairs BPMD, particularly from the secondary and community-based hospitals in the region. Primary care practices were also contacted by email to the 34 clinics asking for details of BPMD used in each practice. This study received locality

ethics approval and was out of scope to be reviewed by the Health and Disability Ethics Committees (HDEC). The devices identified were compared with the STRIDE BP database.⁹ This database is endorsed by the International Society of Hypertension, the World Hypertension League and the European Society of Hypertension.¹⁰ It identifies if BPMD are validated, preferred or equivalent.

There were 528 BPMD identified, with 37 unique models being used throughout the region. There were 28 devices from primary care practices, and the remaining 500 devices were from the secondary care or community-based hospitals. Only 2/37 (5%) models were validated according to the STRIDE BP database. These models were the Dinamap ProCare 400 and Dinamap ProCare. No other BPMD models were preferred, or equivalent. Only 24/528 (4.5%) of all devices were validated for BP measurement. For hospital-based devices, the proportions were 19/500 (3.8%) and for primarycare based devices, this was 5/28 (18%).

This study highlights that only a very small proportion of BPMD in this region were validated. This could potentially lead to serious inaccuracies in BP evaluation in terms of both under- and overdiagnosis. This is concordant with an Australian study that reported that only 5% of available BPMD for purchase were validated.¹¹ BPMDs have many components that can alter a BP reading, including a pressure transducer, amplifier, cuff system, signal processing methods, cuff system and unique manufacture software algorithms.⁶ This is why it is vital to validate each individual make and model of BPMD, as all of these components vary between devices. Recently, consensus recommendations for BPMD manufacturers with requirements considered as Essential, Optimal or Other were provided, which should help healthcare personnel to make the right choices in recommending or purchasing BPMDs.12 Limitations of this study are that we were unlikely to have identified all BPMD in this region, with

limited information from primary care. We did identify that two thirds of primary care practices used these devices. Our study covered 4% of the New Zealand population and could not necessarily be a true representation of New Zealand as a whole.

This study highlights the widespread use of unvalidated BPMD that could lead to inaccuracies

in the diagnosis and management of HT. Going forward, it is imperative that regulatory mechanisms are in place to use validated BPMD. Manufacturers should only be allowed to sell devices validated for precision and accuracy, and healthcare facilities should strive to acquire validated BPMDs.

COMPETING INTERESTS

None.

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Is Chronic Progressive Deafness a Rhinological or Otological Problem?

By Francis P. Emerson, M.D., of Boston, U.S.A.

Read by invitation before the combined sections of Rhinology and Otology at the New York Academy of Medicine 24th October, 1923.

Read by invitation at the New Zealand Medical Congress, 1st March, 1924, Auckland, New Zealand.

The pathological changes that take place in the middle ear, end organ and naso-pharynx during the course of chronic deafness, being demonstrable by section and microscopical evidence, are not open to controversy. Whether the loss of tone perception is due to such pathological changes in the conduction apparatus, interfering with the transmission of sound waves to the end organ, or whether the chronic deafness is due to some etiological cause that gradually impairs the function of the end organ while it at the same time produces tissue reaction in the conduction apparatus, is a debatable question.

Dr. A. Logan Turner stated four years ago that no progress had been made in the treatment of deafness in the last twenty years. If this statement were confined to chronic cases it would be generally accepted. Leland, a trained rhinologist as well as otologist, twenty years ago stated that if a case of deafness were to be treated by a rhinologist or otologist he would prefer the former. He did much valuable pioneer work in calling attention to the importance of the naso-pharynx in the etiology and treatment of deafness, particularly along preventive lines. *Stucky* recognised the toxic element in all long-standing cases.

No definite detailed treatment applicable to all forms of deafness, showing the etiology and progressive pathology has been advanced, however, that has been generally accepted by the leading otologists. Inflation, which clears up no pathology nor takes into account the etiological factor, was and is still employed notwithstanding the fact it never cured a single case nor even retarded its progress.

It might be suggested as a reason for this reflection on otology that until recent years otology was studied and taught with special reference to the end results. Rhinology and otology were practised separately, and the true relation between the two had to wait for the solution of certain rhinological problems necessary in the treatment of chronic deafness. This has come mainly in the last ten years, but a chronic, slowly progressive disease like deafness must be observed over many years to crystallise medical opinion, especially as the leaders in otology and rhinology have still, to a large extent, continued to teach and practise the two specialities as separate entities.

In the opinion of the writer the loss of tone perception is a border-line problem dealing with rhinology and otology, but having definite evidence of its etiology and progressive pathology, which can be supported by clinical cases. An attempt will be made to establish the following propositions:-(1) Of all forms of deafness, the so-called nerve deafness is the most amenable to treatment. (2) We have no method of differentiating between deafness due to nerve degeneration and that due to toxæmia. (3) Lowered bone conduction may exist for years and, by treatment, in some cases be partially restored. (4) In progressive loss of hearing following acute exacerbations of a focal process in the naso-pharynx the hearing is often improved by removal of the cause, without any other treatment. (5) The end organ has been losing in acuteness of tone perception in chronic cases long before the conduction apparatus becomes an important factor. (6) The conduction apparatus may be impaired by loss of the membrana tympani, malleus and incus with epidermatisation of the promontory and yet the hearing may be but little impaired. (7) The eustachian tube is always more open on the side of the more deaf ear. This is true in all forms of chronic deafness including most cases of nerve deafness, if we exclude syphilis, cerebro-spinal meningitis, mumps and traumatism as exciting causes. (8) Inflation has no place in the treatment of chronic deafness. (9) Inflation is of only temporary benefit following acute tubo-tympanic catarrh, for it removes no pathology and does nothing to retard the progress of the disease. (10) Chronic deafness is not a steady loss of tone perception, but follows acute exacerbations of a local focus, and is then stationary until the next toxic invasion with evidence of the local process always present until extreme old age.

Proceedings of the New Zealand Society for the Study of Diabetes Annual Scientific Meeting, 2–4 May 2024, Ōtautahi Christchurch

The projected prevalence of diabetes mellitus in Aotearoa New Zealand, 2020–2044: an ageperiod-cohort modelling study

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BACKGROUND

Rates of diabetes have been increasing in Aotearoa New Zealand by approximately 7% per year and are three times higher among Māori and Pacific peoples than Europeans. The depth of the diabetes epidemic, and the expansive breadth of services required for its management, elevate the need for updated evidence on the projected future burden of this complex disease.

