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Stroke clot retrieval from Taranaki, New Zealand: a real-world regional experience
Bhavesh Dayal Lallu, Jae Beom Hong, Michael Wang, John Chalisery, Roger Blume, Jeanette Langridge, Sarah Davidson, Heather Webb, P Alan Barber

This paper shows that stroke patients with a large artery occlusion from regional Taranaki can achieve the same outcomes as their Auckland metropolitan (Northshore/Middlemore) counterparts. This is despite the significant difference in geographical distance from Taranaki to the Stroke Clot Retrieval Centre at Auckland City Hospital compared to North Shore and Middlemore hospitals. Provided appropriate and rapid systems of stroke care in place, the post-code lottery for hyperacute stroke care can be overcome.

Clinical anatomy through gamification: a learning journey
Vivek Perumal, Sambit Dash, Snigdha Mishra, Nawaporn Techataweewan

We developed a series of games through which medical students could play-learn all aspects of clinical anatomy in their undergraduate course. Novel to the usual pedagogy, we obtained initial ideas from the students, developed a prototype, piloted it, obtained student feedback on the pros and cons and modified the games again. This helped us to integrate user experience into the game process at a very earlier level. Also, as we felt that obtaining player information, experience, feedback and so on would require additional time, we integrated these aspects within the game scenes so that the students provided their consent, detail and feedback as they played the game rather than at the end. With all these aspects, medical students reported that the games were fun, interesting and, of course, helped them learn anatomy.

Diagnostic accuracy of 10/66 dementia protocol in Māori kaumātua (elders) living in Aotearoa New Zealand
Adrian Martinez-Ruiz, Sarah Cullum, Gary Cheung, Susan Yates, Rita Krishnamurthi, Claudia Rivera Rodriguez, Ngaire Kerse, Makarena Dudley

Our study showed that the Māori-friendly 10/66 dementia protocol has adequate clinometric properties, with a sensitivity of 90.0% and specificity of 93.8%. This demonstrates its discriminatory abilities for future population-based dementia studies that involve Māori. To the best of our knowledge, this is the first validity study of the 10/66 dementia protocol focusing on Māori in Aotearoa New Zealand or elsewhere.

Modelling the impacts of tobacco denicotinisation on achieving the Smokefree 2025 goal in Aotearoa New Zealand
Nick Wilson, Janet Hoek, Nhung Nghiem, Jennifer Summers, Leah Grout, Richard Edwards

This preliminary high-level modelling suggests a mandated-denicotinisation policy could have a plausible chance of achieving the New Zealand government's Smokefree 2025 goal. But the probability of success would increase if supplemented with interventions such as mass media campaigns offering Quitline support (especially if predominantly designed for a Māori audience).
Variation in open access vildagliptin use in Waikato patients with type 2 diabetes

Lynne Chepulis, Christopher Mayo, Ryan Paul, Rawiri Keenan, Ross Lawrenson

Vildagliptin is a medication that is used to support type 2 diabetes management in primary care. It is generally not the first agent used, but it is used as an add-on to therapy to keep bring elevated blood sugar levels (measured via HbA1c) down to closer to normal range. Medications that are available open access are those that are available to everyone (in this case everyone with T2D). Our study shows that despite this equitable access, the drug is not prescribed or used equitably and Māori patients are much less likely to have this medication added to the treatment regime.
Assessing progress with the implementation of the New Zealand Medicinal Cannabis Scheme

Vinuli Withanarachchie, Marta Rychert, Chris Wilkins

In 2017, the Labour coalition government committed to making cannabis-based medicinal products more readily available to patients. The decision to legalise cannabis for medical purposes followed growing public demand, including by terminally ill and epileptic patients who advocated for greater access to cannabis-based products. A market research panel survey conducted in May 2019 found over 30% of New Zealanders were interested in accessing medicinal cannabis products when they became available.

Following public consultations, the Medicinal Cannabis Scheme (MCS) commenced in April 2020 with a central objective to improve patients’ access to affordable, quality medicinal cannabis products. Under the scheme, patients with a prescription from a New Zealand-registered doctor can access medicinal cannabis products, both THC and CBD.

When the MCS commenced, the medicinal cannabis product range available in New Zealand was largely limited to imported products. The scheme aimed to reduce reliance on imports by facilitating local manufacture and distribution of medicinal cannabis products, and to support health professionals to confidently prescribe these products to patients.

While New Zealand’s domestic industry worked to achieve the new MCS standards, the Ministry of Health (MOH) approved a six-month extension to a temporary scheme to give patients continued access to CBD imports.

Eight medicinal cannabis products now meet the MCS standards, including 4 Canadian products (Tilray) and 4 products with domestic NZ medicinal cannabis company license holders (SubDrops™ CBD100, SubDrops™ CBD25, ANTG Eve, and RUA CBD100). As far as we can ascertain, three of the four products licensed to domestic medicinal cannabis companies consist of imported flower or other active ingredients with final processing in New Zealand.

The MCS continues to experience implementation issues following the end of the interim scheme (Figure 1). This editorial provides an update on the MCS and reviews key issues to date.

Domestic industry: minimum quality standard

Under the MCS, a Medicinal Cannabis Licence is required to commercially participate in the sector. Producers must meet the Good Manufacturing Practice (GMP) code, a near-pharmaceutical-grade compliance standard that applies to all medicines available in New Zealand, to receive the additional Licence to Manufacture Medicines.

During the MCS public consultations, industry stakeholders and medical practitioners received the GMP standard positively, reflecting the focus on consistency and quality of products. Patients preferred a mixed model of GMP and Good Production Practice, a less stringent compliance standard Canada applies to non-prescription cannabis products.

The current situation of a small number of product approvals, however, raises several concerns as to whether enforcing a single compliance framework remains the preferred pathway to achieving the...
**Figure 1:** Regulation of medicinal cannabis products in New Zealand and the Medicinal Cannabis Scheme implementation timeline.
MCS’s objective. Medsafe has issued several companies a GMP licence, and three domestic medicinal companies obtained MCS “approval” for four products that meet the minimum quality standards (MQS) outlined in the Misuse of Drugs (Medicinal Cannabis) Regulations. Medicinal cannabis products include dried components like cannabis flower and dosage products like capsules containing cannabis-based ingredients. Of the 71 product applications the Medicinal Cannabis Agency (MCA) received between April 2020 and December 2021, only four cannabis-based ingredients and six dosage products met the MQS. Manufactures have expressed frustration with GMP accreditation, describing the requirement to prove final products will sustain their quality over a six-month period as a roadblock in the approval process. The MCA’s recent decision to allow laboratories to comply with the ISO/IEC standard for testing specific materials (rather than only relying on the GMP-accredited laboratories) may help reduce barriers for industry in the product approvals process.

The demands of GMP compliance have discouraged small-scale suppliers from seeking to provide products. This may result in a few companies monopolising the domestic market, and although this could provide better compliance and professional standards, it risks inequitable access for some patients if products are priced too high. Our recent survey of 3,634 medicinal cannabis users found that affluent and Pākehā users were more likely to procure medicinal cannabis through the MCS than low-income earners due to the anticipated high prices of prescribed products. During the MCS consultations, the medicinal cannabis advisory committee highlighted concerns about mark-ups on cannabis products creating access barriers for patients. In April 2021 the MOH anticipated products that meet the GMP standard would likely cost more than products that don’t. As MCS products will not be subsidised by Pharmac, the issue of financial barriers to access is likely to persist in the immediate future for patients, even with domestic products entering the market.

Informal black-market supply

Most cannabis used for broadly defined therapeutic purposes in New Zealand is accessed via the illegal, unregulated market. Before the MCS, a survey of medicinal cannabis users found less than 5% of respondents procured medicinal cannabis with a prescription, the majority choosing to source via drug dealers, relatives or home-growing. Groups like the Green Fairies provide an underground supply of cannabis products to people who may not otherwise have contacts and supply networks in the “street” illegal cannabis market. While in many cases they may be dedicated to medical cannabis provision, there is no official testing of levels of CBD, THC and potential contaminants in these illegal market products, which raises concerns about safety and highlights how delays with the MCS have not addressed reliance on illegal supply and untested products.

Though currently cannabis-based products can still be imported for named individual patients outside of the MCS, there have been media reports of doctors and clinics being investigated for exercising this option too liberally. The slow progress on product approvals may undermine patients’ confidence in the MCS and may mean patients will re-engage with grey and black-market supply routes.

Health professionals’ engagement

Currently, general practitioners have eight CBD and THC products at their disposal. Data on legal market purchases suggest CBD-only products are increasingly prescribed; 16,678 prescriptions were made for CBD products by mid-2021, 75% of the total CBD prescriptions made in all of 2020 (21,964) (Sep 21, personal communication with the Ministry of Health). Despite more prescriptions, there is evidence that prescribing practices may not be uniform. A 2020 exploratory study of 76 general practitioners found 79% of them were hesitant to prescribe medicinal cannabis in the future. Over a third stated there was no evidence to
support cannabis-therapy for specific conditions and just over half had consulted any resources on medicinal cannabis.\textsuperscript{16} The limited scientific clinical trial evidence for the use of cannabis in clinical treatment has been a major issue in implementing similar regimes overseas affecting doctors’ willingness to engage with cannabis prescribing.\textsuperscript{17} There is moderate-quality evidence for the use of cannabis to treat chronic pain, chemotherapy-induced nausea and vomiting and spasticity as a result of multiple sclerosis, as well as insufficient evidence for several other conditions, including epilepsy (better evidence from paediatric samples than adult trials),\textsuperscript{18} post-traumatic stress disorder and anxiety symptoms.\textsuperscript{19} Reluctance to prescribe cannabis as a medicine may also be influenced by its historical status as a prohibited drug with related stigma. On the other hand, prescribing of new medicines is often slow if colleagues are uncertain and/or there is no recent history of prescribing of the therapeutic class of cannabinoids.\textsuperscript{20} As the MCS regime matures, products approved under the scheme may become more normalised. The Medical Council’s statement on good prescribing practice requires doctors to be informed on drug profiles when prescribing them to patients.\textsuperscript{21} Medicinal cannabis deviates from this requirement as products under the MCS don’t require efficacy data to be approved and available on prescription; and without a list of eligible conditions, prescriptions are administered at the clinician’s discretion.\textsuperscript{13} Medsafe also considers products under the MCS as “unapproved” medicines, which means they are prescribed as exceptions to the Medicines Act.\textsuperscript{16} The Best Practice Advocacy Centre New Zealand is currently developing an information resource on medicinal cannabis to help health professionals facilitate conversations with patients.\textsuperscript{21} Though this is a progressive step towards supporting health professionals’ engagement in the MCS, the lack of clinical evidence outlined for using medicinal cannabis to treat commonly enquired about conditions (eg, chronic pain and nausea) is likely to remain an important barrier to expanding prescribing. At present, prescribers may feel cautious about exploring medicinal cannabis as a treatment option as it deviates from the standard regulations for medicines and requires individual doctors to assume personal liability when prescribing these products. Overseas, gaps in general practitioner prescribing have provided physicians interested in cannabis medicines with the opportunity to forge speciality clinics in this area.\textsuperscript{16} Despite patients’ significant interest in medicinal cannabis products in New Zealand and easing of regulatory barriers in recent years, only a third of requests for a medicinal cannabis prescriptions via general practitioners are successful,\textsuperscript{13} and cannabis clinics have increasingly met this need. If implemented and received well, the MOH’s educational resource could reduce the risk of patients compartmentalising their health by seeking separate medical advice from cannabis clinics.

**Conclusion**

The implementation of New Zealand’s MCS has been slower than many expected. Four years on, the scheme’s objective of greater access to medicinal cannabis has progressed in some ways, yet inequitable access to products remains a significant issue for many patients. Compliance standards, black-market activity and inconsistent prescribing practices are gaps that are relevant for health professionals, policymakers and industry stakeholders to consider as the MCS matures. The recent consensus to approve ISO/IEC-accredited laboratories for testing, development of BPAC resource for prescribers and the approval of four products linked to domestic medicinal cannabis companies are positive responses to delays. There is a need for further investment in general practitioner information and training to improve confidence in prescribing cannabis products, and further lateral thinking and innovation to overcome current procedural challenges. Reclassifying non-intoxicating cannabidiol products from prescription to over-the-counter products could improve equity in the MCS by reducing access barriers put up by the current prescription-only system.\textsuperscript{15,22} Currently, the slow implementation of the MCS illustrates challenges in reconciling the views of patients, industry and health practitioners on the best way to implement the new scheme.
Competing interests:
Nil.

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Stroke clot retrieval from Taranaki, New Zealand: a real-world regional experience

Bhavesh Dayal Lallu, Jae Beom Hong, Michael Wang, John Chalissery, Roger Blume, Jeanette Langridge, Sarah Davidson, Heather Webb, P Alan Barber

ABSTRACT

AIM: Stroke clot retrieval (SCR) is now considered a standard of care for select stroke patients with proximal large vessel occlusion (LVO) of the anterior circulation. Here we present the experience of regional Taranaki patients transferred by air for SCR and compare this to metropolitan Auckland patients who were transferred by road. The aim is to present and compare process metrics and outcomes between the regional and metropolitan centres.

METHODS: This is a retrospective analysis of consecutive patients with anterior LVO transferred to Auckland City Hospital (ACH) for SCR from Taranaki, Waitematā and Counties Manukau district health boards (DHBs) between November 2017 and December 2020.

RESULTS: Thirty Taranaki patients were transferred for SCR, compared to 244 patients from Waitematā and Counties Manukau DHBs. Taranaki patients were seven years older and less ethnically diverse but similar in other characteristics. The proportion of patients with an independent Modified Rankin Scale (mRS) score between 0 and 2 at three months was the same as for the regional and metropolitan centres.

CONCLUSIONS: In this real-world study, regional stroke patients can achieve similar SCR outcomes to metropolitan patients. Overcoming the post-code lottery for hyperacute stroke care can be achieved in a New Zealand setting.

Acute stroke care has transformed in recent years, from a largely supportive-management approach to one that aggressively aims to re-establish blood flow to salvageable brain tissue. Treatment options include intravenous thrombolysis (IVT), stroke clot retrieval (SCR) or both. Stroke reperfusion rates in New Zealand are rising. In 2019, 9.4% of patients were treated with IVT, an increase from 6.5% in 2015, with no overall difference between those in regional and metropolitan areas. Increasing numbers of New Zealanders with acute stroke also have access to SCR, with 342 procedures performed in 2019 (4% of all ischaemic stroke patients) compared to 134 (1.4%) in 2017. The percentage of patients with ischaemic stroke who are suitable for SCR is estimated to be around 10%. In 2019, there were 8,555 patients admitted to hospital with an ischaemic stroke, indicating that significant work is required to bridge this gap. Currently, SCR is only performed in Auckland City Hospital (ACH), Wellington Regional Hospital (WRH) and Christchurch Hospital. For patients residing outside the geographical catchment area of these centres, there are barriers to accessing treatment. In 2019, metropolitan patients had an SCR rate of 4.2% compared to 1.2% in regional areas. Transfer of stroke patients from regional centres to an SCR centre is feasible and we have previously described a patient transferred from Taranaki to ACH. Access barriers include inadequate hyperacute stroke assessment, processes, transport logistics and time constraints.

The aim of this study is to determine whether functional outcomes following SCR for anterior circulation large vessel
occlusion (LVO) are equivalent in patients transferred from regional centres (Taranaki) to those in metropolitan (Waitematā and Counties Manakau) centres.

Taranaki District Health Board (DHB) has a catchment population of 120,000 and is located 360kms from ACH by road and 252kms by air, with a flight time of 72 minutes. Waitematā DHB has a catchment population of 628,770. It has two hospitals with road distances of 13kms and 18kms to ACH. Counties Manukau DHB has a catchment population of 578,650. The hospital is 20kms to ACH by road. Key aspects of the Helsinki Thrombolysis Model have been successfully adapted to the New Zealand environment and were localised to the Taranaki system; this has been described previously. “Code Stroke” activations have been utilised since August 2017 and occur via an internal 777 call to the telephonist. During working hours, the stroke team is comprised of an emergency department physician and nurse, medical registrar, medical house surgeon, duty nurse manager, computer tomography (CT) technician, hospital orderly and stroke clinical nurse specialist and stroke physician. After-hours stroke specialist support was via telephone from ACH until December 2018, at which point telestroke support from WRH was implemented. All patients presenting with acute stroke clinical syndrome routinely have a non-contrast computed topography (NCCT) brain and CT angiography (CTA) from the aortic arch to the brain vertex. CT perfusion (CTP) has been available from January 2020. CT, CTA and CTP is the default imaging setting and can be de-escalated when not required. NCCT thins (bone series and sagittal reformats excluded) and CTA 2mm thins (axial) are automatically uploaded to the Picture Archiving and Communication System (PACS) server for ACH and WRH to review. Rapid transfer of images is achieved using a standalone server and by streamlining firewall rules.

A working group involving all stakeholders was established in late 2017 to initiate protocols, pathways and training. Training included biannual, inter-sector stroke simulations for hospital, helicopter and ambulance personnel. Regular, ongoing education sessions have been held for rotating staff and have assisted to embed the stroke pathway that is now seen as a standard of care.

**Methods**

Consecutive patients treated with SCR at ACH who were transferred from Taranaki, Waitematā or Counties Manukau DHBs between November 2017 and December 2020 were identified from the New Zealand National Reperfusion Registry and included for analysis. Since late 2018, after-hours presentations of LVO patients from Waitematā and Counties Manukau DHBs have been transferred directly to ACH. These patients were not included in the analysis.

The following baseline characteristics were captured: age, sex, ethnicity, co-morbidities, National Institutes of Health Stroke Scale (NIHSS) score and Alberta Stroke Program Early CT Score (ASPECTS). Stroke onset was defined as the time the patient was last known normal (LKN). Time points of LKN, hospital admission (“to door”), CT, IVT, arrival at the SCR centre and groin puncture time were collected. Successful recanalisation was defined as a modified Thrombolysis in Cerebral Infarction (mTICI) score of 2b to 3. mRS scores were determined at three months.

The primary outcome was the proportion of patients achieving functional independence, defined as an mRS score of 0 to 2 at three months. mRSs were collected centrally by telephone or physical follow-up at three months. Secondary outcomes included early neurological recovery (defined as a reduction in the NIHSS score of ≥8 points from baseline in 24 hours or an NIHSS score of 0 or 1 at 24 hours), ordinal shift of mRS scores at three months, symptomatic intracranial haemorrhage, seven-day mortality and three-month mortality. New Zealand’s Health and Disability Ethics Committee approved use of registry data (HDEC 19STH/55).

Statistical analysis was performed using IBM SPSS Statistics, version 26.0 (New York, USA). Results are reported as mean ± standard deviation (SD) or median and interquartile range (IQR). Univariate inter-group comparisons of normally distributed continuous measures were conducted using the independent samples t test, following confirmation with Shapiro-Wilk
testing (P>0.05). Non-normally distributed continuous and ordinal data were compared using the Mann-Whitney U test. Categorical data were analysed using Fisher’s exact test. Propensity-score-adjusted logistic or ordinal regression was performed to assess whether there were significant differences in outcome measures between DHB cohorts, with propensity scores being constructed using logit modelling incorporating relevant confounding variables and with a univariate association threshold of P<0.15. All tests were two-tailed, and P<0.05 was considered statistically significant.

## Results

There were 274 patients (150 men; mean±age 68.5±14.9 years, median (IQR) baseline NIHSS score of 16 (11–20)) included in the analysis (Table 1). Thirty patients (10.9%) were transferred from Taranaki Base Hospital (TBH) to ACH by helicopter. Two hundred and forty-four patients (89.1%) were transferred from Waitematā and Counties Manukau DHBs by road. Patients from Taranaki were older (74.1 years vs 67.8 years, P=0.03), had lower rates of smoking (10.0% vs 35.7%, P=0.004) and were less ethnically diverse, with a higher proportion of Europeans (86.7% vs 60.7%, P=0.005) and no Pacific or Asian patients. No baseline differences were observed for sex, baseline NIHSS score, ASPECTS or these co-morbidities: atrial fibrillation, congestive heart failure, diabetes, dyslipidaemia, hypertension, ischaemic heart disease and previous stroke.

Door-to-CT time was shorter for Taranaki than Waitematā or Counties Manukau (15 minutes vs 21 minutes, P=0.001). There was no difference in IVT treatment rates, door-to-needle times or successful recanalisation rates between Taranaki and the two metropolitan DHBs. Transfers from Taranaki had longer door-to-arrival (at ACH) times (190 minutes vs 120 minutes, P<0.001) and door-to-groin-puncture times (217 minutes vs 140 minutes, P<0.001), compared to transfers from the two metropolitan centres. Propensity-score-adjusted logistic regression odds ratios of outcomes are highlighted in Table 2. There were no differences in outcome measures.

## Discussion

This study has shown that, despite experiencing a 70-minute delay in the time from LKN to arrival at the SCR centre, patients transferred by helicopter from a regional centre do as well as those transferred by ambulance from metropolitan centres. Our study confirms that this highly effective intervention can be accessed by those in regional areas, provided that appropriate systems and processes are in place. The HERMES metanalysis of SCR trials shows a declining benefit from intervention, with increasing time from onset of stroke. However, the majority of Taranaki patients were still treated within the recommended time window of six hours from onset of symptoms.

The hyperacute stroke system at Taranaki results in seamless patient transfer between pre-hospital, hospital and transfer teams. Patients remain on the stroke reperfusion pathway until there is a clear contraindication. Patients suspected of having or identified with an LVO are prepared for transport and transferred to the helicopter prior to acceptance by the SCR centre, which has also been proposed by Ng et al. Mobile-phone technology is used to communicate with the helicopter/transfer team who are based on the hospital site.

There continues to be room to further optimise patient workflow. The median door-to-SCR-centre time for Taranaki patients was three hours and 10 minutes, with the shortest time of two hours and 10 minutes. Work from Ng et al shows the longest component of CT-to-groin time was CT-to-retrieval request and includes a breakdown of tasks:

- Imaging acquisition, reconstruction and interpretation
- Acute treatment decision-making
- Imaging transfer to SCR centre
- SCR centre referral
- Transfer retrieval requests

These tasks should be performed in parallel and not sequentially. Optimised inter-hospital image transfer, use of artificial intelligence in LVO detection and communication tools between teams and simulation...
Table 1: Baseline, transfer, procedural and outcome parameters.

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<tr>
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<th>All patients (n=274)</th>
<th>Taranaki DHB (n=30)</th>
<th>Waitematā and Counties Manukau DHBs (n=244)</th>
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<td>IV thrombolysis, n (%)</td>
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<td>55 (40–65)</td>
<td>64 (43–86)</td>
<td>0.13</td>
</tr>
<tr>
<td>Door to SCR centre, mins, median (IQR)</td>
<td>125 (102–155)</td>
<td>190 (162–238)</td>
<td>120 (100–144)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LKN to puncture, mins, median (IQR)</td>
<td>225 (190–285)</td>
<td>314 (265–353)</td>
<td>215 (190–270)</td>
<td>0.007</td>
</tr>
<tr>
<td>Door to puncture, mins, median (IQR)</td>
<td>145 (122–176)</td>
<td>217 (179–276)</td>
<td>140 (120–170)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>mTICI 2b-3 recanalisation, n (%)</td>
<td>239 (87.9%)</td>
<td>28 (93.3%)</td>
<td>211 (87.2%)</td>
<td>0.39</td>
</tr>
<tr>
<td>Outcome measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sICH</td>
<td>6 (2.2%)</td>
<td>0 (0.0%)</td>
<td>6 (2.5%)</td>
<td>1.00</td>
</tr>
<tr>
<td>24-hour early neurological recovery</td>
<td>136 (49.6%)</td>
<td>15 (50.0%)</td>
<td>121 (49.6%)</td>
<td>1.00</td>
</tr>
<tr>
<td>7-day mortality</td>
<td>20 (7.3%)</td>
<td>2 (6.7%)</td>
<td>18 (7.4%)</td>
<td>0.62</td>
</tr>
<tr>
<td>3-month mRS, median (IQR)</td>
<td>2 (1–4)</td>
<td>2 (1–3)</td>
<td>2 (1–4)</td>
<td>0.59</td>
</tr>
<tr>
<td>3-month functional independence, n (%)</td>
<td>149 (54.4%)</td>
<td>15 (50.0%)</td>
<td>134 (54.9%)</td>
<td>0.70</td>
</tr>
<tr>
<td>3-month mortality, n (%)</td>
<td>37 (13.5%)</td>
<td>3 (10.0%)</td>
<td>34 (13.9%)</td>
<td>0.78</td>
</tr>
</tbody>
</table>

Abbreviations: ASPECTS = Alberta Stroke Program Early CT Score; DHB = district health board; IV = intravenous; LKN = last known normal; mRS = modified Rankin Scale score; mTICI = modified Thrombolysis in Cerebral Infarction; NIHSS = National Institutes of Health Stroke Scale; sICH = symptomatic intracranial haemorrhage.

Variables are displayed as absolute number (percentage of column total), mean ± SD, or median (IQR) as appropriate.
training are other areas where workflow can be optimised. Door-to-SCR-centre times should be monitored and considered as an important performance metric by stroke networks.

