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Celebrating 1500 issues: preface to the first Journal

Cannabis in New Zealand: a conundrum, and some good news

Car seat survey at a children's hospital: need a booster?

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The value of frenotomy for ankyloglossia from a parental perspective

Optimising in-patient stays for surgical patients—an analysis utilising the Red and Green Bed Days management system

Boycott of ASA Review of Alcohol Advertising—need for regulation

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Declining adolescent cannabis use occurred across all demographic groups and was accompanied by declining use of other psychoactive drugs, New Zealand, 2001–2012

Jude Ball, Dalice Sim, Richard Edwards, Theresa Fleming, Simon Denny, Hera Cook, Terryann Clark

The Youth 2000 surveys (conducted in 2001, 2007 and 2012) showed that cannabis use declined in New Zealand secondary students between 2001 and 2012. This study, which is part of a doctoral project in-vestigating the decline in adolescent risk behaviours, investigated i) whether changes in adolescent cannabis use occurred across all demographic groups, and ii) whether declining cannabis use was ac-companied by increasing use of other psychoactive drugs. These questions were investigated via sec-ondary analysis of the Youth 2000 data (2001, 2007 and 2012), which is nationally representative. We found that the decline in adolescent cannabis use between 2001 and 2012 occurred across all main demographic groups and was not accompanied by a rise in the use of other psychoactive drugs. Ethnic and socioeconomic difference in adolescent cannabis use decreased over the study period. Note that (as far as we are aware) the data from the Youth ’12 survey is the most recent published data on ado-lescent cannabis use in New Zealand.

Anticoagulation and cataract surgery

Yu-Chieh Hung, Ainsley Morris, Mark Elder

This study retrospectively assessed the impact of the anticoagulants warfarin and dabigatran on patients who underwent cataract surgery at Christchurch Hospital in 2015. The results showed that compared to those who were not anticoagulated, there was no significant increase in the rates of bleeding during and after surgery in anticoagulated patients. Therefore, continuing the anticoagulation in this setting may be appropriate.

Optimising in-patient stays for surgical patients—an analysis utilising the Red and Green Bed Days management system

Odette Hart, Christopher Holdaway

There are significant delays during the admissions of hospital patients. These can lead to poorer patient health, impacts on family support networks and inefficient spending for hospitals. The vascular surgery department at Waikato Hospital New Zealand has delays due to wound dressing requirements, access to surgical theatre and ultrasound imaging. Improving hospital system to reduce these delays may lead to better care of patients and earlier discharge.

Completeness of ANZACS-QI Cardiac Implanted DEVICE Registry and agreement with national datasets: ANZACS-QI 30

Fang Shawn Foo, Mildred Lee, Peter Larsen, David Heaven, Nigel Lever, Susan Sinclair, Martin K Stiles, Scott Harding, Dean Boddington, Rod Jackson, Andrew J Kerr, on behalf of the ANZACS-QI investigators

The ANZACS-QI DEVICE is a national registry for cardiac implantable electronic devices, including permanent pacemakers and implantable cardioverter defibrillators. This study compared the registry to the National Hospitalisation Datasets, which collects data on all New Zealand public hospital admissions. The ANZACS-QI DEVICE registry was found to capture a high proportion of procedures. There was excellent agreement of common data items in both datasets, which supports the use of either datasets for future research.

Mitral valve surgery with or without coronary bypass grafting: eight-year cohort study

Tom Kai Ming Wang, Yi-Wen (Becky) Liao, David Choi, Sophie Harmos, David Haydock, Ivor Gerber

This study reported the characteristics and outcomes of patients undergoing mitral valve with or without coronary bypass grafting at Auckland City Hospital during 2005–2012. Although patients undergoing the combined operation had more serious health conditions and greater risk for surgery than those only having mitral valve surgery, they still had worse outcomes for death and other complications compared to those having mitral valve surgery alone. Existing surgical risk models performed well for mitral valve surgery alone but only moderately accurate for the combined surgery.

Car seat survey at a children's hospital: need a booster?

Navneet Singh, Julie Chambers, James K Hamill

Child car seats and booster seats save lives. Many children >5 years of age are not appropriately restrained. In 2013, the New Zealand Government amended child restraint legislation. We have shown that this has improved child restraint use in children aged 5–7 years. Since the law does not mandate booster seats for children >7 years of age, most of these children are still suboptimally restrained.

The value of frenotomy for ankyloglossia from a parental perspective

Sam Illing, Martin Minnee, Jackie Wheeler, Lydia Illing

We conducted a large study of babies who had a tongue-tie affecting their ability to feed (a tongue tie is where there is a tether of skin holding the tongue down so it can't move normally). A simple procedure was done to cut this skin tether, which resulted in most of the babies able to feed much better. A third of babies who previously had been unable to breast feed despite their mothers' best efforts, were then able to start breastfeeding normally after the treatment. Parents confirmed they found it to be worthwhile procedure, with 97% saying that if they were ever in the same circumstances, they would do it again.

Cannabis-based medicinal products and the role of the doctor: should we be cautious or cautiously optimistic?

Irene Braithwaite, Giles Newton-Howes, Karen Oldfield, Alex Semprini

Most cannabis-based products do not have enough information about how they are made or how safe and effective they are to be licensed as a medicine here in New Zealand. When the medicinal cannabis scheme comes into effect, these products can become available to patients provided they are prescribed. The current medical system in which doctors operate does not support the prescription of products that do not have data relating to quality, safety and effectiveness. Doctors will find themselves caught in a conflict between patient demand and professional obligations.

A unified national cardiovascular disease (CVD) risk generator is required to address equity in the management of CVD risk in clinical practice in New Zealand

Andrew J Kerr, Sue Wells, Allan Moffitt, Mayanna Lund, Jim Kriechbaum, Matire Harwood, Rod Jackson

New New Zealand equations to predict risk of future heart attacks and strokes are an important tool for GPs to use to help address the major inequities in heart attack and strokes in Aotearoa, New Zealand. However, while the new equations provide more accurate assessment of risk, they are more complicated and therefore more prone to error if not systematically implemented in GP electronic systems. To take advantage of this important opportunity to address equity in heart health we need strategic vision and national leadership. In this paper we make the case that to most safely and cost-effectively implement the new equations, the Ministry of Health (MOH) should support a unified national CVD risk generator.

Celebrating 1500 issues: preface to the first Journal

September 1887

In bringing the NEW ZEALAND MEDICAL JOURNAL before the Profession, it is necessary to explain how it came into existence, its aims, and its prospects.

In the Medical Profession a man must either go on gaining knowledge, or he must go back. There is no standing still. Left to himself, he must get into contracted habits of thought, and routine ways of practice. It is only by keeping himself in touch with his brethren throughout the world that he can avoid the perils of stagnation. There are two chief ways of doing this: one is by a diligent study of the current literature of his profession, which is, fortunately, good and abundant; and the other is by personal work at societies, and by contact with his Fellow Practitioners. In all the large centres of New Zealand there are now active and flourishing medical associations. Every one who has taken advantage of these societies has felt the benefit of them in increased knowledge, wider range of experience, and greater zeal for his profession. The union of these various societies, by the formation of the New Zealand Medical Association, for which we have to thank the energy of the Auckland Society, promises to bring the whole Medical Profession in New Zealand into closer relationship than has been possible hitherto.

But valuable as the work may be which is before the Association, it has been felt in Dunedin and elsewhere that there is a want of any means of communication between Medical Men in the Colony, and that there is absolutely no means of recording the local work done. Every country has its own special experience of disease. We have special advantages—and perhaps some disadvantages—in our climate and surroundings, which differ widely from those of our neighbours in Australia, and also from those of Europe and America; and we are more effectively separated from Australia than America is from England.

It is an undertaking of some moment to send cases to Australian or Home journals; and although a great deal of good work in Medicine and Surgery is being done throughout New Zealand, comparatively few records of our experience are ever sent to Australian journals, and fewer still to the Home papers. If some record can be kept of New Zealand practice, it will not only be useful to those who contribute to it, and who read it, as it is published, but it will in time be a valuable storehouse of information for Practitioners. Believing this, the Otago Branch of the New Zealand Medical Association last year communicated with other Branches throughout the Colony, asking their co-operation in the establishment of a New Zealand Medical Journal. None of them at the time saw their way to this, and, after some consideration, it was decided to try the experiment of issuing the Journal from Dunedin, with such material as could be collected locally. This will sufficiently explain why the present number is almost wholly taken up with contributions from Dunedin. This will not be the case, we trust, in future issues. In our next number—which we hope to publish early in December—preference will be given to contributions from other districts. It is the hope of the Otago Society to establish a New Zealand Medical Journal; and we think that the contents of this number—furnished as they have been at very short notice by a few Medical Men in one part of the Colony—are sufficient proof that with the whole Profession of New Zealand to rely on, we may safely count in the future on sufficient material to produce at least four good numbers yearly.

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We shall be glad to receive from Medical Men, to whom this journal is sent, papers on subjects of Professional interest. We hope not only to receive and publish particulars of interesting or unusual cases of disease, but also to get special information from Medical Men in various parts of the Colony as to the climate and tendencies to disease in their own immediate locality. There are wide differences throughout this Colony, in climate and surroundings, which greatly modify disease. It is obviously of great importance to every practitioner to know where he can send patients with pulmonary or other affections, with the best chance of doing good. There are many problems in medicine which we may help to solve. We might instance the origin of typhoid fever, about which a good deal of discussion is now going on elsewhere—What is its relation to Colonial fever? A valuable paper was contributed some years ago to one of the Australian journals, with reference to typhoid fever on the West Coast, from which it appears that a fever with lesions identical with infectious typhoid, appeared among the miners there—apparently without any means of infection from without. This would agree with the experience of physicians in India, at the Cape of Good Hope, and other places; but we want the experience of many men to establish the fact, or to disprove it, in New Zealand.

We may say, then, that our aim is to open a field for discussion of whatever subjects may be of interest to the Medical Profession in the Colony. It has also been decided, after some consideration, not to make the journal the medium of any personal discussions or disputes, but to keep its pages wholly for matters of general interest.

We have explained the origin of the journal, and its aims. We have now to speak of its prospects. There are in round numbers about four hundred Medical Men in this Colony. With a smaller consistuency than this, the *Australian Medical Journal* was begun in Melbourne twenty years ago, and has had a successful and useful career ever since. We can see no reason why our venture should be less successful; and now leave the matter in the hands of our Fellow Practitioners throughout the Colony.

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Cannabis in New Zealand: a conundrum, and some good news

Joseph M Boden

At the present time there is considerable "action" concerning cannabis law and policy in New Zealand, particularly in light of upcoming changes to the availability of medicinal cannabis, and the referendum concerning the legalisation of recreational cannabis in 2020. In this issue of the *NZMJ* appear two timely articles germane to debates around these changes.

Braithwaite et al[1] have examined in some detail implications concerning the effects of the Misuse of Drugs (Medicinal Cannabis) Act,[2] enacted in December 2018. The law was an amendment of the Misuse of Drugs Act 1975[3] and was intended to improve the previously very limited access to cannabinoid-based medicinal products of high quality "on the basis of fairness, quality, safety and compassion".[2] While the public consultation regarding changes to this scheme closed in early August 2019, the authors noted that key components of the scheme have included the delisting of cannabidiol (CBD) as a controlled drug, and the possibility of the inclusion of products either not currently approved by Medsafe (but which are currently undergoing clinical assessment) or those not approved by the Ministry of Health, but which could be supplied to specific named patients with Ministry approval.

Irrespective of the final form of the medicinal cannabis regulations, it is obvious that the normal processes under which medicines are determined to be safe and effective for use in New Zealand is not being followed in the case of cannabis-based medicines. The reasons for this are abundantly clear: many overseas jurisdictions, including Australia, have over the past two decades legalised the use of cannabis for medicinal purposes, and pressure has mounted among the public for New Zealand to follow suit. At the same time, however, there remain concerns about the thin evidence base for the efficacy and safety of cannabis-based medicinal products.[4]

The crux of the argument presented by Braithwaite et al is that if normal processes for the approval of medicines are not being followed, then the responsibility for ensuring patient safety falls to individual physicians, under the scope of several laws and codes of practice and ethics. This is not unusual, in the sense that physicians must always place the highest priority on the wellbeing of patients, but in this particular case it is very likely that patient interest in, and demand for, cannabis-based medicinal products is going to increase. However, in the face of both a) a current lack of evidence for efficacy for many cannabis-based medicinal products; and b) little knowledge of potential side effects or harms associated with these products, Braithwaite and colleagues imply that it is not prudent at the present time for physicians to prescribe cannabis-based medicinal products except in a very limited set of circumstances.

The evidence from overseas jurisdictions shows that in locations where medicinal cannabis has been legalised, a relatively small number of prescribing physicians supply the majority of prescriptions for medicinal cannabis.[5] This pattern suggests that there is clear evidence for 'doctor shopping' for the purposes of obtaining cannabis (for medicinal purposes or otherwise), and there is every reason to expect that this phenomenon will also occur in New Zealand. Braithwaite and colleagues have provided a timely reminder that it is incumbent upon physicians to do their part to ensure that this does not take place here.

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It could also be argued that the possibility of legalisation of cannabis for recreational use via the referendum in 2020 may render certain questions about medicinal cannabis moot (particularly concerns about doctor shopping to obtain cannabis-based products). Concerns remain however as to the extent to which we should be concerned about the effects of legalisation on rates of cannabis use in the New Zealand population, particularly among young people who are more vulnerable to the adverse effects of cannabis use,[6] and among Māori.[7] One key aspect of understanding the potential impact of legalisation is a clear idea of what our current trends are. Ball and colleagues[8] have provided an opportune article that presents evidence from the Youth 2000 National Youth Health and Wellbeing surveys to show that cannabis use among young people in New Zealand was in steady decline between 2001 and 2012. Even more striking were findings for Māori, younger students and those attending lower decile schools, all of whom showed a more marked decline in cannabis use over the period. Although more current data were not available for analysis, Ball et al point out that more recent data for cigarette smoking and alcohol consumption also show declines among this age group, suggesting that it is quite likely that cannabis use has continued to decline in this age group after 2012.

For those involved in the public health sphere, news of a decline in cannabis use among young people, and among those who previously were more likely to suffer adverse effects associated with cannabis use, is welcome indeed. These data are also similar to overseas trends, where a decline in cannabis use among young people has been observed in the US, Canada, the UK and other Western European countries.[9] At the present time however, there is little evidence to suggest that these changes are due to public health and related initiatives worldwide; instead, there is emerging research to suggest that these declining rates of substance use may be related to substantial and generational changes in social interaction among this age group.[10]

In terms of the meaning of these findings for cannabis law change in New Zealand, these findings underscore the need for caution in the manner in which we develop any potential legal cannabis scheme. Evidence from public health approaches to alcohol control clearly show that jurisdictions that employ tight restrictions on the sale and supply of alcohol generally have lower levels of alcohol-related harm,[11] and it stands to reason that similarly restrictive approaches to cannabis legalisation would likely be associated in lower levels of cannabis-related harm. Given the evidence that cannabis use, and by extension cannabis-related harm is on the decline for young people, it is of even greater importance that the laws and policies developed do not reverse this trend, and do not lead to increased use and harm among this group.

Recent public polling suggests that New Zealanders are generally in favour of changing our laws,[12] reflecting the widespread awareness that cannabis use in New Zealand is common, and that prohibition has done little, if anything, to reduce cannabis-related harm. Furthermore, although the evidence base is thin at the moment, it is likely that we will have a better understanding of the potential medicinal benefits of cannabis-based products in the next five to ten years. However, we must recognise that we stand at a pivotal point in our history with regard to the legal status of cannabis, and we must endeavor not to make the same mistakes that have been made in our attempts to deal with alcohol-related harm. Our mantra, as always, must be “First, do no harm.”

Competing interests:
Nil.

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Declining adolescent cannabis use occurred across all demographic groups and was accompanied by declining use of other psychoactive drugs, New Zealand, 2001–2012

Jude Ball, Dalice Sim, Richard Edwards, Theresa Fleming, Simon Denny, Hera Cook, Terryann Clark

ABSTRACT

AIM: Cannabis use declined in New Zealand adolescents between 2001 and 2012. We investigated i) whether changes in adolescent cannabis use occurred across all demographic groups, and ii) whether declining cannabis use was accompanied by increasing use of other psychoactive drugs.

METHOD: We conducted secondary analysis of repeat cross-sectional data from nationally representative surveys of secondary school students (2001, 2007, 2012) to determine trends in never-use of cannabis and other psychoactive drugs by age, sex, ethnicity, deprivation, school decile and urban/rural locale. Logistic regression was used to test whether changes in cannabis non-use over time varied between demographic groups.

RESULTS: Never-use of cannabis and of other psychoactive substances increased between 2001 and 2012 in all included age, ethnic, sex and socioeconomic groups. Māori, younger students and those in low decile schools demonstrated the greatest reductions in cannabis use over the study period.

CONCLUSION: The decline in adolescent cannabis use between 2001 and 2012 occurred across all main demographic groups and was not accompanied by a rise in the use of other psychoactive drugs. Ethnic and socioeconomic inequities in adolescent cannabis use decreased over the study period.

Cannabis law reform is currently being debated in New Zealand, with a binding referendum on legalisation of personal cannabis use to be held at the 2020 general election. The potential impact of law changes on adolescents is likely to be a key feature of the debate.

Regular cannabis use is associated with a range of adverse health impacts[1] and a growing body of evidence suggests that initiating regular cannabis use in adolescence may be particularly harmful. Early age of initiation (<16 years of age), particularly in combination with alcohol and/or tobacco use, is associated with greater risk of psychosis, addiction, poor educational outcomes and long-term functional impairment.[1–5] Therefore, preventing or delaying uptake of cannabis use is of public health importance.

There has been a long-term decline in the prevalence of lifetime cannabis use in New Zealand secondary school students (most of whom are aged 13–17 years) from 38% in 2001 to 23% in 2012.[6] Over the same period, the proportion who used cannabis weekly or more often halved from 6.7% to 3.2%.[6] In contrast, weekly cannabis use in the adult

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population remained relatively stable over the same period, estimated at about 5% of the population in 1998 and 2007/08,[7] and just under 4% in 2012/13.[8] More recent data from the New Zealand Health Survey shows a significant increase in past-year cannabis use among adults, from 8% in 2011/12 to 12% in 2016/17. Unfortunately, more recent findings on adolescent cannabis use in New Zealand are not available. However, based on recent international patterns, we cannot assume that adolescent trends will follow adult trends. For example, the recent increase in cannabis use among adults observed in the US has *not* been accompanied by increasing use among adolescents in that country.[9]

The recent decline in adolescent cannabis use in New Zealand appears to be good news for public health, but the sociodemographic distribution of this decline is unknown. Identifying whether changes in cannabis use in New Zealand have occurred across all demographic groups, or whether the overall decline is obscuring disparate trends in disadvantaged sub-groups, may helpfully inform intervention efforts and policy debate. Such analysis has already been undertaken for adolescent alcohol and tobacco use in New Zealand[10–13] showing that declines have occurred across all main demographic groups, although not necessarily evenly. It is unknown whether trends in adolescent cannabis use in New Zealand follow the same pattern or whether they differ markedly by ethnicity as found in the US, where prevalence of cannabis use disorder has decreased in the adolescent population as a whole, but not in Black adolescents, since the turn of the century.[14] Differing patterns in disadvantaged groups and/or widening disparities would be cause for heightened public health concern in New Zealand. It is also unclear whether the decline in weekly cannabis use is solely due to fewer adolescents trying cannabis, or whether declining frequency of use in ever-users has also contributed to the trend.

The availability of other psychoactive drugs increased in New Zealand during the 2001–2012 period. For example, 'party pills' containing BZP and related substances were legally available from the early 2000s until 2008,[15] and synthetic cannabinoids (eg, 'Spice') emerged in the mid-2000s[16] and remained legally available until 2014. There have also been community and policy concerns about the rising use of illicit methamphetamine in New Zealand since the early 2000s.[17] Therefore it is important to explore the possibility of substitution effects: were adolescents increasingly taking other drugs instead of cannabis?

The current study builds on existing findings about cannabis use in secondary school students[6] and aims to answer the following research questions:

1. Has the proportion of secondary students who have never used cannabis increased in all main demographic groups by sex, age, ethnicity, socioeconomic status and locale (urban/rural)?
2. Are changes evenly distributed across demographic groups, or are there marked differences by demography?
3. Have ethnic and socioeconomic differences in secondary student cannabis use narrowed or widened between 2001 and 2012?
4. Has frequency of use changed in ever-users of cannabis?
5. Has the decline in adolescent cannabis use been accompanied by rising usage of other psychoactive drugs?

Methods

Data and survey methods

This study is based on secondary analysis of repeat cross-sectional data from the Youth 2000 National Youth Health and Wellbeing surveys undertaken in 2001 (N= 9,567), 2007 (N=9,107) and 2012 (N=8,500). These are nationally representative surveys of secondary school students, carried out by the Adolescent Health Research Group at the University of Auckland. Details about Youth 2000 survey methods and the characteristics of participating schools and students are available elsewhere.[6]

The survey was designed to be 'youth friendly' and suitable for those with low literacy. It was administered using a multimedia computer-assisted self-administration interview (M-CASI), with each question read out over headphones as well as appearing on the screen, and from 2007 participants had the option of using English or Māori.

M-CASI has been shown to enhance perceptions of privacy and confidentiality and is associated with increased reporting of sensitive behaviours in comparison with paper-based questionnaires or interviewer-administered surveys.[18] The sample design, administration methods and core question wording were consistent across the three surveys to allow trends to be observed. However, the following differences affected comparability between years: In 2001 and 2007 the answer categories for substance use questions were 'yes', 'no' and 'I don't want to answer any further questions about marijuana/other drugs'. In 2012, the answer categories were limited to 'yes' or 'no'. As a result, the proportion of missing data (including both refusal and item non-response) was relatively high in 2001 and 2007, and considerably lower in 2012. This comparability problem was addressed by focusing on non-use rather than use, and conducting sensitivity analyses as discussed further below.

A further methodological change affecting comparability was the wording of the question about other psychoactive drugs. In 2001 these were described as 'usually illegal' whereas in 2007 and 2012 the question explicitly included 'party pills', which (along with other 'legal highs') had emerged in the early- to mid-2000s. Thus the 2007/2012 question was broader. The precise question wording is provided below.

Variables

Outcome variables

To maximise comparability across years, the analysis focuses on never-use ('no' responses) rather than use, based on the assumption that non-responders were more likely to be users compared with responders, and therefore non-use would be less affected by the change in answer categories and item-response rate.

Never-use of cannabis

The proportion of the sample who reported never having smoked cannabis was based on the question: 'Have you ever smoked marijuana (pot, grass, weed, cannabis)?'

Past month non-use

The proportion of the sample who reported not using cannabis in the past month was based on the question 'In the last four weeks, about how often did you smoke marijuana?', which was only asked of ever-users. Past month non-use comprised those who answered 'Not at all—I don't smoke marijuana anymore' or 'None in the last four weeks' to this question, plus those who had never used cannabis.

Frequency of use

Frequency of use among ever-users was based on the question 'In the last four weeks, about how often did you smoke marijuana?' This question was only asked of ever-users. 'At least monthly' comprised those who responded 'Once in the last four weeks' or more often. 'At least weekly' comprised those who responded 'Once a week' 'Several times a week' 'Everyday' or 'Several times a day.'

Never-use of other psychoactive drugs

The proportion of the sample reporting never-use of other psychoactive drugs was based on the question: "Now there are some questions about other drugs such as party pills, acid, solvents, speed, ecstasy, etc, have you ever tried any of these other drugs?"

As noted above, the question wording in 2001 was slightly different: "We would now like to ask some questions about other drugs. By this we mean drugs that are usually illegal and often cause a high or trip such as acid, solvents, speed, ecstasy, homebake etc. Remember there is no way to identify you from your answers. Have you tried any of these other drugs?"

Demographic variables

Demographic variables were age, sex, prioritised ethnicity, school decile,[19] neighbourhood deprivation (NZDep) and locale (urban/rural).

For reporting purposes, we grouped school decile into three bands: low (1–3), medium (4–7) and high (8–10), where low decile means socioeconomically disadvantaged.

Neighbourhood deprivation (NZDep) was also grouped into three bands: low deprivation (1–3), medium (4–7) and high deprivation (8–10).

Locale (urban/rural) was based on geocoding of participants' home address, and classification of urban areas produced by Statistics NZ.

Analysis

The proportion of the sample who reported never using cannabis was calculated overall and for each demographic group. The percentages and confidence intervals were adjusted for the weighting and clustering in the complex sampling design. The same approach was use for past month non-use of cannabis and lifetime never-use of other psychoactive drugs.

To test whether ethnic or socioeconomic differences in cannabis never-use had narrowed or widened over time in relative terms we conducted logistic regression, and compared odds ratios for ethnicity and school decile (crude, and adjusted for age, sex, ethnicity and school decile) between 2001 and 2012.

To test whether change over time in cannabis never-use varied between demographic groups (after adjusting for other demographic variables), logistic regression models with all predictors included were developed. Each demographic variable was then included in an interaction term with year.

The main analyses used a complete case analysis (ie, missing data was excluded), with both 'I don't want to answer' and item non-response treated as missing. The proportion missing for lifetime never-use of cannabis was 12% in 2001, 13% in 2007 and 5% in 2012. For psychoactive substance use, the proportion missing was 15% in 2001, 14% in 2007 and 4% in 2012. Because missing data was substantial in 2001 and 2007 and because non-response changed markedly between years, the assumptions made about non-responders have a non-trivial impact on estimates of trends over time. Imputation could not be used to address this problem because the data were not missing at random (ie, it is likely that non-response was at least partially driven by the desire to conceal cannabis use). Instead we undertook sensitivity analyses to investigate whether missing data could have affected trends. First, in Excel, we calculated what the population prevalence of 'never use' would be for each year under a range of scenarios, varying from 0% to 100% of those with missing data being 'never users'. Then, using SAS, we repeated the subgroup analysis, first re-coding all individuals with missing data as never-users, then recoding all individuals with missing data as cannabis users.

Unless otherwise stated, all analyses were conducted in SAS, using SURVEYFREQ for descriptive statistics and GLIMMIX for logistic regression, and were adjusted for weighting and clustering.

Results

Never-use of cannabis

As shown in Table 1 and Figure 1, the proportion of secondary school students who reported they had never used cannabis increased in all demographic groups between 2001 and 2012.

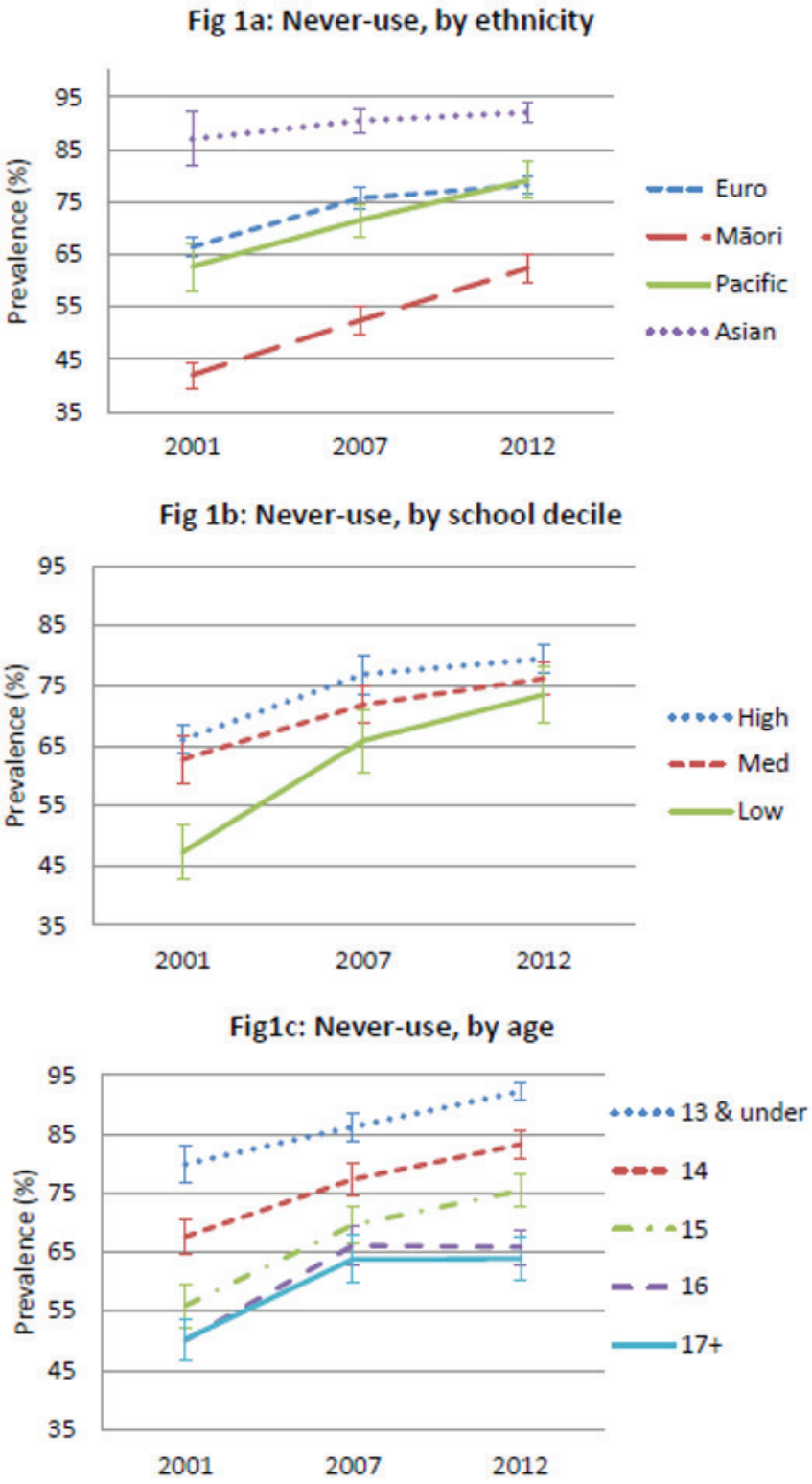
Table 1: Proportion of secondary school students who reported they had never used cannabis, by demographic factors, 2001–2012.

	2001		**2007**		**2012**	
	n (N)	% 95% CI	n (N)	% 95% CI	n (N)	% (95% CI)
Total	5,188 (8,432)	61.8 (59.3, 64.3)	5,774 (7,905)	73.0 (70.9, 75.1)	6,250 (8,117)	77.0 (75.3, 78.7)
Sex						
Male	2,317 (3,789)	61.5 (58.7, 64.4)	3,036 (4,165)	72.8 (70.7, 74.9)	2,762 (3,648)	75.8 (73.6, 77.9)
Female	2,871 (4,643)	62.0 (59.3, 64.8)	2,738 (3,740)	73.2 (70.4, 76.1)	3,487 (4,467)	78.0 (76.0, 80.1)

Table 1: Proportion of secondary school students who reported they had never used cannabis, by demographic factors, 2001–2012 (continued).

