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**Socioeconomic correlates of quality  
of life for non-Māori in advanced age:  
Te Puāwaitanga o Nga  
Tapuwae Kia ora Tonu.  
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## Clinical ethics support services in New Zealand – tailoring services to meet the needs of doctors

Elizabeth Dai, Angela Ballantyne

The New Zealand Health and Disability Commissioner and the courts recommend doctors engage in “broad consultation in difficult clinical situations”, but do not specify mechanisms by which this should occur. Clinical ethics support services (CESS) aim to assist doctors in complicated ethical decision-making. This formal ethics support is well established overseas but relatively new to New Zealand. We did a qualitative study interviewing senior doctors at CCDHB to better understand their needs in regards to ethical support at work and their views of the new CESS at CCDHB. We found some misconceptions about the role of the CESS and wariness regarding abdicating responsibility for ethical decision-making for their patients. Allowing referring doctors to be present for the CESS deliberation would make the process more acceptable to doctors.

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## Socioeconomic correlates of quality of life for non-Māori in advanced age: Te Puāwaitanga o Nga Tapuwae Kia ora Tonu. Life and Living in Advanced Age: a Cohort Study in New Zealand (LiLACS NZ)

Ngairé Kerse, Ruth Teh, Simon A Moyes, Lorna Dyall, Janine L Wiles, Mere Kepa, Carol Wham, Karen J Hayman, Martin Connolly, Tim Wilkinson, Valerie Wright-St Clair, Sally Keeling, Joanna B Broad, Santosh Jatrana, Thomas Lumley

The demographic ageing of the New Zealand population is most marked for those 85 years and over—a cohort predicted to increase six-fold by 2050. Older people contribute to society in many ways and valued contributions continue into advanced age. Those in advanced age also utilise the highest per capita public expenditure, mostly on health and disability support. Knowing more about the health, cultural profile and social status of those in advanced age will help health planners, society, families and older people prepare for the projected increase in those of advanced age. This paper focuses on quality of life (QoL) and presents the demographic, social and cultural characteristics, and aims to identify correlates of health-related QOL, for the non-Māori cohort of Te Puāwaitanga o Nga Tapuwae Kia ora Tonu, Life and Living in Advanced Age: a Cohort Study in New Zealand, (LiLACS NZ).

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## Adherence to the current guidelines for bradycardic pacing in the octogenarian and nonagenarian populations

Vivienne Kim, James Pemberton, Fiona Riddell, Khang-Li Looi

In New Zealand, there is increasing aging population that require bradycardia-support device implantation. Our study showed that there was underutilisation of dual chamber pacemakers in this population. Presence of cognitive impairment and multiple comorbidities influence the device of implanting single-chamber device in this population.

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## Protecting New Zealand children from exposure to the marketing of unhealthy foods and drinks: a comparison of three nutrient profiling systems to classify foods

Cliona Ni Mhurchu, Tara Mackenzie, Stefanie Vandevijvere

Marketing of unhealthy foods and drinks to children is an important, changeable risk-factor for child obesity and development of diet-related diseases. An accepted food classification system is necessary to classify foods as suitable/unsuitable for marketing to children and to implement restrictions. We compared three accepted systems to identify the best one to protect New Zealand children from exposure to the marketing of unhealthy foods and drinks. Under any of the three systems, only about one-third of New Zealand packaged foods would be permitted to be marketed to children. The World Health Organization Europe Model restricts marketing of unhealthy foods more effectively than the other two systems, and should underpin the Advertising Standards Authority revised Children's Code for Advertising Food.

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## What's new with the flu? Reflections regarding the management and prevention of influenza from the 2nd New Zealand Influenza Symposium, November 2015

Nadia A Charania, Osman D Mansoor, Diana Murfitt, Nikki M Turner

Seasonal outbreaks of influenza cause substantial morbidity and mortality that burdens healthcare services every year; thus, focused discussions on improving management and prevention efforts is warranted. The Immunisation Advisory Centre (IMAC) hosted the 2nd New Zealand Influenza Symposium (NZIS) in November 2015. International and national participants discussed current issues in influenza management and prevention. Experts in the field presented data from recent studies and discussed the ecology of influenza viruses, epidemiology of influenza, methods of prevention and minimisation, and experiences from the 2015 seasonal influenza immunisation campaign. The symposium concluded that although much progress in this field has been made, many areas for future research remain.

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## Improved compliance with the World Health Organization Surgical Safety Checklist is associated with reduced surgical specimen labelling errors

Walston R Martis, Jacqueline A Hannam, Tracey Lee, Alan F Merry, Simon J Mitchell

If used properly the World Health Organisation Surgical Safety Checklist has been shown to reduce deaths and complications in patients undergoing surgery. Currently, the biggest related challenge is facilitating optimal use of the checklist by operating room teams. A recent study conducted at Auckland City Hospital found that several strategic process changes resulted in a marked improvement in compliance and team engagement in checklist use. Following on from that, the present study demonstrated that this improvement in checklist use was associated with a reduction in surgical specimen labelling errors to less than half the rate occurring prior to the process changes. This is important because errors in the labelling of specimens sent to the laboratory for analysis can result in misguidance of patient care. The Health Quality and Safety Commission is currently advocating the adoption of the Auckland checklist process changes at hospitals throughout New Zealand.

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## The uses of mental health telephone counselling service for Chinese speaking people in New Zealand: demographics, presenting problems and evaluation of the calls

Christine Yang Dong

This study aimed to investigate the call profiles of a Chinese-speaking mental health counselling helpline service in New Zealand (Chinese Lifeline provided by Lifeline Aotearoa) and to evaluate the calls and explore the possible factors influencing the outcome of the calls. A random sample of 151 answered calls was involved. The results showed that the service receives calls from callers with a wide range of demographics and with a large variety of presenting issues. This study identified several important factors which influenced counsellors' satisfaction of the calls and the length of the calls.

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## Overview of the 2015 American Thyroid Association guidelines for managing thyroid nodules and differentiated thyroid cancer

Bashar Matti, Ruben Cohen-Hallaleh

Thyroid nodules/lumps require clinical assessment to determine whether they are cancerous or not. The American thyroid association has published a multi-level, step-by-step clinical assessment guidelines to help clinicians, generalists and specialists in the assessment and management process. These guidelines however are somewhat long and hence in this paper we attempted to provide a succinct summary.

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# What are clinical ethics advisory groups for?

John McMillan

Calls for greater ethical support for clinicians have been reinvigorated over recent years.<sup>1</sup> However, it is worth bearing in mind that New Zealand, via the research ethics committees established under the Regional Health Authorities, used to have a national network that could give clinical ethics advice. This might mean that the indifference to clinical ethics that Dai and Ballantyne identify<sup>2</sup> is not a new issue and it also seems relevant to note that calls for clinical ethics support have waxed and waned in other countries.<sup>3</sup>

Dai and Ballantyne point out the importance of clarifying for clinicians what Clinical Ethics Advisory Groups (CEAGs) can do.<sup>2</sup> Whether or not CEAGs offer something valuable, over and above discussion with peers, depends upon the nature of the discussion with that peer. It might be that a colleague asks critical questions that challenge assumptions, that they have a good knowledge of the legal context or that they are particularly experienced with this kind of presentation. On the other hand, there is a risk when seeking the advice of a colleague that their thinking is too close to yours to offer more than reassurance, that there are issues that someone from another specialty or health profession would notice or that you share a blind spot with respect to the law or policy. So whether or not a CEAG offers clinicians ethical advice that is better, depends upon whether or not that peer offers good advice and also what constitutes good clinical ethics advice. A number of ethicists have considered what constitutes 'clinical ethics' and suggested structures for how we can improve ethical deliberation.

## What is clinical ethics?

Jonsen and Siegler claim that "Clinical ethics is a practical discipline that provides a structured approach to assist physicians in identifying, analysing and resolving ethical issues in clinical medicine".<sup>4</sup>

This implies that an essential skill is to be able to see the ethical issues in clinical practice. While this might appear to be obvious and something that we all do, there is a risk when talking to peers that they see the same issues as us. But when a clinical situation is discussed with colleagues from a range of specialties, as would be the case with a CEAG, it's likely that any ethical issues are more fully identified and understood in a better way. It could also be that engaging with other specialties will help to clarify any unconscious bias that may have entered into identifying the relevant issues. Likewise, some expertise in the law or policy will result in a more complete range of issues being identified than might be the case via a peer discussion.

Analysing the issues identified can be done in a number of ways and there are some useful resources available for clinicians and medical students that explore this further.<sup>5</sup> All other things being equal, a CEAG is more likely to have a structured approach for working through the issues in a complex scenario than would be the case with a peer discussion. Following through the likely and possible consequences of various courses of action is part of analysing issues, and clinicians are likely to find the assistance of a CEAG a valuable supplement to the advice of peers when they are faced with ethically complex situations.

While a structured approach to clinical ethics won't always 'resolve' ethically challenging situations, Jonsen and Siegler are correct that 'assisting' clinicians in working toward this should be the core aim. Others have suggested that the final step in a structure approached to a challenging ethical case should be to make a justified decision, which is the decision a clinician makes after weighing alternate course of action and being clear about why they are choosing a specific course of

action.<sup>5</sup> So a key thing that a CEAG should be able to do well is assist a clinician to weigh the relevant considerations so as to justify a decision when there might not be a consensus about the best way forward.

### What Clinical Ethics Advisory Groups can do

It might be that a common misconception is that a CEAG fulfils a similar function to a research ethics committee: a group of people outside of your area deliberate about something you are planning on doing and then tell you whether or not you have ethical approval to proceed. There might be instances where CEAGs have operated in this fashion, but that should not be their central function and is likely to detract from the more useful contributions to good clinical ethics a CEAG can make. Supporting clinicians to take an evidence based, structured and well justified approach to clinical ethics is where a CEAG can be the most useful and it is usually built into their terms of reference. For example the Capital and Coast DHB CEAG says it aims "To provide a consultative, advisory and supportive mechanism to assist healthcare professionals to make informed ethical decisions in their management of patients".<sup>2</sup> The emphasis here is clearly upon supporting and enabling clinicians to make the best decisions they can, which implies providing

them with a structured approach to clinical ethics rather than ethical approval.

The majority of ethically tricky situations will continue to be handled well by experienced clinicians after discussion with their peers. The extra time that will unavoidably be added by involving a CEAG is likely to mean that it is cases which are ethically novel, already complicated and contested, or involve innovative therapy where additional support is requested.

### Where to next?

Clarifying what a CEAG can do will help, but they also require support from senior clinicians in the relevant institution. Without that leadership, the trust and relationships that are required in order for a clinician or DHB to openly discuss a situation where things have not gone as well as they might, are much harder to create. A first step for institutions that wish to build their network of clinical ethics support could be to review events that have not gone well, to learn from them and prepare for similar ethically challenging events in the future. That too requires trust, and DHBs are (understandably) cautious in the current environment, yet it seems a way that the value of discussions of this kind can be nurtured after the event and without the pressure that results from the need for a decision to be made.

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# Clinical ethics support services in New Zealand— tailoring services to meet the needs of doctors

Elizabeth Dai, Angela Ballantyne

## ABSTRACT:

**Aims:** To better understand senior doctors' attitudes to clinical ethics support services at Capital and Coast District Health Board (CCDHB), in order to better tailor clinical ethics support services in New Zealand to the needs of doctors.

**Methods:** We conducted in-depth semi-structured interviews with 14 senior doctors at CCDHB in 2011 and 2012. Data analysis was inductive and iterative.

**Results:** Doctors primarily rely on informal avenues of peer consultation for support when making difficult ethical decisions. Many participants saw a potential role for formal ethics support, but expressed concern about how ethics support services would fit into their clinical practice. Primary concerns included the accessibility of support services and moral responsibility for ethical decision making in clinical settings.

**Conclusions:** Doctors are more willing to engage in ethics support services where they are able to participate in, or at least observe, the decision-making process.

Ethical challenges are an inevitable part of the practice of medicine, a vocation that serves people when they are vulnerable. Clinical ethics support services (CESS) aim to assist doctors in complicated ethical decision-making.<sup>1</sup> In New Zealand, CESS are relatively new and have emerged as a clinician-led initiative. In North America and Europe CESS have become increasingly prevalent in and integrated into healthcare delivery. Several models have emerged for the delivery of this support, ranging from formally trained clinical ethicists who work as professional consultants to hospital ethics committees comprising both clinical and lay members. A growing literature is contributing to principles of best practice in clinical ethics support.<sup>2-6</sup>

Appropriate training in ethical reasoning for clinicians and ongoing access to support in ethical decision-making across the span of a clinical career improves doctors' well-being and enhances patient care. A study by Källemark et al conducted in 2003 found that moral distress was experienced at higher rates by clinicians who felt they did

not have adequate support structures to help them process ethical concerns.<sup>7</sup>

The New Zealand Health and Disability Commissioner and the courts recommend doctors engage in "broad consultation in difficult clinical situations", but do not specify mechanisms by which this should occur.<sup>8</sup> In New Zealand there are eight CESS, some serving more than one District Health Board (DHB), and the majority of these have been established since 2008. The most prevalent model is that of a committee-style advisory group composed predominantly of clinicians. In July 2012, the Health Quality and Safety Commission (HQSC) offered a grant to support the establishment of a New Zealand Clinical Ethics Network to support existing Clinical Ethics Advisory Groups (CEAGs) and facilitate the establishment of new services around the country. The HQSC grant highlights a turning point in New Zealand where CESS are being increasingly recognised as critical to safe and reflective medical practice. As such, it is an important time to take stock and reflect on how CESS can be designed to best meet the needs of

clinicians. Our study was independently funded and not part of the HQSC grant.