The main strength of this study is that it has been implemented in a regional hospital with real-world resources and acute stroke care managed by general hospital personnel with specialist stroke support. Also, the complete datasets drawn from nationwide registry data strengthen this study. A number of methodological limitations need to be considered when interpreting the findings of this study. The observational nature precludes the inference of causality. It is possible that unmeasured and residual confounding might have contributed to the results. The small number of patients from a single regional centre limits the generalisability of the findings. Outcome assessors collected the three-month mRS scores as part of the ongoing collection of national SCR registry data for the Ministry of Health, and therefore they were not blinded to treatment. We recommend further analysing all regional transfers. Other outcome proxies, such as hospital length of stay and discharge destination, were not available but should also be considered as key performance indicators.

The Ministry of Health initiated the New Zealand Strategy for Endovascular Clot Retrieval with the goal of achieving geographic and ethnic equity. Successful implementation will require sufficient resources and optimisation of patient care processes to achieve optimal outcomes. Integrated inter-sector and inter-regional systems of stroke care are necessary.

Conclusion

This study has shown that overcoming the post-code lottery for hyperacute stroke care can be achieved in a New Zealand setting. With appropriate hyperacute systems and processes, stroke patients with an LVO from a regional centre can achieve the same outcomes as metropolitan patients.

Table 2: Propensity-score-adjusted logistic regression odds ratios of outcome measures by district health board (DHB).

<table>
<thead>
<tr>
<th>Taranaki DHB versus Waitematā and Counties Manukau DHBs</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-hour early neurological recovery⁴</td>
<td>0.95 (0.44–2.03)</td>
<td>0.88</td>
</tr>
<tr>
<td>7-day mortality⁵</td>
<td>0.92 (0.19–4.35)</td>
<td>0.90</td>
</tr>
<tr>
<td>3-month mRS⁶</td>
<td>1.02 (0.53–1.96)</td>
<td>0.95</td>
</tr>
<tr>
<td>3-month functional independence⁷</td>
<td>0.98 (0.43–2.27)</td>
<td>0.98</td>
</tr>
<tr>
<td>3-month mortality⁸</td>
<td>0.94 (0.26–3.41)</td>
<td>0.93</td>
</tr>
</tbody>
</table>

Abbreviations: ASPECTS = Alberta Stroke Program Early CT Score; CI = confidence interval; DHB = District Health Board; IV = intravenous; LKN = last known normal; mRS = modified Rankin Score; NIHSS = National Institutes of Health Stroke Scale; OR = odds ratio.

Propensity-score adjusted logistic regression odds ratios and P values are presented. Confounding variables incorporated in propensity score construction using logit modelling, with P <0.15 univariate association threshold:

1 Hypertension, baseline NIHSS, baseline ASPECTS, IV thrombolysis, mTICI 2b–3 recanalisation.

2 Age, previous stroke, baseline NIHSS, mTICI 2b–3 recanalisation.

3 Age, hypertension, coronary artery disease, previous stroke, baseline NIHSS, baseline APSECTS, occlusion site, IV thrombolysis, mTICI 2b–3 recanalisation.

4 Age, hypertension, coronary artery disease, previous stroke, baseline NIHSS, baseline APSECTS, occlusion site, IV thrombolysis, mTICI 2b–3 recanalisation.

5 Age, male sex, previous stroke, baseline NIHSS, mTICI 2b–3 recanalisation.
Competing interests:
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REFERENCES
Clinical anatomy through gamification: a learning journey

Vivek Perumal, Sambit Dash, Snigdha Mishra, Nawaporn Techataweewan

**ABSTRACT**

**BACKGROUND:** Gamification has been shown to increase students’ participation and has been widely used in medical education in the recent years. However, there are no dedicated games to deliver complete clinical-anatomy content at an undergraduate level.

**AIM:** This study describes the developmental process of a series of anatomy games for medical students and analyses student participation and experiences around the gamification process.

**METHODS:** Three diverse anatomy games were developed on the undergraduate medical curriculum. Based on students’ playing and simultaneous learning experiences in each game, subsequent game contents were constructively modified. Students from three different universities participated in the study (total cohort=646); their experiences on the different games were documented and compared with each other.

**RESULTS:** Feedback from 219 players showed that the games were fun (95%) and interesting (81%) and assisted their anatomy learning (97%); students’ fun, interest and learning improved significantly in the two subsequent games (p<0.001).

**CONCLUSION:** Carefully designed anatomy games create a fun-filled and interesting learning environment for undergraduate medical students. Learning experiences improved when students’ feedback was appropriately addressed to constructively modify the subsequent learning resources.

Anatomy is a visually demanding discipline, and it is often difficult to appreciate abstract concepts using traditional pedagogical teaching methods.\(^1,^2\) This limitation is compensated for using multimedia resources, like animations, three-dimensional models and smartphone applications, where the learner can visualise complex anatomical structures in an easy-to-understand animated or three-dimensional environment.\(^3,^4,^5\) Although these multimedia resources are undoubtedly informative, their efficiency is limited by a varying degree of user interactivity and they are often monotonous. To overcome these issues of interactivity, the concept of gamification is often applied in the educational setting. The Merriam-Webster dictionary defines “gamification” as the process of adding games or game-like elements to an activity to encourage participation. Gamification has emerged as a potential alternative pedagogy,\(^6,^7\) as it taps into people’s natural desires for competition and achievement. It is well known that games help learning by creating memories and experience,\(^8\) and the use of educational games could improve student interaction and engagement.\(^8\) Educational games, ranging from minor interactive activities within the classroom setting to games involving computer simulations, are increasingly used in healthcare settings to educate physicians, nurses and patients.\(^9,^{10,11}\) The results of these games have been encouraging, showing active user participation and increased learning outcomes in a stress-free learning environment. However, the concept of gamification in medical education is still evolving, and there is a dearth of interactive educational games to supplement clinical anatomy learning within undergraduate-level medical curricula.

To explore the potential effect of gamification in anatomy education, we attempted to develop a complete set of educational games to play-learn human anatomy for the undergraduate medical students. Following
feedback from an anatomy board game built in house for this purpose, we developed two web-based games on clinical anatomy: one on the clinical neuroanatomy, and the other on the integrated basic sciences of the digestive system. This study describes the development process and the outcome of student learning experiences from those three games.

The objectives of the study are (i) to use an iterative design process to guide development of a series of innovative teaching resources for undergraduate medical students and (ii) to explore student experiences (engagement and learning) around clinical anatomy gamification. Our findings from this study will add to the body of literature on gamification in medical curricula and inform future gamification efforts in clinical anatomy education.

**Methods**

Undergraduate medical students from three universities (University of Otago, New Zealand (n=300); Manipal University, India (n=72); Khon Kaen University, Thailand (n=274)) were invited to participate in this study. All three universities teach human anatomy following traditional methods that include didactic lectures, cadaver dissections or prosections; gamification is not a regular mode of anatomy-education delivery at any of the three universities. Institutional approval was obtained for the study from all universities; the project was partly funded by the University of Otago's Committee for the Advancement of Learning and Teaching grant and the Otago School of Biomedical Sciences Medical Education Research Grant.

We experimented with a sequential trial-and-error method and design thinking\(^{12,13}\) to develop the resources; the process involved developing a prototype of the resource, and constructively applied user feedback to modify the game several times. We first built an anatomy board game, and, based on the students' feedback, we then developed a web-based computer game; after analysing the students' experiences and feedback of the first computer game, we deployed a second online game. This progressive experimental learning rectified the technical and pedagogical issues we faced in the previous game versions.

Three steps of the Galvis-Panqueva methodology\(^4\) (analysis and design; development, distribution, data collection and evaluation) were employed while creating the anatomy game project.

**Analysis and design:** Following initial discussions with students and colleagues from the participating universities, two threshold topics (neuroanatomy and the digestive system) were identified as content for game development. During the design process, a detailed story plot was written, along with a list of individual tasks for the player, the anatomy topics to be covered and the clinical concepts to be learnt with them. The authors kept the games clinically oriented, and the subject content for each game was restricted to the learning objectives of undergraduate medical curriculum in the three universities.

**Development:** An anatomy board game was initially developed on the ventricular system of the brain and was distributed by the authors from Manipal university to their students. Student feedback on the game's plot and content, the player's experience and their perception of learning anatomy via a computer game were obtained. Results from the anatomy board game were evaluated to plan and modify the development of the subsequent online computer games.

To address the communication gap between the medical (authors) and computer (game developers) professionals, a prototype animation for the online neuroanatomy game was developed by the primary author (VP) using CourseLab 2.4 software (Websoft, Moscow, Russia). This prototype, a complete list of instructions and preliminary sketches were provided to the professional game developers (Callystro, India), who only had novice knowledge on human anatomy. The development of the entire game process was supervised, and the draft versions were periodically corrected and updated by all the authors.

**Distribution, collection of user-usage analytics and evaluation:** The online games were hosted on the developer's computer server and a link to the games was shared to the students from all three universities. All students were encouraged to play the online game; however, their participation was voluntary. At the end of the academic
year, user-usage data were obtained from the server for analysis. From the feedback questionnaire at the end of the game, the students' playing experience and interest in the anatomy games, their willingness to repeat the games and their suggestions to improve development of more anatomy games were also obtained.

Five major elements of gamification in education suggested by McNulty[15] were incorporated appropriately into the game:

1. Perseverance: The anatomy games were designed such that the player does not get locked at any point within the game; after three repeated failures, the correct answer for the task is given and the player is allowed to continue.

2. Game mechanics: The interface was carefully developed to deliver anatomy content in a fun and interactive way.

3. User engagement: Incentives, cues and fun elements were used in all levels of the games.

4. Modifying content: To ensure repeatability and hold attention, multiple quiz formats and scene transitions were used.

5. Storyboarding: The player can track their path and progress within the game in real time.

Plot overview of the computer games

Plot of the online neuroanatomy game:
The background of the story is of a medical student suffering from a pre-exam encephalopathy; learning excessive anatomy content made his brain swell, blocking the circulation of cerebrospinal fluid and causing a hydrocephalus. The doctors decide to perform a burr hole craniotomy on the suffering student's head and to send in a miniature player to clear the ventricular spaces and revive the affected student from the serious consequences of encephalopathy. The player explores the clinical anatomy of the brain as a series of challenges and tasks, with hints and descriptions as pop-up dialog boxes (Figure 1). In addition to the serious learning tasks, “fun” elements were also included in the game: for example, a hippopotamus is seen in place of the hippocampus of the brain in the temporal lobe (Figure 2). “Visual mnemonics,” whereby the anatomical structures were presented as other familiar objects, were also used to help students remember concepts: for example, the similarity of the cross-section of midbrain to a teddy bear was depicted (Figure 3). The game ends when the patient's hydrocephalus subsides; the player is “tapped out” through a lumbar puncture and receives a certificate.

Plot of the online digestive system game:
In their feedback from the online neuroanatomy game, students requested more interactive tasks and practice questions to revise clinical anatomy knowledge. These suggestions were incorporated into the second online game, the digestive system game, which as a result was longer than the first. To keep the playing time shorter and to maintain student engagement with the resource, the digestive system game was developed in two parts: from oral cavity to the end of pharynx, and then the tubular digestive tract.

Part one of the game starts with the miniature player trying to reach and explore a patient's oral cavity by building a ladder of crossword puzzles. The player then anaesthetises the oropharynx by “cutting” the appropriate nerves, deactivating the gag reflex, and making way into the throat. In the later scenes, the player explores the piriform fossa and identifies some chicken/fish bones and hidden diamonds. Relevance of internal laryngeal nerve injury and the traditional “smuggler's pouch” is learnt there, thereby completing part one of the game.

In part two, the player explores the tubular gut. After squeezing through the four constrictions of the oesophagus to reach the stomach, the player slides down along the rugae to take a boat to escape the acidic gastric juice (Figure 4a). Later, the player travels through the small intestine, identifies the duodenal papillae and circular folds (Figure 4b), explores the ileocecal junction opening to reach the large intestine and finally examines the appendix opening for any blockage. After successfully clearing all the tasks, the player is expelled out of the gut with a certificate of appreciation.
**Figure 1:** Interactive clinical scenarios and tasks used in the online neuroanatomy game: drilling a burr hole and inserting a neuroendoscope into the brain (a, b). The taskbar shows the rewards, lifelines, timer and the navigation map (red circles).

**Figure 2:** Example of fun elements used in the online neuroanatomy game to improve player attention: a hippopotamus placed in place of the hippocampus in the inferior horn of the lateral ventricle.
Figure 3: A labelling task where the cross-section of the midbrain (a) is visualised as the face of a teddy bear (b); these tasks are used as visual mnemonics to improve student learning and memory.
Figure 4: Clinical correlations used within the online digestive system game. (a) The player explores the colonies of *Helicobacter pylori* on the gastric mucosa while safely crossing the gastric juice. (b) Real-time navigation of the player’s journey within the gut.
Results

The anatomy board game was run in a classroom setting, so the results were evaluated soon after the players completed the game. The online games were made available throughout the academic year, and the data were collected at the end of the year. User-usage data, including student demography, completion status, time taken to complete the game and formative scores, were obtained for each anatomy game. However, only qualitative user data related to student experiences were compared between games and between players from the three universities. Comparisons were performed by the Pearson’s chi-squared test using STATA software version 10.1 (Stata Corp, Texas, USA).

Feedback from the anatomy board game

The anatomy board game was played by students from Manipal (n=72). As the game was run as a classroom activity, all students participated and placed their feedback on the game experience. The game was found to be fun (57/72, 79%) and interesting (54/72, 75%) by more than three quarters of the participants, and 72% (52/72) reported that the game helped their learning. Also, 85% of the participants (61/72) expressed their interest of playing a professional computer game if it were developed. In the open-ended feedback on their experiences, students reported that the game was an “interesting educational concept” that made anatomy learning “livelier” and more interesting, and that they felt “motivated” to study neuroanatomy. On the other hand, the students also pointed out that some illustrations on the board game were “not clear” and preferred a three-dimensional game that would give them a “better picture” of the anatomy of the brain. Some expressed that the storyline could have been better; they preferred immediate feedback on the quizzes they answered.

The online neuroanatomy game

Students from Manipal (59/72) and Otago (169/300) played the online neuroanatomy game. Forty-three percent of students (92/228) completed the game in an average of 25 minutes and provided feedback. The rest of the students left the game incomplete at various stages; however, 85% of the players completed at least level 6 (of 10 levels) in the game. Student feedback showed that the game was fun (94.4%) and interesting (80.9%). Playing the game helped them revise their neuroanatomy (95.5%), and they reported a willingness to try more anatomy games (91.1%).

All students (100%) from Manipal reported that the neuroanatomy game was fun and interesting, whereas only 79% and 75% reported that the anatomy board game was fun and interesting. Similarly, the students’ learning experience was 72% for the anatomy board game and 92% for the neuroanatomy game; this improvement in students’ experiences was statistically significant (p<0.001) (Figure 5).

Figure 5: Comparison of player experiences between the three different types of games studied. Blue: anatomy board game. Red: online neuroanatomy game. Grey: online digestive system game.
The students appreciated the storyline, content, visuals and animations of the online neuroanatomy game in comparison to the anatomy board game; the major concern was that the online game was slow paced and the transition time between scenes was long. The students also requested more tasks to perform within the game and more quiz questions in order to revise the anatomy content more effectively.

**The online digestive system game**

Students from all three universities (total=382; Manipal=51; Otago=126; Khon Kaen=205) played the online digestive system game. The average time taken to complete the game was 25 minutes. Two hundred and nineteen of these 382 players (57.3%) completed the game and placed feedback (Manipal=24; Otago=73; Khon Kaen=122). Of these, 95% (208/219) and 80.8% (177/219) respectively found the game fun and interesting, and 96.8% (212/219) reported that the game improved their digestive system anatomy learning.

Comparing the findings from the online digestive system game with the online neuroanatomy game showed that both these online games were equally fun and interesting. However, the percentage of students who felt that the learning process was improved by the online digestive system game (96.8%) was higher than for the online neuroanatomy game (95.5%); this difference was statistically significant (p<0.001) (Figure 5).

**Discussion**

The concept of an anatomy game was broadly welcomed by the undergraduate medical students from three diverse geographical locations – New Zealand, India and Thailand. The gaming experience was described as “fun” and “interesting” for the board game and both online computer games; however, these aesthetic criteria were rated higher for the computer games. The students also reported that all the games helped them revise their anatomy knowledge in the respective study areas.

**The sequential trial-and-error design concept**

To our knowledge, this is the first study on gamification in medical education to sequentially create learning resources, constructively modify and recreate new resources based on students’ feedback. At every stage of game development and distribution, feedback from the previous stages was carefully considered. For example, the anatomy board game was run in small groups, under faculty supervision, and had a time limit to complete. Copies of hand-drawn illustrations were used in the game scenes. The quizzes were evaluated after the session, and the results for the game were provided the next day; all these aspects were described as limitations in students’ feedback, and these issues were all rectified when the first online game (neuroanatomy) was developed: players were given the choice to play independently without supervision, and there was no time limit to answer each quiz. Feedback on the online quizzes was immediate and accompanied by learning tips, and thereby a holistic learning experience was provided. Computer-generated graphical illustrations and animations were used to better depict the anatomical structures.

Despite these changes, there was negative feedback on the length and features of the online neuroanatomy game: it was long, slow and contained fewer tasks and challenges, a factor that we consider a major hindrance for user engagement. While developing the second online computer game (digestive system), these previous issues were addressed. The pace of the game was quickened by shorter transitions between scenes, and the game was distributed as two parts, so each was short. More interactive tasks were included, and more questions were generated for the quizzes; multiple question types, such as crossword puzzles, were also used to encourage interactivity and repeatability.

**Meeting student participation and engagement**

A major part of this study was to develop a series of interactive anatomy games. Following the self-determination theory to increase students’ participation, our online games consisted of several cues to promote an interactive and fun-filled learning environment: players had to collect coins; fun elements (eg, a hippopotamus and teddy bear) were used to relate the neuroanatomical structures; and gastric juice had to be escaped by sailing a boat. Extensive use of clinical facts,
Novelty in the game design process

In addition to the iterative design process, we collected students' demographic data in the game. The players could fill in the details as they sign up for a specific task within the game. Also, student feedback on the game content, and their playing and learning experiences, was integrated within the game tasks. These are novel attempts not described in earlier gamification literature. Students liked this idea of integration; we believe this also took students less time than filling in forms at the beginning and end of the game. This also gave us an opportunity to gain students' opinions at the relevant tasks in situ, rather than at the end.

Potential barriers in development of anatomy games

Two major obstacles often faced in educational technology are cost and translating the medical concepts to the technical team. Although graphic designers are professionals and intimately familiar with designing software, their knowledge in human anatomy is often novice, unless they are primarily involved in medical-education projects. This knowledge gap not only affects the communication between educators and developers. It also increases the cost of the project by prolonging development time. One possible solution for this issue includes involving the students in development of the game content (if they already have a computer proficiency), so that they also learn anatomy during the constructional process; but this is usually difficult with the medical student cohort. Or, as several anatomy board games are already in use, existing games could be adapted, with permission, to reduce the cost of development. In this study, we directly involved the authors in game development; creating a simple animated prototype using open-source software not only reduced the cost of development, but also eased communication with the technical team.

Lessons learnt from the game project

In addition to the already defined elements of gamification, we found the following factors to be beneficial while developing and implementing an educational game: The content needs to be clearly
focused on the students' learning objectives. Interactivity is the key; in addition to integrated basic sciences and relevant clinical facts, fun and creativity within the game can promote student engagement. Involving the student cohort in identification of the threshold topics for content development can improve student participation. Keeping the games short and fast paced, and randomly generating each quiz from a bigger collection of questions, can improve student participation, engagement and the repeatability of activities. Direct involvement of staff in content development, like creating some form of game prototype, could not only reduce the project cost but also decrease the communication gap between the medical and computer professionals.

Limitations
The major limitation is that the game could not meet the criteria for all types of players traditionally defined. Unlike other studies, we did not categorise the students into a control group and a testing group, since we wanted the entire cohort to benefit from these resources. From a pedagogical view, the number of participants that contributed to the study was relatively low, and it was not the same individuals that played the three different games. Although we had a formative score within the game to test each player's learning, it was not compared with any other academic performance. Moreover, these games were not compatible with mobile phones, tablets or e-readers, which is possibly another factor why not all students were able to play them.

Conclusion
This study showcases the pedagogical and technical factors to be considered during the development of educational games. To our knowledge, this is the first study to develop and test computer games for undergraduate medical students to play-learn the clinical anatomy of different body systems. Carefully designed educational games that are constructively modified based on student feedback effectively improve student participation, engagement and learning experience.
Competing interests:
Nil.

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Knowledge and management of sport-related concussion in primary care in New Zealand

Caroline Stuart, Duncan Reid, Alice Theadom, Mark Fulcher, Natalie Hardaker

ABSTRACT
AIM: To assess the current state of knowledge around sport-related concussion (SRC) guidelines and management among primary care doctors in New Zealand.

METHODS: An online, self-administered, 21-item multi-choice questionnaire targeted at general practitioners and urgent care doctors in New Zealand was used. Main outcome measures were knowledge and management of patients with SRC through to return-to-sport.

RESULTS: There were 230 total valid responses. Over half had no knowledge of the Consensus Statement on Concussion in Sport, and only 43% used the Sport Concussion Assessment Tool (SCAT) routinely. Fifty-eight percent would prefer to have a screening tool integrated into their patient management software. Most reported using appropriate management strategies for patients with concussion and recognised the potential benefit of relative cognitive and physical rest. There was low utilisation of referral pathways to allied health practitioners and specialist concussion services. Half (53%) felt confident in managing a patient with SRC and 46% felt comfortable managing return-to-sport.

CONCLUSION: Primary care doctors have good knowledge of SRC but are not as confident managing return-to-sport. Further education opportunities were identified. Development of concussion tools adapted for use in primary care, integrated with patient management software and that support pathways to optimise patient recovery are recommended.

Sport-related concussion (SRC) is a form of mild traumatic brain injury (mTBI) induced by biomechanical forces that can lead to prolonged cognitive, emotional and physical effects.\(^1\,2\) SRC is a significant problem in New Zealand.\(^2\) In 2019, there were 6,217 claims to the Accident Compensation Corporation (ACC, New Zealand’s no-fault accident compensation programme) for SRC, at a cost of NZ$22.5 million.\(^3\) Rugby union, football and cycling were the sports with the greatest number of SRC claims.\(^2,3\) SRC claims have increased steadily across the last decade, up 90% from 2010 to 2019.\(^1\)

The assessment and management of SRC is an evolving field. Recommendations have changed following each of the five Concussion in Sport Group (CISG) International Consensus Conferences.\(^4\) The latest of these guidelines were released in 2017 and cover care of SRC from side-line assessment through to clinical evaluation and steps for recovery.\(^1\) In conjunction with the guidelines, the Sport Concussion Assessment Tool (SCAT) 5th Edition was also published.\(^5\) This tool was designed to be used by medical professionals and includes screening assessments for the cognitive and physiological effects of concussion and a symptom report scale. The SCAT is included in the 2016 ACC guidelines on the management of SRC.\(^6\) The ACC guidelines’ key message to players, coaches and umpires/referees is: “Recognise, Remove and Refer.” The ACC guidelines also recommend that players report to a medical doctor for definitive diagnosis and care.\(^6\) Concussion is a medical diagnosis requiring clinical judgement and consideration of multiple non-specific history and examination features.\(^1,4,6\) Doctors working in primary care must therefore have an understanding of SRC assessment, management and guidelines for return-to-sport, in order to appropriately treat these patients.
A survey of 93 general practitioners (GPs) and emergency doctors (EDs) conducted in Canada identified that GPs and trauma clinicians had limited awareness of consensus statements on SRC and rarely referred to guidelines. In that study, there was very poor usage of the SCAT, with 86% of EDs and 54% of GPs reporting having never used the tool. It is unclear whether this reflected a lack of awareness or lack of utility of the tool outside of the sports-medicine context for which it was originally designed.

Although international studies have explored GPs’ and other primary care and specialist doctors’ knowledge and understanding of SRC, no such studies have been undertaken in a New Zealand medical population. Therefore, the purpose of this study was to assess the current state of knowledge and use of SRC guidelines and management among primary care doctors in New Zealand.

Methods

We used an anonymous, online, 21-item multi-choice questionnaire based on a validated questionnaire used in previous studies. Prior to its distribution, the survey was piloted and reviewed by nine sport and exercise physicians to ensure completeness and readability. The questionnaire included questions about the participant’s place of work, the number of SRC they see in clinical practice, where they obtained information on SRC, the tools they used to diagnose SRC and their knowledge, attitudes and behaviour towards SRC. The response to each question was predominantly captured on a 5-part Likert scale, and where appropriate there was the option for free-text comments. Anonymous demographic information included details about vocational training, postgraduate sports medicine qualifications completed, years since graduation and geographical location.