	2001		2007		2012	
Age						
13 or under	1,376 (1,729)	79.9 (76.9, 83.0)	1,362 (1,582)	86.2 (83.6, 88.7)	1,603 (1,742)	92.2 (90.7, 93.7)
14	1,358 (2,010)	67.6 (64.6, 70.6)	1,384 (1,790)	77.3 (74.6, 79.9)	1,518 (1,824)	83.2 (80.8, 85.6)
15	1,072 (1,926)	55.9 (52.2, 59.5)	1,196 (1,719)	69.6 (66.4, 72.7)	1,254 (1,662)	75.4 (72.6, 78.2)
16	786 (1,575)	50.1 (46.7, 53.5)	521 (1,018)	66.1 (62.9, 69.3)	992 (1,508)	65.8 (62.8, 68.8)
17 or over	594 (1,185)	50.2 (46.7, 53.8)	814 (1,275)	63.8 (59.8, 67.9)	877 (1,371)	63.9 (60.4, 67.4)
Ethnicity						
Euro/ Other	3,455 (5,208)	66.4 (64.4, 68.3)	3,625 (4,779)	75.7 (73.8, 77.6)	3,472 (4,431)	78.2 (76.6, 79.8)
Māori	835 (1,990)	42.0 (39.5, 44.4)	747 (1,427)	52.4 (49.5, 55.2)	980 (1,579)	62.4 (59.8, 65.1)
Pacific	354 (569)	62.7 (58.1, 67.2)	503 (703)	71.5 (68.4, 74.6)	861 (1,088)	79.1 (75.6, 82.7)
Asian	486 (566)	87.0 (81.9, 92.1)	897 (992)	90.5 (88.2, 92.8)	930 (1,010)	92.1 (90.2, 93.9)
School decile						
High	2156 (3,267)	66.0 (63.6, 68.3)	2,098 (2,729)	76.9 (73.6, 80.1)	2,652 (3,335)	79.5 (77.1, 81.8)
Med	2491 (4,024)	62.7 (58.8, 66.6)	2,762 (3,839)	71.8 (68.8, 74.8)	2,423 (3,176)	76.2 (73.5, 78.8)
Low	541 (1,141)	47.2 (42.8, 51.7)	687 (1,046)	65.8 (60.6, 71.0)	1,175 (1,606)	73.5 (68.9, 78.1)
NZ Dep						
Least dep	-	-	2,291 (2,939)	77.8 (75.4, 80.0)	1,918 (2,421)	79.2 (77.4, 80.9)
Med	-	-	2,211 (3,038)	72.7 (70.2, 75.3)	2,352 (3,022)	77.7 (75.5, 79.9)
Most dep	-	-	1,225 (1,865)	65.7 (62.0, 69.4)	1,849 (2,518)	73.6 (70.6, 76.6)
Locale						
Urban	-	-	4,798 (6,567)	73.0 (70.7, 75.3)	5,269 (6,805)	77.4 (75.6, 79.2)
Rural	-	-	931 (1,277)	72.9 (69.4, 76.4)	907 (1,221)	74.5 (70.6, 78.3)

Figure 1: Proportion of secondary school students who reported they had never used cannabis, by demographic factors, 2001–2012.



Ethnic and socioeconomic differences in never-use of cannabis

Ethnic and socioeconomic differences narrowed over time, in absolute terms, based on crude (unadjusted) data, as can be seen in Figure 1. As shown in Table 2, ethnic and socioeconomic differences also decreased in relative terms. Relative ethnic differences were pronounced both in 2001 and 2012, and remained pronounced after adjusting for age, sex and school decile. However, the odds of never-use increased significantly in Māori relative to European/other over the study period. Relative differences by school decile also decreased markedly between 2001 and 2012. The odds of never-use in low decile schools (relative to high decile schools) increased substantially between 2001 and 2012, and the difference between medium and high decile schools was not statistically significant in 2012.

We found significant interaction effects between year and age (p<.0001), sex (p<.0001), ethnicity (p<.0001) and school decile (p<.01). This indicates that, after adjusting for the other demographic variables in the model, the increase in cannabis never-use over time was greater in girls than boys, greater in younger students than older students, greater in students from low decile schools than high decile schools, and greater in Māori students than other ethnicities.

Past month cannabis non-use

Past month non-use of cannabis increased from 80.2% (95% CI 78.6, 81.9) in 2001 to 91.6 % (90.6, 92.6) in 2012. This increase occurred in all demographic groups (not shown). Ethnic and socioeconomic differences in past month non-use narrowed over time in both absolute and relative terms, with the pattern of change similar to that for never-use. For example, relative to European/other, Māori past month non-use increased substantially from OR 0.37 (95% CI: 0.34, 0.39) in 2001 to OR 0.49 (0.45, 0.53) in 2012, after adjusting for school decile, age and sex. In 2001 students from low decile schools were significantly less likely to be past month abstinent (OR 0.61, 95% CI 0.46, 0.82) than students from high decile schools, but by 2012 there was no statistically significant difference between these groups, after adjustment for ethnicity, age and sex.

Table 2: Relative ethnic and school decile differences in never-use of cannabis, 2001 and 2012.

	2001		**2012**	
	OR, Crude (95% OR)	**OR, Adjusted (95% CI)**	**OR, Crude (95% CI)**	**OR, Adjusted (95% CI)**
Euro/other	1	1	1	1
Māori	0.40*** (0.38, 0.42)	0.34*** (0.32, 0.36)	0.49*** (0.46, 0.52)	0.41*** (0.38, 0.44)
Pacific	0.94 (0.84, 1.04)	0.96 (0.86, 1.07)	0.98 (0.89, 1.08)	0.97 (0.88, 1.07)
Asian	3.07*** (2.70, 3.49)	3.51*** (3.11, 4.03)	3.05*** (2.72, 3.41)	3.42*** (3.05, 3.84)
High decile		1	1	1
Medium	0.75** (0.61, 0.91)	0.80* (0.66, 0.96)	0.79 (0.57, 1.10)	0.86 (0.65, 1.15)
Low decile	0.38*** (0.30, 0.50)	0.49*** (0.39, 0.62)	0.58** (0.41, 0.83)	0.71* (0.52, 0.97)

*p=<.05 **p=<.01 ***p=<.001.
Adjusted model includes age, sex, school decile and ethnicity.

Table 3: Prevalence of regular cannabis use in ever-users, 2001, 2007 and 2012.

	2001		2007		2012	
	n (N)	% 95% CI	n (N)	% 95% CI	n (N)	% (95% CI)
At least monthly	1,644 (3,244)	50.9 (48.9, 52.9)	873 (2,131)	41.0 (39.0, 43.0)	674 (1,867)	36.0 (33.1, 39.0)
At least weekly	558 (3,244)	17.5 (15.6, 19.3)	370 (2,131)	17.3 (15.45, 19.2)	260 (1,867)	13.9 (12.0,15.8)

Frequency of cannabis use in ever-users

Among students who had ever used cannabis, regular use declined markedly over the study period, as shown in Table 3. At least monthly use declined by about 30% in relative terms and by about 15% in absolute terms among ever-users between 2001 and 2012. At least weekly use declined about 20% in relative terms and 3.6% in absolute terms.

Never-use of other psychoactive drugs

The proportion of students who reported they had never used other psychoactive drugs also increased over the study period from 89% (95% CI: 87.7, 89.8) in 2001 to 95% (93.9, 95.3) in 2012. There was a slight decrease between 2001 (89%) and 2007 (87%), but it is important to note that the question wording (and context for psychoactive drug use) changed between these years, reflecting the popularisation of 'party pills' between survey waves. Survey wording was identical in 2007 and 2012, and a marked increase in never-use can be seen: from 87% (95% CI: 86.1, 88.6) in 2007 to 95% (93.9, 95.3) in 2012. Detailed sub-group analysis is available on request.

Sensitivity analyses

Our sensitivity analyses showed that, although missing data had the potential to bias our results, in fact our conclusions were robust to a range of assumptions. Table 4 shows what the population prevalence of cannabis never-use would be in each survey year under various assumptions ranging from non-responders all being cannabis users to non-responders all being never-users. As shown, the population estimates vary considerably, but under all scenarios the proportion of never-users increases over time.

Based on their demographic profile and possible desire to hide cannabis use, it is likely that non-responders had a *higher* rate of cannabis use than responders. Therefore the 'true' estimates are likely to fall between the values presented in the main analysis (which assumes that responders and non-responders did not differ with regards cannabis use), and the values based on the extreme assumption that *all* non-responders were cannabis users (ie, the top row of Table 4).

Never-use of psychoactive substances also increased between 2001 and 2012, and between 2007 and 2012 under all assumptions. Turning to subgroup trends, our sensitivity analyses showed that under all realistic assumptions cannabis never-use increased over time in all main demographic groups. Detailed findings are available on request.

Discussion

This study adds to what is currently known about adolescent cannabis trends by providing detailed sub-group analysis. It shows that the proportion of students reporting they had never used cannabis increased in all demographic groups between 2001 and 2012. Ethnic and socioeconomic differences narrowed over time in absolute and relative terms. Younger students (under 16 years), Māori and those from low decile schools showed more marked declines in cannabis use over time, after adjusting for other demographic factors. Regular (at least monthly and at least weekly) cannabis use decreased in ever-users, suggesting decreasing frequency of use over time. Declining cannabis use was not accompanied by an increase in use of other drugs;

Table 4: Population estimates for never-use of cannabis, under various assumptions about cannabis use in non-responders.

Proportion of non-responders that are never-users	2001 prevalence	2007 prevalence	2012 prevalence
0%	54.2%	63.4%	73.5%
10%	55.4%	64.7%	74.0%
20%	56.6%	66.0%	74.4%
30%	57.8%	67.4%	74.9%
40%	59.0%	68.7%	75.3%
50%	60.2%	70.0%	75.8%
60%	61.3%	71.3%	76.2%
70%	62.5%	72.6%	76.7%
80%	63.7%	74.0%	77.1%
90%	64.9%	75.3%	77.6%
100%	66.1%	76.6%	78.0%

in fact the proportion reporting they had never used other psychoactive substances also increased over the study period. These findings are good news from a public health perspective.

Declining adolescent cannabis use in the early 21st century is not unique to New Zealand, and has also been reported in the UK, US, Canada and many Western European countries.[20] These declines are surprising given increasingly liberal attitudes towards cannabis, and debate about, or implementation of, decriminalisation/legalisation in a growing number of jurisdictions. International research has explored the paradox that adolescents increasingly view cannabis as socially acceptable and harmless, and yet adolescent use of cannabis has not risen accordingly. The findings suggest that opportunities for use have become less frequent in Norway[21] and that declining tobacco and alcohol use largely explain US trends.[22,23] The same may be true in New Zealand, where adolescent binge drinking and tobacco smoking declined substantially over the study period,[6] and previous research has shown these behaviours to be highly correlated in New Zealand adolescents.[24] Tobacco use in this country has declined particularly strongly among Māori adolescents since 2000,[25] which may help to explain the substantial declines in cannabis use in Māori adolescents relative to other ethnicities.

The drivers of what appears to be a generational shift in adolescent behaviour away from substance use are not well understood. While many hypotheses have been put forward,[26–28] few have been empirically tested, and this remains an area for future research. In order to ensure positive trends are maintained, we need greater understanding of why substance use is declining among adolescents.

Lack of more recent New Zealand data on adolescent use of cannabis and other psychoactive substances means trends since 2012 are uncertain. However, the ASH Year 10 Snapshot survey shows that regular smoking has continued to decline since 2012 in 14–15 year-olds,[29] and the New Zealand Health Survey shows that alcohol use in 15–17 year olds is stable or declining.[30] Therefore, given that adolescent cannabis use is strongly associated with drinking and smoking, it is unlikely that it has risen substantially since 2012, and may have continued to decline in younger adolescents.

The study has a number of strengths and limitations, which must be borne in mind when interpreting the findings. Strengths include a large, nationally representative

sample, reasonably high response rate and computer-assisted administration mode, which was less likely to lead to social desirability bias than other modes.[18] The data covered a period of more than a decade, showing that declining adolescent drug use has endured over several cohorts.

A limitation is that missing data for questions about drug use means the accuracy of our population estimates, particularly for 2001 and 2007, are uncertain. However, the most likely effect of missing data is to *understate* the magnitude of the decline over time in cannabis use. Assuming non-responders are more likely to be cannabis users than responders, non-use will have been over-estimated in 2001 and 2007 (relative to 2012), which has the effect of 'flattening' the trend. Furthermore, our sensitivity analyses show that our main findings are robust to all plausible assumptions about missing data. 'Due to missing data and resulting uncertainty about population estimates it is unclear whether the decline in adolescent cannabis occured evenly across the study period or was concentrated in the 2001–2007 period.

Changes in question wording have affected comparability across years, in particular between 2001 and 2007/2012 in relation to the prevalence of other psychoactive drug use. The 2007/2012 question wording was broadened to include 'party pills' and the term 'illegal' was removed. This may have had the effect of overestimating never-use in 2001 relative to 2007 and 2012, and thereby underestimating the change over time. However, question wording was identical between 2007 and 2012 and did not impact trend estimates between these years.

Under the current policy settings there have been significant declines in adolescent cannabis use in New Zealand, particularly among Māori and those from low decile schools. Despite this, rangatahi Māori remain more likely to be cannabis users than adolescents of other ethnicities, and therefore the burden of cannabis harm, including criminalisation, falls more heavily on Māori. The current debate about cannabis legalisation in New Zealand must weigh up potential health risks (and health equity implications) against improved equity in terms of criminal justice. Key health risks, if the planned 2020 referendum on cannabis legalisation results in increased access to cannabis, include a potential increase in cannabis use among adolescents and young adults and related harms. As well as mental health and accidental injury risks, these include the possibility of increasing tobacco use and dependence due to a 'reverse gateway' effect which has been documented internationally.[31,32] Any law changes must be implemented in a way that minimises the risk of increasing youth cannabis use and related harms. Any policy changes should be accompanied by careful monitoring and robust policy evaluation and review mechanisms.

International evidence suggests, however, that liberalisation of attitudes and/or regulations does not necessarily result in increased cannabis use in adolescents,[21,23,33,34] though some studies have found an increase in adolescent cannabis use following decriminalisation or legalisation.[35,36] Overseas studies suggest that adolescent cannabis trends are substantially influenced by tobacco and alcohol trends, and opportunities for substance use in general.[21] It is these factors that have been shown to explain the lack of increase in adolescent cannabis use in the US,[22,23] not necessarily the effectiveness of age restrictions. Therefore, tighter tobacco control and alcohol regulations may play a role in mitigating potential harms of cannabis liberalisation for the adolescent population in New Zealand, if it occurs. Better understanding of the contextual drivers of population-level changes in adolescent cannabis use is vital to allow more accurate prediction of the impacts of potential policy changes.

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Anticoagulation and cataract surgery

Yu-Chieh Hung, Ainsley Morris, Mark Elder

ABSTRACT

AIM: To assess the impact of anticoagulation on patients having cataract surgery.

METHODS: Patients who underwent cataract surgery with phacoemulsification and intraocular lens insertion between 1 January 2015 and 31 December 2015 at Christchurch Hospital were identified and retrospectively audited. The outcome measures were the occurrence of intraoperative and postoperative haemorrhage, and thromboembolic events within two weeks after surgery. A control group was included to assess the outcome measures in a sample of patients who were not on anticoagulants or antiplatelets.

RESULTS: Forty-four anticoagulated patients (46 eyes) and 41 controls (46 eyes) were identified. Seventy-four percent of those anticoagulated were on warfarin and 26% were on dabigatran. The incidence of haemorrhagic complications was 18%, 25% and 11% in the warfarin, dabigatran and control groups, respectively, although these differences were not statistically significant. Apart from one vitreous haemorrhage, which may have been present preoperatively, the haemorrhages that occurred were minor and not visually significant. No thromboembolic events were noted in any of the groups.

CONCLUSION: There is no statistically significant increase in haemorrhagic complications in cataract surgery patients who were on warfarin or dabigatran. Therefore, continuing the anticoagulation in this setting may be appropriate.

Cataract extraction is the most commonly performed surgery worldwide.[1] With an ageing population and its associated comorbidities, increasing numbers of cataract surgery patients are on anticoagulants. Perioperative management of anticoagulation involves balancing the risks of haemorrhage with those of thromboembolism. Warfarin is the most frequently used anticoagulant, and is monitored via international normalised ratio (INR) levels. Since July 2011, dabigatran has been available in New Zealand as a newer anticoagulant that does not require routine monitoring, and in fact cannot be easily monitored.[2] This study aims to assess the effect of these anticoagulants on patients undergoing cataract surgery.

Methods

Anticoagulated patients who had cataract surgery with phacoemulsification and intraocular lens (IOL) insertion between 1 January 2015 and 31 December 2015 at Christchurch Hospital were identified from clinical coding, operating theatre list comments and clinical records, and retrospectively audited. Patients were excluded if they had a concurrent procedure on the same eye. The following information was collected: demographic data, type of anticoagulant and its indication, any modification to anticoagulation, and outcome measures of intraoperative and postoperative haemorrhage and thromboembolic events within two weeks after surgery.

A control group was included to assess the outcome measures in patients who were not on anticoagulants or antiplatelets, but underwent the same surgery during the same time period. From a list of these patients, arranged in terminal digit order according to their national health index number, the first 41 patients who had available notes were selected as controls.

This study was conducted in accordance with the New Zealand National Ethics Advisory Committee guidelines as an audit or related activity.

Results

Six hundred and six patients (636 eyes) underwent phacoemulsification and IOL insertion without a concurrent procedure on the same eye at Christchurch Hospital in 2015. Of these, 7% (44 patients; 46 eyes) were on anticoagulation, with 74% on warfarin and 26% on dabigatran. In the anticoagulated group, 52% were male, 48% were female, and the mean age was 78 years (range 36–91). The control group consisted of 41 patients (46 eyes), with 28% males, 72% females, and a mean age of 72 years (range 38–88).

The indications for anticoagulation include: atrial fibrillation/flutter (29 patients), venous thromboembolism (five patients), prosthetic heart valve (one patient) and atrial appendage thrombus (one patient). Eight patients had more than one indication.

Perioperative management of anticoagulation consisted of: continuing the usual treatment regimen (52%), withholding the anticoagulant (15%) or reducing the administered dose (2%). Thirty percent had no documented details regarding whether there were any modifications to the anticoagulation regimen.

The incidence of different haemorrhagic complications is depicted in Table 1. Intraoperative or postoperative haemorrhage occurred in 18%, 25% and 11% of the warfarin, dabigatran and control groups, respectively. The odds ratios for developing haemorrhagic complications were 1.76 (95% confidence interval: 0.49–6.32) for warfarin versus controls, and 2.73 (95% confidence interval: 0.55–13.58) for dabigatran versus controls, and therefore not statistically significant. The one patient with a vitreous haemorrhage had known central retinal vein occlusion and neovascular glaucoma, continued his usual warfarin therapy and had a supratherapeutic INR of 3.1 on the day of surgery. However, it is unknown if the vitreous haemorrhage was present preoperatively, as his cataract had precluded fundal visualisation. In the anticoagulated groups, all patients who developed subconjunctival haemorrhages and the one patient on dabigatran who had a retinal haemorrhage had either continued their usual anticoagulation or had no documented instructions regarding modification of anticoagulation regimen. The patient in the warfarin group who had retinal haemorrhages had a background of mild non-proliferative diabetic retinopathy and a supratherapeutic INR of 3.3 on the day of surgery. She withheld her warfarin that night, restarted it the next evening, and at her one-month postoperative follow-up was found to have new dot-blot retinal haemorrhages, which may have been secondary to worsening diabetic retinopathy rather than a haemorrhagic complication from cataract surgery. All retinal and disc haemorrhages were small and of no visual significance. There were no thromboembolic events in the two-week postoperative period.

Discussion

Other studies have shown that in those undergoing cataract surgery, warfarin therapy was associated with a higher incidence of haemorrhages, but these were not visually significant.[3] A meta-analysis, which assessed five cohort studies and six case series, found that cataract surgery patients on warfarin were three times as likely to develop haemorrhagic complications, compared to non-anticoagulated patients.[4] However, the vast majority of these were subconjunctival bleeds or dot hyphaemae,

Table 1: Haemorrhagic complications.

Group	Vitreous haemorrhage (eyes, %)	Subconjunctival haemorrhage (eyes, %)	Retinal or disc haemorrhage (eyes, %)	Microhyphaema (eyes, %)	Haematoma post sub-Tenon's block (eyes, %)
Warfarin (34 eyes)	1, 3%	4, 12%	1, 3%	-	-
Dabigatran (12 eyes)	-	2, 17%	1, 8%	-	-
Controls (46 eyes)	-	3, 7%	1†, 2%	1, 2%	1, 2%

†This patient also had a subconjunctival haemorrhage.

and no patients had compromised vision as a result of the haemorrhages.[4] Another study, which evaluated 48,862 operations from the Cataract National Dataset in the UK, showed that warfarin was associated with a greater risk of subconjunctival haemorrhages, but not with a significant increase in haemorrhages that were potentially sight-threatening.[5]

In the literature, data on dabigatran in cataract surgery is limited, with only one study, which reported similar rates of periprocedural haemorrhage between patients with atrial fibrillation who were randomised to either dabigatran or warfarin.[3,6] However, this analysis also included various other procedures, such as joint replacement, rather than cataract surgery alone.[6]

In our study, we recognise that there may have been underreporting of haemorrhagic complications from cataract surgery. This is because minor (such as subconjunctival) haemorrhages, may not have been documented. Also, some retinal haemorrhages may have been missed, as patients did not always have a dilated fundus examination at their day-one postoperative review. It is felt that, if present, the level of underreporting would likely have been similar between the anticoagulated and control groups.

In the anticoagulated group, the male-to-female ratio was almost 1:1, whereas in the controls it was 1:2.6. While the reasons for this difference are unknown, studies have shown that, compared to men, women with atrial fibrillation are less likely to be on anticoagulation.[7] However, the anticoagulated and control groups appear to be comparable with regards to the age range and mean age.

We also acknowledge that this study is limited by the small sample size, which needs to be considered when interpreting the results.

In conclusion, our study did not show a statistically significant increase in haemorrhagic complications in cataract surgery patients who were on warfarin or dabigatran. Apart from one case of vitreous haemorrhage, which may have been present preoperatively, the haemorrhages that occurred were minor and had no significant effects on the visual outcome. This suggests that continuing anticoagulation in the setting of cataract surgery may be appropriate, provided that the INR is within therapeutic limits for those on warfarin.

Competing interests:
Nil.

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Optimising in-patient stays for surgical patients—an analysis utilising the Red and Green Bed Days management system

Odette Hart, Christopher Holdaway

ABSTRACT

AIMS: Red and Green Bed Days is a hospital management system designed to identify delays during in-patient stays. This study quantified days when no activity occurred to progress a patient towards discharge.

METHODS: Starting June 2018, 100 consecutive in-patient stays were recorded within the vascular department at Waikato Hospital, New Zealand. A 'green day' occurred when the planned care for that day was achieved. A 'red day' occurred when a patient only received care that did not require an acute bed. The causes of red days were identified.

RESULTS: There were 703 total in-patient days, with 37% red days. Patients aged between 60–79 years accounted for 57% of red days. Patients with peripheral arterial disease experienced 77.3% of the red days (severe chronic limb ischaemia 58.1% and acute limb ischaemia 19.2%). Awaiting wound dressing change, acute theatre (vascular and emergency theatre) and interventional procedure accounted for 31.9%, 11.2% and 9.2% of red days respectively. Delays to vascular ultrasound and rehabilitation review each resulted in 8.4% of red days.

CONCLUSIONS: This study highlights significant delays during vascular surgery admissions and provides a focus to improve patient quality of life and hospital efficiency.

Red and Green Bed Days is a hospital management system recently implemented within the National Health Service (NHS) UK. It is designed to identify delays during the in-patient stay of patients.[1] Dr Ian Sturguss developed the concept, and defined a 'red day' as day when a patient only receives care that did not require an acute hospital bed, such as antibiotics, usual medications and basic observations.[2] More simply, a day where no activity occurred to progress a patient towards discharge.[3] Whereas a 'green day' occurs when the planned patient care for that day was achieved (Figure 1).[1] The approach to judging days as red or green needs to be rigorous, otherwise few red days are identified and the opportunity for improved patient flow will be lost.[4]

Despite the importance of recognising and eliminating the factors that unnecessarily prolong hospital length of stay, there remains a paucity of research within this field in New Zealand. The aim of study was to record the number of red days in a subset of surgical ward patients, being the vascular surgery ward patients, and identify the causes of those delays.

The identification of red days and the cause for the delay allows for improvement of internal and external systems to reduce patient length of stay.[1] Moreover, addressing specific causes of delay in daily hospital practice ensures an increase in capacity at

Figure 1: Definition of Red and Green Bed Days.

A **Red day** is when a patient receives little or no value adding acute care. The following questions should be considered: • Could the care or interventions the patient is receiving today be delivered in a non-acute setting? • If I saw this patient in out-patients, would their current 'physiological status' require emergency admission? If the answers are 1. Yes and 2. No, then this is a **'Red bed day'** Examples of what constitutes a **Red bed day**: • A planned investigation, clinical assessment, procedure or therapy intervention does not occur. • The patient is in receipt of care that does not require an acute hospital bed. • The medical care plan lacks a consultant approved expected date of discharge. • There are no consultant approved physiological and functional clinical criteria for discharge in the medical care plan. **A RED day is a day of no value for a patient**	A **Green day** is when a patient receives value adding acute care that progresses their progress towards discharge. A **Green day** is a day when everything planned or requested gets done. A **Green day** is a day when the patient receives care that can only be in an acute hospital bed. **A GREEN day is a day of value for a patient**

From: Emergency Care Improvement Programme, NHS Improvement. Rapid Improvement Guide to Red and Green Bed Days. Copyright 2016 by ECIP, NHS Improvement (NHS Trust Development Authority). Reprinted with permission.[1]

the stage of the process, which will enable the greatest improvement to efficiency and patient flow. This may arise secondary to changes to resourcing, protocol and patient flow pathways, allowing for improved care delivery.

Methods

This study was approved by the Waikato District Health Board Clinical Audit Service. Ethics approval was deemed not warranted for the audit-based research.

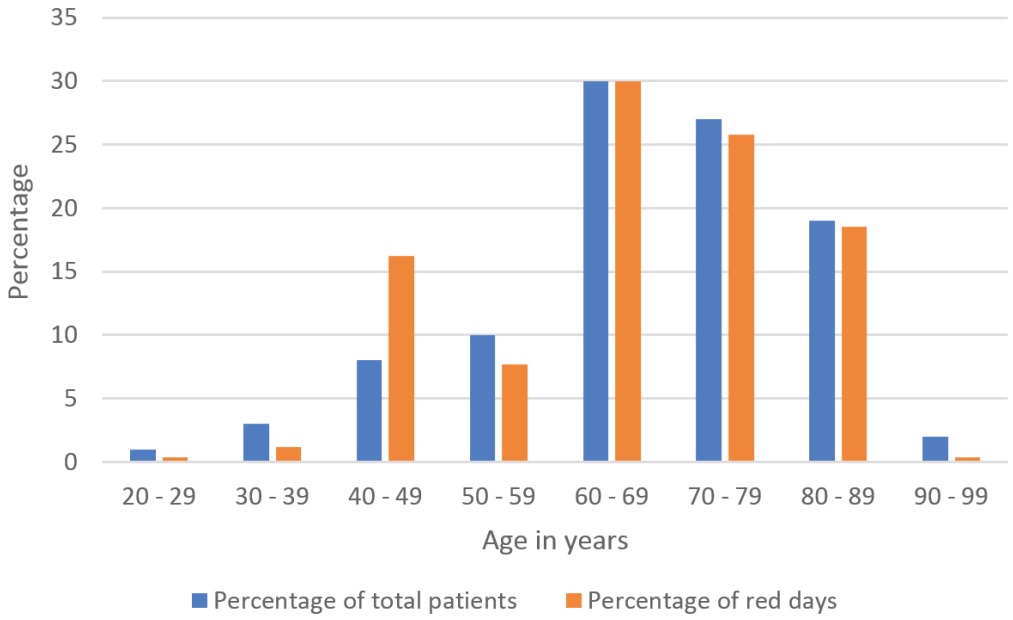
Starting in June 2018, 100 consecutive in-patient stays were recorded within the vascular surgical department at Waikato Hospital, New Zealand. At the conclusion of each day, each day was recorded as green or red as decided by the lead researcher, vascular registrars and vascular nurse in charge. A green day was recorded if any action undertaken could only be done as an inpatient for that patient's circumstances on that day. Red day was recorded when the patient only received care that could have been provided in a non-acute setting, such as personal care, routine observations, IV antibiotics and usual medication.

Subsequently, the specific cause of the red day was identified from a pre-generated list of possible red day causes. See Appendix for list of red days causes.

Results

The study period ran for 54 consecutive days including weekends. There was a total of 703 in-patient days for the 100 consecutive vascular ward patients, with 443 (63%) green and 260 (37%) red days recorded. There was an average 2.6 red days per patient for the 100 patients, and the average length of stay was 7.03 days.

Figure 2: Percentage of total patients and red days as per age bracket.



Overall, 38 patients experienced only green days during their admission, while the remaining 62 patients experienced one or more red days.

There was no difference in the number of red days between genders (p=0.94). Overall, there were 41 females admitted accounting for 189 green days and 110 red days (42.3% of red days). The remaining 59 patients were male, and accounted for 254 green days and 150 red days (57.7% of red days). The highest proportion of patients admitted were between the ages of 60–69 (30%) and 70–79 (27%), and these patients also accounted for the greatest portion of red days (30% and 25.8% of red days respectively) (Figure 1). Importantly, the 48 patients that were aged over 70 years accounted for 44.7% of red days.

In total, patients with peripheral arterial disease (PAD), being either acute or severe chronic limb ischaemia experienced a combined 77.3% of the total red days. Severe chronic limb ischaemia consisted of patients that presented with rest pain, ulceration and gangrene (15.4%, 14.2% and 28.5% of red days respectively), overall accounting for 58.1% of total red days (Table 1). The average age of patients with severe chronic limb ischaemia was 74.8 years for females and 73 years for males. 19.2% of red days were attributed to patients presenting with acute limb ischaemia, with an average age of 56.2 years for females and 70.7 years for males.

Elective surgical presentations to the vascular department such as carotid endarterectomy, renal access cases, varicose vein surgery and elective popliteal aneurysm stenting did not accrue any red days.