METHODS

We have projected the prevalence of diabetes (type 1 and type 2 combined) out to 2040–2044 using Virtual Diabetes Register data on diabetes prevalence trends (2006 to 2019) by age group, calendar period and birth cohort. We then used age-period-cohort (APC) modelling to project diabetes prevalence from 2020 to 2044 (overall, and by gender and ethnicity).

RESULTS

New Zealand will experience a substantial increase in the absolute numbers of people with prevalent diabetes, rising to more than 500,000 by 2044 (approximately 90% increase from 2015–2019). The age-standardised prevalence rate will increase from 3.9% to 5.0%. Both the rate and number of new cases will increase most dramatically for Pacific peoples, especially Pacific females for whom diabetes prevalence is projected to increase to 17% by 2044.

CONCLUSIONS

Increased numbers of people living with diabetes in New Zealand will be driven both by population growth (including our ageing population) as well as increases in prevalence of diabetes in specific groups. These projected increases are likely to stretch our health system to breaking point, if not beyond; and as such, immediate and bold action is required to stem the tide of diabetes and other obesity-related illnesses.

The DiRECT approach in Aotearoa New Zealand: a randomised controlled trial of total meal replacement for adults with diabetes and a desire to lose weight

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INTRODUCTION

Te Kāika DiRECT is a 12-month randomised controlled trial conducted within a Māori primary healthcare provider in Ōtepoti Dunedin to assess the efficacy and acceptability of an intensive weight management intervention (DiRECT) for adults with type 2 diabetes (T2D) or prediabetes, obesity and a desire to lose weight.

METHODS

Forty participants were randomised to the DiRECT intervention or dietitian-supported usual care. DiRECT involved 3 months of total diet replacement followed by 9 months of dietitian-supported food reintroduction and weight loss maintenance. All participants received the same number of dietetic consults. The primary outcome was weight change at 3 and 12 months. Glycaemia was assessed via continuous glucose monitoring.

RESULTS

Mean weight loss was 6.1kg (95% CI 2.3-9.6kg)

greater in the DiRECT arm compared with dietitian-supported care at 3 months, and 4.0kg (7.9–0.05kg) greater at 12 months. Dietitian-supported usual care participants lost an average of <1 kg at 3 months and 2.2 kg at 12 months. The DiRECT group lost >6 kg at 3 months, which was maintained at 12 months. The DiRECT intervention resulted in an average 14.2% increase in time spent in tight glycaemic range (3.9–7.8mmol/L) at 3 months, and a 6.4% increase at 12 months, equivalent to 3.4 and 1.5 additional hours per day, respectively.

CONCLUSIONS

The DiRECT intervention is an effective weight management strategy in our participants with T2D or prediabetes. A larger-scale study investigating the impacts of DiRECT as an Aotearoa-wider intervention is warranted.

Experiences of intergenerational diabetes in a Māori whānau and a Sāmoan aiga

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PURPOSE

Many Māori and Pacific families experience intergenerational diabetes. Little is known about the nature and impact of these experiences on individuals and families or how these experiences influence healthcare needs. This study aimed to explore and understand experiences of Māori and Pacific families burdened with intergenerational diabetes.

METHODS

Two case studies: a Māori whānau (family) and a Sāmoan aiga (family) with intergenerational diabetes. One focus group with each was led by culturally matched medical students supported by experienced researchers. Thematic analysis was used to identify key themes.

RESULTS

Four themes were identified: intergenerational trauma and mental health, understanding diabetes and its consequences, the complexity of diabetes and health management and unmet healthcare needs.

Despite the family history of diabetes, little conversation occurred between generations about this condition and there was limited understanding of diabetes when individuals were first diagnosed. Participants identified many complexities related to diabetes management—particularly around medications and seeking healthcare. Limited consultation times and lack of continuity of healthcare had significant consequences. Additionally, complicated life commitment and the need to address other comorbidities of their own and/ or other whānau/aiga enhanced the experienced difficulties of intergenerational diabetes. Poor mental health and intergenerational trauma were also detrimental consequences.

CONCLUSIONS

This preliminary study found intergenerational diabetes significantly impacted all participants, both individually and collectively. These experiences resulted in substantial trauma and burdens, which influenced the way whānau/aiga members managed their own diabetes, and how they supported other whānau/aiga affected by the disease.

Are people with diabetes on an equal footing? 5-year incidence (2017–2021) of diabetes foot disease hospitalisations in Aotearoa New Zealand

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INTRODUCTION

The extent and characteristics of diabetes foot disease (DFD) hospitalisations in Aotearoa New Zealand are largely unknown. Objectives were to identify any differences between Māori and non-Māori in the incidence and outcomes for DFD hospitalisations and investigate associated clinical and socio-demographic factors.

METHODS

A national cohort of people with diabetes ≥16 years, alive at 31 December 2016, New Zealand resident and with no prior DFD hospitalisation was identified using the Virtual Diabetes Register (VDR). National health administrative data were used to estimate the 5-year incidence of first DFD hospitalisations including lower limb amputations using ICD-10 codes. Pre-admission demographics, socio-economic variables, comorbidities, rurality and use of selected health services were also analysed.

RESULTS

The VDR cohort contained 236,871 eligible individuals. There were 11,888 DFD hospitalisations (including 1,850 minor and 709 major amputations) over the 5-year period affecting 180,686 individuals. The 5-year incidence rate for DFD hospitalisations was 1.08 per 100 person years (CI 1.06–1.10). The incidence ratio for DFD hospitalisations was 1.71 (CI 1.64–1.79) for Māori compared with non-Māori, 1.70 (CI 1.64–1.77) for males compared with females. DFD hospitalisations incidence rates increased with age, deprivation, comorbidity score and rurality.

CONCLUSIONS

Disparities in DFD outcomes between Māori and non-Māori highlight the need to identify and address inequities in access to preventative care. The identified clinical and socio-demographic factors associated with DFD hospitalisations emphasise these factors need to be considered in optimising DFD care and prevention services.

Increased risk of cardiometabolic and renal disease for all women diagnosed with gestational diabetes mellitus in New Zealand (2001–2010)—a national retrospective cohort study

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INTRODUCTION

The prevalence of gestational diabetes continues to increase, driven by the obesity epidemic and demographic changes. The aim of this study is to compare cardiometabolic and renal outcomes for all women diagnosed with gestational diabetes between 2001 and 2010 with women without diabetes, 10–20 years following delivery.