There is a surprising lack of literature on the role, function and effectiveness of emerging CESS in New Zealand. In 2004, Pinnock and Crosthwaite published survey results regarding health professionals' views of the Auckland Hospital's Clinical Ethics Advisory Group (Auckland CEAG).<sup>9</sup> However, to date there has been no previous qualitative study of CESS in New Zealand. Qualitative methods generate nuanced data that allows in-depth exploration of complex themes. We use the CEAG established at Capital and Coast District Health Board (CCDHB) in 2010 as a case study for an in-depth qualitative investigation of the role CESS can play in supporting ethical decision-making in New Zealand hospitals. The CCDHB CEAG Terms of Reference identify two central purposes:

- to provide a consultative, advisory and supportive mechanism to assist healthcare professionals to make informed ethical decisions in their management of patients
- to facilitate education in the area of ethics and to foster a culture of ethical awareness at CC DHB so as to equip healthcare professionals with the means to approach ethical problems and conflicts in clinical practice.<sup>10</sup>

When a case is referred to the CEAG it is considered at their regularly scheduled monthly meeting or, in urgent cases, can be reviewed within 24 hours. The referring clinician provides relevant clinical and ethical details of the case. Patients and their families are not informed that the case has been referred and are not involved with CEAG processes. The CEAG then has a closed session in which they discuss possible approaches to managing the ethical issues. CEAG members have access to patient medical records if necessary. The CEAG provides a formal non-binding opinion in writing to the referring clinician.

## Methods

We recruited participants by emailing invitations to senior doctors. All senior doctors at CCDHB were invited. We chose senior doctors because the culture of ethical

behaviours in a team is often shaped by the most senior clinician and senior clinicians are more likely to have experience of ethical dilemmas to draw on because they have more years of clinical practice. We ensured our sample included surgeons and paediatricians for the following reasons. Previous research showed that surgeons were much less likely than other clinicians to use CESS.<sup>12</sup> Paediatric clinical ethics typically require a different decision-making framework to that used in adult medicine;<sup>13</sup> as a result, some larger centres overseas have developed separate paediatric clinical ethics committees.<sup>14</sup> Within these parameters, we wanted heterogeneity, therefore recruitment was limited to the first three volunteers from each sub-specialty. Interviews were guided by an 18-point questionnaire, with questions grouped under four general headings: clinicians processes for ethical decisions making, ethical decision making in the hospital, services provided by the CEAG, the clinical ethics environment in New Zealand. Interviews were recorded and transcribed verbatim. ED coded the transcripts and ED and AB analysed the results. We conducted an iterative inductive thematic analysis, whereby some emerging themes were integrated into the interview template. The New Zealand Central Regional Ethics Committee approved the study (CEN/11/EXP/073).

## Results

Between 2011 and 2012 ED conducted 14 interviews, ranging from 40 minutes–2 hours duration. All participants gave written informed consent. Recruitment finished when data saturation was reached. This is when no new broad overarching themes were being revealed by each subsequent interview set.<sup>15</sup> Participants' clinical specialties are listed in Table 1. The four main themes relate to awareness of the role of CCDHB CEAG, comparison of informal ethics support to formal CESS, clinician involvement in CESS ethical deliberation and ethical deliberation as a clinical responsibility. These are the key themes arising from the data, and do not correlate exactly to the topic sections of the questionnaire.

**Table 1:** Specialties of participants (in alphabetical order).

Endocrinology
Endocrinology and older adult medicine
General medicine and infectious disease
Intensive care
Paediatrics
Paediatrics/neonatology (2)
Neurosurgery (2)
Obstetrics and gynaecology
Older adult medicine and palliative care
Orthopaedic surgery
Psychiatry
Renal medicine

### Awareness

Many participants were unaware or misinformed of the purpose of the CCDHB CEAG. Two of the participants had referred a case to the CEAG (3 and 14) and four others had been peripherally involved in such cases (2, 6, 7 and 13). Participant 12 sits on the CEAG as a clinical representative. Most of the remaining participants had not heard of the CEAG. Even among the clinicians who were aware of the CEAG, most did not have a clear understanding of its functions or how to access it, including clinicians who had already referred cases to the service. Common misconceptions included whether the advice provided by the CEAG was legally binding or whether accessing it obviated the need for seeking medicolegal advice in instances where there were legal quandaries in addition to ethical ones.

### Comparing informal ethics support to formal CESS

Participants reported that the primary source of ethical support available to doctors is informal, such as seeking the opinions of senior colleagues. Most participants reported feeling well-supported and comfortable about seeking ethics support from peers. Study participants raised three specific concerns about CEAG, reflecting their views that it would not provide superior ethical support compared to their existing informal mechanisms:

- referring a case for consultation to the CEAG is more laborious than a quick

corridor consult; it requires a greater investment of time and energy on the part of both the clinicians accessing the service and those volunteering to provide it. Participant 5 stated “[An ethics committee is] a slow bloody organisation. For individuals it’s too slow...Where you’re dealing with policy and larger picture things, I think that’s where it works really well.”

- the training of CEAG members in ethics is not necessarily greater than the senior colleagues that the doctor might otherwise consult, at least at present.
- despite their diverse clinical backgrounds, members of the CEAG may not necessarily have the specific clinical expertise necessary to grasp the intricacies of the cases referred to them.

Participants described a range of barriers to accessing ethics support (whether informal or formal), which included isolation and a medical culture inhibiting both help-seeking behaviours and constructive criticism. Interestingly, it was common for participants to describe their own team or specialty as supporting open non-judgmental ethical debate, but to assert that other specialties were less receptive. Many clinicians emphasised that the culture of medicine makes it very difficult to raise concerns about the practice of peers—particularly senior peers—and that this can be a barrier to dialogue about ethical issues. “In medicine we’re not very good at criticising people...The more senior the person gets, the harder it is...” (11) Several participants reflected that they found seeking ethical advice as a junior doctor more challenging, and expressed concern that the same barriers may exist for their junior colleagues today. Participants noted that junior staff, in addition to facing the inherent disadvantage of being less experienced, came up against cultural and systemic barriers to being able to seek adequate support in managing ethical concerns. “...going cap in hand to your boss and asking for advice on things like this is often perceived as a sign of weakness.” (9) Some participants felt that having formal services might provide an additional avenue for staff seeking ethics support.

For participants, one of the most significant differences between ad-hoc support systems and using a formal ethics support service was that formal support is *external* to the group of people involved in patient care. Several participants felt that the value of the CEAG was that it could provide an objective sounding board in challenging cases, noting that at times maintaining perspective was difficult when one was immersed in a case. Participant 4 argued that seeking an independent ethical opinion was a sign of appropriate, reflective practice. Participant 3 noted “My experience of it was it actually helped me to see the situation from a slightly different perspective...I found it empowering...rather than stripping me of my clinical autonomy.” Conversely, other participants expressed concern that an external ethics advisory group would be out-of-touch with the specific clinical realities that contextualise ethical decisions in medicine. Participant 5 stated that “if you’re working in a very specialised area of practice, the ethics of what you’re dealing with rotates extremely strongly around knowledge of the topic or the clinical area with which you’re grappling.”

Many participants believed an ethics support service should enhance ethical capacity of the clinical workforce. These participants felt that services should help clinicians attain a degree of ethical competence such that external ethical consultation was required only in exceptional circumstances. Participants offered their perspectives on the role a CESS might play in providing or supporting ethics education. Key ideas were that ethics education needed to be practical and integrated into the workplace and that it needed to break down cultural barriers to open ethical discourse.

### Clinician involvement in CESS ethical deliberation

Many participants were concerned that referring clinicians are shut out from the process of ethical deliberation at CEAG. Participant 7 said he felt concerned with the lack of transparency when he was involved in referring a case to the CEAG. “I presented my case, but then the rest of the stuff was held behind closed doors. And you want to be involved in that discussion...it shouldn’t be secretive—which it isn’t—but that’s what it feels like.” Several participants empha-

sised that any model for ethics support must involve clinicians in the process if it was to be accepted by the hospital community. Participant 1 pointed out that when clinicians were not involved, they did not learn from the consultation process. “I think discussions, which are iterative, would be a lot better.”

### Ethical decision-making as a clinical responsibility

Some argued that ethical decision-making is a clinical responsibility that should not be abrogated. Others contended that accessing ethics support has the potential to enhance ethical decision-making and thus is a mark of responsible practice. These views influenced participants’ perspectives of the value of clinical ethics support.

All clinicians expressed the view that clinical ethics is a core competency for any doctor. Some felt that to “outsource” ethical decision-making to a CESS is to remove the decision-making role from the individual who a) has a professional obligation to fulfil that role and b) is in the best position to make that decision, by virtue of their expertise in the given field of practice. Some participants expressed concern that a CESS may be making unreasonable claims to moral authority by offering to solve clinical ethical problems. Participant 8 stated that there was no reason the CEAG should be any better at making ethical decisions than a well-trained, experienced group of health care professionals from a range of backgrounds. “...If we cannot come to the conclusion altogether, who else could come back and tell us, “Oh, this is exactly the way to go?” However, participant 2 suggested that the role of the doctor as the ultimate decision-maker did not preclude the involvement of a CESS, but rather imposed parameters on it. “An ethicist...can help define the problem but at the end of the day it’s still going to be a clinician’s decision.” (2)

### Summary

Clinicians held a broad spectrum of views about the value of clinical ethics support services. There was, however, consensus on the importance of clinical ethics to the medical profession, which has been further reinforced by the HQSC backing efforts to ensure CESS are available to clinicians nationwide. The practical considerations in the provision of clinical ethics support

are indicative of the environment in which doctors have to make ethical decisions: they are often under stress and time pressure and they know that they will bear responsibility for clinical outcomes. Participants took their ethical responsibilities as doctors seriously and wanted to feel better equipped to manage them.

## Discussion

Our key findings were that within CCDHB we found some common misconceptions about the role of CESS, that clinicians were wary of giving up decision making capacity in difficult ethical cases and that clinicians wanted CESS to improve general ethical reasoning capacity among staff. Our study suggests that support services should work within the pace and complexity of clinical realities if they are to be accepted by doctors as a useful tool for medical practice in New Zealand.

International literature reveals that clinician perceptions of what CESS can offer determine how likely they are to engage with services.<sup>12,16–18</sup> Much of the wariness expressed about the CEAG by participants in this study was fuelled by misunderstandings about what the CEAG does or claims to do. Our research suggests that efforts to disseminate accurate information about the role and procedures of CESS may lead to wider uptake of their services. However, we also note that some DHBs in New Zealand do not have access to a CESS, and that at other DHBs a CESSs may exist on paper but may not be currently active. Some misunderstanding is to be expected given that the formal ethics support service had only been in place at CCDHB for two years at the time of the research. Some clinicians' misgivings stemmed from the fact that in New Zealand CESS are in their infancy, largely being composed of volunteers, many of whom lack formal qualifications or training in ethics. In addition, many CESS are still in the process of establishing formal procedural guidelines even as they begin to accept and consult on their first clinical cases. The dearth of formal curricula to train and accredit CESS has been identified internationally as a problem and research and funding has been increasingly devoted to developing quality assurance mechanisms such as formal qualifications and evaluation processes.<sup>19</sup>

Only a handful of participants had direct experience with the CESS, but all participants had at some stage used informal mechanisms, such as peer consultation, to help resolve ethical issues. Some participants seemed to assume that formal CESS were intended to serve as a substitute for these and found this problematic, arguing that the mechanisms of a formal CESS were too unwieldy to be used for the multitude of day-to-day ethical issues faced. This echoes the findings of DuVal et al and Førde et al that doctors perceive the time consumed by accessing formal ethics support to be a major barrier to accessing services.<sup>17,20</sup> However, CESS are not a substitute for clinician competence in managing ethical issues. There are two things that a CESS should be able to offer clinicians that informal systems cannot. The first is a just, independent process of resolving ethical dilemmas that uses a transparent and systematic approach to ethical deliberation. The second is an opportunity for education and professional development in managing ethical issues.

Some clinicians were reluctant to refer cases because they felt this amounted to relinquishing autonomy over decision-making while retaining accountability for patient outcomes. Even participants who recognised that the clinical ethics consultation is advisory in nature, stated that they would feel compelled to follow CEAG advice. Our research shows this is a major barrier to accessing clinical ethics consultation. This corroborates studies from other jurisdictions. Davies and Hudson identified that among clinicians who were most resistant to accessing ethics support services, their main concern was that they felt devolving decision-making to a third party was an unacceptable abdication of clinical responsibility.<sup>16</sup> Conversely, Orlowski et al found that doctors most likely to refer cases for ethics consultation were also most likely to be the clinicians who perceived ethical decision making to be a shared responsibility.<sup>12</sup> Clinicians in our study recognised that they are accountable for their clinical decisions irrespective of how the decision was made.

Clinician involvement in CESS processes would have three advantages. The first is that clinician participation would improve the transparency of ethical deliberation, promoting clinician trust in the procedures

and, as such, their buy-in to the outcomes. The second benefit is that where clinicians are given the opportunity to be involved in deliberation, it becomes an educative experience that equips them with the knowledge and skills to better address ethical issues arising in the future. An ethics support model that offers ethical reasoning skills to referring clinicians could enhance the ethical culture of the institution as a whole. Third, involving doctors in deliberation quells concerns that the ethics committee may not understand the clinical nuances of the cases concerned, by providing a forum in which the referrer brings that expertise to the table. This would be in line with research ethics review in New Zealand where researchers are invited to listen to the committee's discussion of their protocol.