All doctors working as GPs or urgent care physicians (UCPs) were eligible to participate. An invitation to participate in the online survey (SurveyMonkey Inc., San Mateo California, USA, http://www.surveymonkey.com) was included in the newsletters of the Royal New Zealand College of Urgent Care (RNZCUC) and the primary care continuing medical education (CME) organisation the Goodfellow Unit. Also, in order to gain the largest possible sample, the survey and an open invitation to disseminate were promoted via Facebook on the RNZCUC page and New Zealand medical practitioners’ group pages. In addition, members of the research team attended the Goodfellow Symposium and webinars in 2018 and invited GPs and UCPs to participate. Questionnaire responses were collected from October to December 2017 and from March to May 2018.

Ethical approval was provided by Auckland University of Technology Ethics Committee (AUTEC Reference #16/187). The ACC Research Ethics Committee also approved the study. A survey was considered valid and included for analysis when respondents completed at least 80% of questions. Responses were summarised using frequencies and percentages; descriptive statistics were used to analyse the data. Comments in the free-text fields were categorised using conventional content analysis to assist in the interpretation of the quantitative results.

Results

All data were extracted into SPSS (IBM SPSS, Chicago, version 25). A total of 183 potential participants read the Goodfellow Unit invitation, and 402 doctors on the RNZCUC mailing list were emailed and invited to attend; the total number of invites was 585. There were 145 responses, yielding an initial response rate of 25%. A further 61 completed the survey during the Goodfellow Symposium, and further promotion resulted in 230 total valid responses. We could not calculate the total number of invites, because of the use of social media, the encouragement to freely disperse the link to the study through professional contact lists and the invitation to participate during the Goodfellow Symposium, and so it was not possible to measure our final response rate.

The characteristics of the sample are outlined in Figure 1 and Table 1. The majority of participants were GPs (59%) or GP registrars (14%). Eighteen percent were UCPs or trainees, who were based across all regions of New Zealand (Table 1). The majority (77%) reported working in an urban practice. There were 52 doctors (23%) who reported working for a rural practice. Participants had been practicing clinically for an average of 21 years since graduation,
**Figure 1:** Distribution of responses by geographic area.

**Table 1:** Types of physicians surveyed (n=230).

<table>
<thead>
<tr>
<th>Type of physician</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioner (GP)</td>
<td>136 (59)</td>
</tr>
<tr>
<td>GP registrar</td>
<td>32 (14)</td>
</tr>
<tr>
<td>Urgent care physician (Fellow)</td>
<td>26 (11)</td>
</tr>
<tr>
<td>Urgent care trainee (registrar)</td>
<td>17 (7)</td>
</tr>
<tr>
<td>Emergency physician (Fellow or registrar)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (7)</td>
</tr>
</tbody>
</table>

**Estimated number of SRC patients seen in past two years**

<table>
<thead>
<tr>
<th>Estimated number of SRC patients</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>7 (3)</td>
</tr>
<tr>
<td>1–2</td>
<td>29 (13)</td>
</tr>
<tr>
<td>3–5</td>
<td>55 (24)</td>
</tr>
<tr>
<td>6–9</td>
<td>39 (17)</td>
</tr>
<tr>
<td>10–20</td>
<td>52 (23)</td>
</tr>
<tr>
<td>More than 20</td>
<td>48 (21)</td>
</tr>
</tbody>
</table>
with a range of 1–46 years. A small number (n=26, 11%) had undertaken postgraduate study in sports medicine. Forty-four percent had assessed ten or more SRCs in the past two years, and 3% had not seen any patients with SRC the past two years.

Participants reported using a wide range of information sources on concussion as shown in Table 2. The information sources that were reported to be the most useful were those created by Best Practice Advisory Centre New Zealand (Bpac\textsuperscript{TM} Ltd) and GP conference/CME presentations, with 73% and 69% of participants finding them useful respectively.

All (100%) of the participants indicated that taking a history and conducting a physical exam was important when assessing for SRC. Only 41% had heard of the CISG Consensus Statement on Concussion in Sport. Although 83% had heard about the SCAT, only 43% of them found the tool was easy to use in a clinical setting. Of those familiar with the SCAT tool, 58% would prefer to have it integrated into their patient management software to facilitate its use. Less than half (43%) of all participants usually or always used the SCAT to assist with their assessment. Although we did not specifically ask about barriers to using the SCAT or other diagnostic tools, across the 25 free-text responses in this section of the survey, seven participants commented that time pressures and limitations in funding were barriers to concussion assessment and management, as the SCAT took longer to complete than the appointment time typically allocated. Few participants (3% for each) routinely used computer-based evaluations or diagnostic imaging when assessing for SRC.

Table 3 outlines responses related to the knowledge, attitudes and behaviours of the surveyed medical practitioners. All participants agreed that a player who has been concussed should not return to sport the day the concussion occurred. The majority of participants (82%) agreed that a concussed patient should not return to contact sport for three weeks and should follow a return-to-play protocol prior to returning to sport (94%). Most participants (89%) considered that a SRC could lead to long-term brain damage. Over 80% of those surveyed believed a player should seek assessment from a doctor on the day the injury occurred.

The most agreed upon strategies for management were cognitive and physical relative rest (activity at a level below that which provokes the patient's symptoms). Seventy-eight percent of participants always or usually recommended relative cognitive rest, and 82% of doctors recommended relative physical rest. Seventy eight percent always or usually recommended use of non-narcotic analgesia, and 35% always or usually recommended nonsteroidal anti-inflammatory drugs. Use of opioid analgesia was appropriately low, with 88% never or rarely using them for SRC. There was a low utilisation of referral pathways to allied health practitioners, with a third of participants (34%) never or rarely referring SRC patients to physiotherapy and only a third (34%) usually or always referring a patient for specialist support from a concussion service.

Free-text responses indicated a range of barriers to concussion specialist services, including declined referrals, access issues for rural practices and a lack of knowledge of the ACC concussion service. The majority of participants (66%) recommend that patients get reviewed within 7–10 days of the initial visit. Just under half (49%) stated that they would provide this follow-up, with 46% reporting they refer them back to the patient's usual GP.

Just over half of participants (53%) felt confident in managing a patient with SRC. There was notable variance in participants' confidence in advising on return-to-sport, with only 46% agreeing that they feel confident in advising patients on how to do this. We used Spearman's correlation coefficients to explore whether there were any significant associations between physician type, years since graduation, practice type and number of concussions seen with level of confidence in managing SRCs; there was no significant association between physician type, years since graduation or type of practice (urban vs rural) and confidence in managing SRC at the p<0.05 level. However, participants who saw patients presenting with concussion more frequently had significantly higher confidence in managing these injuries (r=0.26, p<0.001).
Table 2: Usefulness of information sources from the past two years.

<table>
<thead>
<tr>
<th>Information source frequency (%)</th>
<th>Very useful</th>
<th>Fairly useful</th>
<th>Not very useful</th>
<th>Not at all useful</th>
<th>Not applicable (never or rarely used)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP journal articles</td>
<td>15 (7)</td>
<td>81 (35)</td>
<td>65 (28)</td>
<td>10 (4)</td>
<td>44 (19)</td>
</tr>
<tr>
<td>Emergency medicine journal articles</td>
<td>10 (4)</td>
<td>44 (19)</td>
<td>19 (8)</td>
<td>5 (2)</td>
<td>135 (59)</td>
</tr>
<tr>
<td>Sports medicine journal articles</td>
<td>14 (6)</td>
<td>32 (14)</td>
<td>15 (7)</td>
<td>7 (3)</td>
<td>144 (63)</td>
</tr>
<tr>
<td>Best Practice Advisory Centre New Zealand (Bpac® Ltd) articles/website</td>
<td>73 (32)</td>
<td>96 (42)</td>
<td>30 (13)</td>
<td>7 (3)</td>
<td>13 (6)</td>
</tr>
<tr>
<td>ACC SportSmart website contents</td>
<td>38 (17)</td>
<td>69 (30)</td>
<td>22 (10)</td>
<td>7 (3)</td>
<td>79 (34)</td>
</tr>
<tr>
<td>GP conference and CME presentations</td>
<td>72 (31)</td>
<td>87 (38)</td>
<td>23 (10)</td>
<td>6 (3)</td>
<td>32 (14)</td>
</tr>
<tr>
<td>Urgent care conference and CME presentations</td>
<td>29 (13)</td>
<td>27 (12)</td>
<td>9 (4)</td>
<td>6 (3)</td>
<td>139 (60)</td>
</tr>
<tr>
<td>Emergency medicine conference and CME presentations</td>
<td>12 (5)</td>
<td>19 (8)</td>
<td>13 (6)</td>
<td>7 (3)</td>
<td>163 (71)</td>
</tr>
<tr>
<td>Sports medicine conference and CME presentations</td>
<td>15 (7)</td>
<td>16 (7)</td>
<td>13 (6)</td>
<td>8 (4)</td>
<td>161 (70)</td>
</tr>
<tr>
<td>Consultants’ letters</td>
<td>22 (10)</td>
<td>66 (29)</td>
<td>36 (16)</td>
<td>29 (13)</td>
<td>59 (26)</td>
</tr>
<tr>
<td>Hospital rounds or CME</td>
<td>6 (3)</td>
<td>19 (8)</td>
<td>14 (6)</td>
<td>17 (7)</td>
<td>156 (68)</td>
</tr>
<tr>
<td>Mixed media (newspaper, websites, television shows or magazine articles)</td>
<td>4 (2)</td>
<td>50 (22)</td>
<td>54 (24)</td>
<td>31 (14)</td>
<td>70 (30)</td>
</tr>
</tbody>
</table>
Table 3. Knowledge, attitudes and behaviours around sport-related concussion.

<table>
<thead>
<tr>
<th>Knowledge, attitudes and behaviours around sport-related concussion frequency (%)</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>To sustain a concussion a patient must have a blow to the head</td>
<td>11 (5)</td>
<td>33 (16)</td>
<td>19 (9)</td>
<td>105 (49)</td>
<td>45 (21)</td>
</tr>
<tr>
<td>All concussion patients lose consciousness</td>
<td>3 (1)</td>
<td>2 (1)</td>
<td>3 (1)</td>
<td>84 (39)</td>
<td>122 (57)</td>
</tr>
<tr>
<td>Patients who are concussed should not play contact sport for three weeks</td>
<td>77 (36)</td>
<td>98 (46)</td>
<td>17 (8)</td>
<td>17 (8)</td>
<td>5 (2)</td>
</tr>
<tr>
<td>After three weeks a patient can return to normal sporting activities</td>
<td>15 (7)</td>
<td>86 (40)</td>
<td>45 (21)</td>
<td>50 (23)</td>
<td>18 (8)</td>
</tr>
<tr>
<td>SRCs may cause long-term damage to the brain</td>
<td>104 (49)</td>
<td>86 (40)</td>
<td>16 (8)</td>
<td>5 (2)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>A concussed patient may not have any symptoms or signs at the time of assessment</td>
<td>66 (31)</td>
<td>129 (60)</td>
<td>11 (5)</td>
<td>8 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>A player should seek an assessment from a doctor on the day of injury</td>
<td>62 (29)</td>
<td>112 (52)</td>
<td>26 (12)</td>
<td>14 (7)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>A player who has been concussed should not return to sport the day of injury</td>
<td>183 (86)</td>
<td>31 (15)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>A player who has been concussed should follow a gradual return to play protocol before returning to full participation</td>
<td>135 (63)</td>
<td>66 (31)</td>
<td>11 (5)</td>
<td>1 (.5)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Discussion

This study aimed to determine the current state of knowledge of existing SRC guidelines and the management of SRC among primary care doctors in New Zealand. We found that just over half of clinicians surveyed felt confident managing SRCs. However, a higher proportion did not feel confident advising on safely returning to sport. Our current ACC guidelines recommend that sportspeople affected by SRC should seek an assessment from a doctor. These findings highlight the need to address knowledge gaps and provide support to doctors in managing SRC and return-to-sport.

There was a lack of consistency regarding the ease of use of concussion assessment tools. Less than half of participants reported using the SCAT, which is endorsed by ACC guidelines and is currently the most widely used instrument for concussion assessment within the sports context. However, the SCAT does have limitations that might impact its use in primary care. For example, our study showed that time constraints were reported to be a barrier to using the SCAT. This is perhaps unsurprising given that, even for well-practised clinicians, this tool takes a minimum of 10 minutes to complete. The symptom checklist has been reported to demonstrate clinical utility in tracking recovery, although the utility of the remainder of the SCAT appears to decrease significantly 3–5 days after injury. Evidence also suggests that the symptom scale has been found to potentially reflect non-brain injury processes such as migraine. Poor uptake of the SCAT in primary care, as found in similar studies in Canada, suggests the need for the development of a validated concussion assessment tool that can assist in diagnosis, identify patients who would benefit from early referral to multidisciplinary care and be used to track recovery. Any new tool should be time-efficient and able to be completed within a typical primary care consultation. It is also worth noting that doctors will be assessing patients with potential concussion from both sports- and non-sports-related trauma, and any new or modified tool would ideally be applicable to all concussion regardless of environment.

The most recent CISG Consensus Statement on Concussion in Sport recommends an initial period of physical and cognitive rest immediately after sustaining an SRC and a graduated return-to-sport only once concussion symptoms have resolved. A brief period (24–48 hours) of cognitive and physical rest is appropriate for most patients. Following this period, patients should be encouraged to gradually increase non-sporting activity while staying below their cognitive and physical symptom exacerbation thresholds and avoiding activities that have an increased risk of re-injury. More research is needed to evaluate the optimal amount and type of rest after SRC. In the current study, most participants reported using appropriate management strategies for patients with concussion, such as non-narcotic analgesia. That a high number of respondents recommended relative cognitive and physical rest indicates an understanding of the shift towards relative rest rather than absolute rest.

Furthermore, this appears to suggest that these clinicians may have a better understanding of how to manage SRC than prior cohorts of doctors in international studies, where less than half of family physicians were found to be advising appropriate cognitive rest. This finding may also reflect the fact that the evidence advocating relative, rather than absolute, rest is reasonably new and therefore has become more established in clinical practice since the previous studies.

Studies have shown that the use of formal return-to-activity and return-to-school protocols can effectively change healthcare providers’ clinical practice and increase knowledge and confidence in treating concussion. Progression strategies for return-to-sport and return-to-school are available online and incorporated into the SCAT 5th Edition document. However, if less than half of those surveyed were using the tool regularly, and if a greater number were not aware of the CISG Consensus Statement on Concussion in Sport, those surveyed who were not familiar with the SCAT5 or CISG may not be aware of the corresponding rehabili-
tation, return-to-school and return-to-sport recommendations.

In recent years, as those in sport have become more aware of SRC, many New Zealand National Sports Organisations (NSOs) have introduced concussion policies. Aspects of these policies, such as mandatory stand-down periods after injury, differ across codes, which may have caused confusion for both clinicians and members of the public. This is a particular problem for young people who may play several different sports over the course of a week. The lack of consistency may influence clinicians’ confidence managing safe return-to-sport following SRC. It is suggested that NSOs consider developing a consistent return-to-sport message that can be delivered to all players. There does seem to be greater confidence in the recommendation that no player should return to sport on the day of the injury, where the advice is more definite and consistent.

Other knowledge gaps identified include the belief a patient must have a blow to the head to sustain a concussion (21% of respondents). Although concussion is caused by biomechanical forces, it may be caused by a direct blow to the head, the face or the neck, or elsewhere on the body if there is an impulsive force to the head.1 This is an important area for further education to ensure all concussions are recognised and to capture an accurate diagnosis in those patients that may not have sustained a direct blow to the head.

The CISG define persistent symptoms as those beyond 14 days in adults and four weeks in children. Most patients are expected to recover within this timeframe.1 However, this has been challenged by recent research.12 Other studies have illustrated that 30–55% of those who sustain an SRC experience persistent post-concussive symptoms beyond two weeks.12,14,17 Persistent symptoms can result in significant morbidity and impact for the affected individual and their whānau. It is increasingly recognised that there are a range of reasons for patients to experience persistent symptoms and that treatment should be individualised to the patient and their needs.1,20 Prolonged symptoms may be due to persisting physiological concussion, cervical, vestibular and ocular post-concussion defects, psychological variables or a combination of these factors.1,17 Recent research surveying physiotherapists in New Zealand indicated good levels of knowledge of SRC and that physiotherapists currently provide a wide range of primary care services for people with concussion that align with international recommendations.21,22 Physiotherapists have a strong desire to be more involved in side-line recognition and player removal, concussion assessment testing and return-to-sport integration.2 In addition to providing physiotherapy care for concurrent cervical injury and vestibular dysfunction, there may be other benefits of greater physiotherapist involvement in the care of these patients.20 Physiotherapists are more likely to be present during training and games, and they often have a close relationship with players and coaching staff;21 therefore physiotherapists provide a useful role in recognition of possible concussion and are a source for supplementary history of the concussive event.22 Following a doctor’s assessment and medical diagnosis, physiotherapists can then assist in supervising the agreed graduated return-to-sport protocol, monitoring a patient for persistent symptoms and providing a liaison between doctors and coaches. A collaborative approach, involving a range of different clinicians, is therefore most appropriate for SRC patients.1,16,20

Although relative rest and symptomatic treatments form the mainstay of initial management for SRC, recent research supports the use of sub-symptom threshold, sub-maximal exercise, for patients with persistent concussive symptoms.14,16,17,23 Controlled exercise performed at an intensity, and for a duration, that does not exacerbate symptoms is safe and beneficial for adult and adolescent patients with persistent symptoms following concussion.14,17,23 Makdissi et al’s review of the literature on the management of those with persistent concussion symptoms concluded that “cases of concussion in sport where clinical recovery falls outside the expected window (ie, 10 days) should be managed in a multidisciplinary manner by healthcare providers with experience in sports-related concussion.”20 In New Zealand, patients experiencing persistent symptoms can be referred to an ACC-ap-
proved multidisciplinary concussion service for ongoing management, including prescription of sub-threshold exercise for suitable patients. Given a New Zealand study of those presenting for treatment for SRC reported that only 45% of patients were clinically recovered by 14 days, it appears that a large number of patients may benefit from this type of service.\textsuperscript{12} The current study revealed that only one third of doctors usually or always referred their patients to multidisciplinary concussion services, and identified some perceived barriers to access, including a lack of doctor knowledge of the ACC service, barriers in the referral process and geographical barriers to access to concussion services outside large urban centres. Barriers such as these may reduce referral rates. Further research may help to identify areas for system improvement. We agree with Maxtone et al that early access to active rehabilitation services in acute concussion may be an effective use of health resources in New Zealand.\textsuperscript{22}

Finally, the current study also highlights the need to ensure information and guidelines on SRC reach those working in primary care. Our study indicates that primary care doctors do not utilise medical journals or ACC guidelines when looking for treatment recommendations. Provvidenza’s research on transferring knowledge from concussion consensus statements to improve patient care indicates that, although printed education materials are valuable for reinforcing knowledge transfer, they are an ineffective standalone method for improving physician performance.\textsuperscript{24,25} GP CME conferences and Bpac\textsuperscript{26} publications were identified by our participants as the most helpful resources. Interactive education sessions or webinars, supplemented by print or online written material, may therefore provide an effective education strategy.\textsuperscript{24} The integration of treatment pathways and guidelines into patient management software and health pathways may also support primary care clinicians in best practice management of concussion.

This study is the first to look at care of SRC in the New Zealand primary care context. It does have a number of limitations. Multiple methods of distribution were chosen to increase the number of participants and reduce barriers to participating in the study; however, as a result it is difficult to calculate our response rate. Primary care is also a heterogeneous workforce and inevitably there are areas of this workforce who are not represented in these results. Additionally, as the study only explored sport-related concussion, these findings may not be representative to non-sport-related injury. Finally, there is the potential for recall bias in any survey, and there is a risk of selection bias, as it is likely that those clinicians with an interest in sport and SRC were more likely to participate.
Competing interests:
Nil.

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REFERENCES


Diagnostic accuracy of 10/66 dementia protocol in Māori kaumātua (elders) living in Aotearoa New Zealand

Adrian Martinez-Ruiz, Sarah Cullum, Gary Cheung, Susan Yates, Rita Krishnamurthi, Claudia Rivera Rodriguez, Ngaire Kerse, Makarena Dudley

ABSTRACT

AIMS: Dementia is an important health concern for Māori and therefore it is essential to explore the extent and impact of dementia in this community. The 10/66 dementia protocol, a widely used research tool for measuring the prevalence of dementia, was developed to minimise cultural and educational bias in comparisons of dementia prevalence across different countries and/or cultures. The aims of this study are to (i) adapt the 10/66 dementia protocol for use in research within the Māori community and (ii) test the diagnostic accuracy of the adapted (ie, Māori-friendly) 10/66 dementia protocol against the reference standard of a clinical diagnosis of dementia (or no dementia).

METHOD: The sample included Māori aged 65 and over who had been assessed at a local memory service. Ten dementia cases and 10 controls were included. The sample was further enriched by the inclusion of 6 controls from a concurrent dementia-prevalence feasibility study in the local community. The Māori-friendly 10/66 dementia protocol was measured against the reference standard. Sensitivity, specificity, positive and negative predictive values and Youden’s Index were calculated.

RESULTS: The Māori-friendly 10/66 dementia protocol had a sensitivity of 90.0% (95% CI 62.8–99.4), specificity of 93.8% (95% CI 75.3–99.6), positive predictive value of 90.0% (95% CI 62.8–99.4), negative predictive value of 93.8% (95% CI 75.3–99.6) and Youden’s Index of 0.83.

CONCLUSIONS: Our study results provide preliminary evidence that the Māori-friendly 10/66 dementia protocol has adequate discriminatory abilities for the diagnosis of dementia. Our study also demonstrates that the Māori-friendly 10/66 dementia protocol has the potential to be used in a dementia-population-based study for Māori in Aotearoa New Zealand.

Dementia is a neurodegenerative disorder that affects a person’s ability to live independently. Its main clinical manifestations are significant cognitive impairment, functional impairment and the presence of neuropsychiatric symptoms. The prevalence of dementia has been progressively increasing in recent decades, and the World Health Organization (WHO) has recognised dementia as a public health priority. The projections for dementia prevalence indicate that it will increase worldwide, from 46.8 million in 2015 to 131.5 million in 2050. Aotearoa New Zealand is a bicultural country comprised of Māori, who are the tangata whenua (Indigenous people of the land) and represent 16.5% of the total population, and non-Māori (70.2% NZ Europeans, 15.1% Asians, 8.1% Pacific People, 1.5% Middle Eastern/Latin American/African and 1.2% of other ethnicities; this data include people who self-identify with more than one ethnicity; thus, the sum is higher than 100%). The New Zealand Government has a constitutional obligation to respond to Māori health needs and ensure equitable health outcomes with non-Māori. This obligation...
was established in the Te Tiriti o Waitangi (the Treaty of Waitangi), which was signed in 1840 between the British Crown and rangatira (Māori chiefs) and guarantees Māori equity with non-Māori in health outcomes, including the needs of Māori living with dementia and their whānau (relatives).6

The prevalence of dementia in Aotearoa New Zealand is expected to increase from an estimated 60,000 in 2015 to 170,000 in 2050.7 It has been reported that the total share of dementia cases in Māori will increase from 5.1% in 2016 to 8.0% in 2038, compared to a decrease from 87.5% to 77% in NZ Europeans in the same period.7 Another study using routinely collected health data in Aotearoa New Zealand found that the aged-standardised prevalence of dementia was higher among Māori compared to other ethnic groups.8 Furthermore, a secondary care-based study suggested that Māori presented with dementia 8.5 years earlier than NZ Europeans.9 This might be expected, as dementia risk factors such as obesity,10 hypertension11,12 and type 2 diabetes mellitus13 are more prevalent among Māori compared to NZ Europeans. This might be expected, as dementia risk factors such as obesity,10 hypertension11,12 and type 2 diabetes mellitus13 are more prevalent among Māori compared to NZ Europeans.14 A recent study about Māori understanding of dementia and how whānau provide care found that there is an urgent need for information “to assist with their knowledge building and empowerment to meet the needs of a member affected by matewareware (dementia).”15 This would involve a collaborative approach to provide culturally appropriate Māori services.15 In addition, the effects of ongoing colonisation such as difficulties accessing healthcare services, education, and discrimination are some of the life-course social determinants that could place Māori at increased risk of developing dementia.6

Aotearoa New Zealand has never had a population-based dementia prevalence study. Instead, projections using data from overseas have been used to estimate its occurrence.7 To carry out a population-based dementia prevalence study in Aotearoa New Zealand, a research tool that can accurately measure dementia in Māori is needed. Researchers should ideally be able to apply the same tool to non-Māori, in order to make appropriate comparisons on the prevalence of dementia among Māori and non-Māori.6 The need for a non-biased dementia diagnostic instrument that can be applied across population-based studies in different countries was first recognised by the 10/66 Dementia Research Group in 2003.14 This led to the development of the 10/66 dementia protocol, a fair culture and education instrument that has been validated in multiple languages (including Spanish, Arabic, Urdu, Fijian-Indian, Tamil, Malayalam and Chinese) and across different countries.16–20 The 10/66 dementia protocol has demonstrated excellent sensitivity (up to 94%) and specificity (up to 94%).16 However, in Aotearoa New Zealand, previous research has shown that Māori may have a negative response to cognitive tests that have been developed within a western culture.21–23 Therefore, we adapted the 10/66 dementia protocol to include Māori words for a more Māori-friendly experience.