METHODS

National maternity, hospital and pharmaceutical databases provided information for all women who gave birth between 1 January 2001 and 31 December 2010 (n=604,398) to compare primary and secondary outcomes until 31 May 2021. Adolescent girls <15 years, women \geq 50 years and women with pre-pregnancy diabetes were excluded. In total 11,459 women were diagnosed with gestational diabetes and 11,447 were matched (for age and year of delivery) with 57,235 unexposed (control) women.

RESULTS

Controlling for ethnicity, women with gestational diabetes were significantly more likely than control women to develop diabetes—adjusted HR (95% CI) 20.06 (18.46–21.79); a first cardiovascular event 2.19 (1.86–2.58); renal disease 6.34 (5.35-7.51), all-cause mortality 1.55 (1.31-1.83) and women dispensed at least two antihypertensive 2.77 (2.66-2.88) or lipid-modifying 5.61 (5.31-5.94) medications following delivery, all p-values <0.0001. The HR (95% CI) was similar for each outcome after controlling for all significant covariates. When time-dependent diabetes was included, cardiovascular events 1.33 (1.10-1.61), p=0.003, and renal disease 2.33 (1.88-2.88), p<0.0001, remained significant but not all-cause mortality.

CONCLUSIONS

Women diagnosed with gestational diabetes have an increased risk of developing diabetes and cardiovascular and renal disease. Long-term follow-up screening and management of cardiometabolic and renal risk factors is crucial.

Risk of renal disease progression in young adults with type 2 diabetes

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		UACR categories (mg/mol)			
		Normal (UACR <3)	Microalbuminuria (3≤ UACR <31)	Macroalbuminuria (UACR >30)	
eGFR categories (ml/min/1.73m²)	Normal (90≤ eGFR <121)	Minimal risk	Minimal risk	Moderate-high risk	
	Hyperfiltration (eGFR >120)	Minimal risk	Moderate-high risk	Moderate-high risk	
	Mild-severe (eGFR <90)	Moderate-high risk	Moderate–high risk	Moderate-high risk	

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INTRODUCTION

Young adults in New Zealand with type 2 diabetes (T2D) are at high risk of diabetic kidney disease (DKD). This study compared the characteristics of New Zealand European (NZE), Māori, and Pacific young adults (aged 18–40 years) based on a composite urine albumin:creatinine ratio (UACR) and estimated glomerular filtration rate (eGFR) variable in order to better stratify DKD progression risk.

METHODS

A secondary analysis of entrants into a longitudinal primary care T2D audit (DCSS:1994–2018). Ethnic comparisons used Chi-squared or ANOVA tests with *post hoc* Tukey for each DKD risk group defined by the composite UACR/eGFR threshold (see above table).

RESULTS

Of 2,184 young adults, 170 NZE (34.2%), 277 Māori (41.0%) and 481 Pacific (47.5%) were high risk for DKD progression (p<0.001). Compared with NZE, Māori and Pacific at high risk had higher BMI (35.9±8.7 vs 39.3±8.9 and 39.2±8.9kg/m²; p<0.001), lower socio-economic position (21.2% vs 54.5% and 64.9%; p<0.001), and with higher HbA_{1c} (60 \pm 22 vs 73±23 and 75±25 mmol/mol; p=0.001). Additionally, they were more likely to receive antihypertensive (67.7% vs 82.3% and 78.8%; p=0.001), anti-diabetes (88.8% vs 94.6% and 93.8%; p=0.047) and anti-lipid medication (62.9% vs 74.7% and 65.1%; p=0.009). Compared with Māori, Pacific had a lower SBP (132.3±17.9 vs 128.6±15.8mmHg; p=0.010) and DBP (84.7±12.3 vs 82.1±10.9mmHg; p=0.007). Current/ prior smoking was the most common among Māori (51.6% vs 31.2% (NZE); 37.0% (Pacific); p<0.001).

CONCLUSIONS

Significant ethnic differences exist in sociodemographic and clinical characteristics among young adults with T2D. The use of a composite UACR/eGFR allows for more precise measure of DKD risk than utilising these variables individually.

First in human feasibility study; automated insulin delivery utilising the Dexcom next generation algorithm in adults with type 1 diabetes

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INTRODUCTION

Existing commercial closed-loop systems require pre-meal carbohydrate announcement and are therefore termed "hybrid closed-loop." This study assessed a novel "fully automated" closed-loop system that does not require carbohydrate announcement, in adults with type 1 diabetes (T1D).

METHODS

Single-arm feasibility study, comprising 14-day run-in using participants' usual insulin therapy with "blinded" continuous glucose monitoring (CGM), followed by 12 weeks' use of investigational closedloop system incorporating an YpsoPump® insulin pump, Dexcom G6 CGM and control algorithm on an Android smartphone. Outcome measures were CGM metrics (run-in and last 14 days of intervention), HbA_{1c} and adverse events.

RESULTS

Thirty-two participants with T1D (mean age 45 years, range 17–74; 17 [53%] female; 4 [13%] Māori; 13 [41%] existing insulin pump users) were enrolled.

	Baseline	Study end
CGM time in range (3.9–10.0mmol/L)	39% (10–70%)	58% (34–78%)
CGM time below range (<3.9mmol/L)	1.4% (0.0–9.8%)	0.9% (0.0–3.1%)
HbA _{1c}	68mmol/mol (54–113)	59mmol/mol (48–74)

Metrics presented as median (range); CGM metrics for study end reflect final 14 days of intervention.

Seven participants withdrew, of whom two were excluded from analysis due to <14 days intervention data. Reasons for withdrawal were severe adverse events in three participants (worsening retinopathy; severe hypoglycaemia attributable to user error; acute hospital admission unrelated to device), and device intolerance in four pump-naïve participants. No other severe adverse events occurred.

CONCLUSIONS

A fully automated closed-loop system, requiring no meal announcement, demonstrated feasibility in a cohort of adults with T1D, with the greatest benefit seen in participants with suboptimal baseline control.