Days spent waiting in hospital between wound dressing changes for complex dressings that were unable to be managed in community made up 31.9% of red days. This consisted of days between application of vacuum-assisted closure (VAC) dressings (17.7%) and topical dressings (14.2%) (Table 2). Those days when a dressing change occurred were recorded as green days. Patients awaiting acute theatre (acute vascular theatre and emergency theatre) accounted for 29 red days (11.2% of red days), while patients awaiting interventional procedure accounted for 25 red days (9.6% of red days). Delays to vascular ultrasound resulted in 22 red days (8.4% of red days), and to rehabilitation review or rehabilitation bed with 22 red days (8.4% of red days).

Furthermore, 31.9% of red days occurred on weekend days, most commonly due to days between dressing care, both VAC (13 red days) and topical (10 red days), awaiting vascular ultrasound (seven red days) and awaiting physiotherapy review for discharge (five red days).

Table 1: Comparison of presenting complaint by the number of red and green days.

Presenting complaint	Total patients	Total days	Average length of stay	Green days (% total green days)	Red days (% total red days), P value
AAA	7	42	6	39 (8.8)	3 (1.2), p=0.00
Acute limb ischaemia	9	122	13.6	72 (16.3)	50 (19.2), p=0.31
Amaurosis fugax	1	1	1	1 (0.2)	0 (0), p=0.44
Aortic dissection	1	3	3	3 (0.7)	0 (0), p=0.18
Aortic ulcer	1	7	7	6 (1.4)	1 (0.4), p=0.21
AVF thrombus	1	4	4	2 (0.5)	2 (0.8), P=0.26
CEA	6	24	4	24 (5.4)	0 (0), p=0.0001
Cellulitis	1	8	8	5 (1.1)	3 (1.2), p=0.3
Chronic mesenteric ischaemia	2	6	3	5 (1.1)	1 (0.4), p=0.06
Claudication	6	24	4	17 (3.8)	7 (2.7), p=0.42
CVD	1	4	4	3 (0.7)	1 (0.4), p=0.11
DVT	4	19	4.8	11 (2.5)	8 (3.1), p=0.64
Fall	1	4	4	4 (0.9)	0 (0), p=0.12
Foot abscess	1	20	20	9 (2)	11 (4.2), p=0.09
Gangrene	19	171	9	97 (21.9)	74 (28.5), p=0.05
Haematoma	1	10	10	9 (2)	1 (0.4), p=0.08
Ischaemic fingers	1	2	2	1 (0.2)	1 (0.4), p=0.7
Mycotic aneurysm	1	7	7	2 (0.5)	5 (1.9), p=0.06
OM stump	1	2	2	2 (0.5)	0 (0), p=0.28
Popliteal artery aneurysm	1	2	2	2 (0.5)	0 (0), p=0.28
Renal access	2	4	2	4 (0.9)	0 (0), p=0.12
Rest pain	16	104	6.5	64 (14.4)	40 (15.4), p=0.74
Retroperitoneal bleed	1	23	23	10 (2.3)	13 (5), p=0.05
Ulcer	11	76	6.9	39 (8.8)	37 (14.2), p=0.03
Varicose veins	3	6	2	6 (1.4)	0 (0), p=0.06
Wound breakdown	1	8	8	6 (1.4)	2 (0.8), p=0.48
Total	**100**	**703**		**443**	**260**

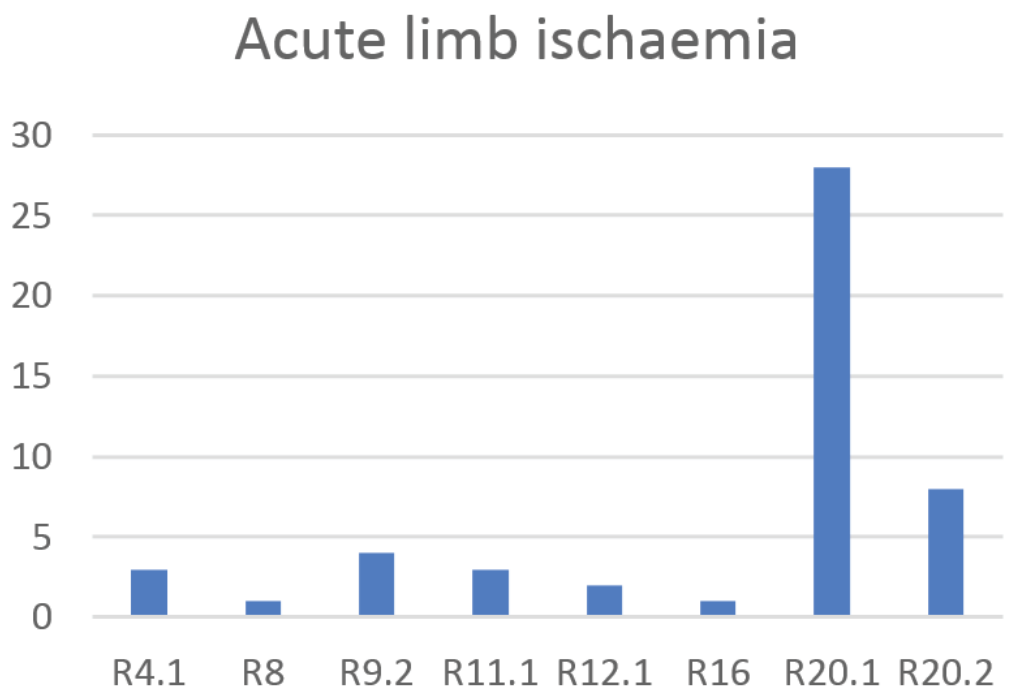
AAA; abdominal aortic aneurysm. AVF; arteriovenous fistula. CEA; carotid endarterectomy. CVD; chronic venous disease. DVT; deep vein thrombosis. OM; osteomyelitis.

Table 2: Comparison of causes of red days.

Cause number	Cause of red day	Number of red days	% of red days (n=260)	% of overall days (n=703)
R1.2	Awaiting aged care review	5	1.9	0.71
R1.4	Awaiting START assessment (home service)	10	3.8	1.4
R3	Awaiting transfer to step down hospital	7	2.7	0.1
R4.1	Awaiting review or transfer to rehabilitation unit	22	8.5	3.1
R4.5	Referral not made to alterative department	2	0.8	0.3
R6	Awaiting consultant opinion	1	0.4	0.1
R7.3	Awaiting histopathology result	5	1.9	0.7
R8	Awaiting other speciality review	8	3.1	1.1
R9.2	Awaiting vascular ultrasound	22	8.5	3.1
R11.1	Awaiting vascular surgery date	23	8.8	3.3
R11.2	Awaiting emergency theatre date	6	2.3	0.85
R11.3	Awaiting interventional radiology theatre date	25	9.6	3.6
R12	Awaiting allied health review	1	0.4	0.1
R12.1	Awaiting physio review	10	3.8	1.4
R12.6	Awaiting MDT	1	0.4	0.1
R13	Awaiting patient or family decision	7	2.7	0.1
R14	Awaiting family meeting	2	0.8	0.3
R16	Discharge planned for tomorrow	11	4.2	1.6
R20.1	Days between VAC dressing change (unable to be managed in community)	46	17.7	6.5
R20.2	Days between topical dressing change (unable to be managed in community)	37	14.2	5.3
R21	Monitoring of patient	9	3.5	1.3
Total		**260**		

NB: table illustrates only those causes with one or more red day allocated. START; supported transfer and accelerated rehabilitation team. MDT; multidisciplinary meeting. VAC; vacuum-assisted closure.

Figure 3: Causes of red days for patients with acute limb ischaemia.



R4.1; awaiting review or transfer to rehabilitation unit. R8; awaiting other speciality review. R9.2; awaiting vascular ultrasound. R11.1; awaiting vascular surgery date. R12.1; awaiting physio review. R16; discharge planned for tomorrow. R20.1; days between VAC dressing change (unable to be managed in community). R20.2; days between topical dressing change (unable to be managed in community).

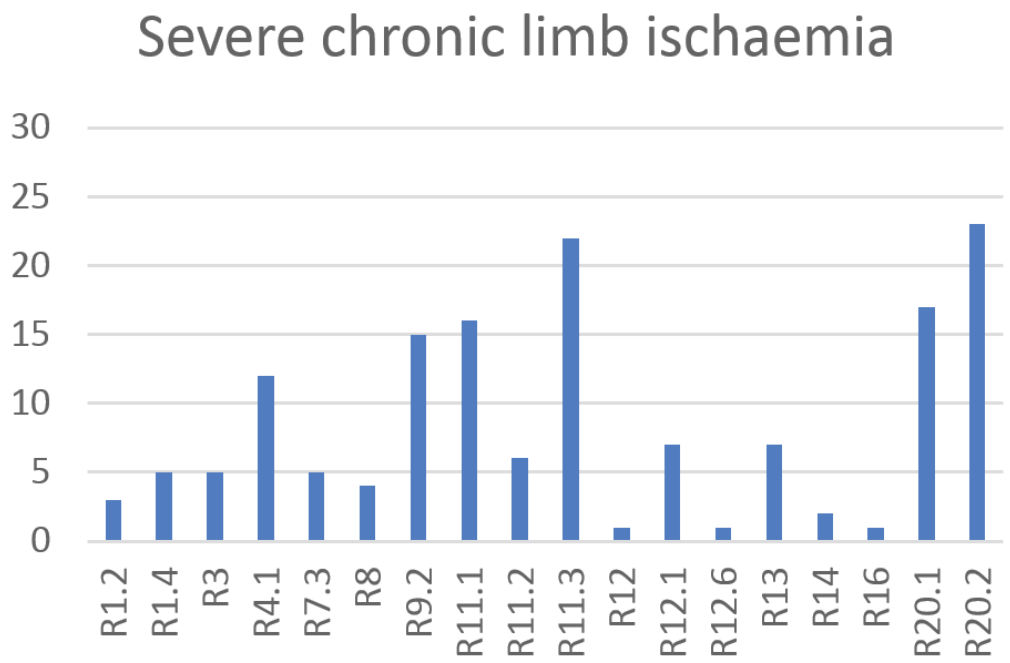
Figure 3 and Figure 4 demonstrate the causes of red days for patients with PAD presenting with either acute or severe chronic limb ischaemia. Patients who presented with acute limb ischaemia experienced red days due to requirements for complex wound dressings, particularly days between VAC dressings that were unable to be managed in the community (cause R20.1). Patients who presented with severe chronic limb ischaemia (being those with rest pain, ulceration and gangrene) accrued red days secondary to awaiting access to rehabilitation review or bed (R4.1), awaiting vascular ultrasound (R9.2) and awaiting surgery date for vascular (R11.1) and interventional radiology (R11.3). Again, days spent in hospital awaiting complex wound dressing change that was unable to be managed in the community, both VAC (R20.1) and topical (R20.2) contributed to a substantial number of red days.

Discussion

Research has shown that a considerable quantity of hospital days is devoted to a level of care that could be delivered in the outpatient setting.[5,6] This study highlights that there were significant delays in the hospital stay of patients admitted under vascular surgery, in total 37% of days were of no value to the patient, hospital and patient's family.

The high number of red days results in a substantial financial burden for hospitals providing care, with a significant waste of resources. The World Health Organization (WHO) estimated in 2005 that the cost per bed per day for a tertiary hospital in New Zealand was NZ$349.50 for the 'hotel' components of hospital bed costs, including personnel and food costs, but excluding diagnostic tests and treatments.[7] Given there were 260 red days in this study period of 54 days, the total wasted expenditure estimates

Figure 4: Causes of red days for patients with severe chronic limb ischaemia (derived from combining red days of patients with rest pain, ulceration and gangrene).



R1.2; awaiting aged care review. R1.4; awaiting START assessment (home service). R3; awaiting transfer to step down hospital. R4.1; awaiting review or transfer to rehabilitation unit. R7.3; awaiting histopathology result. R8; awaiting other speciality review. R9.2; awaiting vascular ultrasound. R11.1; awaiting vascular surgery date. R11.2; awaiting emergency theatre date. R11.3; awaiting interventional radiology theatre date. R12; awaiting allied health review. R12.1; awaiting physio review. R12.6; awaiting MDT. R13, awaiting patient or family decision. R14; awaiting family meeting. R16; discharge planned for tomorrow. R20.1; days between VAC dressing change (unable to be managed in community). R20.2; days between topical dressing change (unable to be managed in community).

to NZ$90,870 overall. This is likely an underestimation given the WHO estimate of per day expenditure excluded basic treatments such as medications provided, and is based on 2005 calculations.

Furthermore, to demonstrate in terms of bed utilisation, if the average length of stay was 7.03 days, then the 260 days lost to avoidable delays corresponds to the potential bed availability for a further 37 patients over a 54-day period in the vascular department. Hence, there is a significant incentive from both a financial and bed utilisation perspective for hospital providers to focus on eliminating wasted days during in-patient stays.

Unnecessary time spent in hospital is associated with reduced patient quality of life.[6,8] In our study, 260 days of patient lives were spent delayed in hospital rather than at home with family, friends and support networks. In addition, unnecessary hospital delay has been shown to be associated with pressure sores, deep vein thrombosis, hospital-acquired infections and deconditioning, therefore further reducing a patient's quality of life.[6, 9] Recognising this association may help in the identification of patients at risk of poor quality of life, and drive changes that improve patient wellbeing.[8]

In addition, delays in patient care place the patient at risk of functional decline.[5] Especially in older patients, the associated inactivity from an unnecessarily prolonged hospital stay leads to a reduction of muscle mass, reduced independence and increased risk of readmission.[10] In this study, 48/100 patients were aged over 70 years, and this cohort experienced 44.7% of red days. The admission of a significant number of elderly patients is not unexpected given the typical demographics of patients suffering from vascular disease. Hence, future action to improve efficiency in the vascular department requires a focus on reducing the burden of delay for this above 70-year-old cohort.

The Red and Green Bed Day management system has been established to improve patient flow for hospital in-patient units.[1,3] It is a valuable tool to objectively detect and quantify delays that restrict patient progression to the next phase of their care.[1,3] Studies worldwide have used numerous methods to identify causes of unnecessary hospital delay. In acute wards, major delays tend to occur in scheduling of tests and test performance, awaiting transfer to another ward, unavailability of post-discharge facilities, delays in clinician decision-making and access to surgery.[5,11] However, the unique niche of each surgical or medical unit within different hospitals will create variable results. As evidenced by Claffey et al, which utilised the Red and Green Bed Day system to analyse patient flow in an acute geriatric medicine unit in Ireland.[3] This suggested that external causes such as awaiting long-term care, home care package, and offsite transitional care were the greatest causes of red days for geriatric patients, rather than internal causes such as awaiting test results. Hence, there is a need for individual hospital units to conduct research that focuses on their specific drivers of delay, in addition to a hospital-based effort to manage constraints and bottlenecks in the care process.

This study has suggested that within the vascular department, the major causes of delays are due to both external and internal factors. Constraints external to the hospital contributed the greatest portion of red days, that being patient days spent in hospital between complex dressing change of both VAC and topical dressings that were unable to be managed in the community. This occurs because standard practice allows for healing time between dressing changes (VAC dressings changed every third day, while topical dressing change routine is variable). Hence advancements in community nurse dressing capabilities may save a large portion of days that patients spend in hospital awaiting dressing change. Delays due to internal hospital bottlenecks in patient care, such as access to vascular ultrasound imaging, emergency theatre, endovascular theatre and vascular theatre, and awaiting rehabilitation bed availability accounted for considerable red days. Thus, future interventions might focus on addressing issues with access to ultrasound, surgical theatres and rehabilitation beds.

Almost one-third of red days occurred secondary to an inability to access services on the weekend (Saturday or Sunday), particularly access to physiotherapy assessment and vascular ultrasound. Carey et al (2005) developed a survey to detect delays in medical care in an urban tertiary hospital in the US, and similarly found that nearly one-quarter of unnecessary hospital days occurred on weekends when testing and surgical capabilities are limited.[6] A focus on increasing availability for services that promote weekend discharges would decrease the accumulation of patients awaiting discharge until Monday when services recommence.

Furthermore, patients most at risk of significant delays were aged 60–80 years presenting with either chronic or acute PAD. The early identification of these at risk patients, ensures the vascular team work preventatively during each patient admission to optimise patient care.

The future requires a focus from hospital management and a clinician lead accountability to reduce unnecessary hospital delays. In part, this could be achieved via implementing the Red and Green Management System into the daily ward rounds which would function each day to identify potential delays during the morning ward round, and to proactively manage constraints or escalate issues during the day to ensure that every patient achieves a green day.[12] Furthermore, within the NHS, the Red and Green Days Management System has worked particularly well when implemented alongside the SAFER Patient Flow Bundle. This has demonstrated improved timeliness of discharge and a positive impact on flow through hospitals.[13] The SAFER Patient Flow Bundle is a combined set of rules for inpatients wards, and blends five elements of best practice.[14] Those being: S—senior review before midday, A—all patients have an expected discharge date and clinical criteria for discharge, F—flow of patients at earliest opportunity, E—early discharge before midday, and R—review via multidisciplinary team for patients with length of stay greater than seven days.[15] While not tested in this

study, implementing a similar programme alongside Red and Green bed days in New Zealand may assist inpatient wards with tackling delays for hospital inpatients.

This study has limitations in that it was performed in a single tertiary hospital in one surgical specialisation, hence results may not be directly correlate to other departments or other hospitals. In addition, the validity and reliability of the monitoring system to identify and classify delays has not been established, particularly due to the lack of a gold standard instrument. Furthermore, this study represents a two-month period and may not accurately reflect hospital activity over one entire year.

Conclusions

This study provides a focus for improving internal and external hospital systems to improve the in-patient stay of surgical patients, in particular vascular patients. Changes to patient care will be achieved through coordinated service revision and improved patient flow pathways.

Appendix

Reasons for red days

Transfers:

1. Waiting for start or restart of supported care package (external)
    - 1.1. Disability
    - 1.2. Aged care
    - 1.3. Palliative care/Hospice
2. Waiting for transfer to specialist centre hospital for treatment (external)
3. Waiting for transfer to step down hospital for ongoing management (external)
4. Waiting for transfer to alternative department/ward for ongoing management (internal)
    - 4.1. Rehab bed
    - 4.2. Aged care bed
    - 4.3. Other internal medicine bed
    - 4.4. Other surgical bed
    - 4.5. Referral not made
5. Delay in referral over previous day to external or internal transfer agency (internal)

Management:

6. Waiting for senior/consultant opinion (internal)
7. Waiting for medical test (internal)
    - 7.1. Echocardiogram
    - 7.2. Stress testing
    - 7.3. Pathology/histopathology result
8. Waiting for another specialist opinion/review (internal)
9. Waiting for imaging modality (internal)
    - 9.1. CT
    - 9.2. Vascular ultrasound
    - 9.3. PET
10. Waiting for blood tests
    - 10.1. Not requested
    - 10.2. Requested, awaiting results

11. Waiting for theatre time (internal)
    - 11.1. Vascular surgery date
    - 11.2. Emergency theatre time
    - 11.3. Interventional radiology theatre time
12. Waiting for allied health review (internal)
    - 12.1. Physiotherapy
    - 12.2. Occupational therapy
    - 12.3. Social work
    - 12.4. Pharmacy
    - 12.5. Podiatry
    - 12.6. MDT meeting

Patient/family:

13. Waiting for patient/family choice (internal)
14. Waiting for family meeting (internal)

Discharge:

15. Waiting for care in own home (external)
16. Discharge planned for tomorrow (internal)
17. Waiting for equipment for home (external)
18. Waiting for discharge medications (internal)
19. End of life pathway (internal)

Wound care:

20. Days waiting between dressing change for:
    - 20.1. VAC dressing not able to be managed in community
    - 20.2. Topical dressing not able to be managed in community

Competing interests:
Nil.

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Completeness of ANZACS-QI Cardiac Implanted DEVICE Registry and agreement with national datasets: ANZACS-QI 30

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ABSTRACT

AIMS: The ANZACS-QI Cardiac Implanted Device Registry (ANZACS-QI DEVICE) collects data on cardiac implantable electronic devices inserted in New Zealand. We evaluated completeness of data capture and quality of ANZACS-QI DEVICE in 2016.

METHODS: Complete datasets within ANZACS-QI DEVICE, comprising DEVICE-PPM (permanent pacemakers) and DEVICE-ICD (implantable cardioverter defibrillators), from 1 January 2016 to 31 December 2016 were linked with the National Hospitalisation dataset (all New Zealand public hospital admissions). The total number of implants included procedures captured in either dataset. Variables assessed included age, gender, ethnicity, procedure type, implanting centre, admission and procedure date.

RESULTS: DEVICE-PPM captured 85.9% of all PPM procedures (n=2,512). This was similar regardless of age, sex and ethnicity. In the 84.4% of procedures captured in both datasets, agreement was >97% for all variables except admission date (90.1%). DEVICE-ICD captured 81.3% of all ICD procedures (n=690). Capture was similar across age, sex and ethnicity groups. In the 76.8% of procedures captured in both datasets, agreement was >96% for all variables except admission date (90.6%).

CONCLUSION: The ANZACS-QI DEVICE registry had a good capture rate and excellent agreement with the national dataset. This high concordance supports the use of both datasets for future research.

The All New Zealand Acute Coronary Syndrome-Quality Improvement Cardiac Implanted Device Registry (ANZACS-QI DEVICE) collects data on cardiac implantable electronic devices (CIED) inserted across New Zealand. The registry includes permanent pacemakers (DEVICE-PPM) and implantable cardioverter defibrillators (DEVICE-ICD), including both first implants and replacement procedures. The registry includes cardiac resynchronisation therapy pacemakers and defibrillators and subcutaneous ICDs. The ANZACS-QI DEVICE registry was collaboratively developed by physicians at Counties Manukau District Health Board and Heart Rhythm New Zealand (HRNZ). It was built upon the ANZACS-QI platform and introduced to New Zealand public hospitals in 2014 through a grant from the New Zealand branch of Cardiac Society of Australia and New Zealand (CSANZ).[1] The purpose of the ANZACS-QI DEVICE registry is to support clinical quality improvement and audit across New Zealand centres. Participation is voluntary. Both DEVICE-ICD and DEVICE-PPM collect procedure numbers, patient demographics, symptoms, ECG findings, device indication, device type, implant physician and hospital as well as complication data. Data collected in the DEVICE-ICD registry also includes cardiac and medical history as well as left ventricular systolic function. For the ANZACS-QI DEVICE registry to be useful as a quality improvement and audit tool it needs to capture the majority of procedures in each centre and

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the data captured needs to be accurate. Data is entered by cardiac physiologists at the time of the procedure and at the four to six week follow-up device clinic, when the data form is finalised. Data quality is facilitated by the use of mandatory datasets, in-form definition statements and in-form automatic validation rules.

In New Zealand, all CIED procedures should be captured in the National Hospitalisation Datasets (NHD), which collects all public hospital admissions in New Zealand using International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD10-AM) coding. This provided an opportunity to evaluate both ANZACS-QI DEVICE registry capture and quality of data items by assessing the concordance with data items held in common with the National Hospitalisation Dataset. The two data sources can be linked anonymously using an encrypted National Health Index number.

As 2016 was the first year with full participation from all 10 PPM and seven ICD implant sites in New Zealand in the ANZACS-QI DEVICE registry, we sought to evaluate the completeness of capture of ANZACS-QI DEVICE compared with those recorded in the National Hospitalisation Dataset. We also aimed to evaluate data quality by assessing agreement between datasets on patient demographics and basic procedural details.

Methods

Cohorts

The National Hospitalisation Dataset included all public hospital admissions in New Zealand from 1 January to 31 December 2016 for patients ≥18 years of age. The ANZACS-QI DEVICE registry dataset included one cohort for PPMs (DEVICE-PPM) and another cohort for ICDs (DEVICE-ICD). All data items in the ANZACS-QI DEVICE registry electronic form are mandatory. This study examined completed ANZACS-QI DEVICE registry forms only, to ensure complete datasets were available for analysis. This analysis was based on episodes of care associated with a procedure rather than individual patients. A third dataset was used for comparison to further validate the use of the National Hospitalisations Dataset. PPM and ICD implant volumes in 2016 were available from HRNZ, who approached each implant centre for a manual count of implant numbers. The HRNZ dataset is not NHI linked and contains total numbers of cases only.

Definitions

Episode of Care (EoC)

In the national dataset, all hospital admissions associated with a CIED implantation code which were separated by no more than a day were 'bundled' together into a single EoC to avoid double counting due to inter-hospital transfers for a single clinical event. In ANZACS-QI DEVICE, subsequent admissions for device adjustment or reoperation within six weeks were captured under a single EoC. If the time periods of EoCs in the two datasets overlapped, they were defined as matching. This 'bundling' methodology has previously been validated for the ANZACS-QI acute coronary syndrome and a coronary angiography cohort.[2]

PPM and ICD implants were identified in the national dataset using ICD10-AM codes (see Appendix). Procedure codes identified in the national dataset in non-implant centres were excluded. If codes for ICD and PPM were both present in a single EoC, this was categorised as an ICD implant. When codes for a new and replacement procedure were both present in a single EoC, if the replacement procedure occurred on the same day or earlier than the new procedure date, this was categorised as a replacement procedure. Conversely, if the replacement procedure date was a day or more after the new procedure date, this procedure was categorised as a new implant.

Analyses

The denominators for total PPM and ICD implantations were procedures recorded in either the national dataset or the ANZACS-QI DEVICE registry. The completeness of capture of PPM and ICD implants in the ANZACS-QI DEVICE registry was calculated as the number captured in ANZACS-QI DEVICE registry divided by the appropriate denominator. The overlap between the ANZACS-QI DEVICE registry and national data is displayed using Venn diagrams. Analyses of agreement between the two datasets included patients who were recorded as having a PPM or ICD implant in

both the ANZACS-QI DEVICE registry and the national dataset. Agreement was assessed for the following variables: age, gender, ethnicity, type of procedure, implanting centre, admission date and procedure date.

Ethics

ANZACS-QI is part of the wider Vascular Informatics, Epidemiology and the Web (VIEW) study. The VIEW study was approved by the Northern Region Ethics Committee Y in 2003 (AKY/03/12/314), with subsequent amendments to include the ANZACS-QI registries, and with annual approvals by the National Multi-region Ethics Committee since 2007 (MEC07/19/EXP).

Results

DEVICE-PPM

There were a total of 2,512 PPM implants recorded in either dataset (all PPM), with 84.4% of implants captured in both datasets, 14.1% in the national dataset only and 1.6% in ANZACS-QI DEVICE-PPM only (Figure 1, Table 1). Overall, the DEVICE-PPM registry captured 85.9% of all PPM implants, with >85% captured in seven of the 10 implanting centres. Capture in DEVICE-PPM was similar regardless of age, sex, ethnicity and procedure type.

In the 84.4% of PPM procedures captured in both datasets, agreement was >97% for all variables except admission date (90.1%) (Table 2).

Overall data completion rate was 94.6% in the PPM registry. Completion of data forms was >93.4% in all but one centre, where the completion rate was 62.3%.

DEVICE-ICD cohort

There were a total of 690 ICD implants recorded in either dataset (all ICD), with 76.8% of implants captured in both datasets, 18.7% in the national dataset only and 4.5% in ANZACS-QI DEVICE-ICD only (Figure 2, Table 3). Overall, the DEVICE-ICD registry captured 81.3% of all ICD implants, with >86% captured in five of the seven implanting centres. Capture in DEVICE-ICD was similar across age, sex and ethnicity groups apart from slightly lower capture in the very young, very elderly and in South Asians.

In the 76.8% of ICD procedures captured in both datasets, agreement between datasets was >96% for all variables except admission date (90.6%) (Table 4).

Overall data completion rate was 87.7% in the ICD registry. Completion of data forms was >82.6% in all but one centre, where the completion rate was 46.6%.

Comparison with the Heart Rhythm New Zealand (HRNZ) dataset

PPM and ICD implant volumes were also compared to a manual count of implant numbers obtained from each centre by HRNZ in 2016 (Table 5). Reassuringly there was a very close agreement between the NHD and this count.

Discussion

The ANZACS-QI DEVICE registry was designed to collect data on all PPM and ICD implanted across public hospitals in New Zealand. Despite participation being voluntary at this point in time, with no registry completion targets set by the Ministry of Health, the overall data capture was good at 85.1% in the PPM registry and 80.4% in the ICD registry. Data capture was similar across age, sex, ethnicity and procedure type. Agreement of data items was excellent at >96% in both registries apart from admission date, which was still >90%. Capture of data was good in all but three implanting centres. One site had a lower registry form completion rate compared to the other centres while the other two sites had perfect registry form completion rates but may not have enrolled all eligible patients in the registry. For the ANZACS-QI ACS and CathPCI registries, where registry completion is supported by a Ministry of Health endorsed national target, registry completion is over 95% when assessed using methodology identical to this study.[3]

Despite the widespread use of CIED registries across the globe, to our knowledge this is the first study to validate data quality of a CIED registry against national datasets using ICD-10 codes. The total number of PPM and ICD implants identified in the national dataset using ICD-10 codes was very close to the total implant volumes collected from each implant centre. Thus, this supports the use of the NHD as the 'gold standard' for analyses of CIED procedural volumes. The high data quality of the ANZACS-QI

Figure 1: Venn diagram showing the overlap in the National Hospitalisation Datasets (NHD) and the DEVICE-PPM registry.

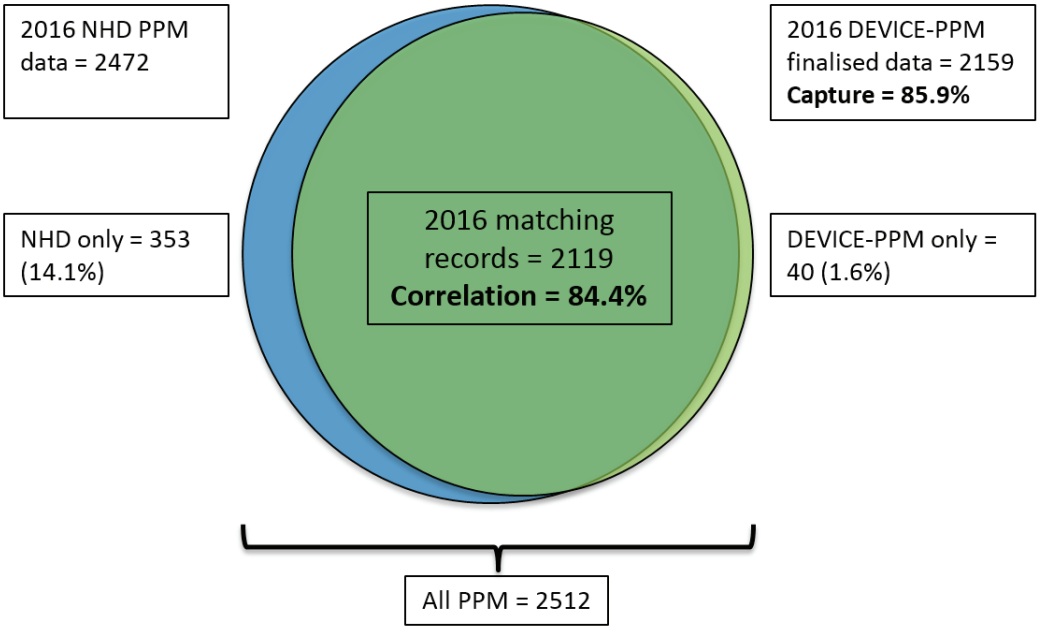

Table 1: Proportions of PPM implant procedures captured in DEVICE-PPM vs all PPM from either DEVICE-PPM or National Hospitalisation Datasets, by demographics and procedure type.