If the 10/66 dementia protocol is successfully adapted for use in Māori, it could be used to better estimate the prevalence of dementia in Māori in a population-based dementia prevalence study and in comparisons with the prevalence of dementia in non-Māori. Using the 10/66 dementia protocol to accurately estimate the prevalence of dementia in Māori communities would provide information regarding the full impact of dementia as well as the burden of dementia on whānau, which would help to inform policy- and decision-makers developing culturally appropriate dementia-prevention and dementia-care services.

**Aim**

The aims of this study are to (i) adapt the 10/66 dementia protocol for use in research within the Māori community and (ii) test the diagnostic accuracy of the adapted (ie, Māori-friendly) 10/66 dementia protocol against the reference standard of a clinical diagnosis of dementia (or no dementia).
Methods

Index test: 10/66 dementia protocol

The methods used for this study have been thoroughly described elsewhere. Briefly, the 10/66 dementia protocol algorithm applies coefficients originated from (1) the Community Screening Instrument for Dementia (CSI-D), (2) the Geriatric Mental State Examination (GMS) and (3) the delayed recall memory test scores from the Consortium to Establish a Registry of Alzheimer’s (CERAD) instrument. The 10/66 dementia protocol takes about ninety minutes to administer and has three main sections, which are completed by the participant, the carer/informant and the head of household.

Adaptation and translation of the 10/66 dementia protocol

The adaptation process engaged an advisory group of four kaumātua who were experts in te reo Māori (the Māori language) and had knowledge of the differences in dialect across iwi. Each individual kaumatua read the original 10/66 dementia protocol and suggested where modification was required so it was more acceptable for all Māori. This was followed by a group discussion until a consensus of changes was reached. For the translation of the 10/66 dementia protocol into te reo Māori, we applied a WHO-approved procedure previously used for the adaptation of the Composite International Diagnostic Interview from English into Malay (described in Figure 1).

Validity study

Settings and participants

To examine the Māori-friendly 10/66 dementia protocol’s diagnostic accuracy, we compared the binary Māori-friendly 10/66 dementia protocol outcomes (“10/66 dementia” or “no 10/66 dementia”) against the clinical diagnosis received in the local memory service (reference standard: “clinical dementia diagnosis” or “no clinical dementia diagnosis”). Clinical diagnosis has been used as a reference standard in multiple 10/66 validity studies. The participants for this study were recruited from a publicly funded memory service. Figure 1: Translation stages of the 10/66 dementia protocol te reo Māori version.
service, and additional controls were recruited from a concurrent dementia prevalence feasibility study. For our sample size calculation, we used a prevalence of dementia of 60%, based on our previously published data from the memory service. We found a minimum sample size of 52 participants (including 31 participants with a diagnosis of dementia) was required to achieve a minimum power of 80% to detect a change in the percentage value of sensitivity of a screening test from 0.70 to 0.90, based on a target significance level of 0.05.

**Memory-service-based participants**

We recruited participants from the Counties Manukau District Health Board memory service, located in South Auckland, Aotearoa New Zealand. The main criteria for someone to access the memory service are subjective or objective memory complaints made by the patient themself, members of their family or by a health professional. Both primary and secondary healthcare services refer the individuals to the memory service—who are usually assessed in their own homes.

Standard clinical criteria for dementia were applied by the memory service at their weekly multidisciplinary team meeting in order to make a clinical diagnosis (reference standard). These criteria included: DSM-IV and DSM-5 dementia criteria, NINCDS-ADRDA criteria for Alzheimer’s disease dementia, NINCDS-AIREN criteria for vascular dementia, criteria for Lewy body dementia and criteria for frontotemporal dementia. The participants were classified into either “clinical dementia diagnosis” or “no clinical dementia diagnosis.” The steps followed by the research team to recruit the memory-service-based participants have been thoroughly described elsewhere.

**Eligibility criteria for participants**

All memory-service-based cases (“clinical dementia diagnosis”) and controls (“no clinical dementia diagnosis”) self-identified themselves as Māori and were aged 65 years or older. Cases and controls without an informant, and those who were unable to complete the interview because of significant sensory or physical impairment, were excluded from the study.

**Eligibility criteria for memory-service-based dementia cases**

The memory-service-based cases were recruited if they had been assessed by the memory service within six months of starting the study. All had been diagnosed with dementia by the memory service team. The study followed the New Zealand Code of Health and Disability Services Consumers’ Rights (Right 7) in regards to participants who were unable to give informed consent. The interview was terminated if at any stage the participant requested or indicated they did not want to continue.

**Eligibility criteria for memory-service-based controls**

Controls were included if they had been assessed by the memory service as not having dementia within six months of starting the study. We decided to not exclude controls with mild cognitive impairment (MCI), as excluding them would have increased the risk of “spectrum bias” causing spuriously accurate results.

**Community-based participants**

The community-based controls were recruited from a sample through a concurrent study aimed at assessing the feasibility of conducting a dementia prevalence study within two areas of the community (served by Counties Manukau District Health Board). They did not have a full specialist assessment; instead, they were included in the study if they scored ≥27 in the Rowland Universal Dementia Assessment Scale (RUDAS) and 1–3 in the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE). The high cut-off scores for RUDAS and low scores for IQCODE were chosen as they effectively excluded any potential cases of dementia.

**Validity study informants**

All memory-service-based and community-based participants had an informant. An informant is defined as a person who knows the participant well—usually the primary caregiver, a family member or someone who was responsible for the participant’s care. All informants signed a separate consent to participate in the study.
Blinding
For the memory-service-based participants, the Māori-friendly 10/66 dementia protocol was performed independently of the memory service clinical assessment. Therefore, the Māori-friendly 10/66 dementia protocol interviewers were blinded to the outcomes of the participants’ clinical assessment. During a 10/66 interview, one interviewer assessed the informant while another interviewer assessed the participant. For the community-based controls, the interviewers swapped the informant and participant after the Māori-friendly 10/66 dementia protocol in order to administer the reference-standard cognitive screen (IQCODE and RUDAS).

Interviewers
All face-to-face and telephone contacts between the research team and potential participants were conducted either in English or te reo Māori, depending on the participant's preference. Interviews were conducted by research assistants with some health background who self-identified as Māori and were bilingual (in te reo Māori and English). All interviewers participated in four training sessions, each one lasting four hours. All sections of the Māori-friendly 10/66 dementia protocol, as well as the IQCODE and RUDAS, were included in the training sessions. These sessions also included the necessary training for obtaining informed written consent and the procedures to manage unanticipated situations. The first three interviews were supervised by the study's principal investigator and a dementia specialist. They gave detailed feedback after the conclusion of the interview, thereby ensuring that the Māori-friendly 10/66 dementia protocol was administered correctly. Furthermore, this enabled the research assistant to clarify any questions presented during the interview.

Interviewing process
The interview was conducted as soon as informed written consent was obtained from the informant and the participant. The interview adhered to tikanga (Māori cultural protocols) for whānau (families) at hui (meeting/gathering), beginning with karakia (prayer) and then mihi (introductions and speeches), whanaungatanga (developing rapport) and kaupapa (explaining the purpose of the interview and how it would proceed). The interview would finish with karakia, and a koha (gift) of NZ$100 was given to the participants and their whānau as a token of appreciation for their time.

Ethical approval
The validity and feasibility studies were approved by the New Zealand Northern A Health and Disability Ethics Committee (numbers 17NTA234 and 18NTA176 respectively).

Data analysis
Dementia 10/66 diagnosis
The 10/66 dementia diagnostic algorithm was applied to obtain the participants’ dementia diagnoses. The algorithm establishes the outcome as either “10/66 dementia” or “no 10/66 dementia” according to the final score from the logistic regression equation developed in the 10/66 international pilot study. The equation predicts the diagnostic probability of DSM-IV clinical dementia syndrome.

Statistical analysis
Descriptive frequency distributions and mean values were used to describe demographic data. By comparing the 10/66 dementia protocol primary outcomes (“10/66 dementia” or “no 10/66 dementia”) against the “clinical dementia diagnosis” or “no clinical dementia diagnosis,” we calculated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), negative likelihood ratio (NLR) and Youden’s index. The 95% confidence intervals were calculated using the Clopper-Pearson statistical method.

Statistical Package for the Social Sciences (SPSS) version 25 (Chicago, IL) was used for data analysis.

Results
Translation and adaptation
The following changes were made to the 10/66 sub-components:
(i) The CERAD word learning list: one word from the 10-word learning list (“queen” was changed to “sailor”).
(ii) The CSI-D participant questionnaire: one item for naming things (“watch” was changed to “table”), three items for the naming of body parts (“knuckles” was...
changed to “fingers,” “elbow” to “ear” and “shoulder” to “cheeks”) and one item for describing things (“what is a bridge?” was changed to “what is a gate?”); all five items were changed to words that were considered by the kaumātua expert advisory group to be of more common usage in te reo Māori. One item for attention and language (the phrase “no ifs, ands or buts” was changed to “neither this nor that”) was modified as it was considered difficult to translate grammatically into te reo Māori. The general knowledge question “What is the name of the mayor/village head?” was changed to “What is the name of the rangatira (chief) of this rohe (area)?” This question was changed since the terms “mayor” and “village heads” are not of common use in te reo Māori. “Mayor” relates to a city in Aotearoa New Zealand and was therefore considered confusing, and “village” is uncommon. “Rangatira of this rohe” is a phrase used commonly by Māori and with the same inference as “mayor/village head.” The long-term memory item was also changed from “What is the name of the civil rights leader who was assassinated in Memphis in 1968?” to “What is the name of the kuia (elderly Māori woman) from Northland who led the Māori land march to parliament in 1975?” This is because few Māori would know the answer to the original question, whereas the answer to the adapted question is common general knowledge amongst Māori.

No changes were made to the CSI-D informant questionnaire or the GMS.

**Sample characteristics**

We recruited 26 participants: 10 dementia cases and 16 controls. All participants and informants completed the Māori-friendly 10/66 dementia protocol (Figure 2). The interviews were conducted in each participant’s preferred language; only one interview was conducted in te reo Māori, with the rest conducted in English.

The mean (SD) age of the participants was 75.3 (5.1) years. Fifty percent (n=13) were female. Seven participants (26.9%) were “married/cohabitating.” The mean (SD) age of the informants was 56.6 (16.9) years. Eighty-five percent (n=22) were female, and 34.6% (n=9) reported being the participant’s spouse. Other sociodemographic characteristics of participants and informants are described in Table 1.

**Figure 2:** Recruitment flowchart.
Table 1. Sociodemographic characteristics of participants and informants by reference standard.

<table>
<thead>
<tr>
<th>Variable</th>
<th>No dementia diagnosis n=16 (%)</th>
<th>Dementia diagnosis n=10 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years) Mean (SD, 95% CI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>75.1 (3.5, 73.4–77.2)</td>
<td>75.3 (7.1, 70.1–80.4)</td>
</tr>
<tr>
<td>Informants</td>
<td>54.0 (21.9, 44.0–65.0)</td>
<td>58.4 (16.9, 45.4–71.4)</td>
</tr>
<tr>
<td><strong>Gender (female)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>7 (43.8)</td>
<td>4 (40.0)</td>
</tr>
<tr>
<td>Informants</td>
<td>14 (87.5)</td>
<td>8 (80.0)</td>
</tr>
<tr>
<td><strong>Marital Status (participants)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/cohabitating</td>
<td>6 (37.5)</td>
<td>1 (10.0)</td>
</tr>
<tr>
<td>Never married</td>
<td>1 (6.3)</td>
<td>1 (10.0)</td>
</tr>
<tr>
<td>Widowed</td>
<td>5 (31.2)</td>
<td>2 (20.0)</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>4 (25.0)</td>
<td>6 (60.0)</td>
</tr>
<tr>
<td><strong>Informant relationship with participant</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spouse/partner</td>
<td>8 (50.0)</td>
<td>1 (10.0)</td>
</tr>
<tr>
<td>Child</td>
<td>4 (25.0)</td>
<td>5 (50.0)</td>
</tr>
<tr>
<td>Son or daughter in law</td>
<td>0</td>
<td>1 (10.0)</td>
</tr>
<tr>
<td>Friend</td>
<td>1 (6.3)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>3 (18.7)</td>
<td>3 (30.0)</td>
</tr>
<tr>
<td><strong>Education level (participants)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary completed</td>
<td>6 (37.5)</td>
<td>4 (40.0)</td>
</tr>
<tr>
<td>Secondary or above</td>
<td>10 (62.5)</td>
<td>6 (60.0)</td>
</tr>
</tbody>
</table>

SD: Standard Deviation, CI: Confidence Interval.
Diagnostic test accuracy

10/66 dementia diagnosis

Out of 10 participants in the “clinical dementia diagnosis” group, nine participants were correctly classified by the Māori-friendly 10/66 dementia protocol (true positives) and one participant was mis-classified as not having dementia (false negative). Out of 16 participants in the “no clinical dementia diagnosis” group, 15 participants were correctly classified by the Māori-friendly 10/66 dementia protocol (true negatives) and one participant was mis-classified as having dementia (false positive). Thus, the sensitivity and specificity of the Māori-friendly 10/66 dementia protocol were 90.0% (95% CI 62.8–99.4) and 93.8% (95% CI 75.3–99.6) respectively. The PPV was 90.0% (95% CI 62.8–99.4), NPV was 93.8% (95% CI 75.3–99.6), PLR was 9.3 (CI 1.4–60.4), NLR was 0.06 (CI 0.01–0.46) and Youden’s index was 0.83.

Discussion

Our study showed that the Māori-friendly 10/66 dementia protocol has adequate clinometric properties, with a sensitivity of 90.0% and specificity of 93.8%. This demonstrates its discriminatory abilities for future population-based dementia studies that involve Māori. To the best of our knowledge, this is the first validity study of the 10/66 dementia protocol focusing on Māori in Aotearoa New Zealand or elsewhere.

The clinometric properties of the Māori-friendly 10/66 dementia protocol mirrored the results of other 10/66 dementia protocols reported in the literature (Table 2). The demographics of the Māori sample were weighted towards those with a low education and therefore our results are comparable to the original 10/66 Dementia Research Group validity study, which found a sensitivity of 94% and a specificity of 94% in people with low education.16

There are some limitations that need to be acknowledged. The main limitation is that our study sample was small compared to previous 10/66 dementia protocol studies, and therefore there will be greater uncertainty about the results. Studies with a small sample size may increase the occurrence of Type II error. We designed our study according to the requirements for minimum sample size (n=52),26 but we were only able to include full data for 16 controls and 10 dementia cases. This was because we experienced difficulties recruiting Māori from the memory service and the community. Only 12% (n=43) of the Counties Manukau District Health Board memory service attendees who received a new dementia diagnosis in a three-year period were Māori.9 We also had a higher-than-expected rate of incomplete assessments in the community due to unavailability of informants (57% of the control group). Only one participant was interviewed in te reo Māori, as the remainder chose to be interviewed in English. However, it should be pointed out that we are testing the diagnostic accuracy of the adapted Māori-friendly 10/66 dementia protocol (as co-developed by an expert group of kaumātua). This Māori-friendly 10/66 dementia protocol has an English and a te reo Māori version. We took advice on this matter from Professor Martin Prince, Director of the 10/66 Dementia Research Group, as we knew that we were unlikely to find a sufficient number of participants who would chose to be interviewed in te reo Māori—as many Māori of this generation were banned from speaking te reo in their childhoods. Professor Prince’s original 10/66 dementia protocol has already been adapted and validated in numerous cultures and languages (Table 2), and the aim of this study was therefore to test that our Māori-friendly 10/66 dementia protocol worked in the target population. We are confident that the Māori-friendly 10/66 dementia protocol is suitable for use in research within the Māori community. However, the diagnostic accuracy of this Māori-friendly 10/66 dementia protocol could be further confirmed in a validity study nested within a future prevalence study in order to confirm our findings. This approach has been used before in other studies using the 10/66 dementia protocol.19

To date, the extent and impact of dementia in the Māori population has never been assessed. The information obtained from a population-based study can be used to compare health outcomes and inequities related to dementia between Māori and...
non-Māori in Aotearoa New Zealand. Further analysis can also be used by government agencies to develop culturally appropriate dementia services for Māori living with dementia and their whānau, in addition to informing the development of strategies to reduce the impact of dementia and specific policies to raise public awareness about dementia and its prevention in the Māori community.

Conclusion
A Māori dementia prevalence study will provide the foundation to achieve equitable outcomes for Māori living with dementia. Our study has demonstrated that the Māori-friendly 10/66 dementia protocol has the potential to be used in a dementia population-based study for Māori in Aotearoa New Zealand.

Table 2: Comparison of sensitivity and specificity of the 10/66 dementia protocol in samples from different populations

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Place, language</th>
<th>Adaptation to local culture and language</th>
<th>10/66 dementia protocol</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present Study</td>
<td>New Zealand, te reo Māori and English</td>
<td>Yes</td>
<td>90.0%</td>
<td>93.8%</td>
</tr>
<tr>
<td>Prince, 2003¹⁴</td>
<td>Multiple</td>
<td>Yes</td>
<td>94.0%</td>
<td>94.0%*</td>
</tr>
<tr>
<td>Prince, 2008⁴¹</td>
<td>Cuba, Spanish</td>
<td>Yes</td>
<td>93.2%</td>
<td>96.8%</td>
</tr>
<tr>
<td>Nozari, 2009⁴²</td>
<td>Iran, Farsi</td>
<td>Yes</td>
<td>98.3%</td>
<td>98.3%</td>
</tr>
<tr>
<td>Subramaniam, 2015¹⁹</td>
<td>Multiple</td>
<td>Yes</td>
<td>95.6%</td>
<td>81.8%</td>
</tr>
<tr>
<td>Phung, 2015⁴⁷</td>
<td>Lebanon, Arabic</td>
<td>Yes</td>
<td>92.0%</td>
<td>95.1%</td>
</tr>
<tr>
<td>Khan, 2020¹⁴</td>
<td>Pakistan, Urdu</td>
<td>Yes</td>
<td>70.3%</td>
<td>91.7%</td>
</tr>
</tbody>
</table>

Clinical diagnosis was reference standard for all included studies.
* Published as a letter to the editor. * In people with low education.
Competing interests:
Nil.

Acknowledgements:
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REFERENCES


Views of health professionals on the impact of early miscarriage on women’s mental health and the accessibility of services and support

Jessica Yang, Anthony Dowell, Sara Filoche

ABSTRACT

BACKGROUND: Miscarriages, the majority of which occur in the first trimester, can have a detrimental impact on women’s mental health.

AIM: To explore health professionals’ views on the impact of early miscarriage on mental health and accessibility of services and support available to women.

METHODS: Semi-structured interviews were conducted with 10 health professionals from an urban tertiary hospital and a community setting, followed by semi-inductive thematic analysis.

RESULTS: Three overarching themes were identified: (1) extent and nature of psychological impact, (2) barriers to accessing mental health support and (3) facilitators of change or improvement. Early miscarriage was regarded as a “loss” that affected not only the women but their partners and other family/whānau members. Establishing how women felt about the pregnancy was regarded as important in directing both the scope of the consultation and subsequent guide to support services. Inequitable access to services and support was identified. Cost of counselling, geographic location and fragmented care were cited as barriers to accessing support. Improved clinical pathways and channels for inter-professional communication, as well as more accessible counselling, were regarded as key areas for service improvement.

DISCUSSION: This study highlights that, although health professionals appropriately recognise early miscarriage as a significant loss, access to support is inequitable and fragmented. Early miscarriage care is an area of unmet need and, given the high incidence of early miscarriage and its impact on mental health, urgent action around service provision is needed.

A quarter of women experience miscarriage in their lifetime. The vast majority (99%) of miscarriages occur early, in the first trimester (12–14 weeks).\textsuperscript{1,2} International literature suggests that early pregnancy loss can have a lasting effect on mental health, from mental distress to symptoms or diagnoses of post-traumatic stress disorder and anxiety.\textsuperscript{1,4} The association with depression seems less clear; however, some evidence indicates a higher risk of suicide and self-harm.\textsuperscript{4} Some studies have explored women’s perspectives of miscarriage alone;\textsuperscript{9} others suggest there is a discrepancy between women’s and health professionals’ awareness of psychological morbidity after miscarriage.\textsuperscript{10,11}

In Aotearoa New Zealand, primary maternity care is provided by lead maternity carers (LMCs), who take responsibility for the care provided to women throughout pregnancy, during labour and birth and up to six weeks following birth.\textsuperscript{12} The majority of women (93.6% in 2015)\textsuperscript{13} are cared for by autonomous, self-employed midwives contracted to the state. Approximately
two-thirds of women register with an LMC in the first trimester (in 2017). There are approximately 25,000 miscarriages annually in Aotearoa, based on an incidence rate of around one or two in every 10 pregnancies. Health professionals can play a significant role in shaping women’s experiences of miscarriage, including their access to services and support. In order to inform service provision for women and whānau experiencing early miscarriage, this qualitative study explored the health professionals’ views on the impact of early miscarriage on women’s mental health and the accessibility of services and support.

Methods
Study development and design
Existing connections and a snowball methodology were used to recruit health professionals from an urban tertiary hospital and a community setting. The participants included, but were not limited to, health professionals working near the research location. Twelve participants from a variety of professional backgrounds with experience in both women’s health and mental health, including a mix of hospital employees and community-based professionals, were invited to participate.

The semi-structured interview guide was developed by the research team (JY, AD, SF) to explore: the extent and ways that early miscarriage (first-trimester loss) may impact on mental health; the different health and support services (including mental health services) that are available to these women, as well as the existing level of access to, and communication between, these services; and potential areas for improvement.

Ten interviews undertaken by one interviewer took place at various sites between November and December 2018. Nine interviews took place in person and one online using Zoom. All were audio-recorded and lasted between 22 and 48 minutes. No remuneration was given.

All interviews were manually transcribed by the interviewer, who removed verbal fillers and any material that could identify the participants. Transcripts were then emailed to key participants for review. Two participants elected to review their respective transcripts before analysis.

Data analysis
Thematic analysis was carried out using a semi-inductive approach. Two researchers independently coded each transcript and identified preliminary themes using QSR International’s NVivo 12 Software. Data were analysed until no new themes emerged. Discussion revealed similarity between the two independent codebooks, though intercoder reliability was not calculated. Consensus was reached through discussion.

Ethical Approval
Ethics approval was gained from the University of Otago Ethics Committee (D18/363), along with appropriate locality approval for the district health board.

Results
Ten health professionals from a range of backgrounds participated in this study (Table 1). Each professional was asked about their background for the purpose of context; all responses indicated experience in women’s health and mental health. No further demographic information, such as age, ethnicity or years of experience, was collected.

Three overarching themes were identified:
- Extent and nature of psychological impact
- Barriers to accessing mental health support
- Facilitators of change or improvement

Table 1: Health professionals’ area of work.

<table>
<thead>
<tr>
<th>General practitioner 1</th>
<th>Clinical psychologist</th>
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<tr>
<td>General practitioner 2</td>
<td>Termination of pregnancy counsellor</td>
</tr>
<tr>
<td>Maternal fetal medicine specialist</td>
<td>Maternal fetal medicine midwife</td>
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<tr>
<td>Termination of pregnancy provider</td>
<td>Emergency department nurse</td>
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<tr>
<td>Maternal mental health psychiatrist</td>
<td>Social worker</td>
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Extent and nature of psychological impact
Participants described wide-ranging impacts of miscarriage on mental health with sub-themes around who else was affected, how they were affected and how to identify those at risk. A consistent finding from all the health professionals was that miscarriage is a significant loss and that grief was the usual response. To ascertain the potential impact of miscarriage, it was considered important to understand whether, and to what degree, the pregnancy was “wanted” or “planned.” When the pregnancy was planned or wanted, the potential for significant impact was deemed greater than when it was unwanted or unplanned (Table 2). However, for some women, the end of the pregnancy may lessen an impact on mental health:

“It can be anything from bereavement and loss—depending on the stage of the miscarriage, or how much they wanted to be pregnant—through to some women [being] quite relieved, [or] struggling with adapting, [or] adjustment reaction and anything in between, [or] grief, guilt…”– Maternity mental health psychiatrist

Establishing how women felt about the miscarriage was an important step in directing women to relevant services and support. However, predicting the impact on mental health was more challenging (except for women with known mental health conditions and risk factors such as misuse of alcohol or illicit drugs) because there are so many different influencing factors:

“Red flags are often difficult because they’re usually not particularly red or being waved particularly kind of furiously. And I think there are different sorts of red flag…” – General practitioner 1

An early miscarriage was also a loss felt by people with close relationships to the woman:

“[Fetal loss] has collateral damage to relationships, children, parents—it affects families, not just the women.” – Maternal fetal medicine midwife

Although several participants noted that women’s partners were also affected, one did give an example to the contrary:

“So many women will say, ‘Oh yeah my husband or my partner, he kind of got it for the first day and then after I had the D&C he was kinda like, ‘Well just get on with it, you gotta go back to work now’ or ‘What do you mean you’re still sad?’” – Clinical psychologist

Barriers to accessing services and support
Several barriers to accessing support services were identified: cost, type of counselling, location/geography, limited
Table 2: Exemplar quotes on the extent and nature of impact on mental health.