First in human feasibility study; automated insulin delivery utilising the Dexcom next generation algorithm in adults with type 2 diabetes

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INTRODUCTION

Automated insulin delivery technology is under-studied in Indigenous type 2 populations. This study assessed the safety and efficacy of a novel "fully automated" closed-loop system that does not require carbohydrate announcement in Māori and Pacific adults with type 2 diabetes (T2D) and elevated HbA_{1c}.

METHODS

Single-arm feasibility study, with a 14-day run-in period where participants continued their standard insulin therapy with "blinded" continuous glucose monitoring (CGM), followed by up to 12 weeks' use of the investigational closed-loop system incorporating a YpsoPump® insulin pump, Dexcom G6 CGM and control algorithm installed on an Android smartphone. Outcome measures were CGM metrics, HbA_{1c} and safety data.

RESULTS

Ten Māori and Pacific participants were enrolled; median age 55 (range 39–69) years, 4 (40%) female, median HbA_{1c} 90mmol/mol (range 59–158mmol/ mol). All participants completed the study. Median time in range (% CGM recordings 3.9–10.0mmol/L) increased from 10% (range <1–51%) at baseline to 55% (range 2–96%) during the last 14 days of the intervention. Time <3.9mmol/L was <1% during run-in and at end of study. HbA_{1c} was 60 (range 52–117) mmol/mol at study completion. There were no episodes of severe hypoglycaemia or ketoacidosis. Mean (±SD) weight change was +6.2 (4.4) kg.

CONCLUSIONS

A novel fully automated closed-loop system, requiring no carbohydrate announcement, safely improved glycaemic control without increasing time spent in hypoglycaemia in a cohort of Māori and Pacific adults with suboptimally controlled insulin-requiring T2D.

CGMs alongside culturally appropriate wrap-around care significantly improves clinical outcomes and selfmanagement in Māori patients with type 2 diabetes: a mixed methods study

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BACKGROUND

In Aotearoa New Zealand, Māori populations are disproportionately affected by type 2 diabetes (T2D) and have higher rates of morbidity and mortality. This pilot study evaluates the use of continuous glucose monitoring (CGM) with culturally relevant education and support in a high-needs Māori population in primary care.

METHODS

Twenty-three participants with HbA_{1c}>80 mmol/L were recruited from Raukura Hauora O Tainui during 2022/2023. The Kaupapa Māori informed study utilised principles of whakawhanaungatanga (relationship building) and manaakitanga (respect/ care) alongside awhi (care) and mana (power). Participants received 2–4 weeks of CGM wear at baseline and 3 months, alongside kaiāwhina-based T2D education. Clinical biomarkers and psychometric measures were recorded at 0, 3 and 6 months. Ten qualitative interviews were completed at 4 and/or 12 weeks.

RESULTS

Mean (\pm SD) HbA_{1c} significantly decreased from 93.4 \pm 15.7mmol/mol at baseline to 76.5 \pm 14.8mmol/mol at 3 months with reductions maintained at 6 months (both P<0.001 vs baseline). Diabetes self-management scores increased from 4.0 \pm 1.5 to 6.2 \pm 1.1 (P<0.05) though no other significant reductions were observed. Interviews identified the equal importance of manaakitanga, education and technology use.

CONCLUSIONS

CGM use alongside wrap-around care grounded in Te Ao Māori has the potential to improve T2D primary care and self-management in Māori adults. Further work is required to understand the importance of the different study components (e.g., CGM vs kaiāwhina) and to explore how to embed this model of care into primary care.

In vivo test results for an opensource, Ultra Low Cost insulin pump

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BACKGROUND

The high cost of commercial insulin pumps may limit accessibility to people with type 1 diabetes (T1D) who would otherwise benefit, exacerbating inequities in diabetes care. An interoperable, opensource, Ultra Low Cost insulin pump (ULCIP) has shown comparable delivery accuracy to commercial models in laboratory tests. This first-in-human study assessed safety and usability of the ULCIP.

METHODS

Six participants with T1D, usually on insulin pump therapy, used the ULCIP during a supervised 9-hour inpatient stay, including two meals with matched boluses. In addition to continuous glucose monitoring (Dexcom G7), venous blood samples were taken hourly for glucose, β -hydroxybutyrate and insulin.

RESULTS

The ULCIP effectively delivered insulin to five participants, evidenced by glucose and insulin levels displaying trends consistent with programmed pump insulin delivery, and β -hydroxy-butyrate consistently <0.6mmol/L. One participant developed mild ketosis; however, they were able to safely resume ULCIP use following treatment and identification of an underlying remediable hardware issue.

CONCLUSION

The ULCIP was able to effectively deliver insulin to participants in an inpatient setting and has potential as a treatment for people with T1D currently unable to access commercial insulin pumps. Further development will address a hardware issue identified in this trial and enhance Bluetooth operability to enable use in closed-loop systems.

Acceptability, enablers and barriers to dietary change for Māori with nutrition-related conditions in Aotearoa New Zealand: a scoping review

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INTRODUCTION

Māori, the Indigenous population of Aotearoa New Zealand, face a substantial burden of nutritionrelated diseases, especially obesity and type 2 diabetes. Weight loss, through dietary change, is a central component of obesity and diabetes prevention and management; however, most approaches have not been designed with or evaluated specifically for Māori. The aim of this study was to review literature on the acceptability, enablers and barriers to dietary change for Māori.

METHODS

Relevant literature published from January 2000 to August 2021 was identified by searches in Medline (Ovid), Embase (Ovid), Scopus, Indigenous health (informit), CINAHL (EBSCO), Web of Science and NZ Research. Studies included Māori and reflected enablers and barriers to dietary change for individuals/whānau (families). Data identifying the aims, methods, interventions, location, population studied and identified enablers and barriers to dietary change and responsiveness to Māori were extracted. Enablers and barriers to dietary change were mapped to a New Zealand Indigenous health framework, the Meihana model.

RESULTS

Twenty-two of 77 identified records met the inclusion criteria. Records included a diverse range of research approaches and most related to mixed ethnic groups rather than solely Māori populations.

CONCLUSIONS

Using a relevant Indigenous model, this study highlights that multiple and diverse enablers and barriers to dietary change exist for Māori. While some are likely common to all populations, this review highlights the critical importance of developing interventions in close partnership with Indigenous communities to mitigate the impacts of colonisation and racism and to be grounded in Indigenous understandings of health.

Dietary fibre more important than carbohydrate amount for adults with diabetes: systematic review and meta-analyses

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INTRODUCTION

We have compared the effects on cardiometabolic risk factors of diets higher in both carbohydrate and fibre with lower carbohydrate diets in people with diabetes.