	All PPM (NHD + DEVICE-PPM) n	**DEVICE-PPM capture n (%)**
n	2,512	2,159 (85.9%)
Age, year		
<40	33	29 (96.7%)
40–59	216	173 (80.1%)
60–79	1,217	1,053 (86.5%)
80+	1,046	904 (86.4%)
Gender		
Female	982	843 (85.8%)
Male	1,530	1,316 (86.0%)
Ethnicity		
Māori	169	147 (87.0%)
Pacific	107	97 (90.7%)
Indian	35	32 (91.4%)
Other Asian	60	49 (81.7%)
European/Other	2,141	1,834 (85.7%)
Implanting centre		
North Shore	346	307 (88.7%)
Auckland	479	454 (94.8%)
Middlemore	197	189 (95.9%)
Waikato	333	296 (88.9%)
Tauranga	159	157 (98.7%)
Palmerston North	74	36 (48.6%)
Wellington	310	176 (56.8%)
Nelson	90	70 (77.8%)
Christchurch	300	257 (85.7%)
Dunedin	224	217 (96.9%)
Type of procedure		
New	1,963	1,710 (87.1%)
Replacement	549	449 (81.8%)

Table 2: Agreement between DEVICE-PPM and National Hospitalisation Datasets for PPM procedures captured in both datasets.

	NHD count	DEVICE-PPM count	Agreement
Age			
<40	29	29	100%
40–59	167	167	100%
60–79	1,032	1,032	100%
80+	891	891	100%
Gender			
Female	827	827	100%
Male	1,292	1,292	100%
Ethnicity			
Māori	136	136	100%
Pacific	92	90	97.8%
Indian	30	30	100%
Other Asian	48	48	100%
European/Other	1,813	1,804	99.5%
Type of procedure			
New	1,690	1,668	98.7%
Replacement	429	417	97.2%
Implanting centre			
North Shore	303	303	100%
Auckland	437	436	99.8%
Middlemore	186	186	100%
Waikato	295	294	99.7%
Tauranga	155	155	100%
Palmerston North	35	35	100%
Wellington	175	175	100%
Nelson	67	67	100%
Christchurch	250	250	100%
Dunedin	216	215	99.5%
Admission date +/- 1day			(1,910/2,119)=90.1%
Procedure date +/- 1day			(2,048/2,119)=96.7%

Figure 2: Venn diagram showing the overlap in the National Hospitalisation Datasets (NHD) and the ANZACS-QI DEVICE-ICD registry.

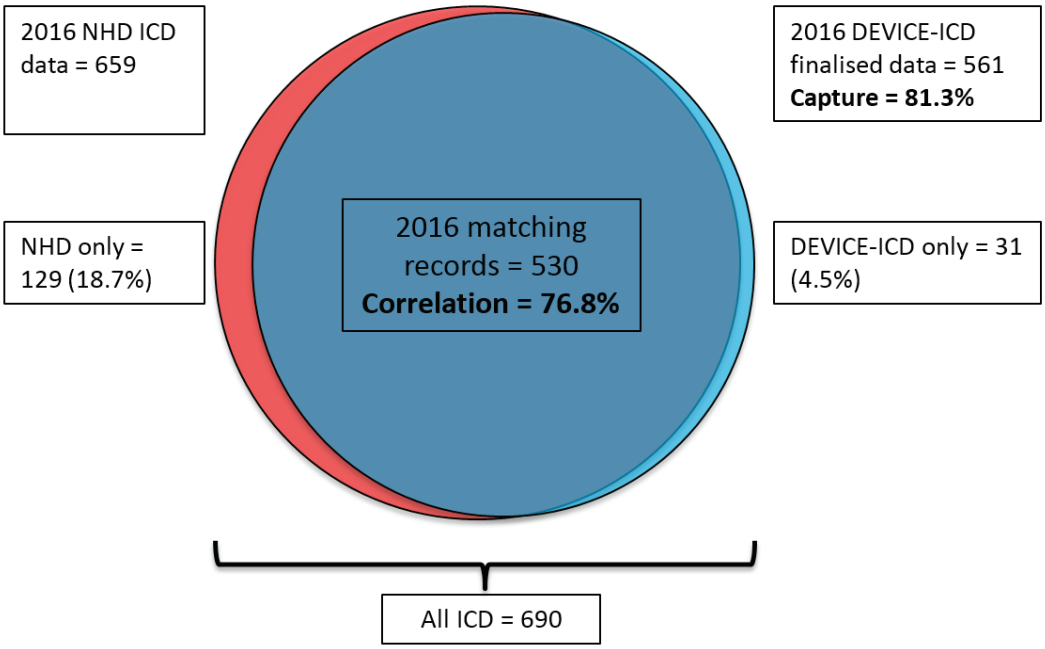

Table 3: Proportions of ICD implant procedures captured in DEVICE-ICD vs all ICD from either DEVICE-ICD or National Hospitalisation Datasets, by demographics and procedure type.

	All ICD (NHD + DEVICE-ICD) n	**DEVICE-ICD capture n (%)**
n	690	561 (81.3%)
Age, year		
<40	56	40 (71.4%)
40–59	240	204 (85.0%)
60–79	369	301 (81.6%)
80+	25	16 (64.0%)
Gender		
Female	163	125 (76.7%)
Male	527	436 (82.7%)
Ethnicity		
Māori	141	111 (78.7%)
Pacific	43	36 (83.7%)
Indian	11	11 (100%)
Other Asian	15	10 (66.7%)
European/Other	480	393 (81.9%)
Implanting centre		
North Shore	65	56 (86.2%)
Auckland	190	172 (90.5%)
Waikato	123	113 (91.9%)
Tauranga	33	33 (100%)
Wellington	132	65 (49.2%)
Nelson	18	10 (55.6%)
Christchurch	129	112 (86.8%)
Type of procedure		
New	510	414 (81.2%)
Replacement	180	147 (81.7%)

Table 4: Agreement between DEVICE-ICD and National Hospitalisation Datasets for ICD procedures captured in both datasets.

	NHD count	DEVICE-ICD count	Agreement
Age			
<40	40	40	100%
40–59	194	194	100%
60–79	281	281	100%
80+	15	15	100%
Gender			
Female	115	115	100%
Male	415	415	100%
Ethnicity			
Māori	103	102	99.0%
Pacific	34	34	100%
Indian	10	10	100%
Other Asian	10	10	100%
European/Other	373	368	98.7%
Type of procedure			
New	406	392	96.6%
Replacement	124	120	96.8%
Implanting centre			
North Shore	52	52	100%
Auckland	168	168	100%
Waikato	103	103	100%
Tauranga	31	31	100%
Wellington	59	59	100%
Nelson	7	7	100%
Christchurch	110	110	100%
Admission date +/- 1day			(480/530)=90.6%
Procedure date +/- 1day			(516/530)=97.4%

Table 5: Comparison of National Hospitalisation Dataset, ANZACS-QI DEVICE and HRNZ implant volumes.

	NHD	DEVICE	HRNZ
PPM			
Total	2,472	2,159	2,457
New	1,934	1,710	1,920
Replacements	538	449	537
ICD			
Total	659	561	660
New	491	414	495
Replacements	168	147	165

DEVICE registry as well as the high concordance with data items in the national dataset supports the use of either dataset for quality improvement or scientific analyses. Indeed, the ANZACS-QI DEVICE registry has very recently been used to report implant volumes and device type in New Zealand.[4]

Limitations and challenges

This study only examined completed registry forms within the ANZACS-QI DEVICE registry to ensure complete datasets for analysis. Thus, data from the incomplete registry forms may potentially affect the results of this analysis. However, the overall registry form completion rates in the DEVICE-PPM and DEVICE-ICD for 2016 were very high at 94.6% and 87.7%, respectively. Therefore we believe this analysis to be representative of the overall ANZACS-QI DEVICE registry.

The ANZACS-QI DEVICE registry does not record leadless pacemakers, His-bundle pacemakers, lead extractions, surgical hybrid procedures or paediatric CIED implants. It also does not allow for recording of lead replacements where an existing PPM or ICD generator is not replaced.

At present, data entry into the DEVICE registry relies on one or more cardiac physiologists at each implanting centre at the time of the procedure as well as at the four to six week follow-up clinic. This task requires additional time and effort over and above their usual clinical duties. In a public hospital system where cardiac physiologists are already overburdened, the expectation of continued entry of high-quality data into the DEVICE registry may not be sustainable unless this task is formally incorporated into their job description and providing specific remuneration.

Overall registry form completion is particularly influenced by completion of the form at the four to six week follow-up at device clinic, where early complications (if any) are recorded. This can be challenging if patients are followed up at a different district health board or a patient does not attend clinic. During the period of this study, 5.4% of DEVICE-PPM and 12.3% of DEVICE-ICD forms were incomplete and therefore not included in the analysis. Improved processes to ensure completion of these forms would help improve the capture rate.

The maintenance of the ANZACS-QI DEVICE registry also faces several challenges going forward. Although the Ministry of Health currently funds the licencing cost of the registry, future funding is not guaranteed. Future funding may require contribution from implanting hospitals, at which point these hospitals may choose to develop their own registries or stop using a registry altogether. However, the strength of the ANZACS-QI DEVICE registry lies in its familiar ANZACS-QI platform that is already being used in ANZACS-QI ACS and CathPCI. It also employs standardised data items and data definitions at all sites across the country. The Ministry of Health is considering adding ANZACS-QI DEVICE Registry completion as a national indicator. As above, improvement in data form completion would automatically improve the capture rate of the registry.

Conclusion

The ANZACS-QI DEVICE registry has a good capture rate and excellent agreement with the national dataset for common data items. This high level of concordance between the registry and the national dataset supports the use of both datasets for quality improvement and research.

Appendix

Appendix Table 1: ICD10-AM codes for PPM and ICD implants.

PPM new	3827800, 3827801, 3828100, 3828101, 3828102, 3828103, 3828104, 3828105, 3828106, 3828107, 3828108, 3828109, 3828110, 3828113, 3828400, 3835000, 3835300, 3836800
PPM replacement	3835001, 3835301, 3836801
ICD new	3839001, 3839002, 3839300, 3852102, 3852103, 3852400
ICD replacement	3835003, 3836803, 3839301, 3852106, 3852110, 3852403

Appendix Table 2: PPM and ICD implant volumes by centre in 2016 (HRNZ).

PPM implant centre	Total PPM	PPM new	PPM replacement
North Shore	316	236	80
Auckland	505	391	114
Middlemore	190	150	40
Waikato	319	271	48
Tauranga	152	129	23
Palmerston North	74	54	20
Wellington	297	219	78
Nelson	87	67	20
Christchurch	299	225	74
Dunedin	218	178	40
Total	2,457	1,920	537
ICD implant centre	**Total ICD**	**ICD new**	**ICD replacement**
North Shore	64	46	18
Auckland	173	120	53
Waikato	118	95	23
Tauranga	34	29	5
Wellington	133	110	23
Nelson	16	14	2
Christchurch	122	81	41
Total	660	495	165

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Mitral valve surgery with or without coronary bypass grafting: eight-year cohort study

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ABSTRACT

AIMS: A significant minority of patients undergoing mitral valve surgery (MVR) have indication for coronary artery bypass grafting (CABG). The risks of combination surgeries are not well appreciated and maybe more than additive. We compared the characteristics and outcomes of MVR+/-CABG performed at our centre.

METHODS: Consecutive patients undergoing isolated MVR or with concurrent (MVR+)CABG at Auckland City Hospital during 2005–2012 were compared for baseline and operative characteristics and outcomes in univariable and multivariable analyses.

RESULTS: A total of 178 MVR+CABG and 407 MVR patients were included. MVR+CABG patients had higher age, CCS and NYHA Class, cardiopulmonary bypass time, and higher prevalence of urgent surgery, hypertension, diabetes, renal impairment, myocardial infarction/coronary artery disease, congestive heart failure/impaired ejection fraction and peripheral vascular disease, although lower prevalence of active endocarditis and previous valve surgery (all P<0.05). MVR+CABG had higher mortality (operative 11.2% vs 2.5% P<0.001; one and five-year survival 85% vs 96% and 78% vs 87% P=0.041) and composite morbidity 53.4% vs 18.9% P<0.001, including acute renal failure, prolonged ventilation, return to theatre (all P<0.001) but not stroke. In multivariable analyses, MVR+CABG was independently associated with higher operative mortality odds ratio 2.07 95% confidence interval 1.09–3.93 and composite morbidity 2.38 (1.03–5.47), but not long-term mortality.

CONCLUSION: MVR+CABG compared to MVR patients had more comorbidities and greater operative risk, and were independently associated with higher operative mortality and composite morbidity, but not independently associated with higher long-term mortality.

Mitral valve surgery (MVR) is the second commonest performed valvular heart surgery.[1–3] It is the conventional gold standard for treatment of severe mitral valve regurgitation (MR) and/or stenosis (MS) with concurrent symptoms, progressive left ventricular dilation or dysfunction, new atrial fibrillation or pulmonary hypertension and high chance of successful repair.[2,3] Some patients with severe mitral valve disease also have significant coronary artery disease warranting revascularisation, and vice versa. The additional risk of combined surgeries is less well-studied and established, but is important to assess in the current era of the ageing population, higher-risk patients being intervened and growth of percutaneous mitral procedures.[4–9] Although surgical indication is clear for primary mitral valve disease, optimal strategy for secondary MR remains controversial.[7,8,10,11] Randomised trials showing no clear reduction in clinical events for combination surgery compared to CABG for ischaemic MR,[10,11] and more recently there was one negative[7] and one positive study[8] for percutaneous Mitraclip for secondary MR.

This study aimed to compare the characteristics and outcomes of patients undergoing MVR and MVR plus CABG (MVR+CABG) at our centre, as well as identifying predictors of adverse outcomes and the performance of surgical risk scores in these patients.

Methods

All consecutive patients undergoing MVR in isolation or with CABG, but not concurrent valve or other surgery, at Auckland City Hospital from 2005–2012 were reviewed. Clinical characteristics including demographics, aetiology, past history, investigations and operative characteristics were collected form computerised records, and conventional surgical risk scores EuroSCORE,[12] EuroSCORE II[13] and Society of Thoracic Surgeon's (STS)[5] Score were retrospectively calculated.

Operative mortality in-hospital or within 30 days, as well as long-term mortality up until 31 December 2017 or date of death were obtained from the New Zealand national deaths registry. Post-operative complications in-hospital including stroke, renal failure, ventilation>24 hours, deep sternal wound infection, return to theatre and their composite following the STS database definitions,[5] as well as length of hospital stay and pacemaker implantation were recorded.

Mean+/-standard deviation and percentages (frequency) were used to record continuous and categorical respectively. Mann-Whitney U test and Fisher's Exact test were used for univariable analysis for these variables respectively. Kaplan-Meier curves and log-rank test were used to analyse longitudinal outcomes. Multivariable analysis was performed using logistic regression for cross-sectional outcomes and Cox Proportional Hazards regression for longitudinal outcomes. Discrimination of risk scores was assessed by the c-statistic area under the receiver-operating characteristics curve, and calibration by observed/expected ratio and Hosmer-Lemeshow tests. P-value below 0.05 was defined for statistical significance and all tests were two-tailed. SPSS (Version 17.0, SPSS Inc., Chicago, IL, US) and Prism (Version 5, GraphPad Software, San Diego, CA, US) were used for all statistical analyses and presentation.

Results

There were 407 and 178 patients undergoing isolated MVR and MVR+CABG respectively during the study period. Table 1 lists the baseline characteristics. MVR+CABG patients were older, and had higher prevalence of secondary aetiology, New York Heart Association Class IV, unstable angina, inpatient urgent surgery, myocardial infarction, percutaneous coronary intervention, congestive heart failure, diabetes, hypertension, hypercholesterolaemia, extracardiac arteriopathy and coronary artery disease, including left main disease on coronary angiogram. MVR+CABG had lower proportion of patients with endocarditis and previous cardiac surgery including valve surgery. Mean EuroSCORE, EuroSCORE II and STS Scores were all higher in MVR+CABG patients.

Operative characteristics and in-hospital are shown in Table 2. Fewer patients undergoing MVR+CABG had mechanical valves, and they had significantly longer cardiopulmonary bypass and cross-clamp time. MVR+CABG patients had high operative mortality compared to MVR (11.2% versus 2.5%, <0.001) and composite morbidity (53.4% versus 18.9%, P<0.001), mainly driven by greater incidence of acute renal failure, prolonged ventilation>24 hours, return to theatre and hospital stay post-operatively. There was no difference between the two groups for stroke and pacemaker implantation. There was no statistically significant difference in operative mortality between mitral valve repair and replacement in isolation 1.5% versus 3.3% respectively, and with CABG 9.7% versus 12.9%, both P>0.05.

Figure 1 shows the Kaplan-Meier survival curves, with mean follow-up of 8.4+/-3.3 years for isolated MVR and 6.9+/-3.8 years for MVR+CABG. MVR+CABG had worse survival (P<0.001), including one-year survival of 86% versus 96%, five-year survival of 77% versus 88% and 10-year survival of 63% versus 81% compared to MVR.

In multivariable analysis as displayed in Table 3, MVR+CABG was independently associated with higher operative mortality odds ratio 2.07, 95% confidence interval 1.09–3.93, P=0.009 and composite morbidity odds ratio 2.38, 95% confidence interval 1.03–5.47, P=0.039, but not long-term mortality. Age and critical pre-operative state were independent predictors of all three outcomes.

Table 1: Baseline characteristics.

Characteristic	MVR	MVR+CABG	P-value
N	407	178	
Demographics			
Age (years)	56.6+/-16.2	66.8+/-9.9	**<0.001**
Female	44.0% (179)	38.2% (68)	0.204
Ethnicity			0.433
New Zealand European	57.4% (234)	60.7% (108)	
Māori or Pacific	33.1% (135)	28.1% (60)	
Other	9.3% (38)	11.2% (20)	
Body mass index (kg/m^2)	28.2+/-6.5	28.5+/-6.2	0.398
Aetiology			
Degenerative/prolapse	49.9% (203)	42.7% (76)	0.126
Rheumatic	21.1% (86)	17.4% (31)	0.315
Endocarditis	15.2% (62)	7.9% (14)	**0.016**
Other primary	10.3% (42)	3.4% (6)	**0.005**
All secondary	4.4% (14)	28.7% (51)	**<0.001**
Ischaemic	2.7% (11)	21.9% (39)	**<0.001**
Functional	0.7% (3)	6.7% (12)	**<0.001**
Presentation			
New York Heart Association class IV	9.1% (37)	16.9% (30)	**0.003**
Unstable angina class IV	0.0% (0)	5.3% (31)	**<0.001**
Syncope	1.5% (6)	0.6% (1)	0.681
Critical pre-operative state	8.6% (35)	7.3% (13)	0.744
Inpatient urgent operation	53.0% (216)	59.0% (105)	**0.010**
Past history			
Previous cardiac surgery	17.7% (72)	3.4% (6)	**<0.001**
Valve surgery	15.5% (63)	2.8% (5)	**<0.001**
Coronary artery bypass grafting	2.2% (9)	1.7% (3)	1.000
Percutaneous coronary intervention	1.7% (7)	14.0% (25)	**<0.001**
Myocardial infarction	6.6% (27)	44.9% (80)	**<0.001**
Congestive heart failure	27.8% (113)	38.8% (69)	**0.009**
Atrial fibrillation	47.7% (194)	43.8% (78)	0.418
Diabetes	8.7% (35)	26.4% (47)	**<0.001**
Hypertension	30.2% (123)	57.3% (102)	**<0.001**
Hypercholesterolaemia	32.5% (132)	74.7% (133)	**<0.001**
Current smoker	13.6% (55)	13.5% (24)	1.000

Table 1: Baseline characteristics.

Cerebrovascular accident	9.3% (38)	9.0% (16)	1.000
Extracardiac arteriopathy	2.5% (10)	7.3% (13)	**0.009**
Chronic pulmonary disease	19.7% (80)	15.7% (28)	0.298
Creatinine clearance (mL/min)	75+/-25	70+/-32	0.180
Dialysis	1.0% (4)	1.7% (3)	0.319
Investigations			
Ejection fraction			0.861
≤50%	85.7% (349)	80.0% (24)	
30–49%	13.5% (55)	16.7% (5)	
<30%	0.7% (3)	3.3% (1)	
Mitral regurgitation	90.7% (369)	87.1% (155)	0.190
Mitral stenosis	15.7% (64)	15.2% (27)	0.902
Aortic regurgitation	1.7% (7)	3.4% (6)	0.230
Aortic stenosis	1.5% (6)	3.4% (6)	0.201
Tricuspid regurgitation	13.0% (53)	16.9% (30)	0.247
Pulmonary hypertension	19.6% (75)	18.5% (33)	0.742
Main coronary vessels >50% stenosis			**<0.001**
1	2.7% (11)	26.0% (46)	
2	0.2% (1)	24.3% (43)	
3	1.7% (7)	49.7% (88)	
Left main artery >50% stenosis	0.2% (1)	23.6% (42)	**<0.001**
Risk scores			
EuroSCORE	7.6+/-8.3%	9.4+/-9.2%	**<0.001**
EuroSCORE II	3.4+/-4.8%	7.4+/-7.8%	**<0.001**
STS Score	3.5+/-7.9%	8.0+/-6.0%	**<0.001**

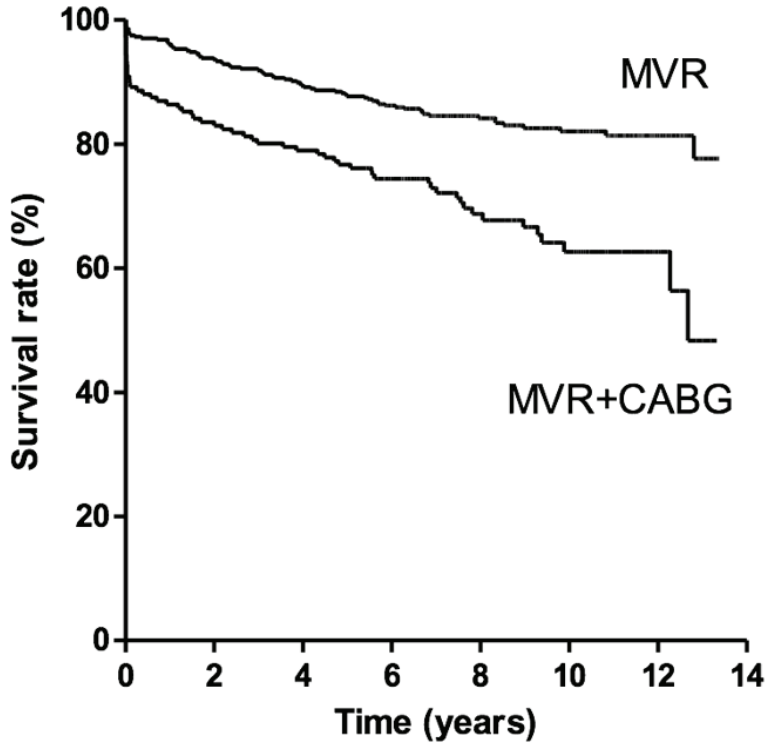
MVR=mitral valve surgery, CABG=coronary artery bypass grafting.

Table 2: Operative characteristics and in-hospital outcomes.

	MVR	MVR+CABG	P-value
N	407	178	
Operative characteristics			
Valve repair	48.2% (196)	52.2% (93)	0.370
Replacement	51.8% (211)	47.8% (85)	
Mechanical valve	79.1% (167/211)	64.7% (55/85)	**<0.001**
Cardiopulmonary bypass time (minutes)	129+/-50	179+/-53	**<0.001**
Cross-clamp time (minutes)	96+/-37	133+/-41	**<0.001**
In-hospital outcomes			
Operative mortality	2.5% (10)	11.2% (20)	**<0.001**
Composite morbidity	18.9% (77)	53.4% (95)	**<0.001**
Stroke	1.7% (7)	3.4% (6)	0.230
Acute renal failure	2.9% (12)	18.5% (33)	**<0.001**
Ventilation >24 hours	13.3% (54)	39.9% (71)	**<0.001**
Deep sternal wound infection	1.0% (4)	1.7% (3)	0.440
Return to theatre	8.1% (33)	20.2% (36)	**<0.001**
Pacemaker implantation	5.2% (21)	4.5% (8)	0.838
Operation to discharge time (days)	9.6+/-8.4	13.0+/-10.6	**<0.001**

MVR=mitral valve surgery, CABG=coronary artery bypass grafting.

Figure 1: Kaplan-Meier survival curve.



N (at year)	0	2	4	6	8	10	12
MVR	407	382	365	328	229	154	52
MVR+CABG	176	147	140	122	72	40	15

MVR=mitral valve surgery, CABG=coronary artery bypass grafting, N=number of patients at risk.

Table 3: Multivariable analyses.

Operative mortality predictors	**Odds ratio**	**95% confidence interval**	**P-value**
MVR+CABG	2.07	1.09–3.93	**0.009**
Age	1.1	1.04–1.16	**0.001**
Female	3.36	1.04–10.9	**0.043**
Critical pre-operative state	3.88	1.18–12.8	**0.026**
Pulmonary hypertension	1.87	1.02–3.43	**0.042**
Long-term mortality predictors	**Hazards ratio**	**95% confidence interval**	**P-value**
Age	1.07	1.05–1.09	**<0.001**
Critical pre-operative state	2.46	1.34–4.54	**0.004**
Previous cardiac surgery	2.12	1.24–3.57	**0.005**
Diabetes	1.72	1.01–2.96	**0.046**
Chronic respiratory disease	1.53	1.06–2.19	**0.022**
Composite morbidity predictors	**Odds ratio**	**95% confidence interval**	**P-value**
MVR+CABG	2.38	1.03–5.47	**0.039**
Age	1.11	1.05–1.17	**<0.001**
Critical pre-operative state	4.79	1.48–15.5	**0.009**
Pulmonary hypertension	1.99	1.01–3.90	**0.046**

MVR=mitral valve surgery, CABG=coronary artery bypass grafting.

Table 4: Performance of risk sores for operative mortality.

Operative mortality	**EuroSCORE**	**EuroSCOREII**	**STS Score**
MVR 2.5%	7.6+/-8.3%	3.4+/-4.8%	3.5+/-7.9%
C-statistic (95% confidence interval)	0.844 (0.745–0.943)	0.817 (0.713–0.920)	0.850 (0.751–0.949)
Observed/expected ratio	0.33	0.74	0.71
Hosmer-Lemeshow test (chi^2, P-value)	0.33, P=0.076	0.74, P=0.54	0.71, P=0.31
MVR+CABG 11.2%	9.4+/-9.2%	7.4+/-7.8%	8.0+/-6.0%
C-statistic (95% confidence interval)	0.744 (0.658–0.831)	0.703 (0.594–0.813)	0.702 (0.586–0.819)
Observed/expected ratio	1.19	1.51	1.40
Hosmer-Lemeshow test (chi^2, P-value)	0.84, 0.61	0.66, 0.56	0.71, P=0.62

MVR=mitral valve surgery, CABG=coronary artery bypass grafting.

All three surgical scores had higher discrimination of operative mortality after MVR (c-statistic 0.82–0.85), and moderate discrimination after MVR+CABG (c=statistic 0.70–0.74). They all overestimated (observed/expected ratio 0.33–0.74), particularly the original EuroSCORE by about three times, the operative mortality after MVR, and underestimated operative mortality after MVR+CABG (observed/expected ratio 1.2–1.5).

Discussion

The main finding of this study were the high rates of operative mortality (11.2%) and morbidities (composite 53.2%) for MVR+CABG patients. There are many baseline and operative factors that could have contributed to these results as discussed below. Important predictors of adverse outcomes beyond MVR+CABG included age, critical pre-operative state and pulmonary hypertension, all established parameters in current risk models.[5,6,12,13] Interestingly, combination surgery was not independently associated with higher late mortality after the initial period, and the survival curves run parallel to isolated MVR in the medium- to long-term, suggesting that the majority of the risk of MVR+CABG was early on in-hospital or within 30 days. Nevertheless, the combination surgery's high risk poses challenging questions as to how best to manage these patients.

Other studies similarly report worse outcomes for combination versus isolated valve surgery, although not as pronounced as this study.[4,5,14,15] At our centre we have previously reported operative mortality of 2.9% for aortic valve replacement but 6.4% when concurrent CABG is performed during the same time period 2005–2012, and composite morbidity of 33.8% and 18.5% respectively, all of which had better outcomes than MVR+CABG.[14,15] This probably influences MVR+CABG to being less commonly performed than AVR+CABG at our centre and globally.[5,15] The original STS studies also reported operative mortality of MVR+CABG of 9.0% to be significantly higher than for isolated MVR 3.7%.[4,5] The STS studies also showed superior results for mitral repair than replacement when in isolation 1.6 versus 5.7% and with CABG 7.4% versus 11.6%, with similar but non-significant trends seen in our study. It is worthy of note, however, that for ischaemic MR, one randomised trial found similar survival but higher recurrence of MR and related heart failure events and readmissions for surgical repair compared to replacement, so aetiology is also an important consideration in deciding surgical technique of the mitral valve.[16]

Fundamentally, patients undergoing MVR+CABG have coronary artery disease and are different to isolated MVR patients with non-ischaemic pathology. Characteristics such as older age, hypertension, hypercholesterolaemia, diabetes and extracardiac arteriopathy are significantly more common in combination surgery patients, and these are known risk factors for both coronary artery disease and cardiac surgery.[5,6,12,13] There are also more MVR+CABG patients with heart failure and severe dyspnoea or angina symptoms adding to operative risk. The only surgical risk factors more common in isolated MVR are endocarditis and previous cardiac and valvular surgeries, but these did not outweigh the aforementioned parameters for combination surgery, which ended up having higher surgical risk scores.