There are several limitations to the study. We interviewed only senior doctors. Future research should investigate the views of junior doctors, who face a unique set of challenges in managing ethical issues, in particular shaped by hierarchical medical culture, and the pressure of juggling training requirements and strenuous on-call demands. Future research should also investigate the needs and views of other health professionals at the hospital such as nurses. A second limitation is the relatively small pool of participants from a single DHB. Given New Zealand's small and close-knit medical community, it may well be the case that similar cultures of ethical decision-making exist in other regions. Further research is needed to establish this, but our study suggests some potential challenges that may exist for newly established CESS in other areas of the country.

## Conclusion

Doctors in our study reported primarily using ad hoc strategies of peer consultation

to manage ethical issues. Not all doctors felt equally able to access informal support and junior doctors may face additional barriers. Many participants were unaware that formal clinical ethics support was available to them at CCDHB and most did not know how formal ethics support worked. Some participants felt that to seek case consultation was to abrogate clinical responsibility and thought that doctors should be able to manage ethical issues themselves. The concerns identified through our research do not present immutable obstacles to CESS. Rather, this feedback gives fledgling support services the chance to optimise services to maximise their utility to clinicians. Emerging CESS in New Zealand should:

1. actively disseminate information about their aims and processes to clinicians to enhance transparency and to clarify misunderstandings about their role
2. involve clinicians in the process of case consultation to increase user trust and to take advantage of the educative value of case consultation
3. conduct monitoring and evaluation of the service to ensure that it achieves and maintains clinical relevance.

At a time when CESS in New Zealand are in their infancy, this study offers a unique insight into the culture of clinical ethical decision making in CCDHB. Given the close-knit nature of the New Zealand medical community and the movement of staff between District Health Boards, the findings are likely to have relevance to emerging CESS throughout New Zealand. Our study indicates key areas of perceived strengths and weaknesses of the existing clinical support services that could inform ongoing evaluation and restructuring of the services to better tailor them to clinician needs.

**Competing interests:**

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# Socioeconomic correlates of quality of life for non-Māori in advanced age: Te Puāwaitanga o Nga Tapuwae Kia ora Tonu. Life and Living in Advanced Age: a Cohort Study in New Zealand (LiLACS NZ)

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## ABSTRACT

**Aim:** To establish socioeconomic and cultural profiles and correlates of quality of life (QoL) in non-Māori of advanced age.

**Method:** A cross sectional analysis of the baseline data of a cohort study of 516 non-Māori aged 85 years living in the Bay of Plenty and Rotorua areas of New Zealand. Socioeconomic and cultural characteristics were established by face-to-face interviews in 2010. Health-related QoL (HRQoL) was assessed with the SF-12.

**Results:** Of the 516 non-Māori participants enrolled in the study, 89% identified as New Zealand European, 10% other European, 1% were of Pacific, Asian or Middle Eastern ethnicity; 20% were born overseas and half of these identified as 'New Zealand European.' More men were married (59%) and more women lived alone (63%). While 89% owned their own home, 30% received only the New Zealand Superannuation as income and 22% reported that they had 'just enough to get along on'. More than 85% reported that they had sufficient practical and emotional support; 11% and 6% reported unmet need for practical and emotional support respectively. Multivariate analyses showed that those with unmet needs for practical and emotional support had lower mental HR QoL ( $p < 0.005$ ). Reporting that family were important to wellbeing was associated with higher mental HR QoL ( $p = 0.038$ ). Those that did not need practical help ( $p = 0.047$ ) and those that reported feeling comfortable with their money situation (0.0191) had higher physical HRQoL. High functional status was strongly associated with both high mental and high physical HR QoL ( $p < 0.001$ ).

**Conclusion:** Among our sample of non-Māori people of advanced age, those with unmet support needs reported low HRQoL. Functional status was most strongly associated with mental and physical HRQoL.

The demographic ageing of the New Zealand population is most marked for those in advanced age (85 years and over) as this population group will increase six-fold by 2050.<sup>1</sup> Older people contribute to society in many ways and valued contributions continue into advanced age.<sup>2-7</sup> Those in advanced age also utilise the highest per

capita public expenditure mostly on health and disability support.<sup>8</sup> Knowing more about the health, cultural profile and social status of those in advanced age will help health planners, society, families and older people prepare for the projected increase in those of advanced age.

The life in years (quality of life), rather than years of life (quantity of life), may be particularly relevant for older people, thus quality of life (QoL) is the topic of this paper. Those in advanced age may have higher life satisfaction than the younger old<sup>9</sup> and certain factors including social support are more important to QoL for the very old than for younger age groups.<sup>10</sup> Economic resources,<sup>11</sup> cannot be ignored and there is a complex interaction between economic hardships and social supports.<sup>12</sup>

In New Zealand the material wellbeing of older people has been examined<sup>13</sup> and qualitative research has outlined contributions to QoL.<sup>14,15</sup> Stephens et al described associations between more and stronger age-related social networks and higher wellbeing<sup>16</sup> in those aged 55–70 than was found for younger cohorts. Other research explores the social context of ageing in New Zealand,<sup>17,18</sup> but there is a lack of specific information about the octogenarian population. Culture, beliefs and religion also influence successful ageing.<sup>19</sup> It is known that social relationships sustain wellbeing, prevent depression,<sup>20</sup> aid longevity,<sup>21</sup> and interconnect with economic wellbeing in complex ways. A better understanding of the current amount and type of social support for those in advanced age is needed.

Te Puāwaitanga o Nga Tapuwae Kia ora Tonu, Life and Living in Advanced Age: a Cohort Study in New Zealand, (LiLACS NZ) was funded to describe the health, social and cultural status and to identify predictors of successful advanced ageing of Māori and non-Māori. In acknowledgement of the disparity in longevity for Māori<sup>22</sup> and the need for equal explanatory power to establish predictors, two inception cohorts were recruited in 2010; Māori aged 80–90 years (a birth decade) and non-Māori aged 85 years (a single year birth cohort).

This paper presents the demographic, social and cultural characteristics and aims to identify correlates of health-related QOL (HRQoL) for the non-Māori cohort. A companion paper reports the Māori data.<sup>23</sup>

## Methods

The detail of LiLACS NZ recruitment and assessment schedule has been described

elsewhere.<sup>24,25</sup> Eligibility included living in the geographic boundaries of the Bay of Plenty District Health Board and Lakes District Health Board (excluding Taupo region) of the North Island of New Zealand, and being born in the calendar year of 1925. A comprehensive list of all persons in the age group was compiled from the New Zealand General Electoral Roll, primary health care databases, residential care lists and word of mouth. Participants were recruited by personal invitation from their general practitioner, a person known to them or by a letter from The University of Auckland. Those interested were visited or telephoned by a researcher and they or a family member gave written informed consent. Ethical approval for this study was given by the Northern X Regional Ethics Committee NXT09/09/88.

A comprehensive baseline assessment was undertaken to assess the health, social, economic, cultural and physical status of participants<sup>25</sup> and is briefly summarised here. In this paper socio-demographic information, family contact and support, and cultural practices are reported along with the main outcome of HRQoL.

Demographic information: age, gender, marital status, type of house, home ownership, education, living arrangement, main lifetime occupation of participant and partner, religion and income data were gathered using standardised questions. Self-perceived economic wellbeing was assessed with the question:

- Thinking of your money situation right now, would you say: I can't make ends meet, I have just enough to get along on, or I am comfortable?

Socioeconomic deprivation related to their residential address at the time of interview was achieved by the geocoded New Zealand Deprivation Index (NZDep).<sup>26</sup>

Ethnicity was self-identified using the 2001 NZ census question<sup>27</sup> and where several ethnicities were identified New Zealand European was prioritised over 'other European'. Where very small numbers were reported they were grouped for analysis.

Size of family, number of living children and number of grandchildren was recorded.

Social support was assessed using the approach from the MacArthur studies<sup>28</sup> with these questions with a yes or no response:

- When you need extra help, can you count on anyone to help with daily tasks like grocery shopping, cooking, house cleaning, telephoning, give you a ride?
- In the last year who has been the most helpful with these daily tasks?
- Could you have used more help with daily tasks than you received?
- Can you count on anyone to provide you with emotional support?
- In the last year who has been most helpful in providing you with emotional support?
- Could you have used more emotional support than you received?

Questions about culture asked of all participants were based on a measure developed in New Zealand<sup>29</sup> and by Te RōpūKaitiaki o ngā tikanga Māori (Protectors of principles of conduct in Māori research in LiLACS NZ), a cultural guidance and governance group gathered together for LiLACS NZ:

- Do you live in the same area as your Hapū (Māori term for extended family)/extended family/where you come from?
- Have you ever been to a marae (sacred Māori meeting place) at all?
- How often in the last year have you been to a marae?
- In general, would you say that your contacts are with: mainly Māori, some Māori, few Māori, no Māori?
- Could you have a conversation about a lot of everyday things in Māori or another language?
- How important is your language and culture to your wellbeing?

Questions about life roles and the importance of aspects of life to wellbeing were asked:

- Roles within the whānau and family (Yes, No)
- Role within the community and neighbourhood (Yes, No)

- Satisfaction with those roles (extremely to not at all)
- The importance of family to wellbeing (extremely to not at all)
- Importance of faith to wellbeing (extremely to not at all)

All participants were asked about discrimination using standard questions from the 2006/2007 New Zealand Health Survey<sup>30</sup>

- Have you ever been the victim of an ethnically motivated attack in New Zealand? (verbal or physical; further ago or within 12 months)
- Have you ever been treated unfairly by a service agency (eg WINZ) because of your ethnicity in New Zealand?
- Have you ever been treated unfairly when renting or buying housing because of your ethnicity in New Zealand?
- Have you ever been treated unfairly by a health professional because of your ethnicity in New Zealand?

Discrimination questions were collapsed into 'ever' vs 'never experienced' discrimination.

HRQoL was assessed with the SF-12 Version 2<sup>®</sup> including the summary scores for physical and mental HRQoL.<sup>31</sup> Scores vary between 0 (worst health/QoL) and 100 (best health/QoL) with a mean score of 50. The Nottingham Extended Activities of Daily Living (NEADL) was used to assess functional status.<sup>32</sup> Scores range from 0 to 22 with higher being better.

The questionnaire was undertaken with the participant by trained lay and nurse interviewers using standardised techniques and took a minimum of two hours. For some participants two or more visits were required for full completion. Each completed questionnaire was quality checked by two different coordinators, and any queries referred back to the interviewer for rectification and contact with the participant if required.

*Analyses.* Descriptive statistics showed status of participants on demographic, social, economic and cultural variables. Generalised linear models or the Cochran-Mantel-Haenszel test were used to compare status by gender as appropriate.

Functional status was *a priori* selected as being known to be highly correlated with HRQoL, and HRQoL differed between genders. Gender and functional status (NEADL score) were considered confounding variables. Each variable in Tables 1, 2 and 3 was tested against mental HRQoL and physical HRQoL adjusting for gender and functional status in a 'brief model'. For those variables showing a significance of  $p < 0.1$  models were further adjusted for the early life socioeconomic status (SES) marker of highest education level, midlife marker of main family occupation ascertained by the higher occupational status of participant or lifetime partner, and current SES marker reflected by perceived economic wellbeing in a 'full model'. Adjusted means are presented for the models. Interactions between gender and marital status and gender and living arrangement were explored.

## Results

Of all eligible non-Māori available in the study area, 59% (516 participants) agreed to participate. All completed a core set of questions (shown in Tables 1 & 2 with shading) and 404 completed the full questionnaire with additional questions expanding on the core set, one participant did not complete the questionnaire because of change of mind. Those completing the full questionnaire differed from those completing only the core. Firstly core questionnaire participants were more likely to be living in residential care 24/111 (22%) of core respondents were in residential care and 23/404 (3%) of those completing the full questionnaire were in residential care ( $p < 0.001$ ). Secondly core questionnaire respondents were more likely to have the questionnaire completed by a proxy 17/111 (15%) of those completing the core questions were represented by a proxy and 16/404 (4%) of those completing the full questionnaire were represented by a proxy ( $p < 0.0001$ ). Thirdly, core respondents were more likely to be dependent in personal care, toileting, getting in and out of bed, making a hot drink, doing shopping and using the phone ( $p < 0.001$  on each).

## Socio-demographic and economic characteristics

Table 1 provides an overview of the socio-demographic and economic characteristics of the sample. About 80% were born in New Zealand and half of those born overseas identified as New Zealand European. Other countries of birth included: Australia (4), England (including northern Ireland, 58), Scotland (12), Ireland or Wales (3), Netherlands (7), Other Central or Western European countries (6), Indonesia (3), Sri Lanka, Japan, Fiji, Canada or Brazil (6). Self-identified ethnicity for non-Māori consists of those who identified as New Zealand European (89%), other European (10%), and 'other' being Pacific (3), Asian, Middle Eastern or South African (4).

More men were married (59% cf 24% of women,  $p < 0.001$ ) and more women were living alone (63% cf 32% of men,  $p < 0.001$ ) with 32 (15%) women living with others and 12 (6%) women living in residential aged care. Overall, 4% had never married and 5% had no children.

Most (89%) owned their own home and income from non-New Zealand Superannuation (NZS) sources included other superannuation (eg workplace schemes) 11%, other pensions 12%, investments 50%, with less than 5% receiving income from salary and wages, tribal land trusts or inheritance.