METHODS

Randomised controlled trials in which both carbohydrate amount and dietary fibre had been modified were identified from the existing systematic reviews on carbohydrate amount. Ovid MEDLINE, Embase and the Cochrane Register of Systematic Reviews were searched up to 2 November 2023. We pooled outcomes from the eligible trials with random effects and conducted robust sensitivity analyses. Pooled evidence was graded.

RESULTS

Ten trials including 499 participants with diabetes were identified from the potentially eligible 812 included in existing systematic reviews. Pooled findings indicate that higher carbohydrate, highfibre diets reduced HbA_{1c} (mean difference [MD] -0.50% [-0.99 to -0.02]), fasting insulin (MD -5.9 pmol/L [-11.0 to -0.9]), total cholesterol (MD -0.16 mmol/L [-0.27 to -0.05]) and LDL cholesterol (MD -0.16 mmol/L [-0.31 to -0.01] when compared with lower carbohydrate diets. Trials with larger differences in carbohydrate and fibre intakes between intervention arms reported greater reductions. Certainty of evidence for these outcomes was moderate to high, with most outcomes downgraded due to heterogeneity unexplained by any single variable.

CONCLUSIONS

Our findings provide further evidence of the importance of promoting dietary fibre intakes, and the relative unimportance of focussing on carbohydrate amount in nutrition recommendations for people with diabetes.

This project was unfunded. Prospective review registration CRD42023473322.

Specialist weight management programme to improve health outcomes in Counties Manukau communities

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INTRODUCTION

In New Zealand there is a high prevalence of obesity and type 2 diabetes, particularly in Māori and Pacific peoples, with very limited secondary care level interventions focussing on intensive weight management besides bariatric surgery. Te Mana Ki Tua (TMKT), a specialist weight management service, was designed to provide an evidence-based model of secondary care incorporating Tiriti principles for intensive weight management, targeting remission of type 2 diabetes and contributing to Ola Manuia outcomes.

METHODS

TMKT is a multidisciplinary team (MDT) programme for people in Counties Manukau. Patients were predominantly type 2 diabetes, with a body mass index (BMI) >35 and low priority for bariatric surgery. Meal replacements (Optifast for first cohort, Counterweight for all subsequent cohorts) were provided for first 20 weeks. Patients attended group and 1:1 support sessions for 1 year with a whānau-based approach addressing equity.

RESULTS

Of 182 (44 Māori, 82 Pacific, 33 European, 16 Asian, 7 other) invited, 64 (12 Māori, 33 Pacific, 14 European, 5 Asian) were enrolled in monthly intakes of 7–15 patients between July 2023 and February 2024. Remission of type 2 diabetes was 42% based on preliminary data at 3 months. Mean weight loss at 3 months is 10.6kg (7.8% body weight). Mean percentage weight loss was strongly correlated with number of group sessions attended. Hua Oranga wellbeing scores improved (data from one group increased from 65.4 to 71.5).

CONCLUSIONS

Early diabetes remission and weight loss results are comparable to that seen at 12 months in United Kingdom in the DiRECT study.

"Piki Te Ora": a qualitative evaluation of type 2 diabetes selfmanagement model in primary care

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AIMS AND OBJECTIVES

Type 2 diabetes (T2D) is a chronic condition, yet despite established guidelines for treatment, there is still suboptimal disease management in primary care. Cultural inequities are also prevalent, with a higher proportion of Māori patients having poorer health outcomes. Difficulties in diabetes care have led to the development of alternative models of care to reduce disparities and improve self-management. This qualitative study aimed to explore T2D patients' experiences of "Piki Te Ora", a holistic chronic care programme running in primary care.

METHODS

Qualitative semi-structured interviews were completed December–January 2023/2024, involving 10 participants (six female, four male), five of whom were Māori, five NZ European. Recruitment was through a Māori health provider, Te Korowai Hauora o Hauraki, located in the Coromandel/ Thames area. Participants were texted a link to opt into a survey (larger study) and then registered their interest by providing their contact details for an in-depth interview (current study). All interviews were audio recorded, transcribed orthographically and thematically analysed.

RESULTS

Four main overarching themes were established including accessibility, support/care (manaakitanga), individualised care and empowerment (whakamana). Patients expressed a preference for the Piki Te Ora programme compared to Westernised mainstream models of care, which they attributed to appointment difficulties (short appointments and long waiting times), financial and travel barriers, discontent with service delivery, transport issues, financial barriers, lack of continuity of care and poor therapeutic relationships.

CONCLUSIONS

The challenges in diabetes management in primary care have led to novel approaches, such as the development of Piki Te Ora. This model appears to be highly successful, with self-reports of differences in T2D disease management and symptomology after the programme. This model goes a long way to improving health outcomes, breaking down barriers and improving health outcomes for T2D patients and their whānau. It demonstrates a promising model for further implementation in primary care settings.

INVITED LONG ABSTRACT: Cancer incidence among those with diabetes in Aotearoa New Zealand: current and projected trends

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INTRODUCTION

Cancer and diabetes are increasingly prevalent, and it is not unusual for an individual to have both at the same time, given both are common and that one can increase the risk of the other. The occurrence of cancer among those with diabetes has significant ramifications to the person, the clinical team providing their care and the broader health system.

METHODS

For the period 2006–2019, we used national-level diabetes (Virtual Diabetes Register) and cancer (New Zealand Cancer Registry) data on nearly 5 million individuals over 44 million person-years of follow-up. We used cancer incidence among those with and without prevalent diabetes to project cancer incidence across the 2020–2044 period, using age-period-cohort modelling to account for factors driving trends in cancer incidence.

RESULTS

Cancer rates were highest among those with diabetes for 21 of the 24 most common cancers. The greatest differences in cancer incidence by diabetes status were in uterine, liver, pancreatic and kidney cancers, which all have a strong relationship with obesity. In terms of projected burden, cancers in people with diabetes were projected to more than double from 20,243 to 48,773, a 141% increase from 2015–2019 to 2040–2044. Age-standardised cancer incidence was projected to increase 2.4 times faster

for people with diabetes (annual relative increase of 0.4% vs 0.2% for those without diabetes).