Notably, mitral valve aetiology was another important difference, with nearly 30% of the MVR+CABG group having secondary (ischaemic or functional) mitral valve disease, compared to 4.4% of the isolated MVR group. Structurally normal valve and chordae apparatus with imbalances in closing and tethering forces due to changes in left ventricular geometry causes secondary MR, most commonly seen in ischaemic and dilated cardiomyopathies, and its presence is associated with worse prognosis.[17] Although MVR is the gold standard for severe primary mitral valve disease, its utility remains controversial for secondary aetiologies, and is not recommended when performed alone in this context due to high operative risk, recurrence rates and no clear benefit.[2] MVR+CABG did not reduce mortality, symptoms and improve left ventricular systolic function despite reducing the severity of MR in randomised trials and their meta-analyses, although the control group in these studies were all isolated CABG rather than isolated MVR.[7–9,18,19] The literature challenges whether MVR with or without CABG is ever indicated for

secondary mitral valve disease, although it is still performed in clinical practice, and perhaps replacement offers more durability than repair for ischaemic MR.[16]

This study has shown that MVR+CABG is a high-risk surgical procedure which has clinical implications. Careful patient selection and the intervention performed should be considered in this population. If the patient has heart failure symptoms with no chest pain or ischaemia demonstrated before, then MVR may be sufficient, while for those with angina without heart failure, or secondary mitral valve disease, isolated CABG could be considered.[7,10,11] Another option is to perform hybrid procedures with one treated surgically and the other percutaneously, while in those with very high risk, medical therapy alone may be the only appropriate option. In all procedural scenarios, peri-procedural optimisation such as treating heart failure to try improve cardiac function should be routine. Risk models can play an important role given their good prognostic performance for mitral valve surgery in our study and others with reasonable calibration.[20] Multidisciplinary Heart Team meeting is warranted to discuss these complex cases.[2]

This study has some limitations. It is a single-centre retrospective observational study. The sample size and therefore power is moderate and may not identify all significant predictors of adverse outcomes. We did not specifically compare different mitral valve aetiologies or between mechanical and bioprosthetic valve prosthesis as the main focus was isolated or combination surgeries, however they were included in multivariable analysis. We also didn't compare the combination surgery to isolated CABG. Follow-up outcomes were restricted to mortality, and longer-term data was not available beyond 12 years. Other variables of interest that weren't collected include symptoms, quality of life, echocardiographic parameters and late complications such as thromboembolism and endocarditis.

In conclusion, isolated MVR and MVR+CABG patients had different pre-operative characteristics and risk profile contributing to the higher operative risk in MVR+CABG patients. High operative mortality and morbidities rates were observed in MVR+CABG patients, whether unadjusted or adjusted for other predictors, which was concerning. Risk scores performed well especially for isolated MVR in terms of discrimination, but calibration was suboptimal. Careful selection including consideration of alternative strategies, and optimising peri-operative management, are warranted for patients with concurrent severe mitral valve and coronary artery disease.

Competing interests:
Nil.

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Car seat survey at a children's hospital: need a booster?

Navneet Singh, Julie Chambers, James K Hamill

ABSTRACT

AIM: Child restraint practices among New Zealand children have fallen short of best practice recommendations. In 2013, New Zealand child restraint legislation was amended. The aim of the present study was to determine the child restraint practices of a cohort of children admitted to hospital and how practices have changed since the amendment in child restraint legislation.

METHODS: We conducted interviews with the parents of 300 paediatric inpatients aged 0–13 years. Data were recorded on their child's usual child restraint use, the restraint used during their trip to hospital, and parental knowledge of child restraint law and best practice recommendations. We compared their responses with those of our survey published in 2013, which was performed before the amendment in child restraint legislation.

RESULTS: The median age of the 300 children was three years: 181 (60%) were aged 0–4 years, 65 (22%) 5–9 years and 54 (18%) 10–13 years. One hundred and thirty-six (45%) were girls. Of children <5 years of age, 97% always used a child restraint. Of children 5–9 years of age, 60% always used a child restraint, 12% sometimes and 28% never. A significantly greater proportion of 5–9 year-old children used a child restraint at least some of the time in the present study compared to the 2013 study (47/65 versus 27/53, OR 2.49 [95%CI 1.09–5.81]). Child restraint use declined in children >6 years of age. On their journey to hospital, five children used no restraint, four of whom were held in the arms of a caregiver. Parental knowledge of child restraint recommendations correlated inversely with their compliance with the recommendations (OR 0.33 [95%CI 0.11–0.91]).

CONCLUSIONS: Consideration should be given to extending child restraint legislation to children older than seven years of age. Further studies could explore the barriers parents face to the use of child restraints and the potential effect of extending child restraint laws to older children.

Road traffic crashes (RTC) injure children at a concerning rate. The Child and Youth Mortality Review Committee reported that 28–32% of all deaths in children aged 1–14 years are caused by unintentional injury, of which 12.5–20% are transport related.[1] Child restraints reduce the rate and severity of injury from RTC.[2] The Eastern Association for the Surgery of Trauma gave the use of child restraints a level I recommendation, noting that 'the highest reductions [in injury and injury severity] come from age-appropriate, properly used restraints'.[3] One form of child restraint, booster seats, have been shown to reduce the risk of injury in older children. Arbogast et al found that booster seats reduced the risk of injury in 4–8 year-olds compared to seat belts alone,[4] while Anderson et al found that booster seats reduced the risk of injury in 8–12 year-olds compared to seat belts alone.[5] Anderson and Sandholt found that booster seats were more effective at reducing mortality in 6–8 year-olds than child car seats, but in children aged 2–5 years, child car seats were more effective at reducing mortality, suggesting that premature graduation to a booster seat could be dangerous.[6] The injury prevention effect of child restraints translate into a cost benefit. Miller et al showed a return on investment of eight to one for mandating booster seats.[7] These data highlight the importance of age-appropriate restraints for child safety.

In New Zealand, child restraint use has been suboptimal. Cameron et al found that only 40% of children who required a booster seat used one.[8] In 2013, we showed that many children had travelled to hospital without a proper restraint;[9] furthermore, few children >5 years of age used a booster seat.[9] In 2013, the New Zealand Government changed the age to which a child must be in an "appropriate approved child restraint" from the fifth to the seventh birthday, or until the eighth birthday if a restraint was available in the vehicle.[10] The change in the Act, known as the Land Transport (Road User) Amendment Rule 2013, noted that "extending New Zealand's requirements to children up to a standing height of 148cm or up to 11 years age… would be more consistent with international best practice and car manufacturer recommendations".[10] This best practice recommendation has been promulgated by the New Zealand Transport Authority and advocacy groups. Overall, the Act fell short of the Paediatric Society of New Zealand's recommendation for "a child restraint on every trip for every child".[11] New Zealand laws lag behind other high-income countries such as the UK, where children must reach 135cm in height or 12 years of age before they may travel without a child restraint,[12] or Germany, Hungary and Switzerland, where a child must reach 150cm in height or 12 years of age before they may travel without a child restraint. How child restraint practices in New Zealand have changed since the 2013 revision of the Act has not been previously documented.

Therefore, we undertook a survey of children in hospital to compare their child restraint use with that of our 2013 study, performed prior to the change in the Act. We hypothesised that the 2013 changes may have increased child restraint use for those to whom the law applies, but in older children, for whom only best practice recommendations apply, booster seat use may not have increased. The purpose of the present study was to determine how families usually restrain their children, what restraint was used on their trip to hospital, and whether parents were aware of the law and current best practice recommendations.

Methods

The Auckland District Health Board Research Review Committee approved the study and granted exemption from full ethics approval by the New Zealand Health and Disciplinary Commission Ethics Committee. The study was set in the wards of a tertiary children's hospital. Recruitment was by convenience sampling over a two-month period, November to December 2015. Convenience sampling was based on the days during which the interviewers were available.

An *a priori* sample size of 300 children was obtained from our experience with our 2013 study[9] and as an estimate of what was reasonably achievable in the study period. The inclusion criteria were children admitted to hospital aged 0–13 years. A child was excluded for any of the following reasons: no parent or caregiver present, the parent was unable to speak English, the parent was distressed; the child was in the resuscitation area of the Children's Emergency Department, the child was in the Paediatric Intensive Care Unit, or the child was a palliative care patient. Patients who were re-admitted during the study period but had already been included in the study during an earlier admission were not included a second time.

Following verbal consent, the investigators conducted semi-structured interviews with parents using a customised questionnaire based on that used in our 2013 study.[9] The questionnaire asked about child restraint use in normal travel, how children travelled to hospital, the restraint used for the journey, parental awareness of child restraint law and parental awareness of best practice recommendations for child restraint use (see Appendix for a copy of the questionnaire). At the conclusion of the interview, the investigators offered parents a brochure about child car occupant safety and, if appropriate, a height chart specifically designed for booster seat education.

When the interviewers were available, they approached all eligible participants in an attempt to minimise selection bias. The investigators explained the purpose of the

study, assured participants of their confidentiality, formulated questions in a neutral manner and read out the questions verbatim as they appeared on the questionnaire in an attempt to reduce social desirability bias. All families were aware that data would be anonymised and that the written questionnaire forms would be stored securely. The interviewers were not involved in the usual care of the participants.

Demographic data was obtained from the hospital front sheets. In cases of multiple ethnicity, parents elected a primary ethnicity (ethnicity was not prioritised by the researchers).

For analysis, participants were grouped into age groups 0–4, 5–9 and 10–13 years, with subgroup ages 5–6, 7 and 8–10 years also investigated to reflect the age groups targeted by legislation and recommendations. Data from age groups 0–4 and 5–9 were compared to data from our 2013 report.[9] Child restraint use was classified as 'always', 'sometimes' or 'never'. 'Compliance' with the law and recommendations was defined as a child <11 years of age who always used a child restraint. Infants who had been in hospital since birth were excluded from the analysis of usual child restraint practices.

Statistical analysis of contingency tables was by Fisher's exact test. Continuous data were tested for normality by viewing density plots and by the Shapiro-Wilk test, and reported as median and interquartile range if not parametric. Compliance with the law and recommendations, knowledge of the law, knowledge of the recommendations and acceptance of further information were analysed in generalised linear models. The models included age, gender and ethnicity as explanatory variables, and treated the outcomes as binomial. We report effect sizes as the odds ratio (OR) and 95% confidence interval (95%CI) of the OR, a 95%CI not spanning one considered statistically 'significant'. We used the package, lme4[13] within the statistical programme, R[14] for the generalised linear models.

Results

Of 340 children invited to participate in the survey, 300 consented. The median age of participating children was three years (interquartile range 0–7.25). The interviewed children represented 40% (300 of 752) of the total population of children aged 0–13 years who had been admitted during the study period (Table 1). Seventeen infants had been in hospital since birth, thus the sample size for analysis of 'usual' child restraint use was 283.

Table 1: Demographic characteristics of study participants.

	n=300 (%)
Age 0–4 years	181 (60%)
Age 5–9 years	65 (22%)
Age 10–13 years	54 (18%)
Female	136 (45%)
Male	164 (55%)
European	155 (52%)
Māori	51 (17%)
Pacific peoples	53 (18%)
Asian/Indian	31 (10%)
Other ethnicity	10 (3%)

Usual restraint use

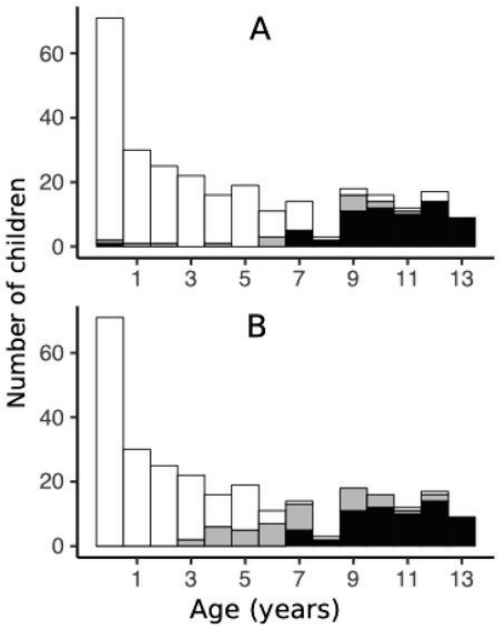
Of children <5 years of age, 159 (97%) always used a child restraint and four (2%) sometimes. One caregiver reported never placing their 10-week old infant in a fitted child restraint but, instead, using a hand-carry seat propped in the back seat of their car.

Of children aged 5–9 years, 39 (60%) always used a child restraint, eight (12%) sometimes and 18 (28%) never (Figure 1A). The odds that a child aged 5–9 years would use a child restraint was 2½ times greater in the present study than in our 2013 study[9] (47/65 versus 27/53, OR 2.49 [95%CI 1.09–5.81]) indicating a significant increase in child restraint use.

Correlation with best practice

Compliance with the law and recommendations decreased as children increased in age. Compliance was 97% (178/183) in 0–5 year olds, 73% (8/11) in six year-olds (these age groups are required by the law to travel in a child restraint), 64% (9/14) in seven year-olds (who are required to travel in a child restraint if one is available in the vehicle) and 14% (5/37) in 8–10 year olds (most of whom should use a booster seat

Figure 1: Child restraint use by age.



A. Frequency of use: white bars—always, grey bars—sometimes, black bars—never.
B. Type of restraint usually used: white bars—fitted car seat, grey bars—booster seat, black bars—seat belt only.

according to best practice recommendations) (Figure 1A).

In the generalised linear model, compliance decreased with increasing age (OR 0.77 per year of age, [95%CI 0.70–0.85]). Compliance was higher for European ethnicity (OR 2.99 [95%CI 1.42–6.55]) but was not significantly associated with other ethnic affiliations and was not significantly associated with gender.

Type of restraint used

In children up to five years of age, the most common type of restraint was a fitted car seat. Booster seats were used by 9% (2/22) of three year-olds and 31% (11/35) of 4–5 year-olds. After five years of age, the most common type of child restraint was a booster seat (Figure 1B).

Restraint on journey to hospital

The most common mode of transport to hospital was by private vehicle (73%). For their journey, 95% (112/118) of 0–4 year-olds and 59% (23/39) of 5–9 year-olds used a child restraint. Five children <5 years old were not restrained at all for the journey, four of whom were held in the arms of a caregiver. Compared to our 2013 study, child restraint use had increased significantly for 0–9 year-olds (135/157 in the present study

Table 2: Method of transport to hospital and child restraint use for the journey.

	0–4 years n=164*	5–9 years n=65	10–13 years n=52†
Car (n=205)			
Child restraint	112	23	7
Seat belt	1	16	29
None/held in arms	5	0	0
Unsure	2	0	0
Taxi (n=6)			
Child restraint	3	0	0
Seat belt	0	0	1
None/held in arms	1	0	0
Unsure	1	0	0
Shuttle/bus (n=13)			
Child restraint	3	1	0
Seat belt	1	0	4
None	2	2	0
Ambulance (n=48)	25	12	11
Helicopter (n=9)	8	1	0

*17 children had been in hospital since birth.
†Data not available for two participants.

versus 99/120 in 2013, OR = 1.9 [(95%CI 1.01–3.70]). Six children (2%) travelled by taxi, one of whom was held in the arms of a caregiver (Table 2).

Parental knowledge

Almost 80% of parents (238/300) agreed that they knew the law. Almost two-thirds (192/300) agreed that they knew the best practice recommendations for child restraint use. In the 0–9 age group, the proportion of parents who were aware of the best practice recommendations for booster seat use had increased significantly since the 2013 study[9] (Table 3). Their information had come from media and/or online sources in one half (120/240) and from a variety of community and social sources in the remainder. Knowledge of the law and recommendations was not related to their child's age (aware of the law, OR 1.05 [95%CI 0.97–1.15]; aware of recommendations, OR 0.98 [0.91–1.06]).

Just over one-third of parents (105/300) accepted our offer of an information brochure or a height chart. Parents of older children were less likely to want further information about child restraints (OR 0.90 [95%CI 0.83–0.96] for each increment in year of age). Knowledge of best practice recommendations correlated inversely with compliance (OR 0.33 [95%CI 0.11–0.91]), that is, parents who said they were aware of the recommendations for booster seats were less likely to place their child in one. They were also less likely to want any further information (OR 0.22 [95%CI 0.11–0.41]).

Discussion

By comparing interviews with 300 families in the present study to our previous interviews with 200 families in our 2013 study,[9] we found that a law change coincided with improved child restraint use in 5–9 year-old children. Before 2013, restraints were required until five years of age: at that time, one half of children five years or older were inappropriately restrained. After 2013, restraints were required until seven years of age (or until eight years, ie, including seven year-olds, if a restraint was available in the vehicle): the present study shows that many seven year-olds and most 8–10 year-olds remain inappropriately restrained. This indicates that while the law change has been partially effective, the parents of school-aged children do not commonly follow best practice recommendations for child restraint use.

According to recent data obtained from observing cars during school hours, 93% of 0–4 year-olds but only 26% of 5–9 year-olds used a child restraint.[15,16] The discrepancy with our data, where almost two-thirds of 5–9 year-olds always used a child restraint, may partially reflect social desirability bias in the present study. Social desirability bias has been shown to cause an approximately 12% overestimate in seat belt use.[17] The discrepancy could also be due to children using backless booster seats that cannot be seen by researchers observing cars on the street.

Table 3: Parental awareness of the law and best practice recommendations for child restraint use, and parental acceptance of an offer for further information.

	0–4 years n=181 (%)	**5–9 years n=65 (%)**	**10–13 years n=54 (%)**
Aware of the law	135 (75%)	57 (88%)	49 (91%)
Aware of best practice recommendations	105 (58%)	49 (75%)	38 (70%)
Awareness of best practice recommendations in 2013 study[9]	54/127 (43%)*	17/53 (32%)†	10/20 (50%)
Accepted further information	79 (44%)	18 (28%)	7 (13%)

*Statistically significant difference between 2013 and the present study (OR 1.86 [95%CI 1.15–3.03]).
†Statistically significant difference between 2013 and the present study (6.37 [95%CI 2.70–15.77]).

Whether backless booster seats are as effective as high-backed booster seats remains controversial. Booster seats are designed to improve seat-belt fit by altering seating position, ensuring that the belt passes over bone and not over the soft parts of the abdomen or neck.[18] The horizontal 'lap' component of the belt should be positioned below the anterior superior iliac spine of the bony pelvis, and the diagonal 'sash' component should pass over the clavicle. High-backed booster seats position both components of the seat belt. Arbogast et al found that high-backed booster seats reduced the risk of injury to 4–8 year-olds in side-impact collisions compared to seat belts alone (OR 0.3), but backless booster seats provided no benefit over seat belts alone.[19] Reed et al showed that a well-designed backless booster seat may perform better than a poorly designed high-backed booster seat.[18] Further high-quality research could help clarify the ideal restraint design for a child's size.

Klinich et al, in their classic study, reported that "a height of 148cm seems to be the threshold above which poor seat belt fit is not a problem".[20] They go on to say that 'a weight of 36kg might [also] be considered a threshold…" except in obese children.[20] This led to the recommendation that children use a booster seat until 148cm in height. The present study shows that, while parental awareness of this recommendation has improved since 2013, many parents remain unaware that their children should remain in a booster seat until 148cm in height. To help improve awareness of health and safety issues, some investigators have used the 'teachable moment' associated with a presentation to hospital to undertake 'brief intervention'. Fernandez et al documented improved seat belt use up to six months after brief intervention in the emergency department of an adult trauma centre.[21,22] Ehrlich et al found that brief intervention in car seat use was feasible at a paediatric trauma centre.[23] Disappointingly, only one-third of parents were open to education in the present study. We found that the parents who knew the recommendations but did not follow them were also least likely to accept further information. A qualitative study could help reveal why some parents accept information and others refuse, how to best educate families in injury prevention, and whether parents prefer an educative or legislative approach, or both.

Legislation has been shown to improve compliance with child restraint use and to reduce injury,[3] however, socioeconomic and ethnic factors influence the effectiveness of the law.[24] Brown et al showed that a new law increased car seat use in 2–5 year olds in low socioeconomic areas of Australia,[25] but Brixey et al found that some children of lower socioeconomic status moved from car seats to booster seats before they were ready as a result of new legislation.[26] Legislators must therefore take care not to exacerbate inequities, perhaps by improving access to child restraints for at-risk groups, and by accompanying any law change with education programs that can reach all members of society.[27]

Limitations

Our study was based on parental reports. Limitations in the interpretation of interview questions and recall bias may have influenced the results. Parents may have been reluctant to admit to non-compliance with the law, leading to social desirability bias.[28] Future research should take specific measures to reduce social desirability bias, such as a randomised response approach.[29] We did not formally validate whether parents truly knew the law and best practice recommendations. The sample was obtained by convenience sampling. A cohort study enrolling all children admitted over a period of time could help address this weakness. We did not record the type of booster seat used, high-backed or backless, nor did we measure children's height or weight. We based booster seat requirements on age rather than size. Current recommendations include both age and height criteria for booster seat use but height is preferred.[8] We did not analyse the effect of the day of admission on child restraint use during transport to hospital, nor the effect of how unwell the child was on transport to hospital. The study sample may differ in demographics from the total New Zealand paediatric population, limiting the generalisability of our results. We excluded children over 13 years of age because few require a child restraint; however, our previous study included 14 year-olds, limiting comparability between the two studies for older children.

We did not record socioeconomic indices, which would be of interest in future studies, particularly for exploring barriers to child restraint use.

Conclusions

The 2013 amendment to child restraint legislation increased the use of child restraints in the age range stipulated by the law, but child restraint use in older children remains suboptimal. Further high-quality research could determine the effectiveness of specific child restraint designs, and explore the implications of turning current best practice recommendations into a legal requirement.

Competing interests:
Nil.

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Appendix

Starship Child Car Seat Interview

Child Name (label) Or NHI			
D.O.B		Pt Height (cms)	
Name of Interview Subject		Relationship to Pt	Pt Ethnicity

Date

Form Number

Interviewer

Q 1. A: Younger than seven years of age (Delete and go to Q1B if child is seven years or older):

Please tell me which best describes [*your child's*] usual child car restraint use

○ Uses child car seat	*No*	*Sometimes*	*Yes*
○ Car seat type	*Forward facing*	*Rear facing*	*Booster*
○ If has a car seat, uses it	*All the time*	*Usually*	*Just now and then*
○ Usual seating location in car	*Front*	*Back (centre)*	*Back (side)*
○ Car seat is	*Own*	*Rented*	*Borrowed*
Include any comment about car seat use:			

Q 1. B: Seven years and older: Please tell me which describes [*your child's*] usual car seating?

○ Uses car seat / booster	*No*	*Sometimes*	*Yes*
○ If adult seat belt only used specify:	*Lap/sash*	*Lap belt only*	*None*
○ Usual seating location in car	*Front*	*Rear (centre)*	*Rear (side)*
Include any comment about seat belt use:			

Q 2. Can you tell me where you bought / obtained the car seat your child normally uses?

Retail Store	Specialist Baby Shop	Plunket	Second hand
Trade Me (New / Old)	Unknown	Other:	
Comment:			

Please continue over the page

Q 3. Did you receive any advice about fitting the car seat into your car? YES NO Don't Know

If YES where did you get the advice from:

Q 4. Can you tell me how [*your child*] travelled to hospital for this visit?

o Family car 'Another' car Taxi Ambulance Other:

o Was a car seat or seat belt used? Car seat Seat belt Held in lap Unsure

Include any comment about this trip to hospital:

Q 5. Please can you tell me which option best describes your plans for your trip home?

Family car 'Another' car Taxi Ambulance Unsure

Other:

Include any comment about travelling home from Starship:

Q 6. New Zealand child car seat law has recently changed to increase the age children need to be in a car seat to age seven – were you aware of this? Yes No

Can you recall where you heard this? Include any comment:

Q 7. In New Zealand it is recommended children stay in car seats until they are tall enough to fit the adult belt (148cm – about age 11 years) - were you aware of this? Yes No

Can you recall where you heard this? Include any comment:

Q 8. Would you like more information about the best use of child car seats? Yes No

If YES: Provision of information leaflet Referral

Include any comment about action:

Thank you

Starship Trauma Service – Please contact Julie Chambers 021 241 5771 for further information

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The value of frenotomy for ankyloglossia from a parental perspective

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ABSTRACT

AIMS: We sought the parental experience of the effects of frenotomy in the presence of ankyloglossia by exploring the reasons for seeking frenotomy, impressions of its value and its impact on breastfeeding.

METHOD: A prospective survey of infants receiving frenotomy in a general practice in Palmerston North was undertaken. Infants aged under six months with confirmed ankyloglossia via a GP and lactation consultant were included. One hundred and seventy-six children met the study criteria. Parents completed a pre-procedure questionnaire and received a follow-up phone call.

RESULTS: Results demonstrated that 97% of parents would seek out frenotomy again in similar circumstances. Initially, 93 mother-infant pairs (53%) were not fully breastfeeding; post frenotomy, 33 of these pairs were able to start fully breastfeeding. One hundred and thirty-two pairs showed no change in feeding method. Nine pairs deteriorated from partial breastfeeding to artificial feeding, and two pairs deteriorated from fully breastfeeding to artificial feeding. Both feeding time and nipple pain improved post-frenotomy. Eighty percent of parents reported a moderate or significant improvement in their presenting issue, and 77% reported moderate to significant improvement in feeding quality. There were no major complications.

CONCLUSION: Frenotomy was reported to be beneficial, with a high level of parental satisfaction and improvement in rates of full breastfeeding and feeding duration, as well as a reduction in nipple pain. Parents were willing to go to significant lengths to access the procedure.

Breastfeeding rates in New Zealand have gradually increased over the past decade, with gains seen in exclusive breast feeding at three and six months.[1] There are, however, women who initiate breastfeeding, but subsequently cease. These causes of breastfeeding cessation are multifactorial and can include nipple pain, latching issues, poor weight gain and prolonged feeding duration.[2] Previous research has linked ankyloglossia to these issues and to breastfeeding cessation.[3–11]

Ankyloglossia is a congenital condition in which a shortened lingual frenulum prevents normal tongue protrusion beyond the lower lip, or prevents sufficient elevation for effective breastfeeding.[3,12,13] Ankyloglossia is present in 1–11% of infants, and is often asymptomatic with approximately one-quarter experiencing feeding difficulties.[3,5,14–21] Frenotomy is the surgical release of ankyloglossia, usually only performed when there is a feeding-related indication.

There are five widely accepted randomised controlled trials regarding frenotomy and its effect on breastfeeding, with a combined population of 302 infants.[14] NICE interventional procedures guidance [IPG149] states: "Current evidence suggests that there are no major safety concerns about division of ankyloglossia (tongue-tie) and limited evidence suggests that this procedure can improve breastfeeding. This evidence is adequate to support the use of the procedure provided that normal arrangements are in place for consent, audit and clinical governance." [22]

The main aim of this project was to determine parental satisfaction or dissatisfaction, and the self-reported benefits or harms following frenotomy. In addition, we analysed how many mothers commenced fully breastfeeding post-frenotomy (if not

able to prior). Secondary aims were to determine the degree of change in feeding time, nipple pain during breastfeeding and method of feeding post-frenotomy. Finally, we the sought to ascertain the proportion of parents who, if in similar circumstances again, would seek a frenotomy procedure. This measure was taken as an overall indication of satisfaction or dissatisfaction with frenotomy.

Methods

Participant/subject

The study participants included infants receiving a frenotomy at Hokowhitu Medical Centre, located in Palmerston North, New Zealand, where a lactation consultant and a general practitioner (GP) with a special interest in ankyloglossia accepts referrals, assesses and potentially treats infants. The study enrolment period was the seven months between September 2016 and March 2017. The inclusion criteria were: an infant aged under six months with confirmed ankyloglossia receiving a frenotomy for feeding-related issues. Infants were excluded if they had had a prior frenotomy (typically from another health provider) that had reattached and were thus requesting a second frenotomy.

Ethical considerations

Written consent was obtained from the infant's parent/caregiver, including consent for data analysis for research and/or audit purposes. The Ministry of Health, Health and Disability Ethics Commission, granted this research an out-of-scope confirmation.

Protocol design and materials

The standardised data collection forms were designed by the primary investigator, two lactation consultants, the GP performing the procedure, a paediatrician and a senior statistician. The purpose of the questionnaire was to streamline consultations and to improve consistency of history-taking and data collection. The form included sections on patient demography, presenting complaints, current feeding method, clinician assessment, and procedure details. The form was used by the GP for several months prior to the beginning of data collection (see Appendices A and B).

In the vast majority of cases, the parent/caregiver bringing the child in for a frenotomy was the child's mother, therefore for simplicity, 'parental' and 'maternal' are used interchangeably.

'Fully breastfed' was defined as the infant currently only breastfeeding, with no other liquids or solids except a minimal amount of water or prescribed medicines. Partial breastfeeding includes the intake of formula while concurrently breastfeeding. Artificial feeding is defined as solely bottle-feeding, whether with EBM or formula.[23]

Preparations and procedure

Upon arrival at the practice, the infant's parent was given the questionnaire and was informed the full assessment and procedure would cost $40. They were assessed by the lactation consultant (LC) who took further history and performed an initial examination. The GP then saw the infant, parent and LC together to clarify the history and perform a second assessment. The Kotlow diagnostic criteria[24] was used to assess the degree of tethering (see Appendix C). It should be noted that under the Kotlow diagnostic criteria the most anterior tongue tie is a type 4, which is in contrast to some other grading systems in which a type one refers to frenulum to the tip of the tongue. If any disparity in professional opinion between the LC and GP occurred, they deliberated and came to a consensus. If history and examination indicated potential benefit from a frenotomy, the procedure was explained to the parent, and informed consent was obtained. No parents declined consent to be involved in this follow-up study.Mild analgesia was achieved by applying lignocaine gel, the tongue was elevated with either gloved fingers or a grooved indicator, and the frenotomy was performed with a scissor cut. The tissue was then blunt dissected/stretched by finger to maximise tongue elevation. In Kotlow 1–2 cases (the most posterior/"deep"), the frenulum was injected with lignocaine and adrenaline by dental syringe, and a tissue crush was performed prior to the incision. Post frenotomy, the mother was then encouraged to breastfeed immediately if possible, with the support of the lactation consultant. The infant was checked frequently for bleeding. Parents were recommended to perform a simple tongue elevation stretch exercise on the infant prior to feeding at least four times daily for seven days.

Completed questionnaires were assessed by the primary investigator for inclusion eligibility. A clinical follow-up of all eligible patients was conducted by phone call. Up to 10 attempts were made to contact each infant's parent. During follow-up, a standardised questionnaire was used, designed to assess any new or ongoing issues with breastfeeding (see Appendix B).

All data were processed using EXCEL. Analyses were carried out by using a general inductive analysis approach.[25] Quantitative analysis was completed using Stata, and paired T-tests were completed when appropriate, with a p value of <0.05 was considered significant.

Results

Response rate

One hundred and ninety-seven infants were eligible for the study. Of these, 20 parents could not be contacted by phone and one could not speak English. The remaining 176 (89%) infants were successfully followed-up. The mean length of time between frenotomy and follow-up was 23 days, with a median of 20 days and a standard deviation of 12 days.

Patient demography

The cause of the imbalance in gender (more males than females, see Table 1) is unknown, but has also been noted in other research.[17] The ethnic breakdown was similar to that of New Zealand as a whole, however Māori were under-represented at 15%, compared to 21% in the Manawatu.[26]

Table 1: Age, gender and ethnicity.