Table 2 shows social support, importance of faith, QoL and functional status. Religious affiliation was recorded with 68 (17%) reporting no religion (not in Table) and 13% reporting that faith was not at all important to their wellbeing. No non-Māori participated in Māori faith. 'Other' religions included Baptist (11), Christian (8), open Brethren (3), Salvation army (4), Seventh Day Adventist, Jehovah's Witness, Protestant and Pentecostal (2 each). Four did not answer the question about religion and one each reported religion as: all encompassing, belief in the creator, interdenominational, Liberal Christian, non-conformist, non-denominational, Spiritual Church, and Theosophical Society.

Social support was reported as present by most with 20% of men reporting that they

**Table 1:** Socio-demographic, economic and family makeup characteristics of non-Māori aged 85 years in LiLACS NZ.

		Men	Women	Total
All participants—core interview Full interview completed		237 (46%)	278 (54%)	515
		190 (47%)	214 (53%)	404
Age, mean (sd)		84.6 (0.5)	84.6 (0.5)	84.6 (0.5)
Country of birth, n (%)	Born in NZ	185 (78)	229 (82)	414 (80)
	Born Overseas	52 (22)	49 (18)	101 (20)
Ethnicity, n (%)	NZ European	213 (89)	251 (90)	462 (89)
	Other European	23 (10)	22 (8)	45 (10)
	Other (Pacific, Asian, Middle Eastern)	2 (1)	5 (2)	7 (1)
Childhood family size, mean (sd)	Total family size	4.6 (2.8)	4.3 (2.6)	4.4 (2.7)
	Sisters	1.7 (1.6)	1.6 (1.7)	1.7 (1.7)
	Brothers	1.8 (1.8)	1.7 (1.6)	1.8 (1.7)
	Sisters still living	0.8 (1.0)	0.6 (0.8)	0.7 (0.9)
	Brothers still living	0.6 (0.9)	0.5 (0.9)	0.6 (0.9)
Marital status, n (%)	Never married	10 (4)	8 (3)	18 (4)
	Widowed	73 (31)	184 (67)	257 (50)
	Divorced	14 (6)	17 (6)	31 (6)
	Married/ partnered	137 (59)	67 (24)	204 (40)*
Number living children, n (%)	None	11 (6)	9 (4)	20 (5)
	1–3	115 (61)	135 (63)	250 (62)
	4–6	62 (33)	69 (32)	131 (33)
Number grandchildren, mean (sd)		7 (6.3)	7.2 (5.3)	7.1 (5.8)
Living arrangement, n (%)	Alone	61 (32)	134 (63)	195 (48)*
	With spouse	106 (56)	48 (22)	154 (38)
	With other	23 (12)	32 (15)	55 (14)
	If with other average number in house, mean (sd)	2.4 (1.0)	2.9 (1.2)	2.7 (1.2)
Type of house, n (%)	Stand alone house	115 (61)	121 (57)	236 (59)
	Unit/apt	26 (14)	33 (15)	60 (15)
	Retirement village	35 (19)	39 (18)	74 (18)
	Residential care	9 (4)	15 (6)	23 (5)
	Other	5 (3)	6 (4)	11 (4)
Home ownership, n (%)	Owns own home outright	155 (89)	170 (90)	325 (89)
	Rental	20 (11)	20 (11)	40 (11)
Deprivation, NZDep area score, n (%)	1–4 Low	34 (14)	41 (15)	75 (15)
	5–7 Med	123 (52)	146 (53)	269 (52)
	8–10 High	80 (34)	91 (33)	171 (33)
Income, n (%)	NZ Superannuation (NZS) only	49 (26)	69 (32)	118 (30)
	Other income as well as NZS	137 (74)	144 (68)	281 (70)
Main family occupation§, n (%)	Professionals	93 (39)	107 (38)	200 (39)
	Technicians	38 (16)	49 (18)	87 (17)
	Clerks	106 (45)	122 (44)	228 (44)
Thinking for your money situation right now—(%)	Can't make ends meet	2 (1)	0	2 (.5)
	Just enough	38 (20)	49 (23)	87 (22)
	I am comfortable	149 (79)	163 (77)	312 (78)
Education, n (%)	Tertiary	38 (16)	30 (11)	68 (13)
	Trade	26 (11)	34 (13)	60 (12)
	Any secondary	125 (54)	170 (62)	295 (58)
	Primary only or none	44 (19)	39 (14)	83 (16)

Shaded items show core questions included in the core interview answered by all and unshaded are questions in the full interview. Childhood family size is siblings only, not including parents.

§Professional: -Legislators, Administrators, Professionals, Agricultural and Fishery Workers

Technicians:- technicians, Associate Professionals and Trades Workers

Non-technical :- Clerks, Service Workers, Sales Workers, Plant/Machine Operators, Assemblers, Elementary Workers. \* significant difference between men and women  $p < 0.05$

**Table 2:** Social support, importance of faith, QoL and functional status of LiLACS NZ non-Māori participants.

		Men	Women	Total
Full interview completed		190 (47%)	214 (53%)	404
Religion, n (%)	Anglican	59 (41)	78 (42)	137 (41)
	Catholic	14 (10)	19 (10)	33 (10)
	Presbyterian	43 (30)	53 (28)	96 (29)
	Methodist	6 (4)	12 (6)	18 (5)
	Other	22 (15)	26 (14)	48 (15)
Importance of faith to your wellbeing, n (%)	Not at all	33 (18)	19 (9)	52 (13)
	A little	13 (7)	16 (8)	29 (7)
	Moderately	39 (21)	40 (19)	79 (20)
	Very	67 (36)	86 (41)	153 (39)
	Extremely	32 (17)	51 (24)	83 (21)
Anyone to help with daily tasks? n (%)	Yes	145 (77)	175 (83)	320 (80)
	No	6 (3)	11 (5)	17 (4)
	I don't need help	37 (20)	25 (12)	62 (16)
Who has been the most helpful? n (%)	Spouse	65 (43)	34 (19)	99 (30)
	Daughter	23 (15)	61 (35)	84 (26)
	Son	10 (7)	22 (13)	32 (10)
	Other relative	7 (5)	7 (4)	14 (4)
	Other	48 (31)	51 (29)	99 (30)
Could have used more practical help? n (%)	Yes	14 (8)	28 (14)	42 (11)
Count on anyone to provide emotional support? n (%)	No	7 (4)	14 (7)	21 (5)
	Yes	142 (76)	177 (85)	319 (81)
	I don't need emotional support	37 (20)	17 (8)	54 (14)
Who most helpful? n (%)	Spouse	78 (55)	30 (18)	108 (35)
	Daughter	22 (16)	68 (40)	90 (29)
	Son	15 (11)	24 (14)	39 (13)
	Other relative	5 (4)	10 (6)	15 (5)
	Other	21 (15)	39 (23)	60 (19)
Could have used more emotional support? n (%)	Yes	7 (4)	15 (7)	22 (6)

\*\*\* difference between men and women  $p < 0.001$

NEADL Nottingham Extended Activity of Daily Living scale.

QoL = quality of life.—a higher score means better QoL, range 0–100.

did not need help. A daughter was the main support for women and the spouse for men for both practical and emotional support. Thirty and 19% of non-Māori received practical and emotional support, respectively, from 'others' which included formal paid support workers, 14% of women and 8% of men ( $p = 0.051$ ) reported an unmet need for practical help.

### Function and QoL

Table 2 shows a mean score of 41 for physical HRQoL which indicates that HRQoL is below the mean for a standard older population<sup>33</sup> and was higher (better) in

men ( $p = 0.005$ ). Mental HRQoL was slightly higher than physical HRQoL, and was similar in men and women.

Functional status was similar between men and women and varied according to living arrangement. Those living with others, including those in residential care, had the lowest NEADL scores with a mean of 13.1 (sd 7.0) compared with means of 17.9 (sd 3.0) for those living with their spouse and 18.7 (sd 2.6) for those living alone ( $p < 0.001$ ). Neither physical HRQoL nor mental HRQoL varied by living arrangement when adjusted for SES and functional status.

**Table 3:** Socio-cultural characteristics of LiLACS NZ non-Māori participants.

		Men	Women	Total
All participants—core interview, n (%)		237 (46%)	278 (54%)	515
Full interview completed, n (%)		190 (47%)	214 (53%)	404
Do you live in the same area as your hāpu/ extended family/ where you come from?	No Yes	219 (93) 16 (7)	247 (89) 29 (11)	466 (91) 45 (9)
Have you ever been to a marae at all?	No Yes	51 (27) 139 (73)	74 (35) 138 (65)	125 (31) 277 (69)
How often in the last 12 months have you been to a marae?	Less than yearly* Once A few times Several times, more than monthly	156 (82) 26 (14) 5 (3) 3 (2)	193 (91) 15 (7) 3 (1) 1 (0)	349 (87) 41 (10) 8 (2) 4 (1)
Are your contacts with	Mainly Māori Some Māori Few/no Māori	1 (1) 51 (27) 137 (72)	2 (1) 71 (33) 140 (66)	3 (1) 122 (30) 277 (69)
Importance of language and culture to wellbeing	Not at all/moderately Very Extremely	64 (35) 103 (56) 17 (9)	70 (33) 120 (56) 23 (11)	134 (34) 223 (56) 40 (10)
Importance of family to wellbeing	Not at all/moderately Very Extremely	27 (15) 105 (56) 54 (29)	13 (6) 105 (49) 95 (45)	40 (10) 210 (53) 149 (37)
Specific role in local community/ neighbourhood	No Yes	160 (85) 29 (15)	177 (83) 35 (17)	337 (84) 64 (16)
How satisfied with role in local community/neighbourhood?	Not at all/moderately Very Extremely	9 (29) 18 (58) 4 (13)	7 (20) 25 (71) 3 (9)	16 (24) 43 (65) 7 (11)
Do you have a specific role in your family?	No Yes	75 (40) 113 (60)	69 (33) 141 (67)	144 (36) 254 (64)
Satisfaction with role in your family?	Not at all/moderately Very Extremely	11 (10) 88 (77) 15 (13)	14 (10) 100 (70) 29 (20)	25 (10) 188 (73) 44 (17)
Discriminated against ever, combined <sup>1</sup>	No Yes	176 (93) 13 (7)	190 (90) 22 (10)	366 (91) 35 (9)
Physical health-related QoL (SF-12®), mean (sd)		43.0 (11.9)	39.7 (12.0)	41.3 (12.0)***
Mental health-related QoL (SF-12®), mean (sd)		55.2 (7.9)	54.9 (8.7)	55.1 (8.3)
Functional status (NEADL, higher is better), mean (sd)		17.7 (3.7)	17.6 (4.3)	17.6 (4.0)
The 15 question Geriatric Depression Scale, (GDS-15, higher is worse), mean (sd)		2.26 (2.1)	2.13 (1.8)	2.19 (2.0)

<sup>1</sup> Any positive response to any of the discrimination questions. QoL—Quality of Life

\* includes never been to a marae

\*\*\* significant difference between men and women,  $p < 0.001$

Just under a third of non-Māori in advanced age had mainly or some Māori contacts (Table 3). While the majority (69%) had been to a marae, few (14%) had been once or more in the last year.

Only 9% lived in the area of their extended family where they had grown up.

More women reported that family were extremely important to their wellbeing (45%) than men (29%,  $p = 0.001$ ) and two thirds of the cohort reported that language and culture were very or extremely important to their wellbeing.

**Table 4:** Characteristics of socioeconomic status associated with physical HRQoL.

Full interview completed n=404 Independent variable of interest		Adj mean Physical HRQoL (CI)	Brief model* F-test (p)	Adj mean Physical HRQoL (CI)	Full model** F-test (p)
1. Living arrangement	Alone	40.1 (38.5–41.7)	3.08 <b>(0.047)</b>	37.1 (30–44.2)	2.39 (0.093)
	With spouse	42.1 (40.4–43.9)		38.6 (31.2–45.9)	
	With other	44.5 (41.2–47.8)		41.2 (33.2–49.1)	
2. Residence Type	House	41.7 (40.4–43.1)	3.52 <b>(0.008)</b>	35.3 (27.9–42.8)	3.56 <b>(0.007)</b>
	Unit/ Apartment	41.1 (38.4–43.9)		35 (27.2–42.7)	
	Retirement Village	40.1 (37.7–42.5)		33.5 (25.9–41.1)	
	Residential care	50 (43.2–56.9)		44.6 (36–53.2)	
	Other	34.5 (28.9–40)		28.9 (19.9–37.9)	
3. NZ deprivation index	Low 1–4	42.7 (40.6–44.9)	2.36 (0.096)	38.4 (31–45.8)	1.82 (0.163)
	Mod 5–7	41.9 (40.2–43.5)		38 (30.8–45.2)	
	Hi 8–10	39.8 (37.9–41.6)		35.9 (28.8–43.1)	
4. Main family occupation	Professionals	42.8 (41.3–44.3)	3.41 <b>(0.034)</b>	38.9 (31.8–46)	1.88 (0.155)
	Technicians	39.8 (37.5–42.1)		36.7 (29.2–44.1)	
	Clerks	40.1 (38.2–42.1)		36.8 (29.4–44.1)	
5. Thinking of your money situation, would you say?	Can't make ends meet	30.2 (9.3–51.1)	4.60 <b>(0.011)</b>	31.3 (10.4–52.2)	4.00 <b>(0.019)</b>
	Just enough	38.5 (36.3–40.8)		38.7 (36.3–41.2)	
	Comfortable	42.2 (41–43.4)		42.3 (40.8–43.8)	
6. Anyone to help with daily tasks?	No	38.8 (33.7–43.9)	2.83 (0.060)	35.1 (26.5–43.7)	3.08 <b>(0.047)</b>
	Yes	41 (39.8–42.2)		37.3 (30.2–44.4)	
	I don't need help	44.2 (41.5–47)		40.7 (33.1–48.3)	
7. Importance of family to wellbeing	Not at all/moderately	45 (41.6–48.5)	2.82 (0.062)	41.7 (33.8–49.5)	2.95 (0.054)
	Very	40.6 (39.1–42)		37.1 (30–44.2)	
	Extremely	41.8 (40–43.5)		37.9 (30.6–45.2)	
8. Satisfaction with role in community	Not at all/moderately	37.2 (31.6–42.7)	4.09 <b>(0.048)</b>	35.2 (29.2–41.3)	5.65 <b>(0.021)</b>
	Very/extremely	43.6 (40.5–46.7)		43.3 (38.6–48.1)	
9. Satisfaction with role in family	Not at all/moderately	38.7 (34.3–43.1)	2.52 (0.083)	35.5 (26.8–44.2)	2.13 (0.122)
	Very	40.3 (38.7–41.9)		37 (29.6–44.5)	
	Extremely	44 (40.7–47.3)		40.5 (32.4–48.6)	

HRQoL- SF-12<sup>®</sup> physical health summary score, CI 95%-confidence interval

Each numbered section is a separate analysis.