CONCLUSIONS

Our findings reinforce the fact that diabetes prevention activities are also cancer prevention activities and must therefore be prioritised and resourced in tandem.

"We are so happy because we have someone that will listen to us": a qualitative evaluation of nurse practitioner led marae-based clinics

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INTRODUCTION

Due to colonisation and ongoing systemic impacts, Māori are three times as likely to develop type 2 diabetes (T2D) compared to non-Māori. Many individuals with T2D receive suboptimal disease management with Westernised biomedical models in primary care, leading to high rates of morbidity and mortality. Initiatives to address these inequities are urgently required. This research evaluates Māori T2D patients' experiences of marae-based healthcare delivery.

METHOD

Kaupapa Māori informed semi-structured interviews were completed in December 2023, involving 11 Māori participants (nine male, two female) who were accessing healthcare at Whiria Te Tāngata, nurse practitioner led clinics in Taupō and Tūrangi. Interviews were audio recorded, transcribed orthographically and thematically analysed.

RESULTS

Unlike mainstream healthcare delivery, Whiria Te Tāngata healthcare delivery is grounded in Te Ao Māori and incorporates six overarching themes: whanaungatanga (relationship building), manaakitanga (support/care), aki (encouragement), mahi tahi (collaboration), whānau ora (whānau & community health) and tino rangatiratanga (selfdetermination). The removal of financial and transport barriers, lack of structured appointment times and involvement of whakapapa connections were described as the catalysts to the success. Participants reported contentment at the clinic, driven by holistic and patient-centred care. Further, they identified the importance of initiatives including health education in kura, kai sovereignty and investment in additional Māori health professionals.

CONCLUSIONS

While New Zealand's mainstream model of healthcare delivery is failing many Māori with T2D, initiatives such as Māori-centric, marae-based health clinics may provide a promising model of care adjunct to primary care clinics to reduce health disparities and improve health outcomes for Māori with T2D.

Enhancing diabetes clinic attendance for high-risk patients in community-based settings

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INTRODUCTION

The global diabetes pandemic has profoundly impacted New Zealand. The Virtual Diabetes Register's 2021 report reveals nearly 300,000 New Zealanders have diabetes, with projections of a 70–90% increase by 2040 and an annual healthcare cost of \$3.5 billion. Māori and Pacific communities suffer disproportionately, experiencing 3–5 times higher rates of type 2 diabetes, compounded by socio-economic challenges. Notably, missed clinic appointments are as high as 43% in these groups, highlighting the need for improved clinic attendance in community settings.

METHOD

Using Lean Six Sigma methodology, our project involved diabetes staff and patients (both attending and missing appointments) from clinics with over 50% Māori and Pacific populations. We engaged in staff meetings, patient interviews and telephonic consultations. Solutions were generated and categorised using the PICK matrix into feasible, implementable, challenging and non-viable options

RESULTS

Key findings showed varied communication preferences, indicating a need for consistent, frequent reminders. Flexibility was crucial, with clinicians encouraged to offer telehealth or rescheduling to manage personal disruptions. Participants desired more accessible appointments, suggesting extended clinic hours or days and the use of telehealth or joint clinics to reduce repeat visits. Empathy was also essential, with a focus on understanding and accepting last-minute cancellations to avoid stigmatising patients.

CONCLUSION

The study identifies effective strategies to improve diabetes clinic attendance in high-risk communities. These include enhanced communication, flexible scheduling, expanded telehealth options and compassionate handling of cancellations. These measures aim to improve healthcare outcomes, particularly for the Māori and Pacific populations heavily affected by the diabetes pandemic.

The "forgotten groups": characterising type 2 diabetes in ethnic minority groups in Aotearoa New Zealand

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BACKGROUND

Health data are often reported on in Aotearoa New Zealand using level 1 ethnicity data, such that any differences between minority ethnic groups are not reported. This study explores the characteristics and medication use of different Middle Eastern, Latin American and African (MELAA) and Asian ethnic groups with type 2 diabetes (T2D).

METHODS

Primary care data were collected by level 3 ethnicity for Waikato and Auckland patients aged 18–75 years with T2D (February 2021 to July 2022, 302 practices, n=57,743). Clinically indicated prescribing was defined as SGLT2i/GLP1RA and statins in renal and/or cardiovascular disease or equivalent risk, ACEi/ARB in renal disease and metformin in all with T2D.

RESULTS

A total of 9,143 Asian and 920 MELAA individuals were identified. For MELAA patients, clinically indicated prescribing for SGLT2i/GLP1RA (~27%), metformin (~80%), ACEi/ARBs (~84%) and statins (86.2%) was comparable across ethnic groups (P>0.05) with no difference in mean HbA_{1c} (58.4±14.6 mmol/mol). In Asian ethnicities, indicated SGLT2i/GLP1RA prescribing was lowest in Korean (7.7%) and highest in Fijian Indian (34%); (mean Asian 28.8%; P<0.001) and metformin prescribing ranged from 79.4–95.6%. Percent at HbA_{1c} target (≤53mmol/mol) was lowest in Fijian Indian (29%) and highest in Chinese (55%; P<0.01).

CONCLUSIONS

Glycaemic control to target and clinically indicated prescribing differs in ethnic minorities with T2D in New Zealand. Care is needed to ensure that these groups are equally represented in health statistics so that culturally appropriate strategies can be designed to optimise care.

Success of the inaugural national NZSSD/University of Waikato Advanced Diabetes Management Course

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INTRODUCTION

The first national NZSSD/University of Waikato (UoW) Advanced Diabetes Management Course (ADMC) was delivered online by the Aotearoa Diabetes Collective between August–December 2023 to health professionals throughout Aotearoa. The ADMC consisted of 8 weekly 30–40-minute webinars and \geq 8 weekly 30–40-minute case discussion sessions followed by a multiple-choice assessment.

METHODS

An online survey was sent in January 2024 to all participants in the 2023 ADMC (n=585 participants). Questions captured demographic data and 5-point Likert scale (1=poor/not at all, 5=excellent/ extremely) ratings on perceptions of the course.