<table>
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<th>Topic</th>
<th>Quote</th>
<th>Source</th>
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<tr>
<td>Grief</td>
<td>“Miscarriage in particular, or especially if it’s a long fought-for pregnancy—IVF, they’ve been on that emotional rollercoaster and then they’ve lost the pregnancy. That sense of failure can be huge, and that has a massive impact on their mental health.” – Social worker</td>
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<td>“There’s no set pattern to an emotional response, it’s a grief reaction often—so it’s your normal grief reaction, but it’s whether their behaviour or response sits outside of those normal reactions. For instance, I’m more interested in someone who has a blunted emotion, who shows no emotion, than one who does. Because if I told you your sister had just been in a car accident, you would have an emotional response, and that would be entirely appropriate. But [] if you sat there and nodded and grinned at me, we just carried on the conversation, my alerts would go up.” – Maternity fetal medicine midwife</td>
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<td>Attitude towards the pregnancy</td>
<td>“I think it depends on if it’s a wanted pregnancy or not. So if it wasn’t wanted, then the chances are that mental health issues are not such a big deal. Maybe age as well, when you start getting pregnant. If you’re 40 and had some help with getting pregnant, and then you have a miscarriage, then it might be a bigger thing than if you’re eighteen, twenty.” – Emergency department nurse</td>
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<td>“As soon as they become pregnant, women are thinking about that baby as a fully formed being, and they’re projecting that child into the future. You know, growing up and—it’s not just, ‘Oh so I’m pregnant so I’ve got this cell that’s been dividing inside of me and now it’s the size of a…’—you know? I think women don’t have that… I think it’s more[,] ‘I’m gonna have a baby and it’s gonna be this and it’s gonna grow up to do this and it’s gonna look like this’” – Clinical psychologist</td>
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<td>Women taking the blame</td>
<td>“People don’t really talk about having miscarriages. And for a lot of women that have been healthy and well, that’s the first time that they’ve felt that their body’s [] let them down, or they’re disappointed… I’m thinking of lots of women that I’ve spoken to. There’s a lot of different [] thoughts for a lot of different people. Some women feel really like their body’s let them down or that they’re useless.” – Social Worker</td>
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<td>“I guess if [it] was a recurrent miscarriage and nothing had been found like the first time, then the second time part of the psychological thing would be doing that search for any underlying obvious medical reasons, but then talking through the psychological implications of that so, ‘We are going to check that you weren’t very anaemic, we don’t think you were but it’s worth doing that… we’ll check a whole bunch of other stuff.’ And part of that I guess is looking at it from a medical scientific point of view and not that it is the woman’s fault that she miscarried, which I think sometimes women would be kind of carrying that around, you know, ‘what did I do that made me miscarry?… could I have looked after myself better?’” – General practitioner 1</td>
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<tr>
<td>Who’s impacted</td>
<td>“It’s multifaceted and it’s very individualised, and really it’s on case-by-case basis. You can’t make assumptions about how someone is going to process information or what their reaction is going to be. But you can bet your bottom dollar that most of the situations that occur in fetal medicine affect every woman’s mental health.” – Maternity fetal medicine midwife</td>
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<td>“I think the other of it of course is blokes tend to get left out—nobody talks about the blokes. And you do wonder if fathers grieve, and nobody ever asks the father, “How do you feel about a miscarriage?” [I’ve] probably never asked a father about that, except when it’s in the moment, so that’s pretty tough. So I think the other big conversation we’re missing is the guys.” – General practitioner 2</td>
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<td>Risk factors</td>
<td>“Are you more at risk when you’re 23 years old, if you have an early termination or if you have a miscarriage?… There’s so many factors to take into account.” – Clinical psychologist</td>
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availability of professionals and gaps in communication between and within services (Table 3). These barriers created inequitable and fragmented access:

“There are always people falling through—we know that. ‘Cause I know the demographics of who we treat, and then the research I’ve done has also shown the demographics of people who do have mental health problems in the community sample... For example, we’re missing young Māori, young Pacific Island women. They’re not coming through to our service, so there’s obviously some kind of barrier there. Our service is predominantly Pākehā, middle class, reasonably well-employed kind of people.” — Maternal mental health psychiatrist

Inaccessibility to the appropriate services was exacerbated by constraints on the system, which was “designed for the mother–baby diad” (Maternal mental health psychiatrist). Organisational factors also acted as a barrier to appropriate services and support, as early miscarriages were identified as not being a priority and women cared for by junior staff (Table 3).

“I think where we have difficulty is that women come in with the miscarriage [] at any time of the day or night [and] they often are not high priority in the hospital service... they often get seen by junior nursing and medical staff who’ve got limited experience both with the problem and they’ve got limited life experience, ‘cause they tend to be younger, and so they probably just don’t get that good a deal” (Maternal fetal medicine specialist.)

Gaps in communication between the different service professionals who women may have seen was viewed as contributing to barriers to accessing appropriate support. Some explained that communication exists but is limited to aspects of physical health, rather than including mental wellbeing:

“You get the letter back saying [the miscarriage] happened, in a timely way. So you know what physically has happened and when it’s happened. So there is communication. There’s not much communication about their mental health state. So it’s just physically what happened and this is what they did.” — General practitioner 2

Communication with women about their obstetric history in relation to their mental health was not routine in all healthcare settings:

“We don’t routinely ask women if they’re suicidal or their mental health is not very good. We don’t say, ‘Have you had a recent miscarriage or are you pregnant?’ We don’t really link that up very well.” – Emergency department nurse

One health professional also raised the scale of reproductive morbidity and an associated unmet need for services and support:

“The women with miscarriage, if they are depressed, they’re a silent voice. Their voice isn’t heard. 15% of all women who have an identified pregnancy will miscarry. So it’s not an insignificant number. We estimate that, if there’s 60,000 births in New Zealand each year, there’s 85,000 pregnancies. The rest don’t make it to 20 weeks, for a variety of reasons. So that gives you an idea of the size of the reproductive morbidity in New Zealand. So what is happening to those 20,000 odd women, who’s looking after them, how good is their care?” – Maternal fetal medicine specialist

Facilitators of change or improvement

Facilitators for improving access to support for women and their whānau included system-, organisational- and community-level solutions. System-level facilitators to improving access included having primary care clinical pathways that would improve the integration of seamless care and follow-up, and communication between professionals/services, particularly where more than one health professional has been involved in a woman’s care (Table 4). Organisational improvements to improve access included incorporating talking therapies into primary care. A consistent finding was a call for more accessible counselling for not only women, but partners and...
Table 3: Exemplar quotes associated with barriers to accessing services and support.

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<th>Cost</th>
<th>Quote</th>
<th>Author</th>
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<td>“I think you’re probably aware that the mental health services in New Zealand would really probably only manage to take this on if it was an acute major depressive illness. They’re just not in a space at the moment to deal with psychological as opposed to psychiatric disorders. So the best the GP could do would be to get counselling… [either] psychological counselling or social work counselling. And psychological counselling in the community is not really available free. So there would be a charge, and you could be looking at in excess of $90 an hour.”</td>
<td>Maternal fetal medicine specialist</td>
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<tr>
<td>Location/geography</td>
<td>“Remembering some women drive in the car for seven hours to get to an appointment here…”</td>
<td>Maternal fetal medicine midwife</td>
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<td>“There is a lot of inequity, and those [who] are educated, well, probably white with good family support, are the ones that will probably be the squeaky wheels and get the most help, because they will describe how they’re feeling, they will front up, they will not DNA. People that are poor, haven’t got transport, haven’t got financial security, who can’t necessarily speak our language, who can’t necessarily understand medical jargon or hospital jargon or clinical jargon—this isn’t their place of comfort, is it? They don’t want to be here, this isn’t where they feel safe. So yeah, there is a lot of inequity.”</td>
<td>Maternal fetal medicine midwife</td>
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<td>System and organisational factors</td>
<td>“The new mental health review’s talking about increasing private professionals, or PHOs. My only comment on that—from being a mental health professional myself and also having experience in that area—is that it can become extremely fragmented. ‘Cause no one actually knows who knows who for what, and you pick up that and there’s not a lot of information sharing and [] it gets really messy. It’s like, ‘Oh yeah she’s known to us but we didn’t know anything about that, and mmm, okay.’ So it’s trying to streamline information that people want to share so that they don’t have to re-traumatisate themselves. I don’t know. It’s messy. Mental health is [] a messy business.”</td>
<td>Maternal fetal medicine midwife</td>
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<td>“So if someone loses their baby, even if they do get depressed, we don’t get to see them. If they have a termination, we don’t get to see them. Ours is specifically designed for the mother–baby diad.”</td>
<td>Maternal mental health psychiatrist</td>
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<td>“There is an issue where, for many clinicians, certainly like me, we only do relatively part-time clinical work, so lots of GPs now are not working full-time, which means there’s always the risk and worry of women in this instance—the follow-up not following through because they can’t come at the times that I would be there as a clinician and so on. So I think there is potentially a real risk of that follow-up not happening, in a particularly coordinated way.”</td>
<td>General practitioner 1</td>
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anyone else affected by the loss too (Table 4). Suggestions to improve the accessibility of counselling included removing or reducing financial barriers and ensuring that counselling meets the needs of those seeking support (Table 4).

Knowing about community support and having community-based care were regarded as areas to improve access. Such supports had been in place but were withdrawn due to lack of funding (Table 4).

**Discussion**

The health professionals interviewed in this study clearly acknowledged that early pregnancy miscarriages have wide-ranging and long-lasting impacts on women's and their families' mental health and wellbeing. These findings are similar to those of other studies. However, the accessibility of services and support for women who have experienced an early miscarriage did not match the extent of these impacts.

Suicide has been the leading cause of maternal mortality in Aotearoa for many years. Its rate in New Zealand is seven-times the rate in the UK. Women who identify as Māori and their whānau experience the greatest burden of suicide. The Perinatal and Maternal Mortality Review Committee proposed a practice point regarding psychosocial health and maternal suicide, which includes identifying “a history of termination of pregnancy or miscarriage in the previous 12 months, and any past or present mental illness, including self-harm and previous suicide attempts.” In a recent study, New Zealand midwives were asked about their perceptions of maternal mental health antenatally, including screening. The findings from this study, drawn from the views of 27 midwives, identified a chronic shortfall primary care mental health services, and that if “routine screening, such as is recommended, is implemented then more services will need to be available.” However, not all women who experience an early miscarriage are in the care of an LMC midwife. In Aotearoa New Zealand and elsewhere, women experiencing a miscarriage frequently seek medical care in emergency departments. International evidence has shown that some emergency-healthcare staff feel insufficiently equipped to manage miscarriages. In an Australian-based study, women who experienced a miscarriage in an emergency department felt marginalised, silenced and that their loss was dismissed. Investigating how to support emergency staff in Aotearoa to support women/whānau experiencing miscarriage, and to enquire about mental health with presentations of self-harm and previous pregnancy loss, appears to be needed.

Participants described a range of ideas that they believed would prove access at both individual-support and system levels. These included locally relevant clinical pathways that are linked to local support groups and services, which would help facilitate coordinated care and follow-up. At the time of writing, an integrated, shared electronic health platform is gaining traction. Such a system would undoubtedly facilitate more seamless care and referral to services and support—if these services and support were available in the first place. Fragmented services and support have been reported in other countries, such as the UK, with one survey estimating that 237 of 300 women reported that they received no aftercare following a miscarriage and only 87 felt well cared for emotionally. Comparable qualitative studies from Canada and Australia also suggest that miscarriage has significant emotional impact and that access to support is limited by health professionals’ awareness as well as system-wide factors.

In our study, more affordable (free) access to mental health services was cited by all the health professionals as being a significant service change that would improve support for women and their whānau. However, an international Cochrane review found insufficient evidence for the benefit of counselling—but none of these interventions were developed with women who had experienced miscarriage, and given the diverse needs of women and whānau who experience miscarriage, it is imperative that women contribute/lead any new initiatives for services and support design.

A strength of this study was the inclusion of a wide range of health professions. Open questions were used in the interviews to minimise research bias. The independent coding by two researchers also served to reinforce the thematic interpretations. While this was a small qualitative sample, analysis of the data was in keeping with...
Table 4 Exemplar quotes for facilitators and ideas to improve access.

| System improvements | “I think there’s the systems level. We should make sure that the clinical pathways are working well, and I mean I am a big believer in up-to-date and locally adapted clinical pathways, which we can log on to and you go, ‘miscarriage,’ ‘management,’ la de da. Locally this is what we do, locally these are the follow-up arrangements that we should’ve made, and then we stick to that clinical pathway.” – General practitioner 1

| “Sometimes those people don’t talk, you know—the GP’s not meeting with the mental health professional, who’s not meeting with the midwife—and my thought was, well if you have a woman who comes in and is pregnant and she’s got a community mental health worker and she has a midwife and she has a GP, then those people should have some communication along the way. And [ ] if there is any risk, there should already be a plan in place about how to manage this woman’s mental health.” – Clinical psychologist

| Organisational improvements | “There would be access to psychological talking therapy from a general practice setting, we’ve got that within the practice, so that’s one route in which you can provide access to services, and depending on the social circumstances, it is likely that would be free. Or if not then there are other referral options.” – General practitioner 1

| Accessible counselling | “I think it’s so individual, that loss stuff, and the cultural component or the societal stuff is quite individual too. I think counselling and counsellors would hopefully be able to see what that need is for that person. And two people from the same whānau—it won’t be the same... there’ll be elements of support that will be good. I think there needs to be cheaper counselling for people full stop. I think that [partners] have the double-whammy of worrying about their partner and the concern that that stirs up for them, as well as their own grief and loss around what that means for them.” – Social worker

| Community support | “There’s got to be a lot more money spent in looking after people in their homes, in their communities, where they live. Things happening, coffee groups, places to go, you know. The previous government wiped out [some services]—for instance, there was [a] drop-in centre for people that could go in and have coffee and meet and who just had no place to go, and no one to talk to… that place is no longer, it wasn’t funded, the funding was withdrawn. That’s cheap, you know, that costs nothing. But they’d rather, you know, maybe employ a psychiatrist somewhere and put them in a tertiary hospital. I don’t know what they want to do but they need to reorganise their priorities hugely and look at community and supporting people.” – Maternal fetal medicine midwife

| “I think we in general practice being more aware of community groups and [ ] support networks—there’s a lot of different ones, and there’s so many we forget them all... somehow [we need] a better interface between us in general practice and knowing what community groups there are. It’s quite hard, cause there’s so many different groups, and we need to know so much that we forget them all the time. So some sort of better way of interacting with community networks and support I think would be helpful.” – General practitioner 2

| Local solution | “What we’ve tried to do is embed some of our workers from our team in the [ ] secondary care services (obstetric or antenatal care services) in the region. So we have what we call ‘the wellness clinic’ here at [the] hospital, so that’s in primary maternity care, where, if [a woman is] identified by the midwife or someone like that, [they] get seen by someone from our service, who then can make a judgment on whether they need to ramp it up and get them in or not.” – Maternal mental health psychiatrist
overseas studies in terms of identified themes, and the data were re-analysed until no new themes were evident. Our recruitment process (using existing connections and a snowball method) may not have gathered a comprehensive representation of all professionals involved in miscarriage care. This study was based in a tertiary district health board, and we do not know whether care has been more fragmented because of the size of the population served, or whether more rural and remote areas of Aotearoa carry greater inequities in access. However, this seems somewhat of a moot point, as we know that miscarriage impacts mental health, and that there is a significant burden of maternal mental health and persistent failings in healthcare for Māori (Wai 2575 the Waitangi Tribunal Health Services and Outcomes Inquiry, and Wai 2700, Mana Wāhine Kuapapa Inquiry).

Conclusions

Our study's findings highlight health professionals' experiences and perception that care is often fragmented for women who have experienced an early miscarriage, and that there are many barriers to receiving appropriate support. Changes to improve equity in access are urgently needed.
Competing interests:
Nil.

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REFERENCES


Modelling the impacts of tobacco denicotinisation on achieving the Smokefree 2025 goal in Aotearoa New Zealand

Nick Wilson, Janet Hoek, Nhung Nghiem, Jennifer Summers, Leah Grout, Richard Edwards

ABSTRACT

AIM: To provide preliminary high-level modelling estimates of the impact of denicotinisation of tobacco on changes in smoking prevalence in Aotearoa New Zealand relative to the New Zealand Government’s Smokefree 2025 goal.

METHODS: An Excel spreadsheet was populated with smoking and vaping prevalence data from the New Zealand Health Survey and we projected business-as-usual trends. Using various parameters from the literature (New Zealand trial data, New Zealand EASE-ITC Study results), we modelled the potential impact of denicotinisation of tobacco (with no other tobacco permitted for sale) out to 2025. In addition to the base case (considered most likely), Scenario 1 used estimates from a published expert knowledge elicitation process, and Scenario 2 considered the addition of extra mass-media campaign and Quitline support to the base case.

RESULTS: With the denicotinisation intervention, adult daily smoking prevalences were estimated to decline to under 5% by 2025 for the European/Other ethnic grouping (in the base case and both scenarios) and in one scenario (Scenario 1) for Māori (2.5%). However, prevalence did not fall below 5% in the base case for Māori (7.7%) or in Scenario 2 (5.2%). In the base case, vaping was estimated to increase to 7.9% in the adult population by 2025, and up to 10.7% in one scenario (Scenario 1).

CONCLUSIONS: This preliminary high-level modelling suggests that mandated denicotinisation has a plausible chance of achieving the New Zealand Government’s Smokefree 2025 goal. The probability of success would increase if supplemented with interventions such as mass-media campaigns offering Quitline support (especially if predominantly designed for a Māori audience). Nevertheless, there is much uncertainty with these results and more sophisticated modelling is forthcoming.

Tobacco smoking caused an estimated 4,790 attributable deaths in Aotearoa New Zealand in 2019 (95% uncertainty interval (UI): 4,510 to 5,100).\(^1\) The total health loss, including morbidity, in 2019 was estimated at 116,000 disability-adjusted life years (DALYs) lost (95%UI: 108,000 to 125,000).\(^2\) Furthermore, smoking causes health inequities and results in poorer health for Māori relative to non-Māori.\(^3,4\) Exposure to second-hand smoke causes an estimated 347 additional attributable deaths per year in New Zealand, and an additional 9,022 lost DALYs per year.\(^4\) This high health burden means that the health benefits of tobacco control can be extremely large. The highest-impact intervention in one modelling study (of a sinking lid on tobacco sales) estimated a saving of 1.21 million quality-adjusted life years (QALYs) and NZ$1.71 billion in cost-savings to the health system (lifetime impacts for the population alive in 2011 and undiscounted estimates).\(^5\) These gains are very large when compared with the majority of health sector interventions in an online league table with hundreds of New Zealand and Australian interventions.\(^6\) Other likely benefits from...
enhanced tobacco control include reduced health inequities (as Māori would potentially receive the greater per capita health gain)\(^5\) and large economic benefits (as reduced illness among workers will improve productivity). For example, one New Zealand study reported that “the majority of the health benefit over a 10-year horizon from increasing tobacco taxes is accrued in the working-age population (20-65 years).”\(^7\)

In April 2021, the New Zealand Government published a discussion document outlining proposals for an action plan to realise the Smokefree 2025 goal.\(^8\) One of the major potential interventions in this discussion document was the reduction of nicotine in smoked tobacco products to very low levels (ie, to levels that are likely to be non-addictive). International interest in this particular “denicotinisation” policy measure is increasing and the US Food and Drug Administration has announced its intention to introduce a risk-proportionate regulatory framework for nicotine products.\(^9\) As such, it issued an Advance Notice of Proposed Rulemaking that recommends developing a tobacco-product standard for minimal or non-addictive nicotine levels in cigarettes.\(^10\) Recent media reports suggest introducing a mandated reduced-nicotine policy for cigarettes is currently under active consideration by the US Administration.\(^10\)

Several reviews and commentaries, and many individual studies,\(^11-39\) have also investigated the impact of very low nicotine cigarettes (VLNCs), which are generally defined as having around 0.4mg or less nicotine per gram of tobacco or per cigarette. Overall, this work has concluded that most people who smoke and who are provided with VLNCs find these cigarettes unrewarding. As a result, study participants often cut down on the number of cigarettes per day, have similar or lower biomarkers of exposure to toxins, experience fewer withdrawal effects, make more quit attempts and become more likely to quit successfully (see elsewhere\(^40\) for a recent review of these issues).

Modelling studies also suggest that a mandated VLNC policy would result in substantial reductions in smoking prevalence and gains in population health.\(^41-42\) A historical modelling study has also estimated that, had the tobacco industry introduced VLNCs when the health effects of smoking were established in the 1960s, millions of lives would have been saved.\(^43\)

The VLNC/denicotinisation approach aligns with the findings of a government inquiry in 2010 by the Māori Affairs Committee, which recommended reducing the additives and nicotine in tobacco to help achieve the proposed Smokefree 2025 goal (recommendation 9).\(^44\) This approach has public support. For example, 80% of respondents in a recent New Zealand survey of people who smoke, or who have recently quit (n=1,090, including 363 Māori), supported mandated VLNCs, provided alternative nicotine products were available.\(^45\) In the next wave of this survey (n=1,020, including 394 Māori), 73% of respondents supported this proposed policy.\(^46\) International studies have also reported very strong support for this policy.\(^47,48\)

Given this support and earlier calls for VLNCs, we modelled the likely impact of denicotinisation to inform the New Zealand Government’s upcoming decision-making.

Methods

Base case analysis assumptions

We assumed the following steps and input parameters for the analysis of our base case (considered most likely):

1. Consultation and deliberation via parliamentary processes (eg, select committee) on the proposed denicotinisation law was assumed to occur in late 2021. In 2021 and 2022, the business-as-usual (BAU) downward trends in smoking prevalence for all groups would be as per the average trend for the eight-year period between 2011/2012 and 2019/2020.\(^49\) For the more recently collected data on vaping in the NZHS (ie, daily e-cigarette use), we used the pattern between 2018/2019 and 2019/2020 (NZHS data)\(^50\) for the BAU trend. The European/Other ethnic grouping includes all New Zealanders who are not Māori, Pacific peoples or Asian peoples in the NZHS data.

2. The denicotinisation law was assumed to pass in 2022 with an imple-
3. We assumed that in 2023 and each subsequent year the initiation of smoking in the 18–24-year-old age-group would reduce by 75% (due to the non-addictive nature of the denicotinised tobacco). Thus, in each year there would be a reduction of around 6,500 smokers (one seventh of the 61,000 smokers in this age-group multiplied by 75%; NZHS data for 2019/2020). Although this 75% value is very uncertain, we considered it reasonable, given what is known about VLNCs (see the introduction, above). However, we note others have estimated a lower value of 50%, which we use in Scenario 1. We did not estimate the proportion that would have taken up vaping instead.

4. We assumed that 33% of smokers would quit in 2023, as per the New Zealand trial data for such products (more specifically, in a trial of 1,410 people, 33% had quit at six months with no reported difference in impact between Māori and non-Māori). The remaining 67% were assumed to continue smoking, using either denicotinised tobacco or regular tobacco (obtained via illicit supply or via home-grown tobacco for personal use, which is legal in New Zealand). Those who would quit were assumed to become either quitters or vapers as per the ratios identified in the EASE-ITC Study (preliminary data were supplied by the principal investigator of this study). Respondents in this study answered the following question: “Which one of the following would you be most likely to do if the amount of nicotine in cigarettes was greatly reduced so that they are no longer addictive?” Response options included: “quit smoking entirely” (13.5% of respondents; a mix of smokers and recent quitters gave this answer) and “switch to vaping/e-cigarettes” (13.2% gave this answer). We assumed there would be no major reductions in the accessibility of vaping products in the time-period studied.

5. We assumed that there would be the same impact in 2024 and 2025 as there would be in 2023 (ie, 33% of smokers using denicotinised tobacco would quit per year). We assumed that this relatively high rate of quitting would be sustained due to the non-addictive nature of the denicotinised tobacco product and the growing denormalisation of smoking as additional tobacco control measures described in the action plan for a smokefree Aotearoa are implemented.