\* Brief model adjusted for functional status (NEADL) and gender

\*\*Full models adjusted for gender, functional status, education (early life) main family occupation (midlife), NZdep and perceived economic wellbeing (current state), (except for models 2 and 3 where the covariate became the variable of interest)

Interactions between: gender and marital status; and gender and living arrangement were not significant and were dropped.

A minority (16%) reported a *specific* role in their local community; those who had a role were highly satisfied with it. Sixty-four percent reported a role in their family and satisfaction was high with this role.

Reports of discrimination were rare. No one reported being treated unfairly by a health professional in the last 12 months and 1% more than 12 months ago. When aggregated, 9% reported being discriminated

against ever. Those born overseas were no more or less likely to have experienced discrimination, however those identifying as New Zealand European were less likely to have experienced discrimination (25/465, 5%) compared with those not identifying as New Zealand European (10/51, 19%; p=0.001). The reported discrimination was experienced by 'other Europeans', not by those of Pacific, Asian, Middle Eastern, or African ethnicity.

**Table 5:** Characteristics of socioeconomic status associated with mental HRQoL.

Full interview completed n=404 Independent variable of interest		Adj mean Mental HRQoL (CI)	Brief model* F-test (p)	Adj mean Mental HRQoL (CI)	Full model** F-test (p)
1.Living arrangement	Alone With spouse With other	54.2 (53–55.4) 56.3 (55–57.7) 54.3 (51.7–56.8)	2.79 (0.063)	52.6 (47.2–58.1) 54.6 (48.9–60.3) 52.6 (46.4–58.7)	2.37 (0.095)
2.Could have used more practical support than received	Yes Not at all	51.8 (49.3–54.3) 55.4 (54.5–56.2)	6.75 <b>(0.010)</b>	50.9 (45.2–56.6) 54.6 (49–60.3)	7.00 <b>(0.009)</b>
3. Anyone to provide emotional support?	No Yes I don't need help	49.6 (46.1–53.2) 55.3 (54.4–56.2) 55.7 (53.5–57.9)	4.84 <b>(0.008)</b>	47.4 (41–53.9) 53.4 (47.9–58.9) 53.7 (48–59.3)	5.14 (0.006)
4.Could have used more emotional support than received	Yes Not at all	45 (41.8–48.3) 55.7 (54.9–56.5)	38.53 <b>(&lt;.0001)</b>	42.5 (36.3–48.7) 53.6 (48.3–58.8)	41.33 <b>(&lt;.0001)</b>
5.Importance of language and culture to wellbeing	Not at all/moderately Very Extremely	53.8 (52.4–55.3) 55.8 (54.8–56.9) 55.3 (52.7–57.8)	2.4 (0.092)	51.5 (45.9–57.1) 53.5 (48.1–59) 52.7 (46.7–58.8)	2.42 (0.091)
6.Importance of family to wellbeing	not at all/moderately Very Extremely	52.1 (49.5–54.7) 55.3 (54.2–56.4) 55.5 (54.2–56.9)	2.74 (0.066)	49.9 (43.8–55.9) 53.3 (47.8–58.8) 53.7 (48.1–59.3)	3.29 <b>(0.038)</b>
7.Do you have a specific role in your family	No Yes	54.1 (52.7–55.5) 55.6 (54.6–56.6)	3.08 (0.080)	51.8 (46.1–57.4) 53.4 (47.9–58.9)	3.47 (0.064)
8.Experienced any discrimination	No Yes	54.8 (54–55.7) 57.5 (54.8–60.2)	3.43 (0.065)	52.9 (47.5–58.4) 55.9 (49.7–62)	3.98 <b>(0.047)</b>

HRQoL-SF-12<sup>®</sup> mental health summary score, CI 95%-confidence interval

Unmet need for emotional support = Could have used more emotional support than received

Unmet need for practical support = Could have used more practical support than received

Each numbered section is a separate analysis.

\*Brief model adjusted for functional status (NEADL score) and gender.

\*\*Full models adjusted for gender, functional status, education (early life) main family occupation (midlife), NZdep and perceived economic wellbeing (current state).

Interactions between: gender and marital status; and gender and living arrangement were not significant and were dropped.

### Correlates of HRQoL

Regression models were used to examine the association between QoL and the socioeconomic and cultural factors in Tables 1, 2 and 3, controlling for functional status and gender, completing analyses for both physical HRQoL and mental HRQoL.

### Physical HRQoL

The brief models in Table 4 show the variables that were associated with physical HRQoL to the level of significance of  $p < 0.1$  with those reaching  $p < 0.05$  bolded adjusting for age and functional status; functional status was strongly associated with physical HRQoL. After adjusting for gender and functional status in the brief models, living arrangement, type of residence, family occupation, and satisfaction with role in community were significantly associated

with physical HRQoL. Those living with others had higher physical HRQoL.

Full models added lifetime SES markers to each of these seven regression models. 'Type of residence' was independently associated with Physical HRQoL with those living in other situations having the lowest HRQoL. 'Economic wellbeing' and 'satisfaction with role in community' were also independently associated with physical HRQoL. 'Not needing help with practical tasks' was independently associated with higher physical HRQoL.

### Mental HRQoL

Mental HRQoL was examined in a similar way with the brief models controlled for gender and functional status. The brief model in Table 5 shows variables that were associated with mental HRQoL to the level

of significance of  $p < 0.1$  with those reaching  $p < 0.05$  bolded. The table shows that unmet need for practical and emotional support and having no one to provide emotional support were associated with lower mental HRQoL. Those who reported that family were very or extremely important to well-being had higher mental HRQoL when fully adjusted for SES. The perceptions of unmet need for practical and/or emotional support were independently associated with lower mental HRQoL. Those who had experienced discrimination reported higher mental HRQoL when fully adjusted for SES. Interactions between: gender and marital status; and gender and living arrangement were not significant.

## Discussion

This study describes the socioeconomic and cultural status and social support factors associated with HRQoL of non-Māori aged 85 years in one region of New Zealand in 2010. Participants mainly lived in moderately deprived areas and HRQoL for mental health was good. HRQoL for physical health was modest.

Women may be less well off financially and are more likely to live alone. Despite these challenges, a higher proportion of women reported they can count on someone to help with daily task (83% vs 77% in men) but they also have higher unmet needs for practical support (14% vs 8% in men). Women and men traditionally have different roles in household tasks, and as more men than women lived with a spouse, their participation in the practical tasks probably differed, thus partially explaining their different perceived unmet need for practical support. Women are more likely to outlive men and thus will need more support for the tasks done by their husbands. The unmet need for practical support may also be related to house maintenance which might not be fulfilled by the daughter (the main support for women).

NZS, the universal retirement pension, is the main source of income for the majority of non-Māori in this study, in accordance with nationally reported economic data.<sup>34</sup> Home ownership of 89% is higher than the average New Zealand home ownership rate of 66.9%<sup>35</sup> (although the denominators

may have differed) despite a national decline in mortgage-free home ownership rates in older age groups New Zealand since 2001.<sup>36,37</sup> Home ownership is also notably higher than that reported in other longitudinal studies; in 1988, 68% of the 80+ group of the Dubbo longitudinal study in Australia owned their own home.<sup>38</sup>

Individual socioeconomic status in the UK predicts health outcomes such as frailty.<sup>39</sup> Here we demonstrate that main family occupation during the working life and perceived economic wellbeing were associated with physical HRQoL. This association was attenuated when other lifetime SES factors were adjusted for, unlike self-perceived economic wellbeing which was independently associated with HRQoL after all adjustment. Education and deprivation status, in our analysis, were not strongly associated with HRQoL. Jatrana and Blakely found that while disparities in mortality related to ethnicity persist into old age, the impact of socioeconomic gradients on mortality appear to be less in the 85+ age group compared with the 65+ age group.<sup>40,41</sup> Our analyses examined HRQoL, not mortality, and this may in part be why there is not apparently such a strong association between education and deprivation and HRQoL. Rather, self-perceived economic wellbeing was important. Potentially self-perceived economic well-being may represent the adequacy of money for day-to-day living while education and deprivation does not tell us adequacy of resource availability.

For women, a daughter was seen as the most common provider of support concurring with English research where it was not so much the size of the family but the presence of a daughter that was associated with higher social contact and better outcome.<sup>42</sup> The main supporter for men in LiLACS NZ was their spouse. Social support is gender dependent.

The prevalence of living alone varies around the world. Fewer non-Māori participants in LiLACS NZ (85 years old) lived alone (48%) than in the Newcastle 85+ study, where 61% lived alone, predominantly women.<sup>43</sup> These two studies had similar eligibility criteria and thus this comparison is fair.

## Correlates of HRQoL

Women more often reported unmet need for practical help and had lower physical HRQoL than men. Living alone requires more resources, and reported unmet need for practical and emotional support is associated with lower QoL. Social support may mediate the association between lower physical HRQoL and poor outcomes,<sup>21</sup> as there was no gender interaction for unmet need. The importance of support for emotional and practical needs is emphasised by these results, confirming other research.<sup>44</sup>

It is interesting that reported discrimination among those identifying as 'other-European' was associated with higher mental HRQoL. When Māori of all ages<sup>45</sup> and the Māori cohort of those in advanced<sup>23</sup> report discrimination, it is associated with worse outcomes. Further work is needed to understand this finding in non-Māori.

It is also intriguing that living in residential aged care was associated with higher physical HRQoL both in the brief and in the full models. Those in residential care had the lowest functional status and both models are adjusted for this. One interpretation is that as functional status is the strongest predictor, the relative difference in HRQoL between the living arrangements is driven by function. For those in advanced age with low function, those in residential care have the highest physical HRQoL. Demand for physical support may be reduced when taken care of by paid care providers, and this relief may improve HRQoL.

Functional status is reinforced here as a key component of physical and mental HRQoL and will be a key outcome to be followed in the longitudinal study.

## Strengths and weaknesses

This study is the first to engage a large number of people aged 85 years old in New Zealand. However, the findings are subject to some limitations. First, this study reports cross-sectional analyses which prohibit drawing causal conclusions. Follow-up data will allow conclusions regarding the direction of effects, allowing causal inferences to be drawn more confidently.

Second, although the population-based sampling is a strength, selection bias might arise in our analyses for the poorly repre-

sented group (eg, those in residential care), hence interpretation should be cautious. The response rate was 59%, and 78% of these answered all the questions (overall 46%). Although the demographic profile is similar to that of the total population, response bias may be operating<sup>24</sup> as those less able to answer are not as well represented. Our response rate is similar to the Newcastle 85+ study.<sup>43</sup> The proportion of our sample living in long-term residential aged care is within the estimated range of 3.4% and 9.2%, though lower than an age group comparison which reported 22% and 15% for women and men respectively in care in 2008.<sup>46</sup> Third, although we have adjusted for many confounding variables, it is possible that the differences we found in outcome and exposure variables could be the result of other factors associated with outcome variable that we did not measure.

## Implications for practice and policy

These findings support the need for maintaining and improving financial resources for those in advanced age, particularly for those living alone. Support for those living alone is needed, but this report does not specify exactly the best combination of supports. More work is needed. Supportive care appears helpful, both for practical and emotional support. Potentially finding ways to buttress informal support with access to formal support, respite care, training for informal caregivers, adaptations to environment, supply of equipment, may facilitate maintenance of QoL.

## Concluding statements

At age 85 years, non-Māori in New Zealand on average, are reasonably able in activities of daily living and have a moderate socioeconomic status. Those with more social support (both practical and emotional support); who have a perception that family and roles in the community are important to their wellbeing and those with perceived comfort with their money situation also have high HRQoL. Those who report unmet needs have poor mental HRQoL. This information can be used for development of strategies to improve health and QoL for people living in advanced age in New Zealand.

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# Adherence to the current guidelines for bradycardic pacing in the octogenarian and nonagenarian populations

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## ABSTRACT

**Aim:** A significant proportion of single-chamber ventricular pacemakers are implanted in octogenarian and nonagenarian patients. We aimed to assess whether the current pacing guideline is adhered for these populations.

**Methods:** We retrospectively identified patients  $\geq 80$  years of age, who received their first pacemaker from July 2010 to June 2013.