Patient demography	**Mean**	**STD**
Infant age	44 days	35 days
Maternal age	30 years	5 years
	Number	**Percentage**
Male infant	109	62%
Female infant	67	38%
Infant ethnicity		
Pakeha/New Zealand European	126	72%
Māori	27	15%
European (other)	10	6%
Asian	7	4%
Other	6	3%

Parents became aware of ankyloglossia and were referred to the practice by a variety of means (see Table 2). Referral was predominantly by a lactation consultant, midwife or Plunket.The reasons given for seeking a frenotomy were varied (see Table 3). The issues most commonly reported were problems with latching and nipple pain.

Table 2: Source of referral for a frenotomy.

Referral source (some have multiple)	**Number**	**Percent**
Lactation consultant	81	46.0%
Midwife	48	27.3%
Plunket	25	14.2%
Self	16	9.1%
GP	5	2.8%
Chiropractor	3	1.7%
Paediatrician	3	1.7%
Osteopath	2	1.1%
Nurse	1	0.6%
Not stated	6	3.4%

Location of participants

Results showed that 65% of participants lived outside Palmerston North, and 40% travelled over 200km for the appointment. Twenty-six participants reported having travelled from Wellington.

Primary outcomes of frenotomy

Ninety-eight percent of parents reported that if they were in similar circumstances again, they would choose frenotomy.

Prior to frenotomy, 93 participants (53%) were not fully breastfeeding. At the time of follow-up, 33 participants reported that following the frenotomy they had been able to start fully breastfeeding (that is 35% of those who were not initially fully breastfeeding).

Eleven mothers (6% of total) reported a decline in feeding method in the interval between frenotomy and follow-up. Two of these reported a decline from full breastfeeding to artificial feeding, while the remaining nine reported a decline from partial breastfeeding to artificial feeding.

Figure 1: Percent of parents who would still get the frenotomy done if in the same circumstances again.

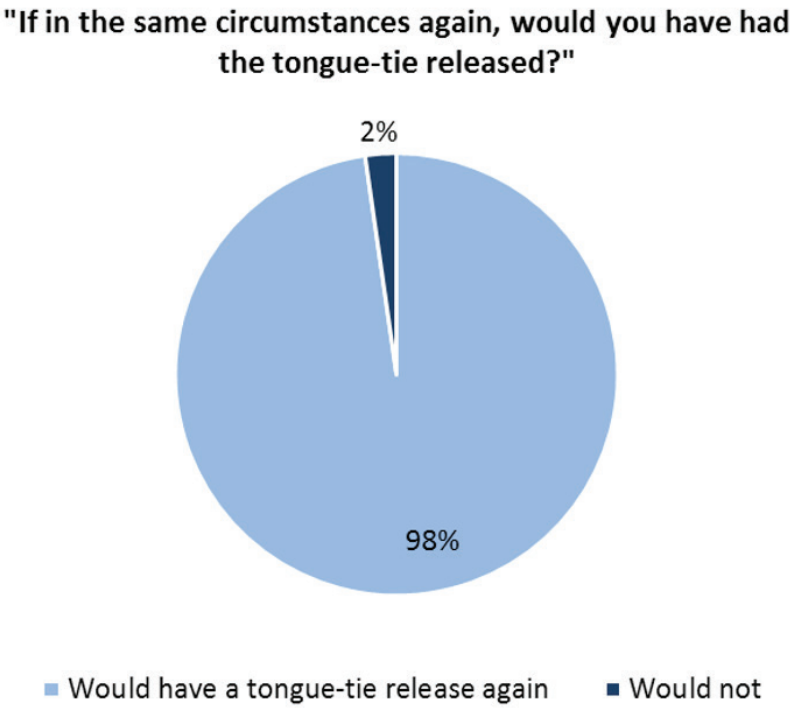
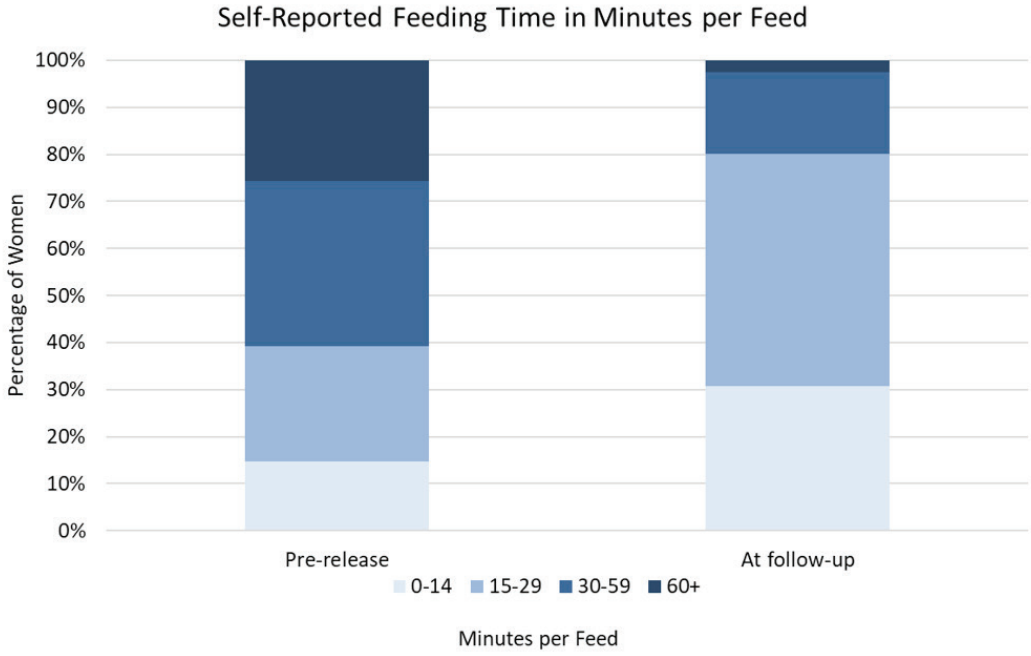


Table 3: Reasons given for seeking frenotomy.

Baseline characteristics		
Reason(s) given for attending assessment	**Number**	**Percent**
Issues with latching	115	65%
Nipple pain when breastfeeding	84	48%
Slow to feed	52	30%
Falling asleep breastfeeding	46	26%
Unsettled/fussy baby	37	21%
Poor weight gain	36	20%
Leaking milk while breastfeeding	36	20%
Not tolerating breastfeeding	22	13%
Windy	20	11%
Very frequent feeding	18	10%
Reflux issues	11	6%
Breastfeeding so painful nipple shields required	8	5%
Maternal milk supply issues	8	5%
Recurrent mastitis	6	3%
Cosmetic concerns	5	3%
Told to by a professional	136	77%
Parental concern of loud clicking while feeding	94	53%

NB: Multiple reasons were typically reported, so the total is greater than population.

Figure 2: Maternal report on feeding time pre- and post-frenotomy.



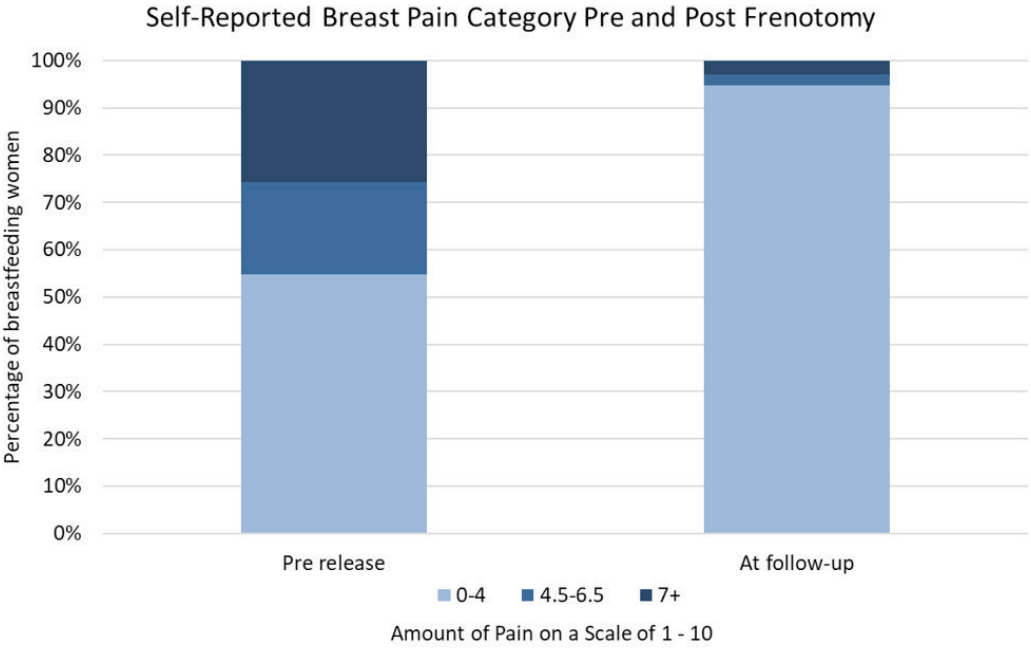
Out of the 11 mothers (6%) who reported a decline in breastfeeding, two stated they had already been planning to bottle-feed due to personal circumstances, and four mothers stated their milk supply had already nearly ceased prior to the frenotomy. These four mothers all stated that they wished they had undertaken the procedure earlier, since breastfeeding improved following it, but that they had waited too long, and their milk supply had already deteriorated prior to frenotomy. Therefore, undertaking the frenotomy may not have influenced the switch to bottle feeding in some cases.

Secondary outcomes

There was a statistically significant reduction in reported feeding time. The pre-frenotomy average feeding time was 39 minutes, which reduced by 20 minutes post-frenotomy, halving the average time spent feeding at the time of follow-up (see Figure 2). This was highly statistically significant with the use of paired T-Test (p value <0.0001).

An improvement in nipple pain when breastfeeding was widely reported, with an average improvement of 3.3 points on the 0–10 pain scale (see Figure 3).

Figure 3: Maternal report on breast pain pre- and post-frenotomy.



Degree of improvement by tongue-tie grade

Figure 4 depicts the results when parents were asked: "before the tongue-tie release you reported having issues with [issue/s], overall how has that changed?" where [issue/s] are the issues reported at baseline as per Table 3. The degree of improvement reported was further disaggregated into improvement according to ankyloglossia grade in Figure 4.

Only one parent reported that the primary issue (in this case pain and latch difficulties) was worse at the time of follow-up. She reported that it had initially improved before deteriorating further and that the frenulum had reattached. She was considering a second attempt at a frenotomy.

If any improvement was reported, parents were asked how long before that improvement came into effect. The mean number of days to improvement was 2.3, with a median of two days and a standard deviation of 3.4 days.

Overall stretch exercises were reported as being continued for the recommended seven-day duration by 79% of parents. Of those who did continue the stretch exercises, 82% reported a significant improvement in the primary presenting complaint, compared to 51% of those who didn't.

Complications

There were no life-threatening or persistent complications at time of follow-up reported. One mother stated that her 24-day old infant, who was breastfeeding prior to frenotomy, had to be syringe fed for two weeks following the procedure due to an altered latch. After the two-week period the infant did re-learn to breastfeed. The mother then experienced a significant improvement in nipple pain relative to pre-frenotomy levels and at the time of follow-up was ultimately very happy with the results of the procedure. Eight other minor adverse events were reported: Four mothers stated their infant was either unsettled or had swelling under the tongue for 1–3 days, three mothers reported frenulum reattachment with their prior feeding issues returning, but at time of follow-up a subsequent release had not been performed. One mother reported their infants feeding deteriorated for one week before resolving.

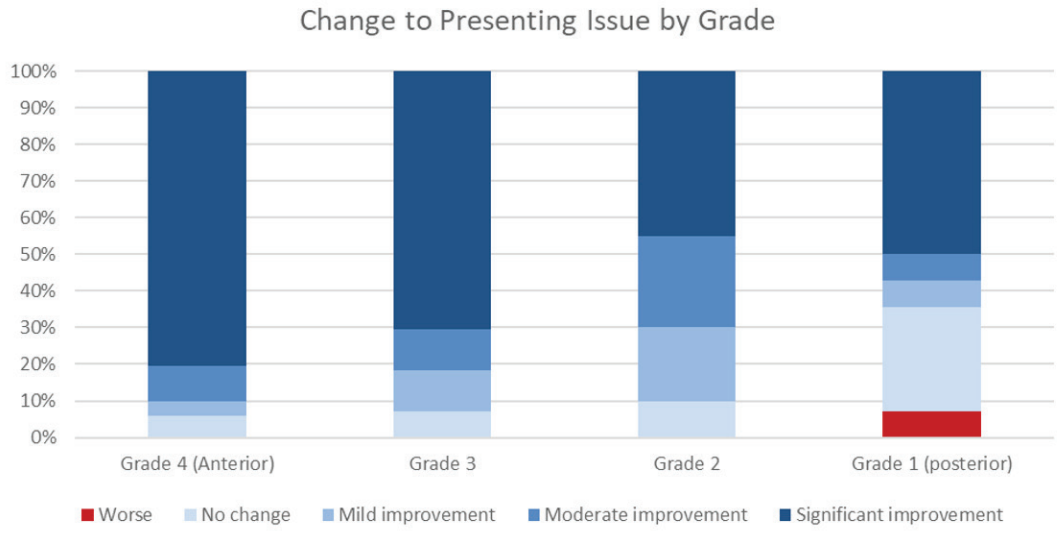
Discussion

Primary findings

This study is a prospective survey after frenotomy for ankyloglossia. There was no control population, and measurements were reported from the parental experience.

Overall, the parental participants had an overwhelmingly positive view of the effect of frenotomy, which is in line with other studies. With over 97% stating that they would do it again in similar circumstances, it shows the parents' self-perceived benefit was significant. This is despite parents witnessing an invasive procedure on their infant, potentially having to care for an unsettled infant, and bearing the financial

Figure 4: Change to presenting issue by ankyloglossia grade.



cost. These contextual factors place parents in a unique position to assess the overall value of frenotomy to their infant and themselves. This result also provides future parents considering frenotomy with a useful perspective given the divergent views on the procedure within the medical community.

A third of infants who were not able to fully breastfeed prior, improved to attain full breastfeeding status following frenotomy. This is a significant finding which shows a huge potential benefit for this subset of the population. The 35% that improved to full breastfeeding does not include those who showed an improvement but did not reach full breastfeeding status. These findings are consistent with other study findings, and can be summarised by a NICE guidance on Ankyloglossia: "By one month, the procedure proved to be effective in facilitating success of breastfeeding for 70% of the babies and was partially effective for another 20%."[17,28,29]

Over any period, there is a natural decline in the proportion of mothers breastfeeding, with approximately 6–10% mothers stopping per month.[1,2] A study based on the Growing up in NZ data showed that while 97% of women initially start breastfeeding, only half were exclusively breastfeeding to age four months, and 16% were exclusively breastfeeding until age six months.[30] Thus, there was expected to be a proportion of mothers who would stop fully breastfeeding regardless. Clearly, mothers who present their infant for frenotomy are a preselected group with significant feeding issues, so the fact that they showed a definitive increase in breastfeeding is therefore highly noteworthy.

Secondary findings

The primary purpose of this study was not to prove or disprove the procedure of frenotomy for ankyloglossia. It cannot, however, be ignored that there were clear reported improvements in many domains, and given the mean reported time to improvement following frenotomy being 2.3 days, where the mean age of the infant was already 44 days, this clearly implies a direct causal relationship from the procedure.

Feeding time was reported to have improved by 20 minutes on average. Maternal self-reported pain scores related to breastfeeding significantly reduced. It is expected that over time the normal infant would become more efficient at breastfeeding and nipple pain reduce, so exclusively attributing this to frenotomy must be done with caution. However, the reduction in nipple pain during breastfeeding post-frenotomy is consistent with other studies.[6,8,11,14,28,31–33]

Feeding quality overall also improved following frenotomy, with 55% and 22% reporting a significant or moderate improvement respectively.

Parents were asked the main reason(s) they sought frenotomy, and whether their particular issue(s) had improved or worsened. Figure 4 shows that there was a graduated response reported. Those infants with Kotlow grade 4 ankyloglossia (the most 'severe' and anterior version) were more likely to have a significant improvement in their presenting complaints, and as expected there was less change among the more posterior and 'mild' grade 1 group. This response indicates that the benefit is linked to the grade of ankyloglossia and is not a result of reporting bias or a placebo effect on the part of the parent.

At time of follow-up there were no ongoing significant adverse events reported from the frenotomy procedure, which is consistent with previous literature.[6,8,14,17,22,27–29,31,32]

Strengths and limitations

This study has a significantly sized population (176) and a high follow-up rate. There was no known selection bias from the doctor performing follow-up, and at least 10 attempts were made to contact the parent before recording them as a non-responder. Because much of New Zealand does not have a readily available publicly funded ankyloglossia frenotomy service this may have led to a delay in presentation, which may impact the generalisability of the results (with the mean infant age of 44 days, which is older than some literature). It is also likely that only more motivated parents would undertake finding a centre offering the procedure and organise to travel there. Expending this effort may make these parents more likely to believe that the frenotomy was beneficial to breastfeeding leading to a placebo effect. This

upfront parental investment may also have meant the treating GP is more inclined to offer frenotomy. However, these factors also potentially select for those with more severe feeding issues, and thus may have resulted in a population that is already likely to have worse feeding outcomes.

Hokowhitu Medical Centre accepts referrals for all grades of ankyloglossia, whereas some practices only attempt release on Kotlow grade 4, as many consider this a technically more simple procedure. This accounts for the apparent overrepresentation of posterior frenulum, and has diluted the improvement in our aggregated statistics, since the largest improvement was seen among grade 4 ankyloglossia.

Another issue for any study including subjective and self-reported data is the potential for reporting bias, where a participant may want to give a good (or bad) response to the follow-up doctor. However, as the follow-up call was by an independent doctor and not the operating clinician, this bias is likely less significant.

As mentioned previously, this paper has a limited role in confirming the efficacy of frenotomy. The biggest inherent issues are the unique and self-selected population, the potential for reporting bias and the potential for placebo effect. Results that can be seen to mitigate these concerns are the absolute improvement in fully breastfeed infants (which is much less likely to be effected by reporting bias); reported time to improvement being approximately two days (rather than instantly); and the differing outcomes based on grade (see Table 4), as it is inconceivable that the participants could knowingly experience a greater placebo effect in the Kotlow grade 4 category than grade 1. To fully account for bias a double blinded randomised controlled trial would be required, but doing so would be difficult given parents reluctance to risk being in a sham procedure group when they are experiencing very real challenge relating to feeding.

Potential impact

This study shows there is considerable demand for frenotomy, and that this demand is not being met by the public sector. We note that 26 participants travelled from Wellington, our Capital city, with tertiary medical facilities where one might expect to have such a simple service available. While there are private options for frenotomy in Wellington, several participants reported quotes in the range of $200–$800 for the procedure (this matches online available data).[34] This cost, alongside travel requirements and subsequent delays to treatment, could create or perpetuate barriers to effective treatment for families with low incomes, limited transport options and poor health literacy.

Of concern is that only five of the 176 participants reported being referred or advised to investigate frenotomy by their GP. Although it was expected the majority of referrals would be from LMCs and LCs, after six weeks of age, the primary care of the infant is transferred to a GP. In this study, half of all infants were aged over six weeks, so it was surprising that GP referrals were rare. It is possible that parents are seeking support from other providers privately, or that GPs are not as familiar with the available options in cases of ankyloglossia.[20]

For clarity, the results of this study should not be used to recommend frenotomy to asymptomatic infants (those without feeding related difficulties), and should not be used to justify indiscriminate frenotomy if no issue exists.

Conclusion

Frenotomy for infants with ankyloglossia and related feeding issues appears to be a safe and effective practice. Parents report high levels of satisfaction, improved quality of feeding and increased rates of full breastfeeding. A significant body of literature now supports frenotomy as being safe and beneficial in the context of feeding difficulties, and postponing this intervention while awaiting further research could mean infants with ankyloglossia and feeding issues experience avoidable negative outcomes.[28] In our society where the benefits of breastfeeding are widely understood to be beneficial, it is difficult to understand why access to frenotomy is so limited.

Further investigation into the availability, and disparities regarding access to frenotomy in the public sector of New Zealand should be undertaken.

Appendix

Appendix A: baseline data

Tongue Tie Questionnaire

Dear Parent/Caregiver, we appreciate your time in filling out this form today. This helps the doctor to get the information needed quickly so that more time can be spent discussing things that will help you / your child, and it will allow us to do an internal audit (and possible subsequent publication) to ensure that your child, and children like yours get the best possible healthcare at our practice. Some of these questions may not apply to you, but do your best to answer as many as possible. If we don't see you in the following week you may be phoned for a free phone follow-up. If you do not wish to be involved please tell the recweptionist or the doctor.
Many thanks, Hokowhitu Medical Centre.

Name of child: _____ Date of Birth: ____ /____ /____

Boy / Girl City of residence: _____ Home Phone: _____
(please circle) *(eg Palmerston North, Wellington, Marton)* Cell-Phone: _____

Who referred you? Midwife / Lactation Consultant / Plunket / Dentist / GP / Other: _____

Mothers age: _____ Ethnicity: _____

First Appointment Date: ___ / ___ / ____

What is your reason for attending this appointment? *(please circle any that apply)*

× Pain breast feeding	× Baby not putting on weight	× Breast feeding slow/takes a long time
× Cosmetic concerns	× Told to by professional	× Baby not tolerating breast feeds
× Baby falling asleep at breast	× Very unsettled/fussy baby	× Trouble latching/delatching
× Clicking when feeding	× Other: _____	

How is your baby fed? Only breastfeeding / breastfeeding with top ups / expressed breast milk / bottle feeding /donor milk

If not breast feeding, is that a *personal choice*, or did you have to change because of *feeding difficulties*? *(please circle ONE)*

How long does the longest breast feeding typically take (ie when actually hungry)? _____ mins

If bottle feeding, how long does the longest bottle feeding typically take? _____ mins

How painful is breastfeeding? 0 - 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10
(Not at all) *(Moderate)* *(Extremely)*

Any other comments that may help us?

For Doctor to complete:

TT Grade : 0 / 1 / 2 / 3 / 4

Ant / Post

Tongue elevation: Good / Limited / Tight

Lip Fraenulum: Full eversion / Mild / Tight

Procedure today: TT / LT / Not indicated / Deferred

Impression: U / L / M / H

Immediate improvement? Y / N

Comment:

Appendix B: follow-up collection

Date:_____ Number _____

Has there been any improvement in [issue/s] you reported since the release of the tongue tie?

Significant / moderate / mild / none / worse

If there was an improvement, how many days until it became apparent? ____ Has it been sustained **Y / N**

As a result of the tongue tie release were you able to start breastfeeding if you otherwise weren't?

Y / N / NA

Was there any change to feeding method following T/T? (**now Brest / Bottle / NA**)

You reported your feeding time was [state time], how long is it now? _____

Do you feel that feeding improved? (unrelated to the issues that lead to frenotomy) **Sig / mod / mild / no / worse**

How is the pain with breastfeeding now? _____ **/ NA**

Did you follow the stretch exercises at all? **Y / N** How many days? _____

Were there any complications you are aware of following the tongue tie release? **N / Y** _____

If you were in the same circumstance again, would you have the tongue tie released? **Y / N**

Appendix C: Kotlow diagnostic criteria

Kotlow grade	Description	Percentage in study (%)
Grade I	Located from the base of the tongue, halfway to the salivary duct	8
Grade II	Located between the back of the salivary duct halfway to the base of the tongue	23
Grade III	Located from the salivary duct half way to the tip of the tongue	40
Grade IV	Located at the tip of the tongue and extending half way between the salivary duct and tip of the tongue	29

Competing interests:
Nil.

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Cannabis-based medicinal products and the role of the doctor: should we be cautious or cautiously optimistic?

Irene Braithwaite, Giles Newton-Howes, Karen Oldfield, Alex Semprini

ABSTRACT

With rapidly changing legislation designed to improve access to cannabis-based medicinal products, we assess the obligations of the law and professional bodies on the proposed prescribers of these products. We argue that the current legal and professional obligations may limit prescribing practices despite legislative change, and that without the usual licensing processes of Medsafe being applied to these products, prescribers and their professional bodies must engage in the process of change to ensure short- and long-term patient safety and to maintain professional standards.

In December 2018, New Zealand legislators passed the Misuse of Drugs (Medicinal Cannabis) Bill into law.[1,2] An amendment of the Misuse of Drugs Act 1975,[3] it is intended to improve access to cannabinoid-based medicinal products made to a quality standard "on the basis of fairness, quality, safety and compassion".[2] With immediate effect, cannabidiol (CBD) was de-listed as a controlled drug and individuals requiring palliation for their medical condition were allowed a statutory defence for the possession and use of cannabis or cannabis-related utensils. The Act heralded the intent to develop a Medicinal Cannabis Scheme that would allow domestic commercial cultivation and manufacture of 'medicinal cannabis'. This scheme would encompass a licensing regimen, quality requirements for production and end products, and the establishment of a medicinal cannabis agency. By December this year, the Minister of Health is required to establish the regulations setting the quality standards for medicinal cannabis products that will be provided under a Medicinal Cannabis Scheme. With regulations due to come into effect before the end of 2019, medical practitioners in particular must consider the implications of the proposed Medicinal Cannabis Scheme on their current practice.

Already we have seen some changes. Prior to the amendment, doctors could only prescribe Medsafe-approved Sativex for spasticity in multiple sclerosis without ministerial approval. All other cannabis-based medications were classed as Class B1 controlled drugs and ministerial approval was required to prescribe, supply or administer these in accordance with regulation 22 of the Misuse of Drugs Regulations 1977.[4]

Now that CBD-only products do not require ministerial approval, some willing practitioners are changing their practice to respond to a perceived patient need.[5] All other cannabis-based products remain Class B1 controlled drugs and still require ministerial approval to be prescribed, supplied or administered. Ministerial approval is currently delegated to the Ministry of Health and applications are considered under two categories; pharmaceutical grade products that do not have consent

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for distribution in New Zealand (but have been trialled and are marketed for therapeutic purposes in other countries) and non-pharmaceutical grade products. In both instances 'appropriate' specialist application is required. No medicinal cannabis products are funded by PHARMAC, and the cost to patients can be prohibitive.[6]

The current consultation document for the Medical Cannabis Scheme indicates three possible pathways for the provision of cannabis-based products to patients; 1) the current approval pathway (only satisfied by the manufacturers of Sativex at this stage); 2) a provisional approval pathway where restricted access may be allowed to products from licensed Good Manufacturing Practice facilities that are currently undergoing clinical assessments; and 3) products not approved by the Ministry of Health to be supplied on prescription to named patients only.[7] It is unlikely that the number of Medsafe 'approved' / 'provisionally approved' cannabis-based products will significantly increase in the six months until implementation of the Medicinal Cannabis Scheme. The consultation document indicates removal of ministerial approvals and 'appropriate specialist' applications.[7] Inherent in this, prescribers will (at least until more products receive Medsafe approval), be assuming a gate-keeping role. Thus, practitioners will be prescribing products that historically fit into the two ministerial approval required categories.

A variety of perspectives have been published in this journal as to the pros, cons and 'how to's' of improving patient access to cannabis-based medicinal products.[9–14] Much of the focus has been on the scarcity of evidence for efficacy, the need for practitioners to get engaged in the current debate, the importance of doing no harm and recognising the importance of the way the market is regulated and the impact this has on the medical community. While not explicitly stated, these themes reflect the underlying principles to which the Medical Council of New Zealand (MCNZ) and the New Zealand Medical Association (NZMA) require practitioners to adhere,[15–17] and associated New Zealand legislation.[1,3,4,8,18]

Little has been written that specifically reflects on the requirements of these principles and legislation of the prescribers of cannabis-based products. Prescribing Medsafe-approved medicines ensures practitioners not only have confidence in the therapeutic effects and quality of medicines, but also indemnification if prescribed in accordance with recommended practice and the law. Most cannabis-based products will sit outside of this safety net. When prescribing outside of this system, practitioners are expected by professional bodies to seek guidance from appropriate legislation and associated regulations such as the Medicines Act 1981,[8] the Medicines Regulations 1984,[18] the Misuse of Drugs Act 1975,[3] the Misuse of Drugs Regulations 1977,[4] and fundamental principles of practice as described in the MCNZ Cole's Medical Practice in New Zealand,[15] the MCNZ Statement of Good Prescribing Practice,[17] the NZMA Code of Ethics,[16] the Code of Health and Disability Services Consumers Rights[19] and any appropriate district health board prescribing and medication policies, procedures and guidelines.

The Medicines Act 1981 permits an authorised prescriber to prescribe or administer approved or unapproved medicines for the treatment of a patient in their care.[8] Section 3 of the Act describes a medicine as *"(a) any substance or article that (i) is manufactured, imported, sold or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose; and (ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological or metabolic means; and includes (b) any substance or article (i) that is manufactured, imported, sold or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or (ii) of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of this Act;"*.[8] While cannabis-based medicinal products may potentially meet (a)(i) and possibly (b)(i) of Section 3, with few exceptions they do not fulfil the requirements of (a)(ii) and

would require a change in regulations to meet (b)(ii). We contend that without appropriate regulatory change, prescribing most cannabis-based products is incautious under this Act.

If cannabis-based products did meet the definition of a medicine, and could be prescribed under the Medicines Act, the next issue to address is that it is an unapproved medication. Section 25 of the Medicines Act lists a series of exemptions to the medicines approval process, allowing for authorised prescribers to *"(ii) sell or supply, or procure the sale or supply of, any medicine to any such patient or to a person who has the care of the patient:"* and *"(iii) administer, or procure the administration of, any medicine to any such patient"*.[8] When prescribing under Section 25, it should be noted that the authorised prescriber must always be working within their scope of practice. It is Medsafe's advice that in this instance "*the Code of Health and Disability Services Consumers' Rights places obligations on the provider of services. The consumer has the right to treatment of an appropriate ethical and professional standard, and the provider has the responsibility to ensure treatment, whether approved or unapproved, meets this standard*".[20] In other words, prescribers must abide by the standards expected by their professional bodies, the Health and Disability Commissioner and the law, therefore in effect, self-indemnify their decisions to the satisfaction of their professional bodies and the law.

The professional body that is primarily invested by law with the capacity of ensuring that doctors are fit to practice medicine is the MCNZ. This body provides oversight with specific reference to clinical competence, cultural competence and ethical conduct under Section 118(i) of the Health Practitioners' Competence Assurance Act.[21] MCNZ expectations are outlined in Cole's Medical Practice in New Zealand,[15] which contains a 'Statement on Good Prescribing Practice'.[17] This document contains 48 specific statements, many with sub-clauses outlining expectations for prescribers. The opening statement reads: "*Good prescribing practice requires that a doctor's customary prescribing conforms within reason to patterns established by the doctor's peers in similar practice. Inappropriate prescribing (which may include indiscriminate, excessive or reckless prescribing) is unacceptable, both clinically and ethically. It is also harmful to patients, the medical profession and society*".[17] In New Zealand there is no "pattern established by the doctor's peers in similar practice" for prescription of cannabis-based medicinal products. International practice may provide some guidance to our professional bodies in setting expectations as a reasonable number of jurisdictions have implemented medicinal marijuana laws. However, implementation of these laws has varied widely and without an understanding of how the New Zealand regulations are intended to change at the end of 2019, looking for appropriate 'established patterns' of prescribing in other jurisdictions is not relevant.