Assumptions for the Scenario 1 analysis (alternative parameters)

As an alternative approach, we considered expert knowledge elicitation work by Apelberg et al, which has also been used in other modelling work examining denicotinisation in the US. Apelberg et al gave the following values when using the 50th percentile estimates from the elicitation exercise (though we have averaged the values for male and female smokers):

In the first year, when only denicotinised cigarettes were permitted on the New Zealand market (the year 2023, as per above):

- 50% reduction in initiation (in contrast to the 75% we used in the base case)
- 20% of smokers quit and do not switch products (ie, end use of nicotine completely)
- 37.5% of smokers quit and switch to non-combustible tobacco products (we assumed these products would be e-cigarettes in New Zealand)

In the second year and each subsequent year up to and including 2025, the respective values were:

- 50% reduction in initiation
- 14.3% quit
- 38.3% switch (to vaping as per the first year detailed above)
Assumptions for the Scenario 2 analysis (extra campaign/Quitline support)

We also considered the impact of promoting cessation via mass media, as well as Quitline support, to the base case's denicotinisation intervention. The impact of New Zealand's Quitline has been well established via multiple studies (including randomised trials) and via a detailed New Zealand modelling study that included media campaign impacts.\textsuperscript{52} We used the results from this modelling study to consider the impact of doubling mass-media campaign expenditure with Quitline support (a “campaign/service” package). That is, in normal times, the routine campaign/Quitline support (taking Māori men and women combined) accounted for 1.055% of the estimated 4.2% background net cessation rate (a 25.1% contribution (1.055/4.2) in the 35–54-year-old age-group (see in the publication by Nghiem et al\textsuperscript{52}: Table 2 for the 1.055% value and Table A2 for the 4.2% value in the main text and Supplementary file respectively). The equivalent proportion from this package for non-Māori was 21.2%. We then applied these two proportions to enhancing the cessation rate associated with denicotinisation. In other words, this extra intervention package was assumed to increase the annual cessation rate from 33% (for denicotinisation as per Walker et al\textsuperscript{31}) to 41% for Māori and from 33% to 40% for European/Other.

The results for the base case and scenario analyses were generated in an Excel spreadsheet, which is available on reasonable request from any of the six authors.

Results

Estimates for the modelled base case and scenario analyses are detailed in Table 1 and Figures 1–3. In the base case and both scenarios there were major reductions in smoking prevalence for both Māori and European/Other compared to the BAU projection. If achieving the Smokefree 2025 goal is assumed to involve adult daily smoking prevalences of under 5%, then Scenario 1 would achieve the goal for both Māori and European/Other (prevalences at 2.5% and 0.9% respectively in 2025). However, the estimates for Māori in the base case (7.7% in 2025) and Scenario 2 (5.2% in 2025) do not realise the Smokefree 2025 goal. Vaping was estimated to increase to 7.9% (in 2025) in the base case and to 10.7% (in 2025) in Scenario 1 (Table 1, Figure 3).

Discussion

Main findings and interpretation

These preliminary high-level modelling results suggest that a tobacco denicotinisation law could come close to achieving, or potentially achieve, the New Zealand Government's Smokefree 2025 goal. However, to be more certain about achieving the goal for Māori, denicotinisation would probably need to be supplemented with mass-media campaigns and enhanced Quitline support that goes beyond doubling of the current level (as per Scenario 2). Targeting these campaigns to Māori audiences could build on the success of “by Māori, for Māori” campaigns in the past (eg, the It’s About Whānau campaign\textsuperscript{53,54}). The addition of other complementary strategies, as outlined in the discussion document,\textsuperscript{8} could also increase the likelihood that the prevalence of smoking falls below 5% among Māori.

However, a partial consequence of these potential outcomes following denicotinisation would probably be a rise in vaping prevalence (as per Figure 3). Vaping still typically involves nicotine addiction, ongoing costs to users and potential long-term harms to health, which are likely to be higher than previously thought.\textsuperscript{55,56} Nevertheless, our estimates of vaping prevalence may be over-stated if ex-smokers who vape were to subsequently quit vaping at higher levels than seen to date. On the other hand, our estimates do not consider a potential increase in the uptake of vaping among those who won't initiate smoking because denicotinised tobacco is non-addictive.

We must emphasise the uncertainty of these high-level modelling results, given the incomplete international experience on the effects of denicotinising a country’s entire tobacco supply. Therefore, these results should be considered preliminary until more sophisticated modelling analyses are performed (eg, similar to the much more elaborate tobacco-control modelling studies...
Table 1: Estimated daily smoking and daily vaping prevalences (%) for BAU projection and the base case model and for two scenario analyses as a result of a tobacco denicotinisation policy (in New Zealand adults aged 15+ years, mid-year estimates).

<table>
<thead>
<tr>
<th>Population group</th>
<th>Years up to, and including, the Smokefree 2025 goal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020*</td>
</tr>
<tr>
<td>BAU</td>
<td></td>
</tr>
<tr>
<td>Māori smoking</td>
<td>28.7</td>
</tr>
<tr>
<td>European/Other smoking</td>
<td>10.1</td>
</tr>
<tr>
<td>Base case intervention (denicotinisation)</td>
<td></td>
</tr>
<tr>
<td>Māori smoking</td>
<td>28.7</td>
</tr>
<tr>
<td>European/Other smoking</td>
<td>10.1</td>
</tr>
<tr>
<td>Total population** smoking</td>
<td>11.1</td>
</tr>
<tr>
<td>Total population vaping</td>
<td>3.5</td>
</tr>
<tr>
<td>Scenario 1 (parameters based on expert elicitation work for the US by Apelberg et al51)</td>
<td></td>
</tr>
<tr>
<td>Māori smoking</td>
<td>28.7</td>
</tr>
<tr>
<td>European/Other smoking</td>
<td>10.1</td>
</tr>
<tr>
<td>Total population smoking</td>
<td>11.1</td>
</tr>
<tr>
<td>Total population vaping</td>
<td>3.5</td>
</tr>
<tr>
<td>Scenario 2 (adding to the base case by doubling mass media campaign/Quitline support)</td>
<td></td>
</tr>
<tr>
<td>Māori smoking</td>
<td>28.7</td>
</tr>
<tr>
<td>European/Other smoking</td>
<td>10.1</td>
</tr>
<tr>
<td>Total population smoking</td>
<td>11.1</td>
</tr>
<tr>
<td>Total population vaping</td>
<td>3.5</td>
</tr>
</tbody>
</table>

* New Zealand Health Survey data for 2019/2020.
** Technically, for the 2020 year these data were collected during 2019/2020 year with some data collection limited by the COVID-19 pandemic in early 2020.

** In addition to the ethnic groups detailed in this table, the total population in the New Zealand Health Survey also comprises Pacific peoples and Asian peoples.
Figure 1: Estimated daily smoking prevalence among Māori for the BAU projection and as a result of a tobacco denicotinisation policy (as per data in Table 1).

Figure 2: Estimated daily smoking prevalence among European/Other in the BAU projection and as a result of a tobacco denicotinisation policy (as per data in Table 1).
previously conducted in New Zealand). Such modelling is currently underway using a Python platform, and it will capture more epidemiologically precise details. It will also quantify impacts on QALYs saved, impact on health inequities (by ethnicity and potentially socioeconomic status) and savings in costs to the New Zealand health system. As such, it is similar to past tobacco\textsuperscript{5,7,52,57–60} and e-cigarette modelling\textsuperscript{61,62} by the BODE\textsuperscript{3} programme.

**Study strengths and limitations**

A strength of this modelling study is that it was relatively simple and therefore it was fairly quick to build the model and easy to check it. Also, we populated the model with detailed New Zealand smoking and vaping data, including a randomised control trial (RCT) using VLNCs conducted in the country. Nevertheless, the overall value of the modelling is limited owing to the constraints with external validation (ie, only clinical trial data) and not real-world, jurisdiction-level experience with denicotinisation.

More specifically, the 33% quit rate from this New Zealand RCT on VLNCs\textsuperscript{31} may underestimate the true impact of a denicotinisation intervention, as it was undertaken in a BAU context. That is, participants could easily access regular tobacco from thousands of retail outlets and via social sources, such as friends and family members. Furthermore, vaping products were not widely available when this trial was undertaken and, therefore, were not the viable alternative that they are in 2021. If only denicotinised tobacco were available, the only legal alternatives would be quitting, vaping or pharmaceutical-grade products (eg, nicotine gum and patches). On the other hand, we have assumed that, among the 33% of people estimated to quit, none would relapse (ie, subsequently use either illicit or home-grown tobacco). Also of note was that the New Zealand RCT by Walker et al\textsuperscript{31} involved people motivated to quit, given they had called the Quitline and were provided with free access to nicotine replacement therapy. Yet there is also evidence from a small pilot study in New Zealand (n=33 participants) that unmotivated smokers given denicotinised cigarettes (when priced according to nicotine content) experience reduced tobacco dependence and increased quitting activity.\textsuperscript{30}

Another limitation is that we did not model potential changes in the size of the illicit and home-grown markets following
a denicotinisation law coming into force. In terms of the current size of the illicit market, reviews have noted the limited number of independent (non-tobacco-industry funded) studies for New Zealand. Nevertheless, the most recent independent estimate from 2013 was that illicit products made up only 1.8–3.8% of the New Zealand market. Commentators have also suggested that any increase in illicit trade is likely to be modest and would not undermine the substantial positive effects of a denicotinisation policy in reducing smoking prevalence. Furthermore, New Zealand has very strong border controls and surveillance, which, coupled with its island status and relative geographical isolation, reduces the likelihood that smuggled tobacco would become a major problem (at least compared to European countries). Nonetheless, surveillance and enforcement should ideally be strengthened further during any period of enhanced tobacco control, as suggested in the government’s discussion document.

Also, given the difficulties of growing tobacco in much of New Zealand, it seems unlikely that supply via this source would be large. The long curing time and difficulties with mould growth in high-humidity environments are other impediments. Finally, the “roughness” of home-grown products that lack additives (eg, flavours and humectants) may not suit the taste of most New Zealand smokers, especially compared to vaping. Furthermore, the government could reduce the amount of tobacco that may be legally grown for personal use by home-growers, or even require home-growers to have a licence to grow (to allow for occasional spot checks and ensure compliance with the law).

Finally, our study did not include results for smoking and vaping among a range of other groups, including Pacific peoples, Asian peoples and groups with differing socioeconomic status. It also used a one-year modelling cycle and so does not capture more fine-grained monthly changes (eg, associated with increased quitting in advance of the new law being operationalised).

Conclusions

This preliminary high-level modelling suggests that policy-mandated denicotinisation could have a plausible chance of achieving the New Zealand Government’s Smokefree 2025 goal. The probability of success would further increase if it were supplemented with other interventions, such as mass-media campaigns and Quitline support (especially if it is predominantly designed for a Māori audience). Nevertheless, there is much uncertainty with these preliminary high-level results and more sophisticated modelling is needed to quantify impacts on QALYs saved and health inequities and to estimate savings in health costs.
Competing interests:
Nil.

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Variation in open access vildagliptin use in Waikato patients with type 2 diabetes

Lynne Chepulis, Christopher Mayo, Ryan Paul, Rawiri Keenan, Ross Lawrenson

ABSTRACT

AIM: To determine what the variation was in the initial use of vildagliptin in patients with type 2 diabetes following approval of open access funding in October 2018, including by ethnicity, gender, age, funding model and patient HbA1c levels.

METHODS: Data were collected from 31 general practices for all adult patients with type 2 diabetes. National Health Index-matched medication data were obtained from the national Pharmaceutical Collection. Patients were included for analysis if they had received at least one diabetes medication in the 12 months prior to funding approval for vildagliptin. The proportion of patients who initiated vildagliptin therapy following open access funding approval was then evaluated, as was the time taken until the first dispensing (days since funding approval).

RESULTS: A total of 724 of 3,971 (18.2%) of patients initiated vildagliptin therapy; mean time to first dispensing was 192.1±112.4 days. In logistic regression, Asian patients were more likely and Māori less likely to receive vildagliptin than Europeans. Younger patients and those with an HbA1c of >64mmol/mol were also more likely to initiate therapy. Vildagliptin use by general practice ranged from 0.0–82.4%

CONCLUSIONS: Despite open access funding, there was inequity in the initial use of vildagliptin. Substantial variation by general practice indicates that practitioner education may be needed to ensure appropriate and early adoption of new diabetes medications.

Diabetes currently affects more than 260,000 people in New Zealand, including a disproportionate number of Māori and Pacific people, with disease prevalence increasing year on year. Approximately 90–95% of these cases are type 2 diabetes, a disease characterised by insulin resistance and insulin deficiency and, in part, to reduced activity of incretin hormones. Importantly, poorly controlled type 2 diabetes is associated with significant micro- and macro-vascular damage such that cardiovascular disease is the greatest cause of mortality in this population.

Treatment of type 2 diabetes requires a multifaceted approach, including diet, exercise and medication. The goal of therapy is to lower glycated haemoglobin (HbA1c) levels to generally less than 53mmol/mol (or, where indicated, to an alternative target) and to reduce cardiovascular and renal risk factors. However, management of type 2 diabetes is often suboptimal, with recent data from the Waikato region suggesting that 60% and 32% of patients had an HbA1c value of greater than 53mmol/mol and 64mmol/mol, respectively. Similarly, only a third of patients with type 2 diabetes were shown to have blood pressure and/or lipids at or below clinically recommended targets, and up to three quarters of all patients were obese, with a body mass index >30kg/m². Concerningly, it was also shown that there was considerable ethnic inequity in diabetes outcomes, with Māori patients being significantly more likely to have elevated HbA1c and a greater prevalence of end-stage renal disease, diabetic eye disease, amputation and cardiovascular disease. Not only does this lead to increased healthcare costs, but more importantly an ongoing reduced quality of life for these patients.

Where lifestyle management is insufficient to manage type 2 diabetes, glycaemic control is typically achieved through a
stepwise escalation of glucose-lowering therapies. Metformin is the usual first-line oral glycaemic agent, with additional agents being added as required. Vildagliptin, a dipeptidyl peptidase IV inhibitor (DPPIVi) that lowers glucose levels by increasing the activity of endogenous incretins, was added to the funding schedule in New Zealand in October 2018. Prior to the long-awaited introduction of sodium-glucose transport protein 2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP1RA) this year, vildagliptin was the preferred second-line funded agent for patients with type 2 diabetes in New Zealand, as, unlike sulphonylureas, insulin and pioglitazone, it does not cause weight gain or hypoglycaemia. Moreover, vildagliptin is the only currently known agent that can delay the need for insulin therapy when taken in combination with metformin, and it has been shown to be a suitable glucose-lowering agent in patients with impaired renal function or established cardiovascular disease.

However, unlike SGLT2i and GLP1RA, no randomised controlled trials have demonstrated that DPPIVi reduces weight or cardiovascular events, such as myocardial infarctions or strokes. As such, SGLT2i and GLP1RA are now the preferred second-line agents for high-risk patients with type 2 diabetes, though PHARMAC has restricted the use of these medications under special authority, including an ethnicity clause to increase the uptake in Māori and Pacific peoples, which has resulted in significant debate. In particular, it is unknown whether needing to obtain special authority approval may increase disparities by adding a further barrier for those who already have reduced access to optimal medications in primary care.

Importantly, the impact of a special authority versus open access on medication use has never been explored in a New Zealand context, and the degree of variability seen with open access diabetes medications is largely unknown. Thus, the aim of this study was to determine the variability in open access vildagliptin use in patients with type 2 diabetes in the Waikato region. This was explored by evaluating the initial uptake and usage of vildagliptin (following funding approval in October 2018), including by patient age, gender, ethnicity and/or the affordability of access to primary care (ie, whether a practice was Very Low Cost Access (VLCA) or not).

**Methods**

**Study design**

This sub-study was part of a larger project assessing the quality of diabetes care in primary care in New Zealand (including diabetes medication prescribing and dispensing). The aim of this specific study was to characterise the initial use of vildagliptin in patients with type 2 diabetes in the 14-month period following PHARMAC’s approval of open access funding (October 2018). Ethics approval was granted by the New Zealand Health and Disability Ethics Committee (ref: 19/CEN/8).

**Data sources**

Primary care data were sourced directly from Hauraki Primary Healthcare Organisation (PHO; 17 practices), and then additionally from the electronic patient management systems of 14 general practices affiliated with Pinnacle PHO during September–December 2020.

National Health Index (NHI)-identified patient information was extracted for all patients who had a confirmed diagnosis (≥12 months) of diabetes (read code C10 (diabetes mellitus)) and were aged ≥18 years on 1 October 2017. Extracted data included age (at time of data collection), gender, ethnicity and HbA1c levels (1 October 2017–30 September 2018). Patient records were also checked against the Waikato District Health Board (WDHB) clinical records to retrieve missing demographic and diagnosis information and to exclude patients with confirmed type 1 diabetes. The latter were identified from the clinical register of the WDHB Regional Diabetes Service, where all had their disease confirmed by an endocrinologist as per standard international criteria. Additional NHI-matched HbA1c data were obtained from Pathlab New Zealand for the same time-period, and these were combined and then averaged to provide a mean value for each patient for the study period, which was then used for all analyses. Ethnicity was coded as Level 1 data as collated from the primary care and or WDHB datasets, with prioritisation to manage multiple ethnicities.
NHI-matched medication dispensing data were obtained from the Ministry of Health’s Pharmaceutical Collection database (1 October 2017–31 December 2019). This included the 12-month “pre-funding period” (to exclude any patients who were already receiving unfunded vildagliptin) and the 14-month “post-funding period” (to ascertain who had initiated vildagliptin therapy). An additional two months were included in the post-funding period to allow for any initial delays in general practitioner (GP) awareness of the new funding guidelines.28

Data processing
For inclusion in the data analysis, patients with type 2 diabetes had to have been dispensed a glucose-lowering therapy (oral hypoglycaemic agents and/or insulin) at least twice during the pre-funding period. This ensured that the dataset only included patients who were being actively treated with medication. Patients were then excluded from this sub-group if they had died between 1 October 2018 and 31 December 2019 (n=46), or if they had been dispensed unfunded vildagliptin at least once during the pre-funding period (n=14).

General practices were coded as “VLCA” or “non-VLCA” based on their published patient fee structures. HbA1c levels were categorised as <53mmol/mol (current glycaemic target),6,7 53–64mmol/mol (previous Ministry of Health target)8, 10 and >64mmol/mol.

Statistical analyses
Initially, the type 2 diabetes cohort was characterised for the 12-month pre-funding period, including by gender, age group, ethnicity, VLCA status and diabetes medication regimen. Initial vildagliptin use during the 14-month post-funding period (October 2018–December 2019) was then similarly described. The date of the first vildagliptin dispensing was recorded for each patient, and the cumulative uptake of vildagliptin (time to first dispensing) were plotted in a series of cox-regression plots by age, gender, VLCA status, ethnicity, medication adherence and HbA1c levels. Subgroup differences were analysed with chi-squared test, student t-tests and Mann-Whitney U tests.

A cross-sectional logistic regression adjusted for gender, age, ethnicity, rurality, VLCA and diabetes treatment regimen was used to estimate the odds ratio of a patient being dispensed vildagliptin during the post-funding period.

All data analyses were performed in Python 3.7 using the Pandas 0.25.3, Scipy 1.3.2 and Statsmodels 0.10.2 libraries with significance accepted at P<0.05.

Results
We identified a total of 4,031 patients with type 2 diabetes who had been dispensed diabetes medication ≥2 times during the pre-funding period. After excluding patient deaths (n=46) and unfunded-vildagliptin users (n=14), the final pre-funding study cohort consisted of 3,971 patients.

The demographics of the pre-funding type 2 diabetes cohort (n=3,971) are shown in Table 1, with the median age of participants being 64.5±12.8 years. Medication used included metformin monotherapy (37.4%), insulin (alone or in combination; 31.7%) and/or medication combinations. The mean HbA1c was 64.4±18.1mmol/mol, with 40% of patients having an HbA1c of >64mmol/mol (Table 1).

Use of vildagliptin during the 14-month post-funding approval
A total of 724/3,971 patients (18.2%) were dispensed vildagliptin at least once in the 14-month post-funding period (October 2018–December 2019). The mean HbA1c of these patients was 72.5±18.2mmol/mol compared to 62.6±17.6mmol/mol in those who did not initiate therapy (P<0.001). The characteristics of patients who started vildagliptin therapy are given in Table 1. Vildagliptin users were more likely to be younger, Asian or Pacific and have a higher HbA1c level (all P<0.001). Patients on more than one diabetes medication were more likely to be prescribed vildagliptin than patients on one medication (62.9% vs 45.8%, p<0.001), and there was no difference in use with regard to gender or the VLCA status of the practice. Overall, 79 of the 724 patients who initiated vildagliptin (12.2%) had a mean study HbA1c of <53mmol/mol, including 20 Asian (19.1%), 42 European (14.6%), nine Māori (5.0%), four Pacific (6.7%) and four Other (30.8%).

Initiation of vildagliptin therapy also varied considerably between general practices (Figure 1). The total proportion of type
2 diabetes patients within each practice who were dispensed vildagliptin at least once ranged from 0.0% to 82.4%. A small number of practices were shown to initiate vildagliptin therapy in a large proportion of patients, and four practices did not add vildagliptin to therapy at all (Figure 1).

As shown in Table 2, logistic regression with adjustment for age, gender, medication regimen, VLCA status and HbA1c level showed that there was no difference in initiation of vildagliptin therapy between European, Pacific or other ethnic groups, though vildagliptin was less likely to be dispensed to Māori patients (OR 0.67, 95% CI: 0.53–0.84; P=0.001) and more likely to be dispensed to Asian patients (OR 1.34, 95% CI: 1.02–1.78; p=0.039). Similarly, vildagliptin was less likely to be dispensed to those aged >74 years (OR 0.69, 95% CI: 0.52–0.90; P=0.007), those with an HbA1c of <64mmol/mol and those receiving insulin (OR 0.64, 95% CI: 0.43–0.99; P=0.043; Table 2). However, younger patients were more likely to have vildagliptin added to therapy, as were patients on combination therapy (metformin plus sulfonylureas) compared to those dispensed metformin monotherapy.

Cumulative uptake of vildagliptin (time to first dispensing)

The overall, unadjusted cumulative uptake of vildagliptin after October 2018 by ethnicity, VLCA status and HbA1c band is shown in Figure 2. Māori and European patients had a comparable uptake of vildagliptin during the 14-month post-funding period (P=0.08), and uptake for both was lower than for Asian, Pacific and other ethnic groups. VLCA practices were faster to initiate vildagliptin therapy (P=0.02), but the proportion of patients using the medication in VLCA and non-VLCA practices was comparable by December 2020 (approximately 400 days). Initiation of vildagliptin therapy did not differ between males and females but was slower in older patients (P<0.05). As expected, vildagliptin uptake was highest in those with an HbA1c of >64mmol/mol (P<0.01; Figure 1).

The mean overall time to first vildagliptin dispensing was 192.1±112.4 days, and nine of the 31 general practices (29%) had a mean time to vildagliptin use of less than 192.1 days (Table 2).

Discussion

**Figure 1:** Proportion of type 2 diabetes patients within each practice initiating vildagliptin therapy (October 2018–December 2019; blue bars) and mean time to initiation (orange line). Note that practices 28–31 had zero patients commencing vildagliptin therapy.
Table 1: Characteristics of the type 2 diabetes study population prior to vildagliptin funding (n=3,971) and then for those patients who initiated therapy after October 2018 (n=724).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall type 2 diabetes cohort&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Vildagliptin-initiation cohort&lt;sup&gt;2&lt;/sup&gt;</th>
<th>P value&lt;sup&gt;4&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>% of overall cohort</td>
<td></td>
</tr>
<tr>
<td>Age (mean ± SD) years</td>
<td>64.5±12.8</td>
<td>60.2±12.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age bands</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>&lt;44 y</td>
<td>284 (7.2%)</td>
<td>76 (10.5%)</td>
<td>&lt;0.001</td>
</tr>
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<td>45–59 y</td>
<td>1,048 (26.4%)</td>
<td>266 (36.7%)</td>
<td></td>
</tr>
<tr>
<td>60–74 y</td>
<td>1,751 (44.1%)</td>
<td>294 (40.6%)</td>
<td></td>
</tr>
<tr>
<td>≥75 y</td>
<td>888 (22.4%)</td>
<td>88 (12.2%)</td>
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</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2,090 (52.6%)</td>
<td>372 (51.4%)</td>
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<tr>
<td>Female</td>
<td>1,881 (47.4%)</td>
<td>352 (48.6%)</td>
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<td>VLCA status of practice</td>
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<td>Yes</td>
<td>2,874 (72.4%)</td>
<td>527 (72.8%)</td>
<td>0.818</td>
</tr>
<tr>
<td>No</td>
<td>1,097 (27.6%)</td>
<td>197 (27.2%)</td>
<td></td>
</tr>
<tr>
<td>Medication regimen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metformin only</td>
<td>1,485 (37.4%)</td>
<td>189 (26.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Metformin + sulfonylureas</td>
<td>948 (23.9%)</td>
<td>236 (32.6%)</td>
<td></td>
</tr>
<tr>
<td>Metformin + insulin</td>
<td>475 (12.0%)</td>
<td>94 (10.0%)</td>
<td></td>
</tr>
<tr>
<td>Metformin + insulin + Sulfonylureas</td>
<td>358 (9.0%)</td>
<td>82 (11.3%)</td>
<td></td>
</tr>
<tr>
<td>Insulin only</td>
<td>306 (7.7%)</td>
<td>38 (5.2%)</td>
<td></td>
</tr>
<tr>
<td>Sulfonylureas only</td>
<td>168 (4.2%)</td>
<td>27 (3.7%)</td>
<td></td>
</tr>
<tr>
<td>Other&lt;sup&gt;3&lt;/sup&gt;</td>
<td>161 (4.1%)</td>
<td>43 (5.9%)</td>
<td></td>
</tr>
<tr>
<td>No consistent regimen</td>
<td>70 (1.8%)</td>
<td>15 (2.1%)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>European</td>
<td>1,924 (48.5%)</td>
<td>319 (44.1%)</td>
<td></td>
</tr>
<tr>
<td>Māori</td>
<td>1,283 (32.3%)</td>
<td>212 (29.3%)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>464 (11.7%)</td>
<td>111 (15.3%)</td>
<td></td>
</tr>
<tr>
<td>Pacific peoples</td>
<td>250 (6.3%)</td>
<td>69 (9.5%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>50 (1.3%)</td>
<td>13 (1.8%)</td>
<td></td>
</tr>
<tr>
<td>HbA1c (mean ± SD) mmol/mol</td>
<td>64.4±18.1</td>
<td>72.5±18.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HbA1c banded</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&lt;53 mmol/mol</td>
<td>993 (28.7%)</td>
<td>79 (12.2%)</td>
<td></td>
</tr>
<tr>
<td>53–64 mmol/mol</td>
<td>1,067 (30.9%)</td>
<td>162 (25.0%)</td>
<td></td>
</tr>
<tr>
<td>&gt;64 mmol/mol</td>
<td>1,395 (40.4%)</td>
<td>407 (62.8%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>3,971</td>
<td>724</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup>Includes those patients with type 2 diabetes dispensed at least two diabetes medications between 1 October 2017 and 30 September 2018 and who were alive at 31 December 2019 and had no unfunded dispensing of vildagliptin.