RESULTS

Approximately 56% of participants (n=325) completed the survey, with 15% being general practitioners, 7% nurse practitioners, 44% registered nurses, 17% pharmacists, 9% dietitians and 8% other professions, with responses from all old district health board regions. Feedback was overwhelmingly positive with mean scores all \geq 4.6/5 for overall quality of the ADMC, organisation, content and delivery of the ADMC, focussing on improving health outcomes for Māori and Pacific,

improvements in own clinical practice and likelihood of recommending course to peers. Approximately 35% reported difficulty accessing the UoW online platform at some point and 83% were keen for points towards a postgraduate qualification. Only 59% (n=585) of those who registered for the ADMC attended at least one session, but >80% (n=477) of these participants completed all components.

CONCLUSIONS

The inaugural national NZSSD/UoW ADMC was well received and led to a subjective improvement in clinical practice. Improvements to the online platform, academic accreditation and optimising registration are underway for the 2024 ADMC.

Specialist nursing care and realtime continuous glucose monitoring in reducing cardiovascular risk in high-risk adults with insulinrequiring type 2 diabetes: a subanalysis of the 2GO-CGM study

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INTRODUCTION

We assessed the effects of a diabetes specialist nurse led model of care and real-time continuous glucose monitoring (rtCGM) on predicted cardiovascular disease (CVD) risk in type 2 diabetes (T2D) in a subanalysis of the 2GO-CGM study.

METHODS

The 2GO-CGM study randomised 70 people with insulin-requiring T2D with suboptimal glycaemic control to rtCGM or routine care with self-monitoring of blood glucose levels (SMBG) for 12 weeks. Both groups had their glucose-lowering and cardiovascular therapies optimised by prescribing-capable diabetes specialist nurses. An extension phase is ongoing with all participants using rtCGM. Predicted CVD risk was calculated at baseline and RCT end using the NZSSD CVD/ESRD calculator. Actual event rate was compared to baseline predicted event rate during the extension phase.

RESULTS

Predicted CVD scores were compared in all participants with complete data (n=55), who were predominantly Māori (54.5%). CVD risk scores improved across both groups (absolute risk reduction rtCGM 2.196 \pm 1.471%, p=0.005 and SMBG 1.376 \pm 0.861%, p=0.003), with no between-group difference (p=0.24). Improvements in CVD risk correlated significantly with increased HDLc and reduced HbA_{1c} and microalbuminuria (p<0.05 versus baseline). Mean follow-up at time of analyses was 1.6 \pm 0.1 years, with an actual event rate of 0.63/year compared to the predicted 1.6 events/year prior to rtCGM initiation.

CONCLUSIONS

A specialist nurse supported care model, including rtCGM application, can reduce cardiovascular risk in a high-risk population with insulin-requiring T2D.

DECLARATIONS

Study funded by Dexcom.

M de Bock: received honoraria, advisory board member for Dexcom.

R Paul: advisory board member for Dexcom.

Extended use of real-time continuous glucose monitoring in adults with insulin-requiring type 2 diabetes: the 12-week continuation phase following the 2GO-CGM randomised controlled trial

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INTRODUCTION

The impact of real-time continuous glucose monitoring (rtCGM) on glycaemia for Māori and non-Māori with type 2 diabetes in Aotearoa is unestablished. The 2GO-CGM study assessed efficacy and safety of rtCGM in a cohort of adults with insulin-requiring type 2 diabetes.

METHODS

Both groups of a 12-week randomised controlled trial comparing rtCGM (Dexcom G6) with selfmonitoring of blood glucose (SMBG) entered a 12-week continuation phase where SMBG users (designated the SMBG-rtCGM group) crossed over to use rtCGM alongside rtCGM users (the rtCGM-rtCGM group). Analyses of all 24 weeks of data, including within-subject and between-group differences, were conducted to examine an overall treatment effect of rtCGM versus SMBG.

RESULTS

Sixty-one participants completed the 24-week study period (52% Māori, 57% female, median age 54 (range 16–69) years. Baseline-adjusted mean TIR was 15.2% (95% CI 10.4–20.1; p=<0.001) higher in the rtCGM users versus SMBG users. Mean HbA_{1c} (±SD) decreased in both groups from 85 (19) mmol/ mol to 59 (11) mmol/mol in the rtCGM arm and from 82 (12) mmol/mol to 59 (12) mmol/mol in the SMBG arm (p<0.001 for both). One participant withdrew in the continuation phase due to unmanageable skin reactions to CGM device. There were no severe hypoglycaemia or ketoacidosis events in either group.

CONCLUSIONS

Use of rtCGM over 24 weeks demonstrates safe and sustained glycaemic improvement in Māori and non-Māori rtCGM users.

SGLT2I/GLP1RA agents appear to be improving clinical outcomes in New Zealand patients with type 2 diabetes and cardiovascular/renal disease

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BACKGROUND

Type 2 diabetes (T2D) associates with significant cardiovascular/renal disease (CVRD) risk and patients must be optimally managed to optimise health outcomes. This study aimed to evaluate the impact of newly funded access to GLP1RA/SGLT2i on BP, LDL-C and HbA_{1c} in patients with T2D and CVRD.

METHODS

Waikato/Auckland primary care data were collected for those 18–75 years with T2D during 2021–2022 (302 general practice clinics). We reviewed mean values and percent of patients at target (%PAT) for BP (\leq 130/80 mm/Hg), LDL-c (\leq 1.8 mol/L) and HbA_{1c} (\leq 53 mmol/mol; 7%) at July 2022 vs January 2021 in those with CVRD who did/did not initiate SGLT2i/GLP1RA therapy (\geq 2 prescriptions).

RESULTS

Overall, 8,036 of 17,068 CVRD patients (47.1%) initiated SGLT2i/GLP1RA therapy, with higher uptake in NZ Māori compared to NZ European patients (54.5% vs 41.8%; P<0.001). In patients with CVRD who initiated therapy, the %PAT increased for HbA_{1c} (10.7% to 15.8% [+5.1%]), LDL-c (43.5% to 44.6% [+1.1%]) and BP (39.7% to 41.5% [+1.8%]) (all P<0.05) compared to minimal improvements of 0.1–0.3% in patients with CVRD who did not commence therapy. Mean HbA_{1c} decreased by 4.0 vs 0.3mmol/mol and LDL-c by 0.1 vs 0.0mmol/L in those prescribed vs not prescribed SGLT2i/GLP1RA (both P<0.05) though no change was observed in BP.

CONCLUSION

SGLT2i/GLP1RA use appears to be associated with improved glycaemic and cardiovascular markers in patients with T2D and CVRD. Further research is required to evaluate the longer-term impact of these medications on clinical outcomes and hospitalisation rates.