**Results:** A total of 356 patients were identified. Mean age was 86.1 years and 82.6 years for single and dual-chamber pacemakers respectively ( $p < 0.05$ ). Total procedure-related complications occurred in 9.5% and were comparable between both groups ( $p = 0.08$ ). At the time of implantation, 185 patients who received single-chamber pacemaker were in sinus rhythm (52%). They were older ( $86.2 \pm 4.3$  vs  $82.6 \pm 2.9$ ,  $p < 0.05$ ), more likely to have ischaemic and valvular heart disease (68 vs 27,  $p = 0.02$  and 22 vs 13,  $p = 0.01$ , respectively), and cognitive impairment (34 vs 0,  $p = 0.001$ ). They were also more likely to be discharged to a residential care facility (17 vs 1,  $p < 0.01$ ).

**Conclusion:** The utility of dual-chamber pacemaker in this age group remains below expectation and did not comply with current cardiac pacing guidelines. The presence of older age, multiple co-morbidities, cognitive impairment and residential care on discharge likely influenced the type of device implanted.

## Background

With improved life expectancy and advances in medical care, the number of pacemakers implanted in people  $\geq 80$  years of age has been steadily increasing. Current pacing guidelines favour implantation of dual-chamber pacemakers for brady-arrhythmias including sinus node disease and higher degree atrioventricular (AV) block except in patients with chronic atrial fibrillation (AF).<sup>1,2</sup> Dual-chamber pacing resembles more closely to the normal cardiac physiology and maintains the AV synchrony. Therefore, dual-chamber pacemaker is thought to be potentially more advantageous in older adults who have increased contribution of atrial contraction to ventricular filling with their haemodynamic changes of ageing.<sup>3,4</sup>

However, there is still a significant proportion of single-chamber pacemakers being implanted in the octogenarian and nonagenarian patients perhaps because of the paucity of data and evidence specifically addressing this in the very elderly group.<sup>5-7</sup> In clinical practice, the specific determinants of pacing mode selection in patients remain unspecified even if there are guidelines to assist the implanting physicians.

The objective of this study was to assess our local practice of dual-chamber pacemakers vs single-chamber ventricular pacemakers' implantation rate in octogenarian and nonagenarian patients at Auckland City Hospital. We aimed to assess whether the current cardiac pacing guideline is adhered in this population and aimed to identify whether there are any variables between the two groups

that affected the decision of pacing mode selection. We also aimed to assess whether there were any differences in their clinical outcome and complication rate.

## Methods

This is a retrospective observation study involving octogenarian and nonagenarian patients who required pacemaker implantation. We identified patients aged 80 years or older, who received their first pacemaker at Auckland City Hospital (ACH) for a conventional reason for long-term pacing for the three-year period (July 2010 to June 2013) from a centralised ACH pacing database. We identified the patient demographics, medical co-morbidities, indications for pacing, type of pacemaker implanted, acute (within 24 hours of implant), early (from >24 hours to two weeks) and late (from two weeks to three months after pacemaker implantation) complications and patients' discharge destinations from the local hospital electronic medical records. Most octogenarian and nonagenarian patients are expected to have some degree of valvular heart disease and chronic kidney disease. For the purpose of our review we included only severe symptomatic valvular heart disease that will be otherwise considered for surgery or patients with post valve surgery as medical co-morbidity. For chronic kidney disease, only stage 4 or more advanced kidney disease were included as their medical co-morbidity.

## Statistical Analysis

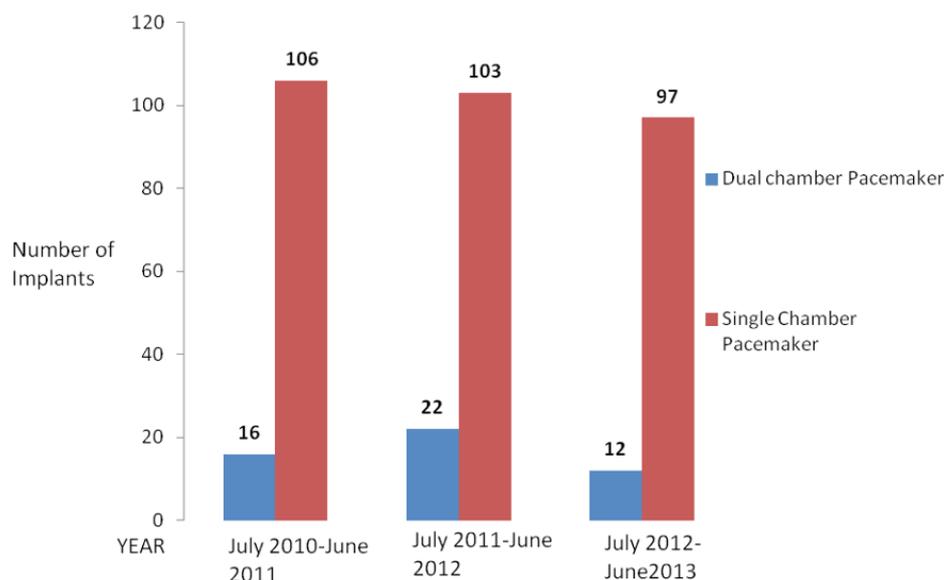
Statistical comparisons for continuous data were performed using ANOVAs single factor, unpaired t-tests and chi-squared tests and Fisher's exact test were used for categorical data. Continuous variables are presented as mean  $\pm$  SD, and categorical data as counts or percentages. Ethics approval was obtained from the Auckland DHB Research Review Committee.

## Results

A total of 357 patients  $\geq$ 80 years of age who received their first pacemaker implantation were identified for the study period. We excluded one patient who had an atrial pacemaker (AAI) and left with 356 patients for the analysis. Figure 1 showed the number of dual and single-chamber pacemakers implanted in these populations throughout the study period. Only 50 patients  $\geq$ 80 years of age received dual-chamber pacemakers. Mean age of the patients at the time of first implant was  $86.1 \pm 4.3$  years (range 80 to 99 years) and  $82.6 \pm 2.9$  years (range 80 to 90 years) for single and dual-chamber pacemakers respectively ( $p < 0.05$ ). 54% of the patients were male.

The indication for pacemaker implantation was showed in Table 1. The most common indication for pacing was high-grade AV block (43.5%) followed by AF/flutter with slow ventricular rate/pauses (35.9%).

**Figure 1:** Number of dual and single-chamber pacemakers implanted in those  $\geq$ 80 years of age for three-year period.



**Table 1:** Indications for pacemaker implantation.

Indications	Number
Atrioventricular (AV) Block	155 (43.5%)
Sinus node disease	28 (8%)
Mixed AV block and sinus node disease	41 (11.5%)
Atrial fibrillation (AF)/flutter with slow ventricular response	128 (35.9%)
Ventricular tachycardia and empiric pacing for recurrent syncope	4 (1%)

Table 2 showed the demographic data of the patients who received single and dual-chamber pacemakers. Those who received single-chamber pacemaker were older (86.1 vs 82.6 years,  $p < 0.05$ ), more likely to have

valvular heart disease ( $p < 0.05$ ) and cognitive impairment ( $p < 0.05$ ). However, there were no differences in terms of the procedure-related complications or discharge status between the two groups.

**Table 2:** Baseline characteristics of the patients who received single and dual-chamber pacemakers.

	Single-chamber (n=306)	Dual-chamber (n=50)	P Value
Mean age	86.1 ± 4.3	82.6 ± 2.9	<0.05
Median age	86	82	
Gender			0.13
Male (%)	161	32	
Female	145	18	
Previous IHD	123	27	0.07
Valvular heart disease	35	13	<0.05
Congestive heart failure	58	10	0.86
Previous stroke	66	9	0.57
CKD	51	9	0.82
Active malignancy	21	2	0.44
Cognitive impairment/dementia	53	0	<0.05
<b>Procedural complications</b>			
Acute complications	16	3	0.82
<i>Pneumothorax</i>	8	0	0.25
<i>Lead remanipulation</i>	6	1	0.97
Early complications	10	4	0.12
Late complications	0	1	0.14
<b>Discharge status</b>			
Death	4	0	1.0
Home	275	49	0.06
Residential care	27	1	1.0
<i>Rest home</i>	23	1	0.15
<i>Private hospital</i>	4	0	1.0

Abbreviation:

IHD: ischaemic heart disease

CKD: chronic kidney disease

Within three months' follow-up, a total of 9.5% of procedure-related complications occurred in 34 patients. Most common complications were lead-related problems (11/34) and pocket haematomas (11/34). Most patients were on at least one antiplatelet therapy due to co-existing ischaemic heart disease (IHD) or history of transient ischaemic attack (TIA)/stroke. Four patients with pocket haematomas were also taking warfarin with their international normalised ratio (INR) between

2 to 2.5. Another patient with moderate pocket haematoma had exacerbation of chronic idiopathic thrombocytopenia (ITP) and was re-admitted with platelet count <10 and was managed with prednisone and plasmapheresis. All the patients with haematoma were managed conservatively with pressure dressing.

Less than 50% of all patients with complications required another procedure to manage their complications: 11 (3%) required lead re-manipulation and 4 (1%)

**Table 3:** Baseline characteristics of non-AF patients who received single-chamber pacemakers vs patients who received dual-chamber pacemakers.

	<b>Non-AF single-chamber pacemakers patients (n=185)</b>	<b>Dual-chamber pacemaker patients (n=50)</b>	
Mean age	86.2±4.3	82.6±2.9	<0.05
Median age	86	82	
Gender			0.28
Male	78	18	
Female	107	32	
Previous IHD	68	27	0.02
Valvular heart disease	22	13	0.01
Congestive heart failure	27	10	0.35
Previous stroke	35	9	0.88
CKD	33	9	0.98
Active malignancy	16	2	0.27
Cognitive impairment/dementia	34	0	0.001
<b>Complications</b>			
Acute complications	9	3	0.72
<i>Pneumothorax</i>	4	0	0.58
<i>Lead remanipulation</i>	5	1	1.00
Early complications	4	4	0.07
Late complications	0	1	1.00
<b>Discharge status</b>			
Death	2	0	1.00
Home	166	49	0.06
Residential care	17	1	<0.01
Rest home	14	1	<0.05
Private hospital	3	0	1.00

*Abbreviation:*

AF: Atrial fibrillation

IHD: ischaemic heart disease

CKD: chronic kidney disease

patients required chest drain for pneumothorax. Complication rates between the two groups were comparable (Table 2). At the end of three-month follow up, four patients were deceased and there was no pacemaker-related death.

At the time of implantation, 185 patients who received a single-chamber pacemaker were in sinus rhythm (52%). The baseline characteristics of these patients compared with those who received dual-chamber pacemakers were shown in Table 3. Patients who received single-chamber pacemaker tended to be older (86.2 +/- 4.3 years vs 82.6 +/- 2.9 years,  $p < 0.05$ ), more likely to have IHD (68 vs 27,  $p = 0.02$ ), significant valvular heart disease (22 vs 13,  $p = 0.01$ ) and cognitive impairment (34 vs 0,  $p = 0.001$ ). They were also more likely to be discharged to a long term residential care facility (17 vs 1,  $p < 0.01$ ).

## Discussion

Our study showed that utilisation of dual-chamber pacemakers in the octogenarian and nonagenarian populations remained low and did not comply with the current cardiac pacing guidelines. The important predictor that determines the choice of pacing mode was presence of cognitive impairment. Furthermore, those patients who received single-chamber pacemakers who were in sinus rhythm were older, more likely to have significant co-morbidities and more likely to be discharged to a residential care which might imply poorer baseline functional status before implantation.

New Zealand, like many developed countries, has an ageing population and the number of people aged 85 years and over is expected to increase from 67,000 in 2009 to over a quarter of a million by 2051.<sup>8</sup> Those who aged >85 years have been the most rapidly expanding segment of our population over the past decades and they will make up 22% of all New Zealanders aged 65 years and over, compared with 9% in 1996.<sup>8</sup> To date, there is no published prospective and randomised trial on the choice of pacing mode specifically assessing those octogenarian and nonagenarian patients.

There is evidence of superiority of dual-chamber pacing over ventricular pacing alone in patients, especially in patients with

sinus node disease. In 2000, The Canadian Trial of Physiologic Pacing (CTOPP) was the first large randomised study (N=2,568) to investigate the effects of dual-chamber versus single-chamber ventricular pacing on the risk of stroke or death due to cardiovascular causes.<sup>9</sup> After a mean of three-year follow-up, there was no significant benefit of dual-chamber over single-chamber ventricular pacing in reducing stroke or cardiovascular death (4.9% vs 5.5%,  $p = 0.33$ ). The mean age of the patients in the CTOPP was 73 +/- 10 years and was much younger than our study population. There was no difference in the incidence of heart failure hospitalisation.<sup>9</sup> However, the study showed a modest benefit of dual-chamber pacing on the development of AF and similarly, the Mode Selection Trial (MOST) in 2002 also demonstrated a beneficial effect of dual-chamber pacing on progression to chronic AF.<sup>10</sup> In our study, 52% of the patients who received a single-chamber pacemaker were actually in sinus rhythm at the time of implantation. AF is a common arrhythmia in the elderly population.<sup>12</sup> Having a dual-chamber pacemaker potentially can reduce the incidence of AF in this group. Because of the age and underlying comorbidities, these patients were preferentially given a single-chamber pacemaker despite the current cardiac pacing guidelines.

There were more perioperative complications reported in CTOPP study, mainly lead-related problems.<sup>9</sup> This was different from our study where there was no difference in the complication rates between the two groups.