All of the statements are relevant to would-be prescribers of cannabis-based medicines, the most pertinent of which follow. Good Prescribing Practice advises practitioners that they must "*Be familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the medicines that you prescribe. Be aware that promotional and other information on medicines that are distributed by commercial interests are unlikely to be impartial; and independent expert sources of information (such as the New Zealand Formulary, and Medsafe Prescriber Update) are preferred where available*." Medsafe provide practitioners with confidence in the characteristics of medications and a degree of indemnification via the current medicines approval process. Establishing an appropriately informed knowledge base about each new cannabis-based medicine without the exhaustive systems Medsafe bring to bear is likely to outstrip the resources of most practitioners.

We are also advised that "[*You*] *must give careful consideration before prescribing any medication with a risk of addiction or misuse or psychotropic medication, and ensure that there are robust systems in place to manage the care of these patients. It is never appropriate to prescribe medicines with a risk of addiction or misuse, or psychotropic medication, for the first time to a patient who has*

not been appropriately assessed in person." This behoves doctors to ensure appropriate addictions histories are taken and monitoring of the potential for the development of a use disorder. In the case of illicit cannabis use there is little question it is a substance of abuse, with other psychiatric consequences also. [22,23] What the potential is for diversion and/or the development of a substance use disorder in THC containing cannabis-based products is not yet established. Monitoring for these potential issues is not always easy. Secondary services are in no position to undertake this, leaving the question of who is intended to do the monitoring unclear.

And finally, "*Make the care of patients your first concern…Medicines or treatment must not be prescribed for your own convenience or simply because patients demand them*." The Amendment has been passed with the express intent of improving access to cannabis-based medicinal products. It is intended that patients will increasingly 'request' cannabis-based medicinal products from practitioners and that they will in return respond 'appropriately' to these requests. At what point a patient request becomes a demand is highly subjective. Prescribing practices have been seen as enabling access to cannabis-based medicines in other jurisdictions as medical marijuana laws have been introduced. A number of US states that have enacted medical marijuana laws have seen a rapid growth in registered cannabis-based medicine users, with a large proportion of users registered by a surprisingly small number of practitioners. Colorado enacted medical marijuana legislation in 2000, allowing registered users to access a liberal range of marijuana and marijuana products.[24] By 2009 there were in excess of 100,000 registered users, average age early-to-mid-40s, registered predominately for severe/chronic pain,[24] with over 70% of registrations endorsed by only 15 physicians.[24] Michigan enacted the Medical Marijuana Act in 2008. Within eight months there were 37,330 registered users, and by May 2011 this had grown to 75,000, 45,000 (60%) of whom were registered by 55 physicians.[24] By 2016 this had risen to 218,000 registered users, 80% of them with 'severe and chronic pain'.[26] For so few physicians to assess and register so many people may infer the development of a 'medical marijuana specialist'. Whether such a role develops in New Zealand practice either by virtue of a training programme or practitioners 'leading the charge' is yet to be seen. The prior background expertise of these physicians also appears relevant, although what this background should be remains murky. If a 'medical marijuana specialist' role does develop, it must not be in the context of enabling access to marijuana or acceding to patient demand, but in the context of considered and appropriate management of medical conditions as is expected from medical practitioners.

It is our concern that, at the current time, the prescribing of cannabis-based medicines may not meet the standards of the MCNZ and this could have an impact not only on indemnity, but more importantly, patient trust and the public belief in doctors.

The NZMA may be the next organisation from whom guidance may be sought by practitioners considering whether to prescribe cannabis-based medicinal products. They updated their position statement on 'Medicinal Cannabis' in November 2017.[27]

On the basis of this position statement, is seems unlikely that the NZMA would be prepared to advocate medico-legally for practitioners that undertook widespread prescribing of cannabis-based medicines, or purported themselves to be 'medical marijuana specialists'.

The government has signalled legislative change and promised a population view of further change by way of referendum. The medical community need to, and will, respect this. However, the medical community also need to work within the remit of the law and the NZMC, and this may significantly limit prescribing practices.

Irrespective of how barriers to prescribing these products as medicines is overcome, adequate foresight and planning is required now to consider how best to assess the impact of these changes both in the immediate future and the many years beyond. On an individual level, physicians need to be informed about the specific products they may prescribe, the manufacturing quality of those products, the evidence of benefits and harms and commit to careful and objective

Figure 1: NZMA Position Statement on Medicinal Cannabis.

NZMA position and recommendations

1. The medical profession should be actively engaged in the debate about the use of cannabis for medicinal purposes.
2. The framework for the approach to medicinal cannabis should be consistent with that for medicines, and kept separate from debate about the legal status of cannabis for recreational use.
3. Doctors should not be enablers for the recreational use of cannabis.
4. The NZMA supports measures that facilitate research of medicinal cannabis, to widen and deepen the evidence base from which to make informed decisions.
5. Given the possible harms associated with smoking cannabis and the availability of other modes of administration, it is difficult to justify a place for smoked cannabis as a medicine.
6. Given the known harms of cannabis and weak evidence of efficacy as a medicine, caution is required before recommending cannabis for loosely identified medical reasons.
7. It is important to acknowledge the wide range of risks associated with cannabis, but these need to be considered in a similar light to the risks and side-effect profile of existing medications.
8. Doctors are well placed to educate people regarding the use of cannabis and to assist those with problems associated with cannabis. It is important that doctors engage in continuing education as the evidence regarding cannabis continues to evolve.

follow up. On a collective level, in accordance with the NZMA position statement, and with clear guidance from the MCNZ, physicians must engage constructively in the process of legislative change to prescribing, and around the forthcoming legalisation referendum of which the wording is critical. Physicians, their professional bodies, patients, carers and legislators need to learn from the experience of other jurisdictions that have enacted laws relating to access to cannabis-based medicines in order to work towards a legislative system that reflects New Zealanders' wishes, without the unintended consequences found overseas.

With respect to cannabis-based medications themselves, in the absence of pre-emptive Medsafe review and guidance, data needs to be collected to allow us to understand the quality of the decisions that are made. Data should capture beneficial (and adverse) clinical outcomes, and also allow us to assess the wider domains of social, health, economic and employment impacts. From a health systems perspective, collecting data around the products prescribed, the clinical condition for which it is prescribed, pre-natal exposure rates, changes in mental health prevalence, changes to referral rates and waiting lists for services such as specialist pain clinics, proportional workforce effects on general practice appointments and variation in use of current standard therapies such as opiates are all essential to informing progress and evolving clinical expectation around cannabis-based medicines. New Zealand is ideally placed to action such longitudinal data collection within our already existing National Health Index and centralised prescription and health databases. Together these have the potential to provide continual outcomes to inform and constantly update clinical practice to ensure the optimum outcome for patients.

Physicians play an important part in this process, beyond putting a pen to the prescription pad.

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Competing interests:
All authors are members of the Medical Marijuana Research Collaborative, an impartial collaboration of academics and regulatory experts in the field of cannabis-based medicine development. The Medical Research Institute of New Zealand has undertaken research activity unrelated to this article for Helius, and Whakaora Pharma, both of which are New Zealand-based medicinal cannabis companies. There are no other conflicts of interest to declare.

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A unified national cardiovascular disease (CVD) risk generator is required to address equity in the management of CVD risk in clinical practice in New Zealand

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ABSTRACT

There is a strong body of evidence that supports identifying and managing people according to their risk of a future cardiovascular (CVD) event. Since 2012 the New Zealand public health sector has achieved 90% CVD risk assessment (CVDRA) for each eligible person across New Zealand using a modified version of an overseas risk equation, through incentivising Primary Health Organisation (PHO) performance. In 2018 the New Zealand Ministry of Health endorsed the use of a suite of four new CVDRA equations which were developed using the large NZ Predict cohort (500,000 people). These equations more accurately reflect an individual's CVD risk and incorporate both traditional CVD risk factors, such as smoking and diabetes, but also sociodemographic factors including ethnicity and a deprivation score. The new CVDRA equations are an important tool to address the major inequities in CVD incidence, prevalence and mortality in Aotearoa-New Zealand. However, while the new equations provide more accurate assessment of risk, they are more complicated and therefore more prone to error if not properly validated and systematically implemented. To take advantage of this important opportunity to address equity in heart health we need strategic vision and national leadership. In this paper we make the case that to most safely and cost effectively implement the new equations, the Ministry of Health (MOH) should support a unified national CVD risk generator.

A single, electronic, national CVD risk generator would:

a. ensure national consistency and quality control—a single set of validated and current equations would be available to both clinicians and patients;

b. avoid substantial replication of effort and cost in both developing and validating multiple calculators;

c. enable central collection of the encrypted dataset required to develop more accurate risk assessment equations in population subgroups, both now and in the future, as CVD risk evolves;

d. provide a platform to facilitate systematic and consistent national CVD risk communication and management; and

e. facilitate ease of updating the tool and practice in the future as changes to the algorithm are agreed.

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There are deep and persisting differences in cardiovascular outcomes in New Zealand with people of European ethnicity and those who are wealthier, on average, living much longer and healthier lives than Māori, Pacific people and those who are less well off.[1,2] These inequities could be reduced substantially by better targeted use of cheap and readily available medications, which used in combination, can halve the risk of CVD events within just a few years.[3]

The benefits of cardiovascular preventive medications, including lipid and blood pressure-lowering and antithrombotic drugs, are directly proportional to the level of a person's pre-treatment CVD risk. Also, a person's CVD risk level is determined more by the multivariable interactions of multiple risk predictors, including their ethnicity and deprivation level, than by high levels of single risk factors. New Zealand led the world in introducing CVD risk prediction calculators in the 1990s to help clinicians identify the highest risk patients most likely to benefit from treatment, as well as the lowest risk patients least likely to benefit. As a result, New Zealand general practitioners now prescribe cardiovascular preventive medications more effectively and cost-effectively than their international counterparts.[4]

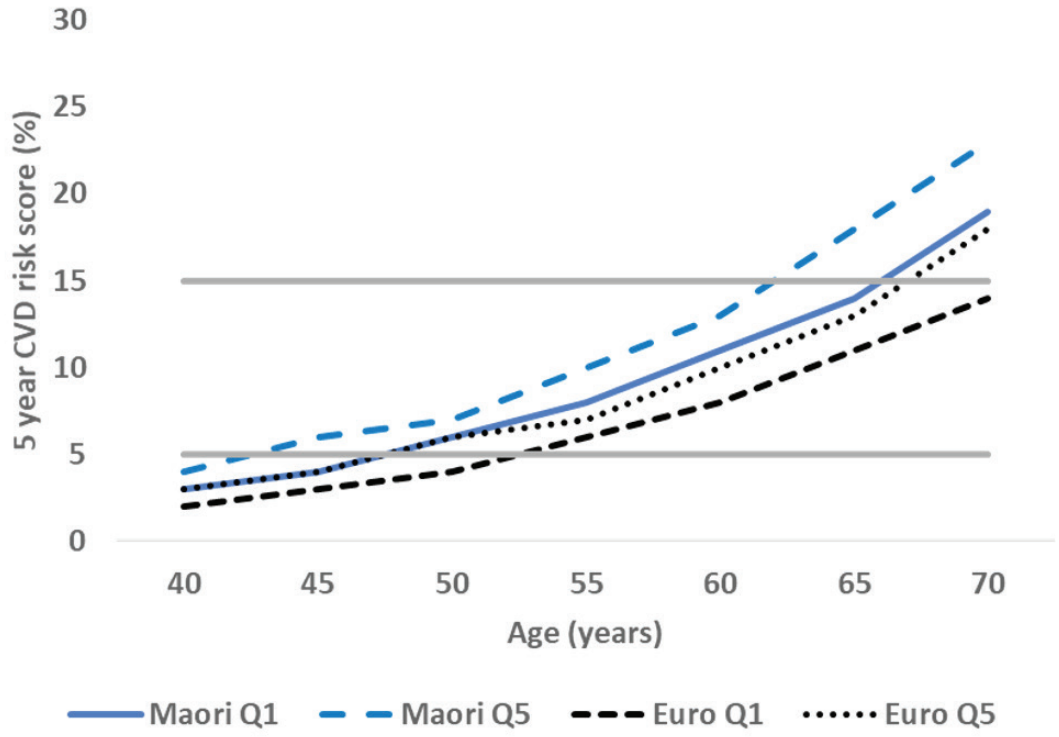
However, at the time they were introduced, the only available CVD risk calculators were derived from a White American population recruited for the Framingham Heart Study. So, while the calculators helped identify high-risk patients based on their standard CVD risk factors, they did not take account of the additional CVD risk that has been observed in a number of ethnic and socioeconomically deprived populations. To help address these inequities in CVD burden, the calculators needed to be modified. Therefore in 2003, national CVD risk assessment and management guidelines recommended that the CVD risk calculated for Māori, Pacific and South Asians using the American equation, should be modified by adding a standard additional increment. This had the desired effect of facilitating earlier treatment in these high CVD risk populations, but was simplistic and its accuracy was unknown because the necessary evidence to more accurately predict risk in different populations was not available.

The new PREDICT-CVD equations

Now, after 15 years of research funded largely by the Health Research Council and National Heart Foundation, new CVD risk prediction equations, based on over 400,000 New Zealand primary care patients from the PREDICT study are available. The **PREDICT-CVD 1⁰** primary prevention equations for men and women and the **PREDICT-CVD diabetes** equations for men and women with diabetes were made available in 2018.[5] The **PREDICT-CVD 1⁰** equations have been endorsed by a recent Ministry of Health Advisory Committee on CVD risk assessment and management to replace the modified US calculators that have been used since 2003.[6] Taking advantage of a larger patient cohort and more follow-up time updated versions of **PREDICT-CVD 1⁰** equations which include body mass index (BMI) as a variable are now available. In addition, research funded by the National Science Challenge will produce three further population specific primary prevention equations - for Māori, Pacific and Indian. There are also new equations being developed for patients with serious mental illness, a group who are at both increased risk of cardiovascular disease, and less likely to have appropriate cardiac care.[7] A secondary prevention equation to estimate CVD risk in patients with known CVD is available and is being updated to provide five-year CVD risk estimates. Furthermore, CVD risk in the population changes over time and equations need to be updated regularly to reflect this.

The new equations specifically address health equity by including separate predictors for all major ethnic groups represented in New Zealand and also include predictors for socioeconomic deprivation, using the national socioeconomic deprivation score (NZDep). They are considerably more accurate than the previous equations in identifying patient groups at highest (and lowest) CVD risk. Māori women, for example have a 50% higher risk than European women, all other risk factors being equal, and there is a similar difference in risk between the most socioeconomically deprived and least deprived 20% of New Zealanders.

Figure 1: The impact of both ethnicity and socioeconomic status on the risk of CVD and the implications for the equity of CVD risk management.



In Figure 1 we illustrate the impact of ethnicity and socioeconomic status on the age-related CVD risk trajectory using an example with four men—two Māori and two European—when all the other standard risk factors are identical. For illustrative purposes they all have the same blood pressure (BP 140/90mmHg), total cholesterol to high density lipoprotein ratio (TC/HDL 4.6) and are smokers, have a BMI of 30 but have not as yet developed diabetes. Using the new **PREDICT-CVD 1**[9] equation, the European patient living in a neighbourhood of least deprivation (Q1) has the lowest risk trajectory, and would be nearly 55 years old before he reaches the 5% 5y CVD risk threshold at which more intensive management, including medication, would be considered clinically appropriate. In contrast, the Māori patient living in Q5 would be considered for more intensive management 10 years earlier, because he reaches the 5% 5y CVD risk threshold when he is 44 years old. Furthermore, the Māori/Q5 man also crosses the 15% threshold at which medication is strongly recommend 10 years earlier than the European/Q1 man.

The new New Zealand equations also demonstrate that the previously used American equation now substantially overestimates risk, particularly among European and Chinese populations and those in the least socioeconomically deprived groups. Therefore, the new calculators will facilitate a reduction in overtreatment of those at lowest risk and of the overtreatment of those at lowest risk.

The development of these new equations, which are unique internationally, was only possible because of the combined efforts of a number of PHOs, university researchers and research funders, along with substantial support from the Ministry of Health and other healthcare organisations. In addition, without access to the high-quality electronic routine national health databases covering drug dispensing, hospitalisations and deaths that can be linked by New Zealand's National Health Index (NHI) number, the research required to develop these equations would have been prohibitively expensive.

The Ministry of Health, several DHBs, PHOs, the Health Research Council of New Zealand and the National Heart Foundation supported the establishment of the PREDICT study in 2002, but, the game-changer came in 2012 when the Ministry instituted the national 'more heart and diabetes checks'

target. The goal was to complete formal CVD risk assessments on at least 90% of all eligible New Zealanders and the Ministry provided funding that enabled PHOs to help primary care practitioners to achieve this goal by 2016.[8]

Making the CVD risk equations nationally available—what is needed?

To take advantage of this important opportunity to address equity in heart health we need strategic vision and national leadership.

CVDRA is being used to help make individual treatment decision for patients and is a great opportunity to improve equity for our patients. It is therefore critical that the risk estimate calculated is accurate otherwise there is a risk of inappropriate treatment decisions, and even harm to patients. In New Zealand, CVDRA in primary care is delivered using electronic decision support systems integrated with the patient management systems. To deliver accurate risk assessment is dependent on several steps. These include:

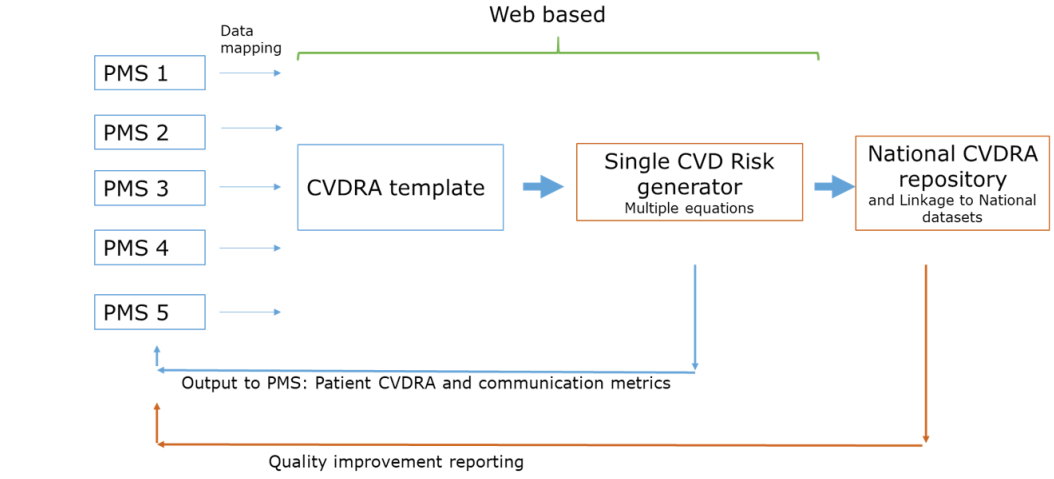
1. the accuracy of initial data entry in the PMS
2. the mapping of risk data to the risk calculator
3. the programming and output of the risk calculator
4. good governance of the data dictionary, PMS implementation and risk generator content

To support national implementation the Ministry of Health (MOH) have commissioned a CVD Consensus Data Dictionary to describe the data elements required for input to the calculator, standardise their definitions and consider the metadata requirements for a risk calculator.

This is a key first step, but the next important decision is whether to have a single national risk generator or to have the multiple PMS software vendors develop their own. Currently we are aware of at least five software vendors who are developing their own risk calculators based on the 2017 published equation. While the new equations provide more accurate assessment of risk, they are more complicated and therefore more likely to be prone to error if not properly validated, and systematically implemented and tested within PMSs. In addition, 15 years of research have led to development of a suite of more tailored personalised equations so the complexity of validation, implementation and testing is magnified. Furthermore, the Consensus statement also recommended that CVD risk be paired with visual CVD risk communication tools (such as Heart Age and CVD risk trajectory) and risk-benefit tools for initiating management. To address equity of health outcomes, these health literacy tools are vital and a consistent national approach is needed.

We propose an alternative approach using a single, freely available, web-based National Risk Generator.

Figure 2: Proposed Schema for Implementation of a Single National CVD risk generator.



CVDRA Data items defined according to National CVDRA Data dictionary
PMS = GP Practice management system, CVDRA = cardiovascular disease risk assessment

All CVD risk data items should be defined according to the CVD Consensus Data Dictionary (PMS = GP Practice management system, CVDRA = cardiovascular disease risk assessment).

A common, single, web-based data entry template would be presented, auto-populate data from the PMS and be completed for each patient. The risk generator would receive data from the template, access the appropriate equation for that patient and then present the risk, with a visual risk communication display as well as the risk/benefit of management. The risk score could be saved in the PMS linked directly to which equation was used. The risk generator would contain all the equations, but also an algorithm for choosing the most appropriate one to use for each patient, eg, which primary prevention equation for patients with diabetes, ethnic specific equation, severe mental illness equation, etc. Information technology (IT) such as an application programming interface (API) is one option that could be utilised. It would also be able to be accessed via a standalone web-based template on a website for the public, cardiologists in public or private services, laboratories, pharmacies, occupational health clinics and even overseas (eg, Pacific countries).

Accurate CVDRA positively impacts three of the Ministry of Health's medium-term priorities. The proposed schema would allow primary care physicians to have accurate information available as a starting point to discuss the best options for risk reduction with patients. It increases equity of care by preventing under-treatment of groups at elevated cardiovascular risk because of ethnicity or socioeconomic deprivation. The schema would also ensure that a new risk equation for people with severe mental illness could be applied nationally when developed so this at risk group would benefit without delay.

Beyond the CVD Risk Generator

A web-based CVD risk tool also makes a National CVD Database possible. If established according to best practice clinical, ethnic and consumer governance and data stewardship, it could provide valid, consistent, robust clinical data and form a comprehensive national CVD and diabetes database. While the new equations took over 15 years of research to complete, the infrastructure required to rapidly update them and to develop more accurate and more individualised equations is now largely in place across the country, because electronic CVD risk calculators are now used in almost every PHO. If all PHOs now joined one centralised electronic CVD risk system, it would be possible to develop new equations for specified high-risk sub-populations within just a few years. This national database would support existing clinical performance indicators and identify in real time equity gaps in CVD health outcomes across the whole population.

Competing interests:
Dr Jackson and Dr Kerr report grants from HRC during the conduct of the study. Dr Wells reports grants from HRC and The Stevenson Foundation during the conduct of the study. Dr Harwood reports grants from HRC and National Science Challenge—Healthier Lives during the conduct of the study.

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Primary umbilical endometriosis

Rebecca McLean, Simon Richards, Katherine Hulme

A 32-year-old woman presented to the surgical outpatient clinic with a six-month history of a painful umbilical lump. Prior to this, she was asymptomatic and had normal umbilical anatomy. She had no prior history of abdominal surgery or laparoscopy. Since first noticing, the lump has increased and decreased in size and she had cyclical bleeding coinciding with her period over the three months prior to presentation. She described two episodes where she developed irritation and erythema at her umbilicus, and she was prescribed antibiotics with no effect. Her medical history was unremarkable, she had never been diagnosed with endometriosis nor had recurrent urinary tract infections. She was a non-smoker, non-drinker and had no significant family history. On examination, she had a soft, non-distended abdomen with no surgical scars and a 3cm diameter lesion protruding from her umbilicus. It was firm to palpate and not clinically a hernia. There was some skin darkening over the lesion (Figure 1).

She proceeded to have an outpatient ultrasound for further assessment. This showed a 26mm subcutaneous solid lesion with internal vascularity at the umbilicus. There was no definite deep extension or evidence of a communicating urachal remnant deep to this (Figure 2).

Figure 1: Pre-operative appearance of the umbilicus.

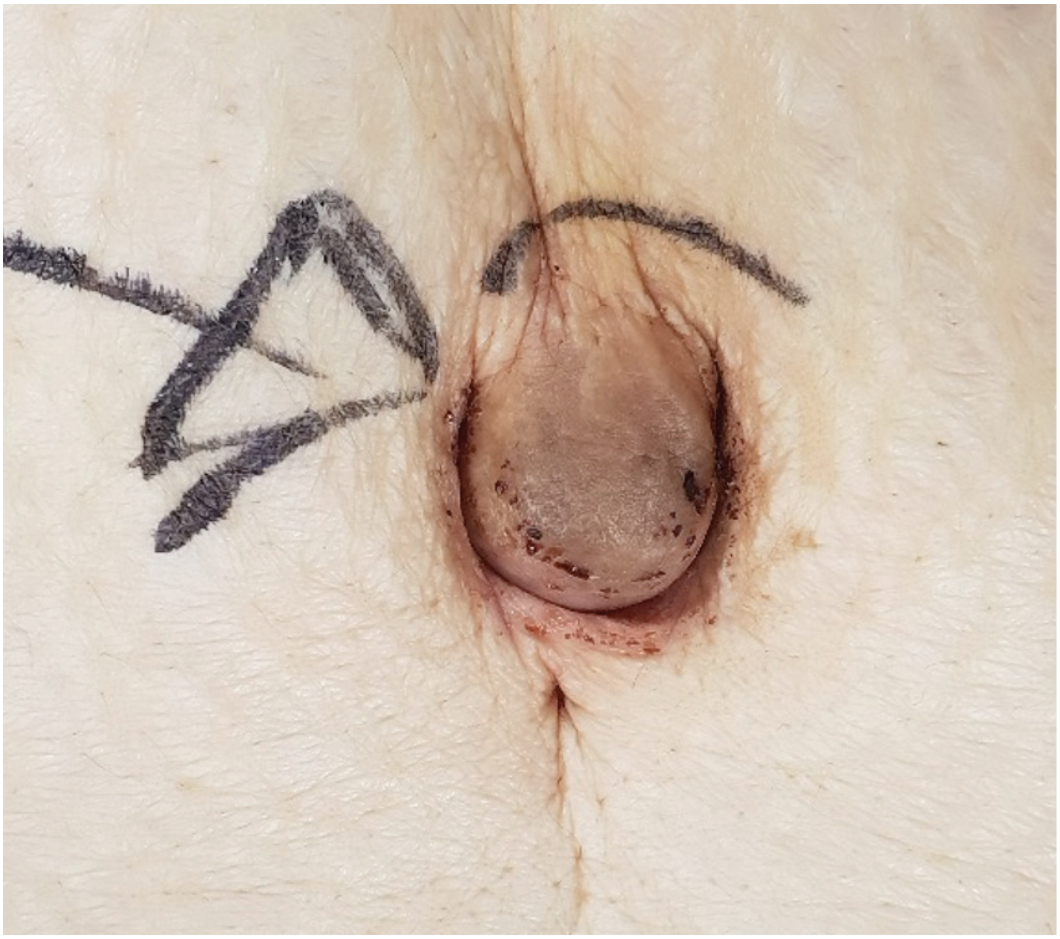

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Figure 2A: Demonstrates a well-defined mass superficial to and not involving the fascia, within the subcutaneous tissue at the umbilicus.

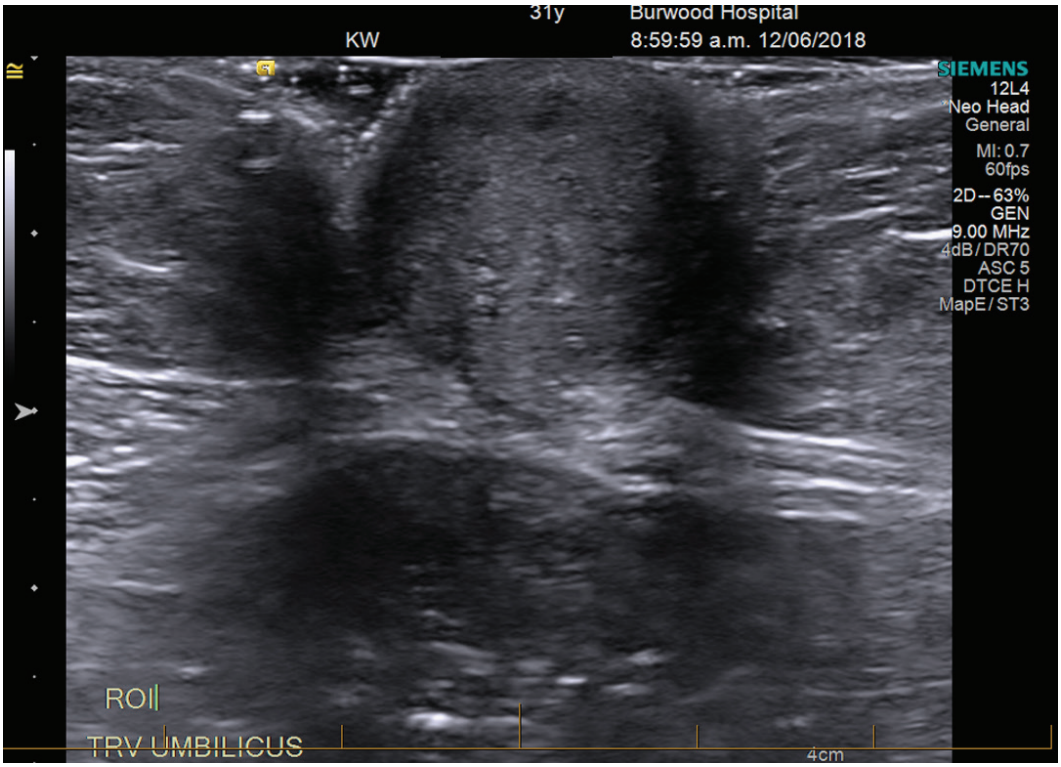

Figure 2B: Demonstrates internal vascularity of the mass.