Glucose and psychosocial outcomes

12 months following transition from multiple daily injections to advanced hybrid closed loop in youth with type 1 diabetes and suboptimal glycaemia

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OBJECTIVES

To investigate 12-month glycaemic and psychosocial changes following transition from multiple daily injections (MDI) to advanced hybrid closed-loop (AHCL) therapy in youth (aged 13–25 years) with type 1 diabetes and suboptimal glycaemia (glycated haemoglobin [HbA_{1c}] \geq 8.5% [69 mmol/mol]).

METHODS

Prospective, single-arm, dual-centre study in 20 participants. Extension phase outcomes reported after 12 months, including HbA_{1c} , time in glycaemic ranges, AHCL system performance and psychosocial questionnaires assessing quality of life, diabetes treatment and sleep.

RESULTS

After 12 months, 19 out of 20 participants continued to use AHCL. Average time-in-range 70–180mg/dL (3.9–10.0mmol/L) improved from 27.6%±13.2% to 62.5%±11.4%. This translated to an average 2.5 percentage-point (27.1mmol/mol) improvement in HbA_{1c} from 10.5%±2.1% (91.2mmol/mol) at baseline to 8.0%±0.9% (64.1mmol/mol) at 12 months. Psychosocial questionnaires and very high HbA_{1c} at study entry indicated significant diabetes-associated burden for both individuals and parents. Safety data were reassuring with a diabetic ketoacidosis rate of 0.15 per participant-year after 12 months of AHCL (compared to 0.25 per participant-year in the 12 months before the study). **CONCLUSIONS**

After 12 months of AHCL usage, this study highlights the potential for substantial and sustained glycaemic and psychosocial improvements among individuals experiencing considerable diabetes burden and suboptimal glycaemia following their switch from MDI to AHCL.

Relationship between carbohydrate counting and carbohydrate announcement to glycaemic control in young people using AHCL insulin delivery

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INTRODUCTION

Little has been investigated regarding the predictors of glycaemic control for individuals with high-risk glycaemia after transitioning to the Minimed 780G AHCL system. This project investigates the relationship between glucose control and food announcement behaviour and method in youth (7–25) with type 1 diabetes and elevated glycaemia.

METHODS

This project takes data from two studies (n=100, n=64 in this abstract), Co-Pilot and AHCL in highrisk youth, which both targeted youth with highrisk glycaemia (HbA_{1c} \geq 8.5% [69 mmol/mol]) and had similar inclusion/exclusion criteria. Measures of glycaemic control (HbA_{1c}⁻ time in range [%CGM 3.9–10mol/L]), meals and carbohydrates input per day and time in automation were gathered over a 3-month period post-transition to AHCL.

RESULTS

On average, HbA_{1c} decreased by -29.0±22.6 mmol/mol. Meals inputted per day predicted glycaemic control, with the greatest change in HbA_{1c} seen in those entering 3 or more meals/day (-34.2±21.1mmol/mol). Those entering <1 meal per day still saw HbA_{1c} improvement (-22.8±49.6mmol/mol). Total carbohydrate entered per day was also associated with decrease in HbA_{1c} , though with a more complex relationship. Participants spending more than 80% of time automation also saw greatest HbA_{1c} improvements.

CONCLUSIONS

Participants in these studies on average saw a significant decrease in HbA_{1c} after transitioning to AHCL, with even those inputting minimal meals seeing on average a >20mmol/mol improvement in HbA_{1c} . However, predictors for optimal improvement remain frequent meal announcements and high use of automation.

The Child Disability Allowance is used to subsidise continuous glucose monitoring in type one diabetes

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INTRODUCTION

The child disability allowance (CDA) is a nonmeans tested benefit that all whānau with a child aged <18 years with type one diabetes (T1D) are eligible to receive. However, it is not known how many whānau access the CDA, nor is it known what the CDA is used for in relation to T1D.

METHODS

A 40-item survey was developed to gather demographic information along with information about access to, and use of, the CDA in relation to T1D. We report on current survey completions from recruitment via New Zealand T1D Facebook groups.

RESULTS

Ninety parents completed the survey. Most children were European (81.6%), with 6.9% Māori and 5.7% Pacific. Mean duration of diabetes was 2.4 years. Sixty point four percent of children used an insulin pump and 86.8% used a CGM. Losing access to the CDA would impact CGM use severely for 71.0% and moderately for 15.9% of whānau and impact quality of food purchased severely for 39.1% and moderately for 21.7% of whānau.

CONCLUSION

In this sample of families, the CDA is a key source of funding for CGM. Further recruitment is planned via Diabetes New Zealand and regional diabetes youth organisations. A larger sample will facilitate an equity analysis. Further research should examine the impacts of "ageing out" from the CDA at 18 years on access to CGM for young adults with T1D.

Insulin pump initiation in a naïve population

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INTRODUCTION

A multidisciplinary specialist diabetes service, integrated into primary care, has recently been

established in Te Whatu Ora Tairāwhiti. In 2021 a review described it as a "service in crisis." There were 41 adults with T1DM with a mean (SD) HbA_{1c} 79.4 (25.2) mmol/mol; five were using an insulin pump. The diabetes team and patients were not familiar with availability of insulin pumps, or confident with initiation or management. We sought to change this, identifying opportunities for education, mentoring and telehealth to develop an insulin pump service.

METHODS

This retrospective audit aimed to identify all adult insulin pump users in the Tairāwhiti diabetes service, to describe the population initiated on a pump, use of CGM and hybrid closed loop, and changes in HbA_{1c} during this time.

RESULTS

Tairāwhiti currently has 98 adults with T1DM managed within the specialist diabetes service. Nineteen (18.4%) use an insulin pump.

Current pump users are: 13 female, six male; mean age 44 years (range 23–76); five Māori, 14 Pākehā. Fourteen use a CGM and 10 use a hybrid closed loop system.

Mean (SD) HbA_{1c} prior to pump initiation was 69.5 (16.6) mmol/mol. At 3 months HbA_{1c} was 57.2 (11.6) and the most recent HbA_{1c} was 58.1 (10.4).

There is an increasing number of people waiting for a pump, limited by staff resources.

CONCLUSIONS

Proactive development of an insulin pump service in a remote population is possible with the use of local and remote specialist support, and active education. For patients, developing a trusting relationship is key to successful initiation and management.