Although dual-chamber pacing does not provide survival benefit on published studies, the mortality endpoint is probably not the crucial determinant for mode selection in the majority of octogenarian and nonagenarian patients. Pacing is generally considered primarily as a means of improving quality of day-to-day life. Expectations, values and needs are different from patients who are younger. Small improvement in cardiac output and exercise tolerance with dual-chamber pacemakers may be a crucial factor in allowing continued independence and improving quality of life in our octogenarian and nonagenarian populations.

Pacemaker syndrome consists of a constellation of signs and symptoms that occur in response to loss of AV synchrony and might have significant impact on older person's quality of life.<sup>14,15</sup> Octogenarians and nonagenarians belong to a highly heterogeneous group with regards to the presence and severity of medical co-morbidities and functional capabilities. Older people with pacemaker syndrome might have recurrent presentations to general or geriatric service with vague and nonspecific illness and over time recurrent admissions might exert substantial increase on health care expenditure as well as negative impact on their quality of life until proper diagnosis is made. Interestingly in MOST study, there was high rate of crossover from single-chamber pacing to dual-chamber pacing due to pacemaker syndrome (18.3%).<sup>13</sup> At the last follow-up, 313 patients (31.4%) assigned to ventricular pacing alone were receiving dual-chamber pacing. In the Pacemaker Selection in the Elderly (PASE) trial, the pacemaker syndrome occurred in 26% of patients during an average follow-up of 18 months.<sup>16</sup> In contrast, CTOPP reported very low (2.7%) crossover rate.<sup>9</sup> Currently there are no clear diagnostic criteria for pacemaker syndrome and different studies have different clinical thresholds for the diagnosis of such a subjective condition. In the CTOPP, re-operation was required to change from ventricular to dual-chamber pacing whereas only re-programming was necessary in the MOST and PASE trial so likely the two studies had lower threshold for the crossover.<sup>9,10,16</sup> None of our patients were upgraded to physiological pacing during the study period for pacemaker syndrome and we acknowledge the limitation of our retrospective study and the need for upgrade to a dual-chamber system due to intolerable pacemaker syndrome must be weighed against the increased risk of complication and cost with dual-chamber pacemaker. At current stage we have no means of determining who will be more susceptible to pacemaker syndrome.

Our review highlights the need for further research in this area. Risk stratification of octogenarian and nonagenarian patients meeting current pacing guidelines for dual-chamber pacemakers should be improved and standardised to achieve optimal patient

outcome. At the start of the study, our hospital did have a policy that all octogenarian and nonagenarian patients should receive only single-chamber pacemaker as the published data suggested no mortality benefit of dual-chamber pacing over single pacing. The local policy regarding our conservative approach to pacing in the elderly was not published anywhere and the final decision to implant type of pacemaker in this group of population has always been at operators' discretion. Co-morbidities/frailty and cost were factors considered in our centre as well as the lack of resources to offer dual-chamber pacemaker for the growing population of octogenarians and nonagenarians. There were no national guidelines that we were aware at that point and there is none still at present. Given the large number of potential candidates (growing elderly populations) and the practical constraints of limited implanting specialist resource and funding in New Zealand, our local policy of implanting single-chamber pacemaker in octogenarian and nonagenarian represent a conservative but pragmatic prioritisation from the available trial evidence. We acknowledge this as one of the limitations of our study. With increasing availability of resources, the number of dual-chamber pacemaker implantation in the octogenarian and nonagenarian patients slowly increased but remained low as showed in Figure 1. This may be reviewed as part of clinical practice in the future.

A number of clinical studies have shown that, unnecessary chronic right ventricular pacing can cause a variety of detrimental effects, including AF and heart failure.<sup>17-19</sup> With the advance in the pacemaker technology, new pacing algorithms have influenced our clinical practice in implanting dual-chamber pacemakers to allow a more physiological pacemaker yet minimise ventricular pacing. Previously we may have put a single-chamber ventricular lead back-up (ie VVI) to minimise pacing in patients with sick sinus syndrome, but new dual-chamber pacing mode such as Managed Ventricular Pacing (MVP) allows a functional single-chamber atrial pacing (ie AAI) with ventricular monitoring and automatic switch from AAI to dual-chamber pacing (DDD) during episodes of AV block.<sup>18,19</sup>

Unfortunately, there is very limited data on the cost-effectiveness analysis of dual versus single ventricular pacemakers in this age group and further research is required in this area to help the clinicians to make informed decision. Multidisciplinary comprehensive geriatric assessment including assessment of cognition and frailty score prior to pacemaker implantation might assist in pacing mode selection by having more accurate information on their functional and cognitive status. Much work remains to be done with regard to the development of new algorithm.

## Limitations

A number of limitations should be considered in interpreting the results of our study. Our study is a single-centre retrospective observational study, the selection of pacing mode ie device prescription is not randomised. The local policy regarding our conservative approach to pacing in the elderly might have influenced the operators' decision on the choice of devices implanted. Information on patients' frailty and functional status were not available. Patients with poor functional status and limited expected survival were likely to be implanted preferentially with single-chamber pacemakers. This opens the door for bias. Our study did not have cost-effective analysis; therefore, we do not know whether single vs dual-chamber pacemakers

would potentially have any cost-saving in these populations. Our main strength is our results are a representation of 'real-world' practice. It provides a useful perspective for both clinicians and implanting physicians on the selection of pacing mode based on an individual patient clinical status. A multidisciplinary approach involving the geriatrician and implanting cardiologist to provide a comprehensive assessment prior to implantation should be considered.

## Conclusion

Utility of dual-chamber PM in the octogenarian and nonagenarian populations remains below expectations and did not comply with current pacing guidelines. The presence of cognitive impairment was the strongest independent predictor for receiving single-chamber pacemaker. In addition, patients who received single-chamber pacemaker with sinus rhythm were noted to be older and more likely to have IHD, significant valvular heart disease and more likely to be discharged to residential care which might imply poorer baseline functional status. Those factors likely influenced the decision of type of device implanted. Balancing patients' comorbidities and the potential for device-related complications against the potential benefit is recommended on a case-by-case basis.

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### Competing interests:

Nil.

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# Protecting New Zealand children from exposure to the marketing of unhealthy foods and drinks: a comparison of three nutrient profiling systems to classify foods

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## ABSTRACT

**Aim:** Promotion of unhealthy foods and drinks is a significant, modifiable risk factor for child obesity and diet-related non-communicable diseases. We compared three accepted nutrient profiling systems: the Health Star Rating (HSR), the Ministry of Health Food and Beverage Classification System (FBCS) and the World Health Organization (WHO) Regional Office for Europe Nutrient Profiling Model, to identify the best system to protect New Zealand children from exposure to the marketing of unhealthy foods and beverages.

**Methods:** 13,066 packaged foods from the 2014 New Zealand Nutritrack database were classified as 'restricted' or 'not restricted' as per the WHO model; 'everyday/sometimes' or 'occasional' as per the FBCS model; and '<3.5 stars' or '≥3.5 stars' as per the HSR model. The proportion and types of packaged foods that met the criteria for all three systems or none of the systems, and the types of food products classified as 'restricted' under the WHO model but classified as 'everyday/sometimes' (FBCS model) or as having >3.5 stars, were determined.

**Results:** Under any of the three nutrient profiling systems, approximately one-third (29–39%) of New Zealand packaged foods would be permitted to be marketed to children. The WHO Model would permit marketing of 29% of products; the HSR system would permit 36%; and the FBCS system would permit 39%. The WHO Model restricts marketing of unhealthy foods more effectively than the other two systems. The HSR and FBCS systems would permit marketing of a number of food products of concern, particularly high-sugar breakfast cereals, fruit juices and ready meals.

**Conclusion:** The WHO Regional Office for Europe Nutrient Profiling Model should underpin the Advertising Standards Authority revised Children's Code for Advertising Food. The effectiveness of the new Code in reducing New Zealand children's exposure to marketing of unhealthy foods and drinks should be subject to evaluation by an independent body.

Promotion of unhealthy foods and beverages to children is a significant, modifiable risk factor for child obesity and development of diet-related non-communicable diseases.<sup>1</sup> Comprehensive, independent reviews of the evidence consistently find that commercial food marketing has a direct effect on children's food preferences, purchase requests, consumption patterns and diet-related health.<sup>2-4</sup>

Current marketing practices in New Zealand predominantly promote unhealthy foods and drinks to children.<sup>5</sup> The most common categories of food products promoted to children are pre-sugared breakfast cereals, soft drinks, savoury snacks, confectionery and fast foods.<sup>3</sup> Estimates of the proportion of food marketing promoting these product categories to children vary from 60% to 90%.<sup>3</sup>

A US federal Trade Commission survey of industry expenditure reported 63% of the marketing spend directed to children was for carbonated drinks, fast food and breakfast cereals.<sup>6</sup> Analysis of UK television channels popular with young people found six of the 10 most frequently advertised food items were fast food, high sugar/low fibre breakfast cereals, confectionery and snack foods.<sup>7</sup> A similar study in New Zealand reported that 66% of food advertisements on a free-to-air channel popular with children were for foods high in fat, salt or sugar.<sup>8</sup>

Several national governments and food and beverage manufacturers have acted to restrict unhealthy food marketing to children or to allow the promotion of healthier choices only. Countries such as Norway, Sweden and the province of Quebec, Canada have statutory regulation (a formal legislative requirement by government) restricting the advertising of any product to children, and Ireland, UK and South Korea have regulations to restrict advertising of specified foods and beverages during children's programming or peak viewing times.<sup>9</sup> A number of food and beverage companies have also responded with voluntary pledges (non-legislatively required commitments) to change their marketing activities directed to children, and the mix of foods advertised to children.<sup>10,11</sup> New Zealand does not have statutory legislation on the advertising of foods to children but 67% of the major packaged food manufacturers and 20% of the biggest fast food restaurants have a voluntary policy on food marketing to children on their company website. However, none of those include an accepted nutrient profiling model.<sup>12</sup>

A systematic review of the impact of statutory and voluntary codes to limit the advertising of foods to children found a sharp division in the evidence however, with scientific peer-reviewed evidence showing small or no reductions in promotion of less healthy foods and children's exposure to food marketing, except in response to statutory regulation.<sup>9</sup> In contrast, industry-sponsored reports indicate high adherence to voluntary codes.<sup>9</sup> Discrepancies are likely to be due to lack of complete coverage of voluntary

codes across all food companies, differences in audience definitions (times children are likely to be watching television versus 'children's programming' times), and different systems to classify foods as unhealthy or 'non-core'. Adherence to voluntary codes may therefore not sufficiently reduce the advertising of unhealthy foods or children's exposure to such advertising.<sup>9</sup>

An accepted food classification or nutrient profiling system is necessary to classify foods as suitable/unsuitable for marketing to children and to implement restrictions. Examples of systems used for this purpose are the UK Ofcom model, the Scandinavian Keyhole model, the US Interagency Working Group proposals<sup>13</sup> and the World Health Organization (WHO) Regional Office for Europe Nutrient Profiling Model.<sup>14</sup>

In February 2016, the Advertising Standards Authority (ASA) announced a review of the ASA Children's Codes (Code for Advertising to Children and Children's Code for Advertising Food).<sup>15</sup> The consultation document contained a specific question on the role of nutrient profiling systems in the Children's Codes, *Is there a role for a nutrient profiling system such as the health star rating system in the Children's Codes? If yes, in what way and which system would you suggest?*

To inform our response to this question, we compared three accepted nutrient profiling systems: the Health Star Rating (HSR), the Ministry of Health Food and Beverage Classification System (FBCS) and the World Health Organization (WHO) Regional Office for Europe Nutrient Profiling Model (WHO Model) to identify the best system to protect New Zealand children from exposure to the marketing of unhealthy foods and beverages.

## Methods

### Selection of Nutrient Profiling Systems

Three nutrient profiling systems were selected for comparison. Two were established New Zealand systems: the HSR and the Ministry of Health FBCS, and one was an international system: the WHO Model. Table 1 provides an overview of each system.

HSR is an interpretive, front-of-pack nutrition labelling scheme adopted by New

Zealand in 2014.<sup>16</sup> HSR rates the nutrition content of packaged foods in half-star increments from half a star (least healthy) to 5 stars (most healthy) and is designed to help consumers compare foods within categories. The number of stars is calculated based on the nutritional profile of the food. To calculate the HSR score, a product is placed in one of six HSR food categories; baseline points are calculated based on energy, saturated fat, total sugar and sodium content per 100g; modifying points are calculated based on the amount of fruits, vegetables, nuts and legumes (V points) and in some instances, protein (P points) and fibre (F points). The final HSR score = Baseline points – (V points) – (P points) – (F points). Lower scores indicate a better (healthier) nutrient profile. HSR is a continuous scoring system with scores ranging from approximately -24 to +45 (unpublished analysis of a 2012 database of approximately 17,000 New Zealand packaged products), and a cut point to dichotomise foods as healthy/unhealthy has not yet been widely agreed. However, work commissioned by the New South Wales Ministry of Health on the alignment of HSR with existing Traffic Light schemes and the 2013 Australian Dietary Guidelines reported that “healthy core foods with a HSR of  $\geq 3.5$  can be confidently promoted in public settings as healthier choices”.<sup>17</sup> This cut point has been proposed for use in New Zealand as a means of identifying packaged foods consistent with District Health Boards’ Healthy Food Policy and suitable for sale in hospitals.