<sup>2</sup>Includes those patients from the initial type 2 diabetes cohort dispensed vildagliptin at least once between 1 October 2018 and 30 December 2019.

<sup>3</sup>Includes Insulin (Ins) + Pioglitazone (Pio); n=93; Ins + Metformin (Met) + Sulfonylureas (Sulf) + Pio; n=27; Met + Sulf + Pio + Insulin (Ins; n=144); Met + Ins + Pio (n=9); Sulf + Pio (n=5), Met + Pio (n=8), Ins + Pio (n=2), Pio alone (n=2), Ins + Sulf + Pio (n=1).

<sup>4</sup>Statistical comparisons are provided for the vildagliptin initiation cohort, comparing within each subgroup (age, gender, ethnicity, etc.).
Table 2: Odds ratio (with 95% confidence intervals)\(^1\) of patients initiating vildagliptin therapy.

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>P value</th>
<th>95% confidence interval [0.025</th>
<th>0.975]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethnicity (vs European)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>1.34</td>
<td>0.039</td>
<td>1.02</td>
<td>1.78</td>
</tr>
<tr>
<td>Māori</td>
<td>0.67</td>
<td>0.001</td>
<td>0.53</td>
<td>0.84</td>
</tr>
<tr>
<td>Pacific peoples</td>
<td>1.25</td>
<td>0.212</td>
<td>0.88</td>
<td>1.78</td>
</tr>
<tr>
<td>Other</td>
<td>1.74</td>
<td>0.113</td>
<td>0.88</td>
<td>3.45</td>
</tr>
<tr>
<td><strong>Age (vs 60–74 years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤44</td>
<td>1.51</td>
<td>0.012</td>
<td>1.09</td>
<td>2.10</td>
</tr>
<tr>
<td>45–59</td>
<td>1.41</td>
<td>0.001</td>
<td>1.14</td>
<td>1.74</td>
</tr>
<tr>
<td>≥75</td>
<td>0.69</td>
<td>0.007</td>
<td>0.52</td>
<td>0.90</td>
</tr>
<tr>
<td><strong>Medication regimen (vs metformin only)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>0.64</td>
<td>0.043</td>
<td>0.425</td>
<td>0.986</td>
</tr>
<tr>
<td>Metformin + insulin</td>
<td>0.88</td>
<td>0.418</td>
<td>0.63</td>
<td>1.20</td>
</tr>
<tr>
<td>Metformin + insulin + sulfonylureas</td>
<td>1.01</td>
<td>0.953</td>
<td>0.72</td>
<td>1.41</td>
</tr>
<tr>
<td>Metformin + sulfonylureas</td>
<td>1.68</td>
<td>&lt;0.001</td>
<td>1.32</td>
<td>2.14</td>
</tr>
<tr>
<td>Others</td>
<td>1.34</td>
<td>0.075</td>
<td>0.97</td>
<td>1.85</td>
</tr>
<tr>
<td><strong>HbA1c (vs &gt;64mmol/mol)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 53mmol/mol</td>
<td>0.22</td>
<td>&lt;0.001</td>
<td>0.16</td>
<td>0.29</td>
</tr>
<tr>
<td>53–64 mmol/mol</td>
<td>0.43</td>
<td>&lt;0.001</td>
<td>0.34</td>
<td>0.54</td>
</tr>
<tr>
<td><strong>VLCA (vs non-VLCA)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (vs male)</td>
<td>0.95</td>
<td>0.627</td>
<td>0.74</td>
<td>1.15</td>
</tr>
</tbody>
</table>

\(^1\) Derived from a binomial multivariate logistic regression model with all variables included.
Figure 2: Mean time to first dispensing (with 95% confidence intervals) of vildagliptin following PHARMAC's approval of open access funding in October 2018 (A) by ethnicity, (B) by VLCA status and (C) by HbA1c group (mmol/mol).
Our study shows that initiation and/or early use of vildagliptin was associated with inequity in patients with type 2 diabetes in the Waikato region, with Māori being less likely to receive the medication after adjustment for age, gender, HbA1c level and VLCA status. This agrees with other studies that have shown that Māori are less likely to be dispensed oral diabetes medications,28–31 with many researchers suggesting that this is due to Māori being less engaged with primary care.32,33 The barriers for Māori accessing primary care (and healthcare in general) are well recognised in New Zealand,34–36 and a recent report shows that access to medications has not improved for Māori in recent years.37 It is clear that substantially more work is required to provide equitable access to health services in New Zealand.38–40

One way to improve access is by making primary care affordable for those in need,38 For example, the VLCA scheme initiated in 2002 provides additional funding (and subsequently lower patient fees) to general practices where at least 50% of the enrolled patients are deemed “high needs”.39,40 Indeed, we show that the mean time to the first dispensing of vildagliptin was lower in VLCA compared to non-VLCA practices, suggesting that that the lower costs associated with these practices may result in a faster uptake of new medications because of increased access to primary care (though there was no difference in the proportion of patients initiating therapy after 12 months). However, our study also showed that the VLCA status of the practice did not influence the proportion of patients with type 2 diabetes who initiated vildagliptin therapy during the 14-month post-funding period. Rather, we demonstrate that the practice (and therefore the GPs themselves) may be one of the most important factors that contribute to variability in initiation of therapy. Similarly, other studies have reported on the substantial variations seen in diabetes medication prescribing in primary care (particularly in the use of second-line medications),41–43 and it has been suggested that this may be due to changes in, and/or lack of ease of use of, national policies and prescribing guidelines,42 as well as differences in clinician-specific and environmental factors.43

Education has also been identified as a significant factor to consider when evaluating the initiation and update of newly approved medications. Primary care guidelines may change, for example, but doctors are often reluctant to immediately implement these changes; they cite reasons such as lack of evidence, organisational constraints, lack of knowledge about the guideline recommendations44 and the uniqueness of individual cases as reasons.45 Further, updated and/or new data are often not available via a central resource. Indeed, during the study period, the national guidelines on the management of type 2 diabetes were not updated to include vildagliptin,46 and other resources, such as those published by the Best Practice Advocacy Centre (BPAC)47 and the New Zealand Society for the Study of Diabetes,48 may not have reached all prescribers.5,17,18,49 Collectively, these issues cause discontinuity and variation in disease management, and this is congruent with our finding that the proportion of patients who initiated vildagliptin by practice varied from 0.0% to 82.4%.

Importantly, our study showed that, while the time to initiation of vildagliptin therapy was comparable for Māori and European, Māori were less likely to have vildagliptin dispensed. This has impact for the funding and access models used for the provision of other new medications in New Zealand: in particular, whether the ethnicity clause of the special authority criteria for SGLT2i and GLP1RA reduces the disparities in access to glucose-lowering therapies in Aotearoa New Zealand.49 Although the full impact of the special authority criteria will not be known for some time, the data from the current study suggest that inter-practice variability in prescribing may be a significant contributor to medication use over and above whether a medication is available open access or via special authority, and it could be that GP education is required to increase new medication use for Māori patients.

Our study is the first to review the initiation and use of funded vildagliptin in a New Zealand population, though we do note the following study limitations. Firstly, we reviewed the use of vildagliptin without any assessment of whether the medication was clinically indicated. For inclusion in our
study, patients with type 2 diabetes needed to have been receiving oral hypoglycaemic therapy, but it is possible that some of these had already met their individual clinical targets and thus did not require escalation of therapy. Indeed, 12.2% of those who initiated vildagliptin in our study had a most recent HbA1c of <53mmol/mol. Further, we did not include patients who had an HbA1c of >53mmol/mol and were not taking any glucose-lowering therapies for legitimate reasons. Thus, further work is required to evaluate the uptake and use of this drug in patients who meet the clinical threshold for use.

Secondly, our study involved only those patients dispensed two or more medications during the study period—that is, patients indicated as already accessing and/or engaging with primary healthcare. Our dataset excluded 1,118 patients who did not meet this criterion, but we do not know the reasons behind why patients had <2 dispensings (eg, it was not clinically indicated, the patient was newly diagnosed and/or the patient had not visited their GP). This warrants further investigation, as at least some of these patients would likely benefit from the use of glucose-lowering therapies.

Our study was also restricted to only those practices in the Waikato region affiliated with two specific PHOs; we had no information about whether patients had moved out of region or changed PHOs during the study period. The inclusion of additional practices, particularly those from the National Hauora Coalition (NHC; the third PHO in the Waikato region) may have altered our findings because of the inclusion of Māori-led healthcare providers. As nearly a third of all patients who initiated vildagliptin in our study were Māori, we suggest that our study was not skewed by a lack of inclusion of NHC patient data. However, we do acknowledge that the Māori-led healthcare providers may have been more proactive at prescribing medication to Māori patients, and where possible these data should be included in future evaluations.

Fourth, our patient cohort was also largely defined using primary care read codes, which can be inaccurate. It is possible that the accuracy of these data may be different for different patient groups (eg, by ethnicity, VLCA status, etc) and the reliability of using read codes to define patient diagnoses should be validated before larger studies are undertaken.

Fifth, although our results preliminarily suggest that dispensing of vildagliptin is not reduced in Pacific patients compared to European, we must note that our cohort study was not powered appropriately to assess this outcome. As such, we suggest that further studies comprising larger numbers of Pacific type 2 diabetes patients are warranted. And lastly, it is possible that practice-level factors (eg, nurse-led clinics and/or onsite pharmacists) might influence the usage and uptake of new agents. This too should be evaluated in future studies.

In conclusion, there appears to be inequity in the initial uptake and use of open access vildagliptin in the Waikato region.

**Authorship credit**

LC, RL, RK and RP all contributed to the conception and design of the study, as well as interpretation of data. LC collected the data and CM analysed it. LC, CM, RP and RL drafted the article for publication. All authors revised it for critically important intellectual content. All authors give their approval for publication.
Competing interests:
Nil.

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URL:

REFERENCES


The term “mental health crisis” was originally defined as an emergency that poses a direct and immediate threat to an individual's emotional well-being. The definition has been expanded to refer to problems in community mental health and in mental health services (MHS) as a whole. A mental health crisis has been widely used to describe the state of New Zealand's mental health. For example, recent headlines include “New Zealand mental health crisis as Covid stretches a struggling system”¹ and “New Zealand mental health crisis has worsened under Labour, data shows,”² suggesting deteriorating mental health in the population and an overwhelmed health system.

This paper sets out to test the veracity of these headlines. First, we will present data on whether rates of mental distress and the use of services are increasing in New Zealand. Second, we will consider the mental health system's response to evaluate whether it has been effective. Third, we will consider where the limited available resources could most effectively be used.

We conclude that New Zealand’s mental health planning is heading in the wrong direction by directing resources and thus services away from people with serious mental illness who are often affected by social exclusion and deprivation. The current government's plans, yet to be implemented, will expand psychotherapy to the “middle class,” an approach labelled as the “Big Community.”³ Evidence from both the UK and Australia indicates that such initiatives might not reduce population distress in New Zealand, as intended. Instead of spending on programmes for moderate psychological distress, we suggest that the limited resources available for mental health should be carefully targeted towards those with serious mental illness, using integrated services located in areas with the highest levels of deprivation, which is often determined by ethnic, cultural and historical factors.

Is there a mental health crisis?

Two major approaches have been used to measure mental health (or illness) in New Zealand. The first is to study service use. Publicly available MHS data lag behind the headlines about the ongoing impact of the COVID-19 pandemic. The latest data are from 2017/18 and published in 2021.⁴ The figures may not be directly comparable to previous reports due to increasing non-government organisations reporting, resulting in some inflation of numbers. Nevertheless, the figures are the most accurate guide available. They show that increasing numbers of New Zealanders have been accessing MHS over the past decade. In 2017/18, 181,924 patients were seen by mental health and addiction services. The rate of increase since 2008/9 in non-Māori is 47% (1,931.5 to 2,840 per 100,000) and in Māori it’s 26% (4,119.7 to 5,201.2 per 100,000), the latter from a higher base rate. Anecdotally, it appears that the rate of increase has continued to rise since these figures were published. There is also significant pressure and significantly increasing demand for acute mental health beds, despite increased service provision in primary care and the community.

Roger T Mulder, Tarun Bastiampillai, Anthony Jorm, Stephen Allison

New Zealand’s mental health crisis, He Ara Oranga and the future
The second approach to measure mental health is the use of population surveys. We are fortunate in New Zealand to have the NZ Health Survey, an annual health survey performed in a random general population and which includes measures of mental health. The measure most sensitive to change in psychological distress is assessed using the K10 scale. The survey publishes the percentage with a very high probability of depressive or anxiety disorder, that is, a K10 score of 12 or higher. This percentage has steadily grown from 4.5% in 2011/12 to 8.6% in 2017/18. However, the rates now appear to have stabilised at 7.4% in 2019/20. Rates of diagnosed mental disorder, such as major depression and anxiety, have also stabilised over the past four surveys following steady increases between 2011/12 and 2016/17. Rates of hazardous or heavy drinking have also been stable since they were first measured in 2015/16.

A further plausible measure of mental health is the suicide rate. The latest data from the Office of the Chief Coroner reported that 654 people had died by suicide in the year July 2019 to June 2020, which equates to 13 deaths/100,000, a decrease from both the 2017/18 (13.7 deaths/100,000) and 2018/19 (13.9 deaths/100,000) figures.

We should also consider the World Happiness Report conducted by Gallup. In this report, New Zealand ranks highly on wellbeing, having come ninth out of 149 countries on overall happiness measures (average life evaluation) in 2020. This is similar to its ranking and overall score between 2017 and 2019, in which New Zealand ranked eighth.

So, what has been happening to MHS funding? Like most high-income countries, spending has increased; in New Zealand, mental health funding rose from NZD 1.1 billion in 2008/09 to 1.4 billion in 2015/16. The number of psychiatrists and psychologists almost doubled from 2005 to 2015. More people are taking psychotropic medications than ever before. In 2015, PHARMAC data reported that 13.7% of New Zealanders have been dispensed antidepressants and 3.1% antipsychotics. Both rates have increased by more than 50% over the prior decade. However, over this same period, psychological distress was worsening rather than improving. It seems that increasing resources was not accompanied by any evidence of improved mental health at a New Zealand-wide level. We can derive some comfort from the fact that most high-income countries report similar findings. A recent review by Jorm et al noted that the prevalence of mood and anxiety disorders has not decreased in Australia, Canada, England or the USA, despite substantial increases in the provision of treatment in the four countries.

We therefore have a somewhat mixed picture before the COVID-19 pandemic. The use of MHS appeared to be increasing while the community rates of psychological distress had been levelling off after a major increase in the first half of the last decade. Overall happiness and life satisfaction measures have been stable since the beginning of 2010. It’s hardly good news. But it’s also inaccurate to say there’s a “mental health crisis” in New Zealand. The major crisis, if there is one, may be in gaining access to MHS, which are having to manage increasing numbers of patients. This is consistent with international epidemiological research pointing to a high, but relatively stable, incidence and prevalence of mental disorder, coupled with evidence that more and more people are using MHS and consuming psychotropic medication.

Although we may not have a mental health crisis in the traditional sense of increasing rates of psychological distress, mental disorders and suicide, we do have a crisis in the sense that demand for MHS is increasing and that the expansion of those services and treatments is not leading to improvements in mental health at a community level. To add to the confusion, we have experienced a major epidemic in the past year. The impact of COVID-19 on mental health is not yet clear. New Zealand is relatively unique in that the impact and experience of COVID-19 is around a brief strict lockdown and the post-lockdown economic effects rather than the direct effects of the virus. Early evidence suggests a significant proportion of the population was adversely affected by the lockdown—particularly young people. However, our experience may be very different from those countries where the direct effect of the virus was much greater.
The He Ara Oranga Report

Partly in response to the perceived mental health crisis, the New Zealand government set up a commission that produced the He Ara Oranga (HAO) Report in 2018. The government, in response to the HAO Report, announced a $1.9 billion mental health package in their Wellbeing Budget. The report correctly recognised that doing more of the same was not a good strategy, given the evidence discussed above.

The HAO Report suggested two major ways to improve New Zealanders' mental health. The first, which could be seen as a preventative strategy, is based on individual psychological therapies like Cognitive Behavioural Therapy. This “Big Community” policy seeks to extend psychological treatment to those suffering psychological distress so that around 6.5% of the population (325,000 people per annum) with mild to moderate anxiety and depression will receive an intervention (Wellbeing Budget 2019).

In our view, there are two major flaws in this strategy. The first is how it would be organised and funded. It would be difficult, perhaps impossible, to train sufficient staff to implement such a programme. At the current rate of training psychologists and counsellors, it is estimated that it will be more than a decade before the workforce is sufficient to meet the current need. In addition, at present only a small proportion of those diagnosed with a mental disorder actually receive psychological treatment—so why would (or should) less severe individuals be prioritised?

The second flaw is that similar, albeit less ambitious, programmes have been initiated in Australia (Better Access; 4.7% population coverage) and the UK (Improving Access to Psychological Therapies: IAPT; 1.5% population coverage) and the results are not encouraging. In Australia, a recent review reported no impact on population mental health outcomes or suicide rates, and the introduction of IAPT in the UK has not been associated with a reduced prevalence of common mental disorders (based on the Adult Psychiatry Morbidity Survey). On the contrary, these disorders have continued to increase. Given this evidence, we are concerned that there appears to be no systematic plan to assess the efficacy of the proposed psychotherapy programme.

The second major strategy in the HAO Report recommends a decisive shift from Big Psychiatry to a new sector called “Big Community.” This sounds good, that is, moving away from a medically led system where “most resources are used for psychiatric treatments, clinics and hospitals” and which the HAO Report labelled as having a colonising world view with a legacy of paternalism and human rights breaches. In contrast, the HAO Report praised Big Community as having a strong commitment to partnership, recovery, spirituality and human rights. This is all very well as far as it goes but runs into a major flaw: “big” psychiatry in New Zealand is actually rather small. For the latest available country data between the years 2016 and 2020, New Zealand was ranked 32nd out of 38 OECD countries for the number of hospital psychiatric beds. New Zealand reported 32 psychiatric beds per 100,000 population in 2020 while the OECD average was double that at 65. Moving resources from struggling, already under-resourced, public MHS into the community appears a dangerous and an inequitable strategy. We appear to have forgotten that the hospital component of a community health is an essential part of good and balanced practice. In addition, we do not appear to have well-resourced community facilities. A recent global report notes that New Zealand, as well as having very low bed numbers, also has the lowest number of community care facilities of all countries surveyed. Overall, it would have been more accurate for the HAO Report to have used the term “Small Psychiatry,” which would have helped explain the problems facing the public sector.

Possible responses

1. Serious mental illness: The risk of following the HAO Report is that we may establish widespread inverse care by tailoring health services for the mild and moderately ill and increasingly neglecting the most severely and chronically ill patients, as has occurred in other English-speaking countries, particularly the USA. Rather than focussing on reducing Big
Psychiatry, we suggest that the government increases resources for it and tries to raise psychiatry bed numbers from the current 32 beds per 10,000 to at least 50 beds per 100,000 (OECD average is 65 beds per 100,000).22,23 This is where there is the most need and where those who suffer deprivation are likely to seek help.

To better identify, follow-up and assess treatment outcomes among people with serious mental illness, we suggest that New Zealand is an ideal location for a mental health registry. A useful first step would be to link health datasets between primary, secondary and tertiary mental healthcare to enable mental health service researchers to evaluate the cost–benefit of new policies and investments in reducing hospital demand and improving overall mental health related outcomes. A more comprehensive mental health registry would also link social and non-health related datasets (education, unemployment, housing, corrections) with healthcare datasets at the individual level. This would enable a more comprehensive understanding of the likely bi-directional impact between social and non-health-related policy changes and mental health service utilisation (primary, secondary, tertiary) and outcomes (psychological distress, suicide, etc). Careful consideration of privacy issues would need to be part of database setup. A specific example that New Zealand should consider adopting is the national Danish Schizophrenia Registry, which was first established in 2003 and covers all patients diagnosed with schizophrenia who are receiving mental health care in psychiatric hospitals or outpatient clinics.24 The Danish Schizophrenia Registry contains 21 clinical quality measure in relation to the following domains: diagnostic evaluation, antipsychotic treatment including adverse reactions, cardiovascular risk factors including laboratory values, family intervention, psychoeducation, post-discharge mental healthcare, assessment of suicide risk in relation to discharge and assessment of global functioning.24 This registry also links its data with other national non-health related datasets. The Danish Schizophrenia Registry has been an invaluable tool for clinicians, researchers and policymakers helping to understand and improve the quality of care for this important patient cohort.24

In conjunction with setting up national mental health registries, consideration should also be given to setting up national mental health service evaluation and research units to analyse the effectiveness of government policy changes and investments. We suggest that approximately 2–3% of existing and new investments in mental health should be allocated to mental health service research and registry investment. Such investment will ensure that new programmes are fully evaluated before endorsing and implementing these measures nationwide.

2. Population distress: In terms of New Zealand’s levels of population distress, rather than reducing Big Psychiatry and offering therapy to all, an alternative strategy is to target resources towards individuals who suffer most from mental distress. Increasing international data has allowed more sophisticated ecological studies to show what factors are associated with psychological distress. These factors are consistent and not surprising: lower incomes, poor housing and unemployment (possibly better expressed as “deprivation”), as well as discrimination, neighbourhood safety, gender equality and corruption.25 None of these appear likely to respond to individual counselling.

New Zealand already has in place some important characteristics of mentally health nations, which we generally take for granted. Our quality of government, assessed using measures of freedom and perception of corruption, is high. Education, lifespan and gender equality are reasonable, albeit with obvious room for improvement.25 Income inequality has increased, but while it negatively affects mental health, the effect sizes are small and inconsistent.26 As we noted, New Zealand is highly ranked in the World Happiness Report.

However, we also have a significant section of the population that suffers from deprivation, and this group has much more psychological distress. Thus, we suggest that resources should be directed towards this group. Data from the New Zealand Health Survey show that those in the most deprived decile were around 30 times more
likely than those in the least deprived decile to report a K10 score suggesting clinical anxiety and depression.\textsuperscript{27} The suicide rates for the lowest quintile in 2016 were two to three times higher than the least deprived quintile.\textsuperscript{28} These groups are also much more likely to use mental health services; the latest Ministry of Health data on mental health service use report that the most deprived quintile in New Zealand is three to nine times more likely to use various MHS.\textsuperscript{29}

Since relying on healthcare alone to improve mental health outcomes can be expensive and inefficient, we advocate for integration with social services and practical help. We suggest, as have others,\textsuperscript{30} that areas associated with higher levels of deprivation should receive more targeted focus in terms of resources, prevention and management of serious mental illness. Specific programmes (particularly supported employment, which has a strong evidence base\textsuperscript{31}) could be resourced and evaluated. Providing quality care and education early in life and strengthening economic support to families is likely to be associated with fewer adverse childhood experiences.\textsuperscript{32}

E-therapies may be more practical and efficient for population groups who respond to individual psychological therapies. In recent reviews, e-therapy has appeared superior to no treatment or waitlist controls for patients with depression,\textsuperscript{33} generalised anxiety disorder, panic disorder and social anxiety disorder.\textsuperscript{34} Although the effect sizes are modest and tend to fade over time,\textsuperscript{35} this is similarly true for face-to-face therapies. This may be enhanced by using therapist guided e-therapies.