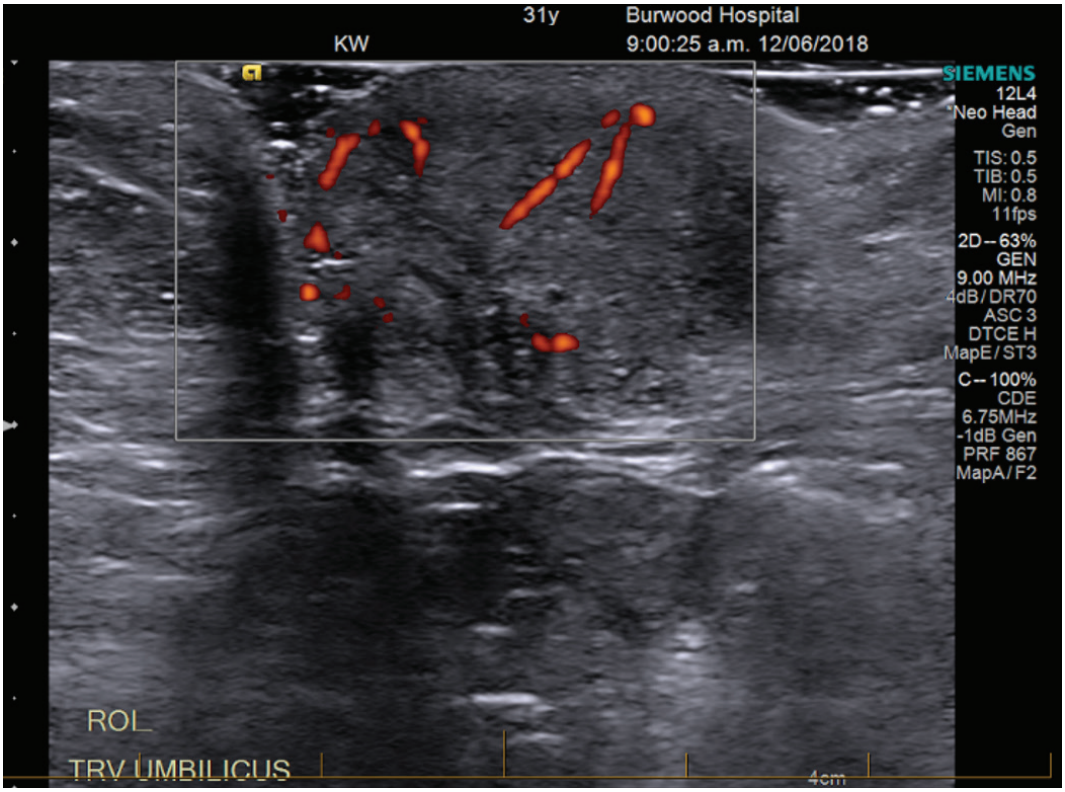

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Figure 3A:

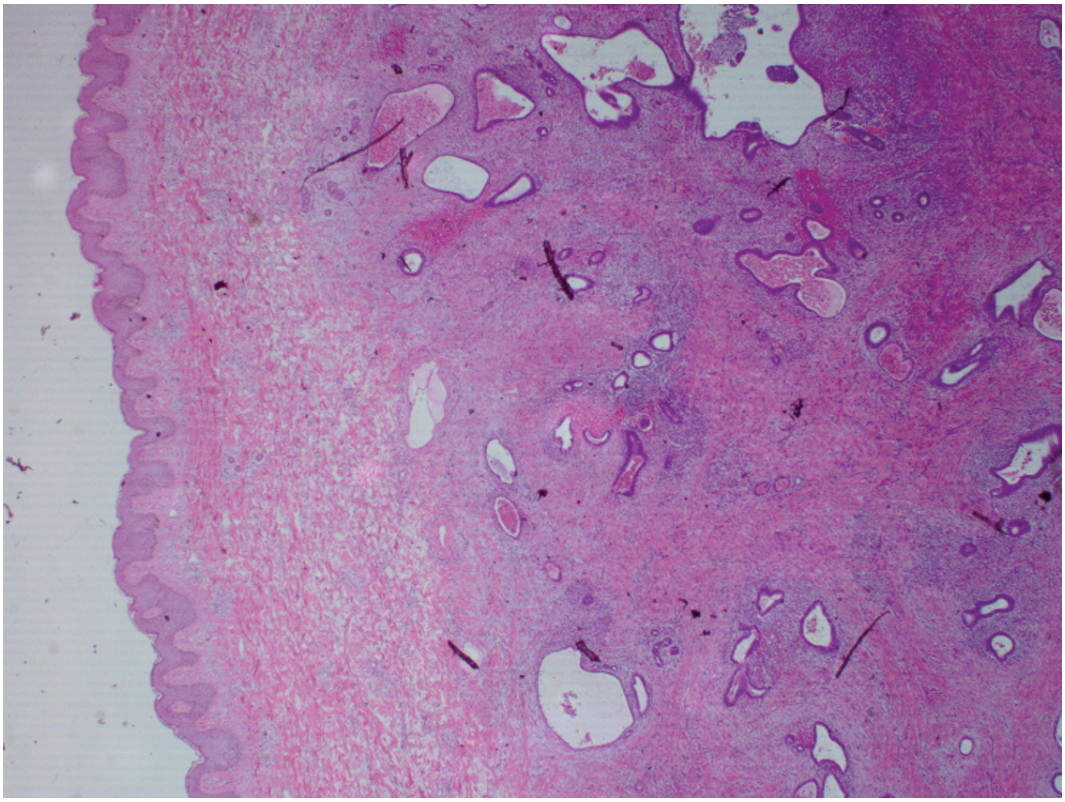
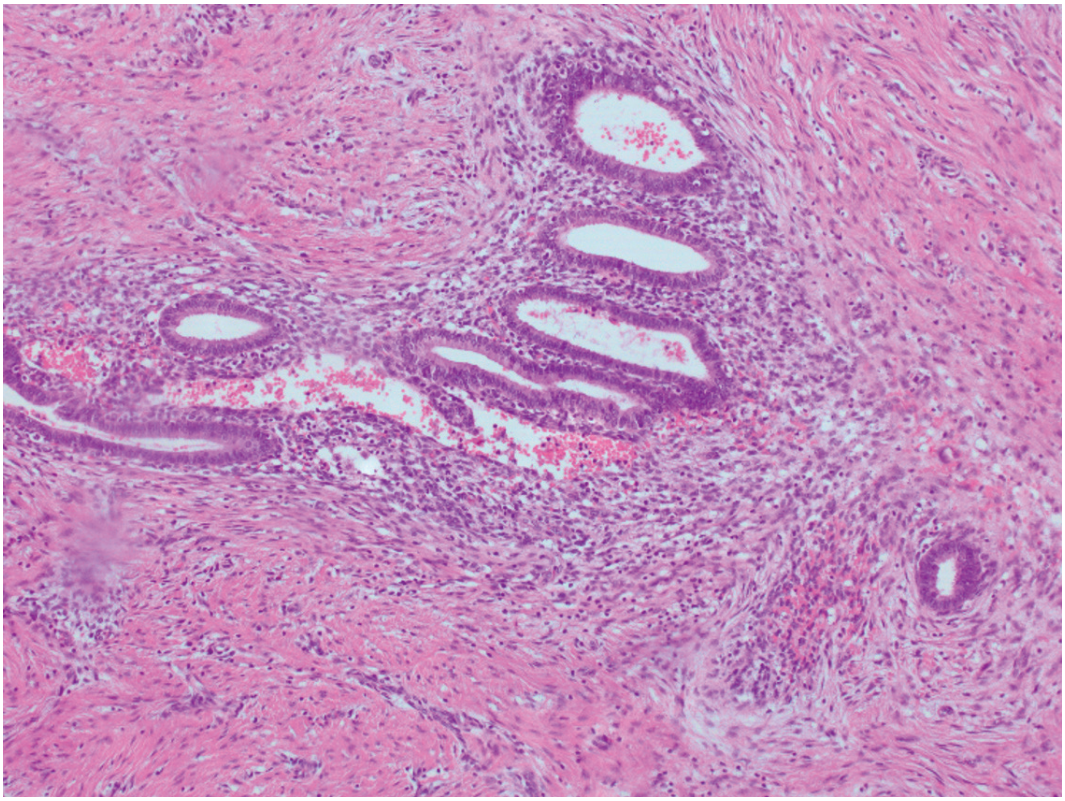


Figure 3B:



Above histological specimens show a dermal/subcutaneous lesion comprising of endometrial glands, endometrial stroma and fibrosis. Some glands contained haemosiderin and fresh haemorrhage was also present; features representative of endometriosis. Supplied by Christchurch Hospital Pathology Department.

She proceeded to have an elective excision of the umbilical mass. An elliptical excision of the lesion was taken with a 5mm margin down to fascia including the anterior rectus sheath and the overlying skin. Post-operative histology showed evidence of endometriosis (Figure 3). Her post-operative recovery was uncomplicated, and she was referred to gynaecology for further management.

Discussion

Endometriosis is a benign presence of endometrial tissue outside the endometrial cavity, and it affects 10–15% of all women of reproductive age.[1] Extrapelvic endometriosis represents 1% of all endometriosis deposits; common places include the bowel, peritoneal cavity, lung and cutaneous sites (primary or surgical scars). Of this small proportion, only 0.5–1% of patients have primary umbilical endometriosis (PUE).[2,3] Of all cutaneous endometrial sites, umbilical endometriosis is the most common, although most relates to previous surgical incisions (30–40%).[3,4] PUE is rare, and in a case report by Van den Nue et al, the authors describe that since 1990, less than 100 cases of PUE have been reported.[4] Originally described in 1886 by Villar, it is often referred to eponymously as a Villar's Nodule.[5]

Primary umbilical endometriosis may present rarely with an umbilical lump, often with cyclical bleeding in a patient without a history of endometriosis. The exact pathogenesis remains unknown; however, it has been hypothesised that Müllerian remnants from the umbilical fold that have failed to properly differentiate or migrate can form extrapelvic endometriosis deposits.[1,4] Alternatively haematogenous or lymphatic spread of endometrial cells has been proposed as a cause.[1,4]

Umbilical endometriosis more commonly occurs secondarily, usually caused by 'iatrogenic seeding' during surgery causing a spread of endometrial tissue from the pelvis to a surgical scar.[4] Despite being more common than PUE, the true incidence is not known.

Radiological findings are non-specific[3] and there are no pathognomonic imaging findings characteristic of PUE. Imaging in the form of CT, USS or MRI may be employed when assessing an umbilical mass, and their main use lies in the exclusion of other diagnoses such as a hernia or urachal remnant. Fine needle aspiration (FNA) cytological analysis may be useful to confirm the diagnosis after imaging confirms a solid mass and prior to surgical excision.[6] Histological findings typically are of hypervascularity surrounding metaplastic endometrial glands and cytogenetic stromal fragments in the deep and middle dermis with possible haemorrhagic and haemosiderin filled macrophages.[7] Surgical excision is widely accepted as standard treatment,[2] however, there is no consensus on whether a laparoscopy should be performed concurrently in the absence of abdominal or pelvic symptoms.[7] Surgery should preferentially be performed at the end of the menstrual cycle when the endometrioma is as small as possible. Recurrence rates are low.

Competing interests:
Nil.

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Age of first menstruation in New Zealand: findings from first ever national-level data and implications for age-appropriate education and support

Sarah Donovan, Lucy Telfar-Barnard

Age at first menarche is a key index of adolescence and an important developmental milestone, up-to-date knowledge of which is important to guide age-appropriate care and education to young girls about menstrual self-management.[1,2,3] However, national-level data has not previously been collected in New Zealand/Aotearoa. We have had little option but to extrapolate from overseas data to provide any guidance in this area, despite research showing considerable inter-country age differences[4] and without consideration of important, contextual factors such as New Zealand's ethnic and socioeconomic mix.

This lack of local guiding data appears to have led to menarche being assumed to be occurring at a later age, resulting in mistimed health education for schoolgirls, and absence of standardised school infrastructure such as sanitary disposal bins for female pupils. This issue was highlighted in 2016 media coverage, when an Auckland mother complained to her GP that the principal at her then nine-year old daughter's primary school had asked her to stay home from school during her periods, or to start taking the oral contraceptive pill, because the school did not provide sanitary disposal units.[5] The story also shed light on the related issue of 'period poverty'—girls missing school due to the cost of pads and tampons—with data gathered by charity 'Kidscan' echoing a significant demand for donated menstrual products at both primary and intermediate schools.[6]

This local data gap appears to have hindered the ability of healthcare professionals, parents and schools to adequately support young girls in developing skills and confidence in self-management, at ages when this is most needed.[7]

For the first time, national-level data has now been collected on age at menarche (although repeat data collection is not planned). The Ministry of Health provided percentages of women who participated in the Sexual and Reproductive Health Module of the 2014/15 New Zealand Health Survey by age of menarche . Manual and locally weighted scatterplot smoothing was used to interpolate percentages of girls menstruating by age in months. School year was then assigned to each age in months, using the New Zealand standard of 1 July as the cut-off between school years. The limited data provided did not allow for more complex analysis.

Our analysis shows that the average age of menarche in New Zealand is roughly 13.2 years; this is slightly higher than the 12.9-year mean found by the Dunedin Multidisciplinary Health and Development Study (drawing on a sample of 415 girls).[8] However, while it appears to be popularly assumed in New Zealand that girls usually get their first period at secondary school, our analysis per school year confirms that this is not the case for nearly 50% of New Zealand girls. This would suggest that nationwide, around 11,700 girls—4,150 in year 7 and 7,550 in year 8—start menstru-

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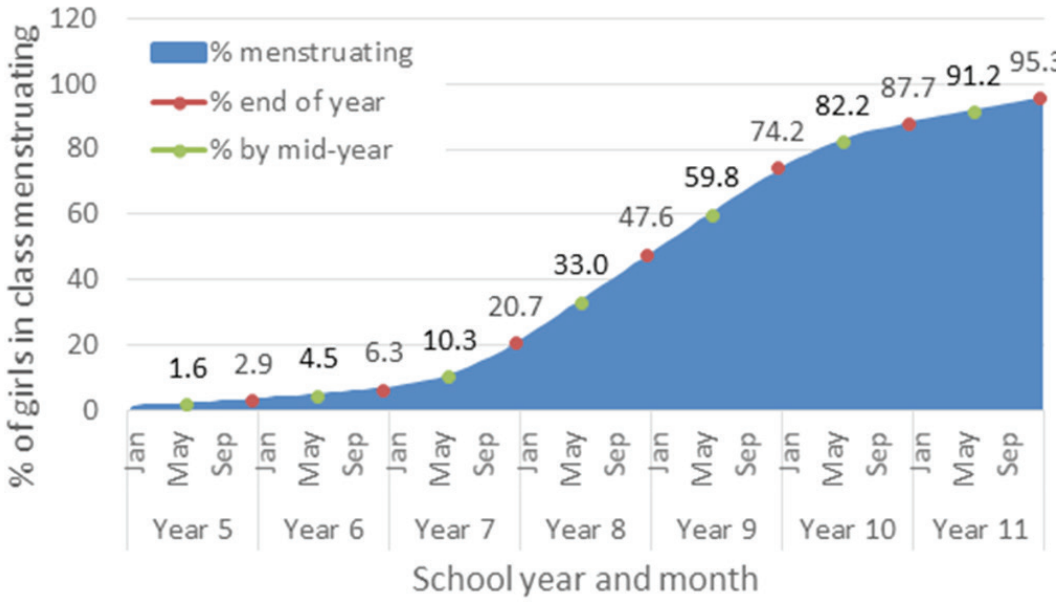
Figure 1: Percentage of girls menstruating by school year and month (women aged 25–34 years in 2015).



ating during the intermediate school years. Most significantly these data indicate that 1,900 girls (6.3% or one in 16 girls) start menstruating while of pre-intermediate primary school age.

These findings indicate the need to target health education, resources and support to a significantly younger age group than we currently do, in order for girls to be prepared to manage their periods without disruption to their schooling, and without embarrassment. This ought to be done in a standardised way, as matters of both student welfare and provision of basic school infrastructure.

This new New Zealand data will also allow us to make comparisons with international data, which indicate that globally the age of menarche continues to decrease,[1] a phenomenon variously hypothesised as due to the impact of environmental toxins and/or increasing BMI in young girls, but yet to be definitively explained.[2] Beyond the psychosocial and educational implications, such trends have further clinical implications in terms of evidence of links between early menarche and development of conditions such as CVD and breast cancer later in life.[9,10] Data on age at menarche by ethnicity was not available at time of writing, but further analysis along these lines would be illuminating for providing culturally appropriate care and education in schools. This may also be valuable data in analysing potential links between early menarche, BMI and the development of breast cancer in groups with particularly high rates in New Zealand, such as Māori and Pasifika women.[11,12]

In conclusion, these new findings show policy makers, educators, health professionals and possibly even parents need to rethink how best to support young girls as they reach this important developmental milestone: specifically, that primary school is the correct place to educate girls about periods and to start providing sanitary bins and pads. At present, no oversight is provided by the Ministry of Education or the Education Review Office (which audits other welfare-related school infrastructure) to ensure that New Zealand schools provide sanitary bins for female pupils, and local research within Wellington schools (primary, intermediate and secondary levels) by the researchers uncovered an ad hoc approach and generally no provision made at primary schools. This is likely to be partly due to a lack of guiding data available to the Ministry and to schools, and we hope this may now be addressed with some urgency.

Competing interests:
Nil.

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Boycott of ASA Review of Alcohol Advertising—need for regulation

Sally Casswell, on behalf of the interim Board of Health Coalition Aotearoa

This open letter is in response to the Advertising Standards Authority's (ASA) review of the Alcohol Advertising and Promotion Code. We will not be making a submission to this review.

The ASA is an industry body that develops voluntary advertising codes. However, voluntary codes have been ineffective at restricting alcohol marketing.

The alcohol industries in New Zealand rely on heavy drinking for profits. Almost half (48%) of alcohol in New Zealand is consumed in heavy drinking occasions as defined by the World Health Organization. Therefore, both alcohol and advertising industries have a strong conflict of interest in their self-regulatory role.

Alcohol marketing normalises alcohol use by its association with sporting teams and events, music festivals and charities; its placement in retail outlets, on hoardings, on television, in films and radio; and its prominence on social media platforms.

Voluntary advertising codes have failed to protect people from marketing techniques designed to increase alcohol's appeal to them, such as the use of music, colour, characters, sound effects and brand logos. None of these techniques contravene the voluntary codes.

A recent study found New Zealand children were exposed to alcohol marketing four to five times per day on average. It also found Māori children were exposed to alcohol marketing more than five times as often as New Zealand European children. Internationally, more exposure is known to lower the age at which young people start drinking alcohol and to increase the amount they drink.

Alcohol advertising must be reduced to protect the public from its glamorising and normalising impacts.

This can only be achieved by the government putting in place regulation that restricts alcohol marketing. This action was recommended by the Law Commission Review of the Regulatory Framework for the Sale and Supply of Liquor in 2010, the Ministerial Forum on Alcohol Advertising and Sponsorship in 2014 and the Government Inquiry into Mental Health and Addiction in 2019. It's also strongly promoted by the United Nations as a cost-effective policy to reduce alcohol harm.

Competing interests:
Nil.

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Pollyanna's guide to the regulation of alcohol marketing

Gerard Hastings

The New Zealand government has just hit upon an inspired new policy. It is going to abolish the criminal justice system in its entirety. Between the courts, lawyers, police, prisons and rehabilitation services it is estimated this will save over $5 billion a year. There will be no more miscarriages of justice; no more fruitless incarceration; no more families riven and children neglected by parents torn from the domestic hearth. Instead of harassing motorists, traffic cops will become tourist guides. High court judges can hang up their wigs and join the after-dinner circuit recounting how asinine were the old days, when they donned fancy dress and dispensed wisdom parsed to destruction by obscurantist and arcane legal proscriptions. The time parliament has heretofore devoted to devising ever more laws and punishments will now be put to beneficent purpose—and the budgets released will ensure that these deliver on their promise.

All our costly and contentious legal rigmarole—and here lies the real genius of the move—will be replaced with a brand new 'Citizens' Code of Conduct' (CCC), to which everyone will be able to subscribe. This ground-breaking document will lay out a complete list of unacceptable behaviours. A big challenge, you will agree, but it has been done before and The Ten Commandments will provide a great start. These will of course need to be updated to address modern living: out will go graven images, and in will come Twitter feeds; coveting, that essential skill in any consumer society, will move from vice to virtue and the Sabbath will now be kept sacred by visiting the mall rather than the church.

These revolutionary changes will be made in a deeply democratic way. The text of the new CCC will be the subject of comprehensive consultation with the New Zealand population—especially those of a criminal disposition. An initial draft will be prepared by a newly established Standing Committee on Human Behaviour, made up of criminals, lawyers and politicians, and chaired by Pollyanna. The draft document will be published and made the subject of rigorous public discussion and debate. Everyone will be able to have their say. Nor will anything be hide-bound or set in stone: the CCC will be constantly updated and improved to match the country's evolving needs. If you don't like a particular provision—being nice to your neighbour perhaps, or telling the truth—just write in, and get your mates to write in, and the code will be revised accordingly.

As he or she reaches maturity, each citizen will be invited to put their name to the CCC. Note the word invited—this is, after all, a voluntary Code. But fear not, such is the brilliance of this innovation that people will embrace it with joy and relief; they will see that self-regulation is the future. Signing up to the CCC will become an invigorating rite of passage; a sort of Kiwi bar mitzvah. And as for the few who don't, well we'll know who to watch won't we?

We doubt if many readers of the New Zealand Medical Journal will buy this simplistic drivel. Rather you will be reaching for pen and phone to protest; to cry justice for the victims of violence and robbery that the criminal justice system is designed to protect; to argue that transgressions need to be balanced with effective sanctions.

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Well do not stay your hand, for this naïve system of voluntary regulation is not a fanciful invention; it is precisely how alcohol marketing is currently controlled in New Zealand. The Advertising Standards Authority, in its wisdom, is now consulting on the precise wording of the latest iteration of its toothless voluntary code.[1] Alcohol kills over 800 Kiwis a year,[2] is instumental in at least 30% of crimes[3] and costs the exchequer $7.85 billion per year.[4] It also drives poor mental health[5] and is heavily implicated in New Zealand's shamefully high suicide rates.[6] Why then does the Government insist on treating the perpetrators and profiteers as boy scouts? So, take hold of that that pen, switch on that phone and tell the Government, in no uncertain terms, that this consultation is a disgrace which will do nothing to improve wellbeing or mental health in New Zealand.

Competing interests:
Nil.

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Regulation urgently needed to protect Māori from alcohol advertising

David (Rāwiri) Ratū

Tēnā koutou

The Advertising Standards Authority (ASA) has been a law unto itself for a very long time and the notion of a *voluntary code* to control alcohol marketing has not worked and will not work. Moreover, we have concluded that making submissions to the current review of the voluntary code will not make an ounce of difference to Māori being exposed to alcohol advertising, eg, signage plastered all over off-licensed premises in the more pohara areas, where there is a predominately high Māori population.

For example, on Dawson Road, Ōtara in Auckland there are four off licenses. On the periphery of those off licenses are a secondary school, a kura kaupapa, a kōhanga reo and two primary schools. Our tamariki and mokopuna are exposed to the alcohol advertising on those premises when they are going to and coming from their places of learning. We are not convinced that our contribution to the ASA's review of standards will change this picture anytime soon, in fact I would venture to suggest that the status quo will not change at all. We are of the opinion that the review of their standards is nothing more than a box ticking exercise.

I have only advanced our thoughts on signage on and around off licenses and not commented on other forms of advertising that fall under the so-called authority of the ASA. It is our view that submitting to the ASA review on these issues would be an exercise in futility. *Maumau te wā.* Moreover, the adour of conflict of interests is potent, ie, profit vs public good—why is the alcohol industry still at the policy making table? It would be inconceivable to have Big Tobacco at the policy making table.

Because of this situation, a decision has been made to vigorously pursue a claim against the ASA as part of our Treaty claim against the Crown which argues that, among other things, the Crown has failed to afford Māori active protection by abdicating its responsibilities for the regulation of advertising standards, thereby exposing Māori to unwanted and harmful advertising especially around alcohol.

We can look to the legislation that bans tobacco advertising which has, for the most part, been successful for Māori. We call on the Government to implement a similar proportionate response to alcohol given that it causes more harm to Māori than tobacco.

Competing interests:
Nil.

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Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma

Primary open angle glaucoma and ocular hypertension are habitually treated with eye drops that lower intraocular pressure. Selective laser trabeculoplasty is a safe alternative but is rarely used as first-line treatment.

This research project has thrown light on this issue. Seven hundred and eighteen appropriate patients were enrolled from six UK hospitals. Half were randomised to have selective laser trabeculoplasty. The other half were treated with eye drops—usually prostaglandin analogues or beta blockers.

The authors report that trabeculoplasty is associated with lower cost, good clinical outcomes with lower symptom scores and drop freedom for most patients, and should be offered as first-line treatment for open angle glaucoma and ocular hypertension.

***Lancet* 2019; 393:1505–16**

A randomised trial of progesterone in women with bleeding in early pregnancy

Bleeding in early pregnancy is strongly associated with pregnancy loss. Progesterone is essential for the maintenance of pregnancy. Several small trials have suggested that progesterone therapy may improve pregnancy outcomes in women who have bleeding in early pregnancy.

In this trial the researchers recruited 4,153 appropriate women from 48 hospitals in the UK. Half of them were randomly assigned to receive vaginal suppositories containing 400mg of progesterone twice daily from the time of presentation with bleeding through 16 weeks of gestation. The other half were treated similarly with a matched placebo. The primary outcome was the birth of a live-born baby after at least 34 weeks of gestation.

The conclusion reached was that among women with bleeding in early pregnancy, progesterone therapy administered during the first trimester did not result in a significantly higher incidence of live births than placebo.

N Engl J Med 2019; 380:1815–24

Adiposity and risk of decline in glomerular filtration rate

The objective of this international cohort study was to evaluate the associations between adiposity measures (body mass index, waist circumference and waist-to-height ratio) with decline in glomerular filtration rate (GFR) and with all-cause mortality.

Cohorts from 40 countries with data collected between 1970 and 2017 were examined. The participants included adults in 39 general population cohorts (n=5,459,014), of which 21 (n=594,496) had data on waist circumference; six cohorts with high cardiovascular risk (n=84,417); and 18 cohorts with chronic kidney disease (n=91,607).

The findings of this study were that obesity is associated with an increased risk of GFR decline and mortality in individuals with and without chronic kidney disease.

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Masked Epilepsy or Petit-Mal

By GORDON MACDONALD, M.D., Dunedin

Sceptic: Did you ever know two doctors to agree ? Doctor (after reflection) : F-e!-s, at a post mortem. (Observer, 09 February 1907). Alexander Turnbull Library, Wellington, New Zealand. /records/6968636

On 28th September last C.N., aged 32, single, and a labourer, consulted me regarding a peculiar deformity of the bones of his occipit. His story was as follows: "I was born in London, and when about 10 years of age I fell down a stair and injured my head. I was ill for some time thereafter, and forget all particulars about the nature of the injury and what was done for it. On recovering and returning to school my schoolmates used to remark, 'C— is funny at times'—that is, mentally peculiar. I left school when 14, as I made little progress with my lessons. Afterwards I worked at various occupations, but I never could find an employer who wished to employ me continuously, as they all said I was very funny at times. A few years ago I came to New Zealand, thinking my bad luck in London would be unknown, and so I could start afresh in the world. After a few months' employment in New Zealand my employers began to dismiss me from my jobs while I did not wish to be dismissed, nor could I see

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any reason for their dismissing me, as I was very anxious to please them. I asked some of them why they dismissed me, but their answers were generally evasive; occasionally, however, the master would say, 'C—, you are sometimes very funny, and I am afraid to keep you on, in case of accident.' While working at the West Coast last year I was asked to consult a doctor about my head. I did so, and consulted three different men, asking them to examine my head and see if they could do anything to improve matters, but none of them suggested anything, nor could I get any information from them as to the nature of my supposed defect. I then went to Christchurch and consulted two doctors there, with exactly the same result. Then I decided to come to Dunedin, and on making enquiries as to whom to consult, your name, among others, was given to me. I feel quite well and can see nothing wrong with me, myself, only other people say I am sometimes very funny. The only thing I am conscious of is that sometimes I am very forgetful, other times so confused that I have some difficulty in finding my lodgings, other times irritable without much reason. These things, however, occur only for a moment or so, and I think nothing of them, as by an effort I pull myself together and go on as if nothing had happened."

To look at him, he seemed a man of sound body and mind, clean, well dressed, well spoken, and altogether a man above the average run of labourers. On examining his head, it seemed as if the two parietal bones had been torn from the occipital bone and then depressed at their upper junction line to an unusual degree. The occipital bone, also, at this point seemed unusually thickened, and altogether the condition was most unusual. Two likely conclusions presented themselves to my mind, namely, pressure and injury to the brain substance, with adhesions. With those two ideas in my mind I sent him to Dr. Cameron to have his head skiagraphed, and to Dr. Hall to have his eyes examined.

Dr. Cameron reports as follows:—"An X-ray plate of C.N.'s skull taken on 30th September, 1918, giving a lateral view, shows a distinct protuberance in the occipito-parietal region, with increased thickness of the bone. On following up the normal contour of the skull from the occipital protuberance, it is evident that the parietal bones were depressed, presumably by the accident at the age of 10 years, and at this area of depression, occipito-parietal junction, proliferation of the inner table has occurred."

Dr. Hall reports as follows on 3rd October:— "Vision: Right eye 5/40, left 5/6. Right cornea has a small linear scar in the pupil area. Discs papery white, not sharply defined, vessels normal calibre. Fields of vision normal. The condition of the nerve head suggests some secondary or post-neuritic atrophy."

Dr. Williams saw him in consultation on 3rd October, and we concluded that he was suffering masked epilepsy due to pressure, and that operation was the only means of relief.

Operation.—I operated upon him on 4th October and removed two large discs from the junction of the parieto-occipital bones at the upper angles. The occipital bone was fully half an inch in thickness, while the parietal bone joining it was only about one-sixth of an inch thick. The bone on the right side was adherent to the dura mater, while the latter was much thickened and adherent to the pia mater—in fact, all the structure seemed glued together from bone down to brain substance. The brain underneath was found to be pulsating and normal, so that no further exploration was deemed necessary. On the left side the bony structures were much the same as upon the right, with no adhesions nor thickening of the membranes, while the brain substance was quite normal. Both discs were returned to their position and the wounds closed. He made an excellent recovery and was up and out of the hospital in fourteen days.

Comments.—Epilepsy, or some of its various manifestations, are fairly common in this community. I have practised medicine in Dunedin for upwards of 35 years, and so have had time to observe the results of habits and diseases in many individuals. I have observed that various types of mental and physical defects in the parents have frequently been transmitted to their children, and among these defects is epilepsy. I have also observed that several young men and young women who habitually indulged in onanism and

excessive venery developed epilepsy and frequently insanity. Some of these individuals were committed to the asylum as epileptics and maniacs, and most of them are dead. Old mother Nature is a fairly kind and considerate mother to the wise, but the remorseless enemy of the unwise. Would that all of us should continually utter the old prophet's prayer, "Give me neither riches nor poverty, but give me wisdom." Then would almost all of us go down to our graves full of years and of happiness. I have oftentimes thought of the occasional insane conduct of men and women I have known for many years, or from childhood, both here and elsewhere, and have wondered if masked epilepsy or other brain disease was a factor in their conduct. In the same way I have wondered if some of the crimes and sultry destructive speeches that startle us occasionally are the result of similar conditions. The larger one's knowledge of humanity and of diseases grows the more one wonders if disease be a common factor in the many things which startle a community from time to time, The subject is a complex one, but one which medical men who have lived a lifetime in one locality and observed parents and their children should be able to discuss intelligently and interestingly in the columns of a medical journal.

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