Conclusion

Although characterising New Zealand’s mental health as being in crisis may be overstating the evidence, there seems little doubt that significant changes in the conceptualisation and delivery of MHS are necessary. Based on the evidence, we suggest that the focus should be on deprivation and the severe mental illness. Rather than expand psychotherapy to middle class New Zealand and further reduce resources to those with serious mental illness, we advocate for better resourced MHS integrated with social services, such as supported employment, supported housing and early interventions. In addition, we suggest locating these integrated services in areas with higher levels of deprivation and that they consider ethnic, cultural and historical factors associated with deprivation. We also support specific investment in mental health registries integrated with service evaluation and policy research units, to ensure that new and existing mental health programme investment delivers better public mental health outcomes and also delivers value for money.
Competing interests:
Nil.

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Early childhood education staff are falling through a vaccination policy gap in New Zealand

Namrata Prasad, Nikki Turner, Sarah Alexander

ABSTRACT
The recent COVID-19 vaccine mandate among early childhood education (ECE) staff highlights the important role ECE staff have in the transmission of infectious diseases. However, there are no data on general vaccine uptake for this group in New Zealand. Additionally, the importance of ECE staff vaccination as a strategy to prevent illness has been rarely promoted in the past, and recommendations for other vaccinations in this group are lacking. Here we present a section of data accessed from an ECE-sector employment survey of more than 4,000 teaching staff, which inquired into the immunisation status of respondents. The data indicated that self-reported immunisation coverage for whooping cough, hepatitis A, and hepatitis B among ECE staff was approximately 50%. Self-reported immunisation status was higher for measles, mumps, rubella, and chickenpox in this group. The findings highlight the need for more comprehensive vaccination policy and research in ECE settings.

The Ministry of Education 2020 census count, for the last week of June 2020, showed that there were 190,348 children up to six years of age participating in early childhood education (ECE) in New Zealand, of whom approximately 18% were younger than two years of age. Over the same period, there were 30,476 teaching staff in teacher-led education and care centres such as kindergartens, or working as visiting teachers in home-based care arrangements. (Note that given the Ministry of Education’s definition of “teaching staff,” home-based carers and adults working in Playcentre and Nga Kōhanga Reo were not included in this number).

Evidence from several international studies suggest that non-parental group care is associated with an increased risk of communicable disease transmission and disease among children. This is also the case in New Zealand, where the Growing Up in New Zealand longitudinal study found that being in ECE at both nine months and two years of age was independently associated with a 1.5–2.5-times greater risk of ear infections, chest infections and gastrointestinal illnesses. The study also found that, compared to children not attending ECE, attendees experienced an increased risk of hospitalisation due to ear, chest, or gastrointestinal infection.

It is not possible for adults working in ECE to effectively social distance and avoid close contact with children. As such, both children and adults are at risk of acquiring and transmitting communicable diseases in an ECE setting. Moreover, many children in ECE are too young to be fully protected against vaccine-preventable diseases.

To manage these risks, the Health (Immunisation) Regulations 1995 has required all ECE services to keep an immunisation register of attending children. This is to promote and encourage informed choice for childhood immunisation uptake and to enable quick identification of the immunisation status of children, so unimmunised children can be asked to stay at home in the event of an outbreak. In contrast, no such regulations exist for adults working in group care—except that, from January 2022, all ECE services will need to maintain a COVID-19 vaccination register and ensure
only vaccinated staff and support people have contact with children. Additionally, Regulation 57 of the Education (Early Childhood Services) Regulations 2008 encourages ECE staff members to stay at home and seek medical advice when ill. However, no similar recommendation is made to staff regarding vaccination as a preventative strategy. Finally, although the New Zealand Immunisation Handbook (which provides clinical guidelines regarding vaccinations to health professionals) recommends that ECE staff be vaccinated against pertussis (whooping cough), polio, measles/mumps/rubella, varicella (chickenpox), hepatitis A, hepatitis B, and influenza (annually), we are not aware of any recommendations made directly to ECE staff to acquire these vaccines at the point of registration as a teacher and/or commencement of employment.

To our knowledge, there have been no previous investigations on vaccination coverage among ECE staff in New Zealand. In this paper, we present data on self-reported immunisation status from an ECE-sector survey.

Methods

Between late January and mid-February 2020, a survey of people employed by licensed ECE services in New Zealand was undertaken by The Office of Early Childhood Education (OECE). The purpose of the survey was to inform improvements within the sector by gaining information on a range of factors related to employment, wellbeing, and work environment. Teaching staff employed in any licensed ECE service, including those on sick or other leave, were surveyed. The sampling criteria therefore differed from the scope of the Ministry of Education annual census, which counts adults in teacher-led centres or home-based visiting teachers who have contact with children over a one-week period (June 22–28 for the 2020 census).

ECE staff were invited to participate in the survey via an email mailing list and social media channels. As respondents self-selected to participate, they were not necessarily representative of all those who have contact with children in services. Further details of the survey can be found on the OECE website.

Respondents were asked to indicate whether they were vaccinated against several well-known, vaccine-preventable infectious diseases, including measles/mumps/rubella, whooping cough, hepatitis A, and hepatitis B. They were also asked whether they had vaccination or previous infection from chickenpox. No information was sought on the number of doses of a vaccine. Respondents could choose to answer each disease-specific question item by ticking the response choices of “Yes,” “No,” or “Don’t know,” or by leaving the response blank. Chi-squared tests were used to compare the age distribution of survey respondents to the Ministry of Education 2020 census data for ECE teaching staff and to assess significant differences in self-reported vaccination status by age.

Results

Respondent characteristics

The ECE-sector employment survey was completed by a total of 4,021 ECE teaching staff, who account for approximately 13% of the total New Zealand ECE workforce, based on the Ministry of Education’s 2020 census data.

Table 1 shows the age distribution of the ECE-sector employment survey respondents compared to the Ministry of Education’s census data. The ECE-sector employment survey respondents included fewer ECE staff from the youngest and oldest age groups.

Respondent responses on vaccination

Table 2 shows that around half of respondents believed they were immunised against whooping cough (48%), hepatitis A (45%) and hepatitis B (46%). A higher proportion of staff reported they were immunised against measles, mumps, and rubella (85%) and believed they had immunity against chickenpox (82%).

 Twenty-one respondents (0.5%) chose not to answer the question. Of these, five commented that they objected to the question being asked, as they did not see it as relevant to their role as teachers:

• “What does this have to do with teaching?”
• “I don’t see this is a relevant question.”
Table 1: Age of survey respondents compared to the Ministry of Education’s 2020 census data for adults teaching in teacher-led services.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Survey respondents</th>
<th>Census data</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>(%) of total*</td>
<td>N</td>
</tr>
<tr>
<td>25 years and under</td>
<td>264</td>
<td>(6.6)</td>
<td>3,519</td>
</tr>
<tr>
<td>26–45 years</td>
<td>2,372</td>
<td>(59.0)</td>
<td>1,5620</td>
</tr>
<tr>
<td>46–65 years</td>
<td>1,340</td>
<td>(33.3)</td>
<td>9,648</td>
</tr>
<tr>
<td>66 years and over</td>
<td>44</td>
<td>(1.1)</td>
<td>1,450</td>
</tr>
<tr>
<td>Missing</td>
<td>50</td>
<td>-</td>
<td>14</td>
</tr>
</tbody>
</table>

*Excludes missing.

Table 2: Self-reported immunisation status among ECE teaching staff.

<table>
<thead>
<tr>
<th>Immunisation Status</th>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>(%)</td>
<td>N</td>
<td>(%)</td>
</tr>
<tr>
<td>Whooping cough (booster shot within the last 10 years)</td>
<td>1,878</td>
<td>(47.7)</td>
<td>1,267</td>
<td>(32.2)</td>
</tr>
<tr>
<td>Measles, mumps and rubella (MMR)</td>
<td>3,399</td>
<td>(85.1)</td>
<td>244</td>
<td>(6.1)</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>1,771</td>
<td>(45.1)</td>
<td>606</td>
<td>(15.4)</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>1,822</td>
<td>(46.4)</td>
<td>587</td>
<td>(15.0)</td>
</tr>
<tr>
<td>Chickenpox (vaccinated or had disease)</td>
<td>3,225</td>
<td>(81.5)</td>
<td>540</td>
<td>(13.6)</td>
</tr>
</tbody>
</table>
“Why is this even relevant??!!!!”
“None of your business.”
“Why?”

Three of the remaining respondents who did not answer vaccination questions offered the following comments:

“I don’t wish to answer.”
“Prefer not to answer.”
“Don’t wish to answer.”

There were differences in self-reported immunisation by age group. In general, younger ECE teaching staff were more likely to report immunisation against diseases than older staff (Table 3). Finally, we did not detect any differences in self-reported immunisation status by type of ECE service, such as between teaching staff in kindergartens and home-based visiting teachers.

Discussion and recommendations

The current survey provides useful insights into vaccination uptake among ECE staff. It also highlights key gaps in policy aimed at reducing the spread of vaccine-preventable diseases.

In this ECE-sector employment survey, only half of ECE staff reported vaccination for whooping cough (pertussis), hepatitis A, and hepatitis B. Self-reported immunisation status among ECE staff was higher for measles, mumps, rubella, and chickenpox. Additionally, we found self-reported vaccination to vary significantly by age, with younger ECE staff more likely to report being vaccinated compared to older aged staff. Finally, a small number of ECE teachers strongly disapproved of being asked about their immunisation status, as they considered this irrelevant to their work.

When comparing these survey findings to a similar study from Australia, we found self-reported vaccination uptake rates in Australia for whooping cough, hepatitis A, and hepatitis B to be considerably higher, at 73.3%, 73.4%, and 75.3% respectively. Australia appears to have more advocacy and attention, and stronger recommendations for ECE staff vaccination, which may explain their higher reported vaccine uptake. The Australian Government National Health and Medical Research Council has published guidelines, *Staying Healthy: preventing infectious diseases in early childhood education and care services,*12 that emphasise that “all education and care service staff should be advised of the potential consequences if they refuse reasonable requests for immunisation.” Such consequences include only being able to work with children aged over 12 months old; having to take antibiotics during outbreaks of bacterial diseases; and being excluded from work during vaccine-preventable disease outbreaks. The guidelines also recommend that ECE employers develop staff immunisation policies, develop and maintain staff immunisation records, and provide staff with information on vaccine-preventable diseases through in-service training and written material.

The key strength of the ECE-sector employment survey presented in this paper is its large number of respondents. However, it also has limitations that warrant attention. Firstly, it was not designed to be representative of all adults that have contact with children in ECE: for example, it did not include service owners who may have contact with children; volunteers, including students-in-training; or teaching staff who work as independent contractors. An additional limitation of the ECE-sector employment survey was that it relied on self-reported vaccination status and was therefore susceptible to social desirability bias, misclassification and recall bias, particularly in older age groups. The survey was also susceptible to selection bias towards individuals more (or less) interested in vaccination. However, as the survey focused on many aspects of ECE employment and respondents’ experiences of working in ECE, respondents were unlikely to have chosen to do the survey solely based on their interest in vaccination.

Despite these limitations, findings from this paper can act as a starting point for future work. Given the scale and impact of the 2019 measles outbreak, as well as SARS-CoV-2 community transmission in New Zealand, which has led to a COVID-19 vaccine mandate among ECE staff, understanding and improving vaccination awareness and vaccine uptake for other important infectious diseases among ECE staff in New Zealand needs to be a health priority.
Table 3: Self-reported immunisation status among ECE teaching staff by age group.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Yes N (%)</th>
<th>No N (%)</th>
<th>Don’t know N (%)</th>
<th>Total N</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Whooping cough (booster shot within the last 10 years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 years and under</td>
<td>164</td>
<td>35</td>
<td>65</td>
<td>264</td>
<td>Ref</td>
</tr>
<tr>
<td>26–45 years</td>
<td>1,211</td>
<td>672</td>
<td>460</td>
<td>2,343</td>
<td>0.001</td>
</tr>
<tr>
<td>46–65 years</td>
<td>480</td>
<td>548</td>
<td>261</td>
<td>1,289</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>66 years and over</td>
<td>22</td>
<td>12</td>
<td>5</td>
<td>39</td>
<td>0.494</td>
</tr>
<tr>
<td><strong>Measles, mumps, and rubella (MMR)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 years and under</td>
<td>235</td>
<td>11</td>
<td>18</td>
<td>264</td>
<td>Ref</td>
</tr>
<tr>
<td>26–45 years</td>
<td>2,102</td>
<td>97</td>
<td>165</td>
<td>2,364</td>
<td>0.962</td>
</tr>
<tr>
<td>46–65 years</td>
<td>1,029</td>
<td>132</td>
<td>163</td>
<td>1,324</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>66 years and over</td>
<td>32</td>
<td>4</td>
<td>6</td>
<td>42</td>
<td>0.021</td>
</tr>
<tr>
<td><strong>Hepatitis A</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 years and under</td>
<td>169</td>
<td>13</td>
<td>81</td>
<td>263</td>
<td>Ref</td>
</tr>
<tr>
<td>26–45 years</td>
<td>1,140</td>
<td>226</td>
<td>975</td>
<td>2,341</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>46–65 years</td>
<td>449</td>
<td>354</td>
<td>475</td>
<td>1,278</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>66 years and over</td>
<td>12</td>
<td>13</td>
<td>15</td>
<td>40</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Hepatitis B</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 years and under</td>
<td>170</td>
<td>14</td>
<td>78</td>
<td>262</td>
<td>Ref</td>
</tr>
<tr>
<td>26–45 years</td>
<td>1,182</td>
<td>221</td>
<td>939</td>
<td>2,342</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>46–65 years</td>
<td>458</td>
<td>342</td>
<td>481</td>
<td>1,281</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>66 years and over</td>
<td>11</td>
<td>10</td>
<td>16</td>
<td>37</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Chickenpox (vaccinated or had disease)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 years and under</td>
<td>229</td>
<td>19</td>
<td>16</td>
<td>264</td>
<td>Ref</td>
</tr>
<tr>
<td>26–45 years</td>
<td>1,947</td>
<td>304</td>
<td>91</td>
<td>2,342</td>
<td>0.1343</td>
</tr>
<tr>
<td>46–65 years</td>
<td>1,017</td>
<td>215</td>
<td>78</td>
<td>1,310</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>66 years and over</td>
<td>31</td>
<td>2</td>
<td>7</td>
<td>40</td>
<td>0.122</td>
</tr>
</tbody>
</table>
Firstly, the Ministry of Education and Ministry of Health should engage in more dialogue with ECE staff regarding the importance of vaccination. Secondly, steps should be taken to address current gaps in vaccination policy. The Ministry of Education has recently embarked on a review of the Education (Early Childhood Services) Regulations 2008 and the Ministry of Education’s licensing criteria that accompany the regulations, and it would be within the scope of its review to consider working with the Ministry of Health to draft a proposal to amend the Health (Immunisations) Regulations 1995 to require all ECE services to also keep an immunisation register for vaccine-preventable disease in addition to COVID-19 among staff. Such registers should improve outbreak responses in ECE settings and raise staff awareness of the importance of vaccination. Additionally, amendments to current occupational health guidelines for ECE employers to encourage staff vaccination and the safe placement of unvaccinated staff should also be considered. Finally, more research into the attitudes towards and barriers to vaccination among those who work in ECE is needed. For example, to date there has been little work done to assess the impact of free on-site vaccination delivery on vaccine uptake among ECE staff, attending children and their families.

Conclusion

By not receiving the recommended vaccines, ECE staff are at risk of exposing themselves, children, and the wider community to a range of vaccine-preventable diseases. Data from a national ECE survey of teaching staff suggests that immunisation for common vaccine-preventable diseases among ECE staff is low. More research on the attitudes towards and barriers to vaccination in this group, in conjunction with policy that encourages and supports vaccination, is necessary.
Competing interests:
Nil.

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REFERENCES
The re-emergence of a transmittable cause of blindness: a catch

Sugapriyan Ravichandran, Nishanthan Ramachandran, Shira Sheen-Ophir, Ewan A Fraser

Syphilis is known as a great masquerader because of its wide range of presentations.¹ It is a vision-threatening sexually transmittable infection (STI), and its presentation with posterior uveitis is more likely with human immunodeficiency virus (HIV) co-infection. Rates of syphilis in New Zealand are on the rise.

Case report

A 39-year-old, otherwise-healthy Māori male presented to a regional centre with decreasing vision in the left eye for four weeks. His best corrected visual acuities (BCVA) were 6/4 in the right eye and hand movements in the left eye. Intraocular pressures were normal. His history revealed multiple unprotected sexual intercourses with male and female partners. His left eye had panuveitis with the following exam findings: conjunctival ciliary injection, non-granulomatous keratic precipitates, anterior chamber 2 plus cells and flare (Figure 1), posterior synechiae, vitritis with snowballs and chorioretinitis with periphlebitis and arteritis (Figure 2). The right eye was normal on exam.

Extensive investigations were requested, including polymerase chain reaction from an aqueous sample. Treatment for toxoplasma (co-trimoxazole 960mg orally twice a day) and acute retinal necrosis (valaciclovir 2g orally three times a day) was commenced while we awaited the results of his investigations. He was also placed on topical Pred Forte hourly and cyclopentolate 1% three times a day for the anterior chamber inflammation.

His investigations were positive for syphilis and HIV. An urgent referral to infectious diseases was made and he was commenced on intravenous penicillin 2.4 grams every four hours for syphilis and high active antiretroviral therapy (dolutegravir, tenofovir disoproxil and emtricitabine) for HIV. Oral valaciclovir and co-trimoxazole were stopped when aqueous sampling was negative for toxoplasma, herpes simplex, varicella zoster and cytomegalovirus.

Seven days after diagnosis he developed cystoid macular oedema (CMO) and required peribulbar triamcinolone (Figure 3). His BCVA on 5 May 2021 with resolving CMO was 6/18. Room for visual improvement was expected.

Discussion

The prevalence of syphilis in New Zealand is increasing at an alarming rate among men who have sex with men (70% of cases) and heterosexuals.²,³ There was a six-fold increase in cases between 2013 (n=82) and 2018 (n=543) when population growth was only 11%.³ Māori men and men placed on pre-exposure prophylaxis for HIV are disproportionately afflicted.⁴,⁵ Treatment for ocular syphilis is the same as for neurosyphilis, hence our rationale for commencing intravenous penicillin in our patient.⁶ Posterior segment involvement is more prevalent with HIV co-infection and is indicated by floaters in the history. Syphilis chancre increases the risk of HIV transmission with up to 40% co-infection reported in the literature.⁷ Our patient was not immunocompromised, but the management of his ocular syphilis would have been no different if he was. He was observed closely during the first 24 hours of treatment for Jarisch-Herxheimer reaction, an immune response.
towards syphilitic-endotoxin-like products that creates further ocular inflammation and irreversible vision loss if not treated promptly with systemic steroids. Our patient was fortunate enough to not experience this.

Vision loss with ciliary injection, photophobia and floaters indicates uveitis with posterior segment involvement and requires prompt referral to ophthalmology for further investigations, including the consideration of STIs. It is important for healthcare professionals to be cognisant of the increasing incidence of syphilis in New Zealand and its association with HIV.
Figure 1: Anterior chamber photograph two days after presentation and commencing of treatment.

Figure 2: Colour fundus (right) and fundus fluorescein angiogram (left) photograph of the left eye with effected structures labelled.

Affected left eye—hazy view of disc and posterior pole due to vitritis.

Figure 3: OCT images show cross-sections of the macula before and after treatment with anti-VEGF intravitreal injection.

| 7th April 2021 | 5th May 2021 |
Competing interests:
Nil.

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www.nzma.org.nz/journal-articles/the-re-emergence-of-a-transmittable-cause-of-blindness-a-catch

REFERENCES
Prevention of Eclampsia

1921

By J. P. Hastings, M.D.

In regard to the treatment of eclampsia, De Lee (1) writes: “Since we do not know the cause of eclampsia the treatment is all empiric. Even so, more can be accomplished by prevention than by treatment, because after the convulsions have set in the nervous balance is overthrown. We cannot prevent the action of the primary cause of eclampsia, but by carefully watching the pregnant woman we may discover the first manifestations of the action of such noxious influences and by appropriate measures, the disease reaches a climax. It is the pregnancy that favours the development of eclampsia, if we cannot prevent and cure eclampsia we can remove the pregnancy. If the earliest signs of the impending catastrophe can be detected, emptying the uterus will almost invariably prevent a fatal issue.”

It is obviously the duty of the attending physician to prevent, if possible, the development of eclampsia. During the latter months of pregnancy the urine should be examined every two weeks. The presence of albumin is the most important danger signal, especially when the albumin increases and the amount of urea steadily decreases, it behoves one to be on his guard. In suspected cases, weekly, and even daily examinations of the urine should be made. Symptoms such as headache or œdema of the feet appear even before the urinary evidence. When the first signs of toxæmia appear commence treatment at once. Put the patient to bed and allow nothing but water by the mouth. After a few days, when improvement is marked, allow milk in the addition to water. In a day or two milk foods may be added. As the patient progresses satisfactorily, vegetarian diet is allowed, but on no account must a full meat diet be permitted. The dietetic restrictions are based on common sense rules. Commence treatment with a brisk saline purge. Henceforth it is probably better to rely on the use of the enema, as continued purgation may devitalise the patience, and, in my opinion, may even increase the tendency to toxæmia. Hot water by the mouth and morning helps to eliminate the toxin. Hot wet packs may be cautiously tried when the patient is not improving. When, in spite of treatment eclampsia is threatening, subcutaneous injections of normal saline are indicated.

If in spite of the treatment as above outlined the symptoms of renal insufficiency persist or grow worse, especially if twitchings or other ominous signs such as pain in the epigastrium should develop, the pregnancy should be terminated. Another danger signal in threatened eclampsia is a persistently high blood pressure; 150 m.m. Hg. or higher. In my opinion where the blood pressure (systolic) is high or shows an increase day by day for few days, in the presence of epigastric pain or other serious symptoms, the pregnancy should be terminated. How should this be done? In multiparae simple rupture of the membranes is usually sufficient. In primipara induction of labour is a slow process. Various methods are advised, such as packing the cervix and lower uterine segment with gauze followed by puncture of the membranes and insertion of the colpeurynter; vaginal caesarian section, etc.

When in spite of adequate prophylactic treatment (starvation for some days, etc.) the patient is getting worse, in the case of primipara, I am of opinion the pregnancy should be terminated by abdominal caesarian section performed under spinal anaesthesia. General anaesthetics are very dangerous in threatened eclampsia because of their destructive action on the liver, kidneys, and blood. This effect is more marked with chloroform than with ether. I look upon the use of spinal anaesthesia in these cases as a life-saving procedure. The mortality of eclampsia is from 20 to 45 per cent. for the mother, and 30 to 60 per cent. for the child.

It is of the utmost importance to note that in the last hundred years, in spite of our marked advances in surgery and medicine...
there has been practically no amelioration of the high death rate. In a subject such as this, I contend that these continued bad results in themselves condemn the methods of treatment treatment which are generally accepted by the medical profession to-day. A few years ago most people who suffered from what was called “inflammation of the bowels” were allowed to die. Then, when the appendix was shown to be largely responsible for these cases, results began to improve in proportion to the early date at which the appendix was removed. To-day a practitioner who would knowingly allow an appendix to go on till rupture of the abscess occurred before advising operation, might rightly be held guilty of malpractice. I am of the opinion that time will come when any practitioner who allows a case of threatened eclampsia to go on to convulsions without terminating the pregnancy will be held equally culpable. It appears to me to be as irrational to allow the pregnancy to continue in such cases as it is to leave the inflamed appendix in the abdomen.

A more accurate idea of the progress of cases of threatened eclampsia will be possible in the near future by the closer study of the blood chemistry of the patient. According to Chase (2), patients with more than 5 mg. of creatinine in the blood generally die—the normal being 2 mg. It is useless to terminate the pregnancy when the albuminoid and fatty degeneration of the liver have reached a stage incompatible with life.

It might be of some interest to cite a case which recently came under my care.

Patient Mrs. B.—age 27 years—par. 1. She consulted me on 10th November, 1921. She was then 8 months pregnant. She had marked œdema of both lower extremities extending up as high as the hips. Both hands were swollen. She complained of severe headache. Examination of the urine showed a large among of albumin and microscopically cases and blood were found. Treatment: She was put to bed and brisk purgative administered. For three days nothing but water was given by the mouth. The œdema diminished; on the third day her headache was much better, and she was allowed a little milk in addition to the water. She was put on urotropin Gr.v., t.d.s. On the 16th she complained of severe epigastric pain; the headache returned and twitching of the hands and face was observed. She was markedly somnolent. On the 15th her B.P. (S) was 140; on the 16th B.P. (S) 150. Quantity of urine 20 ounces; large among of albumin present. I now decided to terminate the pregnancy by abdominal caesarian section under spinal anaesthesia. Apothesine (1 4-5th grains) was injected intradurally; the needle being inserted at the second lumbar interspace. Complete anaesthesia and relaxation were obtained in a few minutes. The operation was performed in the usual manner. When the baby was extracted its heart was beating, but efforts to induce breathing were fruitless. Following the operation the patient’s general condition rapidly improved and she left the hospital on 16th December feeling extremely well, although there was still a trace of albumin in her urine. Examination of urine on 24th December showed that the albumin had completely disappeared.


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