The FBCS was developed by the Ministry of Health in 2007 to support healthy eating environments in New Zealand schools and identify healthy foods suitable for provision in schools.<sup>18</sup> The FBCS classifies foods and beverages as ‘everyday’, ‘sometimes’ or ‘occasional’ foods based on the Food and Nutrition Guidelines for Healthy Children and Adolescents. ‘Everyday’ foods are from the four core food groups, while ‘sometimes’ foods are mostly processed foods with some added fat and/or salt and/or sugar, and ‘occasional’ foods are high in saturated fat and/or salt and/or added sugar (eg confectionery, deep-fried foods and sugar-sweetened drinks). The FBCS is the basis for the Heart Foundation’s Fuelled4Life programme<sup>19</sup> and the TVNZ

and Mediaworks ThinkTV children’s food advertising guidelines.<sup>20</sup>

The WHO Model was specifically designed for the purpose of restricting the marketing of foods to children and was published in 2015.<sup>14</sup> It was developed following extensive consultation with European member states, and is based on three nutrient profile models currently in use in Europe for restricting marketing to children. It encompasses 17 food categories including fruit, vegetables and ready-made meals. Certain food categories are not permitted to be marketed to children under any circumstances. These include chocolate and confectionery, cakes and sweet biscuits, juices and energy drinks. Conversely, unprocessed meat and fish, and fresh/frozen fruit and vegetables can be marketed without restriction. Maximum nutrient level cut points are applied to determine the eligibility of foods in all other categories to be marketed to children.

A key difference between HSR and the other two systems is that HSR is for packaged foods only while the FBCS and the WHO Model also incorporate fresh, mixed and cooked meals.

### Database of New Zealand packaged foods

In order to compare nutrient profiling schemes, a common set of products were classified using each scheme and compared. The 2014 New Zealand Nutrtrack packaged food database was used for this purpose. Nutrtrack food composition data are collected directly from labels of all packaged foods and non-alcoholic beverages available in four Auckland supermarkets during field surveys undertaken between February and May each year. Standardised data collection methods were developed for an international collaborative project to compare and monitor the nutritional composition of packaged foods.<sup>21</sup> Supermarkets chosen for data collection represent the biggest retail brands of the main supermarket retailers in New Zealand (Foodstuffs (54% grocery market share) and Progressive Enterprises (38% market share)<sup>22</sup> and stores were selected for their large product ranges. Nutrition information is recorded for all packaged products displaying a Nutrition Information Panel. Alcohol and products

**Table 1:** Summary of criteria used under each nutrient profiling scheme.

Nutrient profiling system	Purpose	Scoring	Nutrients to limit	Nutrients or components to promote	Examples
HSR <sup>16</sup>	Front-of-pack nutrition labels on packaged foods to assist consumers in discriminating and comparing foods within categories	Products receive a Health Star Rating between ½ star and 5 stars from an overall score based on food components with positive or negative associations with chronic disease.	Energy, saturated fat, total sugars, sodium	Protein, fibre, percentage of food that is fruits vegetables nuts and legumes	Sugar sweetened soft drinks = 100% of products receive <3.5 stars  Frozen vegetables = 100% of products receive >3.5 stars
FBCS <sup>18</sup>	Guidelines for schools to identify healthy food and drink options for sale on campus	Foods are either 'everyday' 'sometimes' or 'occasional' foods depending on alignment with food and nutrition guidelines	Added fat, added salt, added sugar		Sugar sweetened soft drinks = 'occasional'  Frozen vegetables = 'everyday'
WHO Model <sup>14</sup>	Restriction of marketing of unhealthy foods to children	Foods are either 'permitted' or 'not permitted' according to nutrient thresholds for different food categories	Total fat, saturated fat, total sugars, added sugars, non-sugar sweeteners, salt, energy		Sugar sweetened soft drinks = 'not permitted'  Frozen vegetables = 'permitted'

that do not carry a Nutrition Information Panel, eg fresh produce, bakery and delicatessen items are excluded.

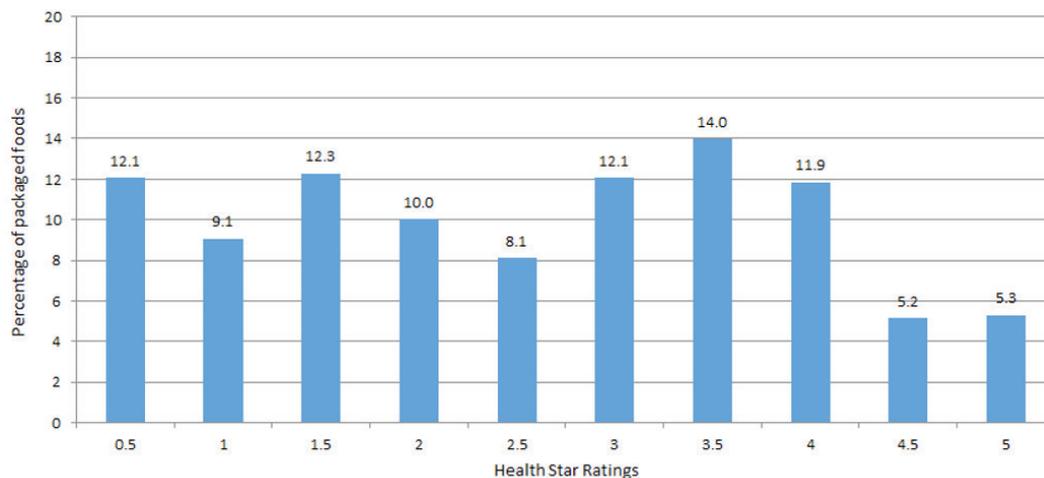
For each packaged product with a Nutrition Information Panel, the brand name, product name, ingredient list and content of energy, protein, total fat, saturated fat, total carbohydrate, sugars, fibre (where available) and sodium per 100 g or mL are recorded in a searchable web-based database. Nutritional information recorded is for products 'as sold' (ie not 'as prepared') in order to maximise within-category product comparability (since preparation instructions vary and can have a significant impact on final composition) and different pack sizes of the same product are recorded as separate items. All data are checked and cleaned before analysis. Any data entry errors identified by value range checks and random checks are corrected using source data (product photographs). Each product is assigned to a basic food group (Level 1, 13 groups) and a specific food category (Level 2, 41 categories).<sup>21</sup> Level 4, the most finely grained food grouping in the system, has 428 categories. Where fibre content is not listed on a product Nutrition Information Panel (it is not mandatory), we apply the food category average. We also apply a standardised category-specific fruit, vegetable,

nut and legume (V Points) value, based on expected content within food category, in order to calculate HSR scores.

## Analysis

A total of 13,066 packaged food products across 14 broad food categories were analysed after exclusions were made. Food categories in the Nutrtrack database not included in the analysis were: alcoholic beverages, herbs and spices, coffee and tea, sugars and baking ingredients, coatings/breadcrumbs, baby food and supplements, as these were not covered by the three nutrient profiling systems.

The remaining 13,066 packaged foods were classified as 'restricted' or 'not restricted' as per the WHO model; 'everyday/sometimes' or 'occasional' as per the FBCS model; and '<3.5 stars' or '≥3.5 stars' as per the HSR model. The FBCS does not apply to certain food groups, including cooking oils, sauces and spreads, jam and marmalade, honey, butter and margarine, pickled vegetables, so these were excluded (N/A) for that model. The proportion and types of packaged foods that met the criteria for all three systems or none of the systems and the types of food products classified as restricted under the WHO model but classified as 'everyday/sometimes' (FBCS model) or as having >3.5 stars, were determined.

**Figure 1:** Proportion of New Zealand packaged foods (n=13,066) within each Health Star Rating category.

## Results

There was a fairly even distribution of New Zealand packaged foods across the 10 HSR categories from 0.5 to 5 stars, although proportions of packaged foods with 4.5 stars (5%) or 5 stars (5%) were noticeably lower than those in other HSR categories (range 8–14%, mean 10%) (**Figure 1**).

The three nutrient profiling systems were broadly similar in their proportional classification of permitted foods overall with approximately one-third (29–39%) of packaged foods meeting the eligibility criteria for each system: 29% under the WHO model, 36% under the HSR system ( $\geq 3.5$  stars), and 39% under the FBCS system (everyday or sometimes foods) (**Table 2**).

In general, the WHO Model applies stricter eligibility criteria and fewer foods would be permitted to be marketed to children under this system. However, there were important differences between the three systems in their classification of specific food categories. Notably, the WHO Model would only permit marketing of 33.5% of New Zealand breakfast cereals included in this analysis, whereas the HSR and FBCS would permit marketing of 77% and 75% of breakfast cereals respectively. The HSR system would also permit marketing of substantially more fruit bars and fruit/vegetable juices (57% and 62% respectively) compared with the WHO Model (0% for both) and the FBCS (0% and 12%). In contrast, the FBCS would permit marketing of substantially more convenience foods and dairy products (83% and 61% respectively) compared with the WHO Model (34% and 14%) and HSR (56% and 33%) (**Table 2**).

While 87–88% of packaged foods restricted under the HSR system ( $\leq 3.5$  stars) and the FBCS system (occasional foods) would also be restricted under the WHO Model, 42% of those permitted under the HSR system and 47% permitted under the FBCS system would be restricted under the WHO Model (**Table 3**).

The most common packaged foods restricted under the WHO Model but receiving 3.5 stars or more were fruit and vegetable products (22%, of which 27% were fruit in juice or syrup, 17% dried fruit and 14% frozen potato products), dairy products (19%, of which 25% were cheese and 23% yoghurt and yoghurt drinks), convenience foods (14%, of which 66% were ready meals and 18% soups), cereals and cereal products (14%, of which 61% were breakfast cereals and 16% cereal bars) and non-alcoholic beverages (11%, of which 99% were fruit or vegetable juices) (**Figure 2**).

The most common types of products restricted under the WHO Model but classified as ‘everyday/sometimes’ by the FBCS system were dairy (34%, of which 62% were cheese and 17% yoghurt and yoghurt drinks), fruit and vegetable products (21%, of which 28% were dried fruit, 26% fruit in juice or syrup and 12% frozen potato products), convenience foods (15%, of which 59% were ready meals) and cereals and cereal products (11%, of which 66% were breakfast cereals) (**Figure 3**).

In total 17% of all New Zealand packaged foods met the criteria for all three nutrient profiling systems and would be eligible to be marketed to children under any selected system. **Table 4** lists the top 10 food cate-

**Table 2:** Classification of New Zealand packaged foods (n=13,066) by each nutrient profiling system.

Food category and key sub-categories		HSR		WHO Model		FBCS		
		<3.5 stars	≥3.5 stars	R	NR	O	E/S	N/A
All foods	13,066	63.7	36.3	70.9	29.1	41.4	39.3	19.2
Bread and bakery products	1,603	73.1	26.9	74.3	25.7	63.6	36.4	0.0
<i>Biscuits</i>	736	88.5	11.5	99.7	0.3	89.1	10.9	0.0
<i>Bread</i>	484	30.6	69.4	15.3	84.7	7.0	93.0	0.0
<i>Cakes, muffins and pastries</i>	383	97.4	2.6	100.0	0.0	85.9	14.1	0.0
Cereal and cereal products	1,264	38.8	61.2	50.4	49.6	34.7	65.3	0.0
<i>Breakfast cereals</i>	358	22.9	77.1	66.5	33.5	24.6	75.4	0.0
<i>Cereal bars</i>	221	80.5	19.5	100.0	0.0	92.8	7.2	0.0
Confectionery	804	89.2	10.8	100.0	0.0	94.7	5.3	0.0
Convenience foods	726	44.2	55.8	66.3	33.7	16.7	83.3	0.0
<i>Pre-prepared salads and sandwiches</i>	51	35.3	64.7	92.2	7.8	11.8	88.2	0.0
<i>Pizza</i>	54	74.1	25.9	100.0	0.0	63.0	37.0	0.0
<i>Ready meals</i>	274	31.0	69.0	97.4	2.6	19.3	80.7	0.0
<i>Soups</i>	330	49.7	50.3	29.1	70.9	3.6	96.4	0.0
Dairy	1,743	67.4	32.6	85.9	14.1	39.3	60.7	0.0
<i>Cheese</i>	600	78.0	22.0	86.7	13.3	0.0	100.0	0.0
<i>Cream</i>	50	98.0	2.0	98.0	2.0	98.0	2.0	0.0
<i>Desserts</i>	172	78.5	21.5	100.0	0.0	65.1	34.9	0.0
<i>Ice cream and edible ices</i>	336	96.7	3.3	100.0	0.0	82.4	17.6	0.0
<i>Milk</i>	293	21.5	78.5	70.3	29.7	59.4	40.6	0.0
<i>Yoghurt and yoghurt drinks</i>	292	46.2	53.8	73.6	26.4	25.0	75.0	0.0
Edible oils and oil emulsions	303	46.9	53.1	20.1	79.9	0.0	0.0	100.0
Eggs	76	0.0	100.0	0.0	100.0	0.0	100.0	0.0
Fish and seafood products	484	18.8	81.2	10.3	89.7	12.0	88.0	0.0
Fruit, vegetables and nut products	1,539	35.7	64.3	62.8	37.2	10.1	68.5	21.4
<i>Fresh packaged fruit and vegetables</i>	51	0.0	100.0	0.0	100.0	0.0	100.0	0.0
<i>Dried fruit</i>	179	56.4	43.6	98.9	1.1	19.0	81.0	0.0
<i>Frozen fruit</i>	40	0.0	100.0	0.0	100.0	0.0	100.0	0.0
<i>Fruit bars</i>	35	42.9	57.1	100.0	0.0	100.0	0.0	0.0
<i>Nuts and seeds</i>	198	41.9	58.1	37.4	62.6	40.4	59.6	0.0
<i>Jam and marmalades</i>	151	96.0	4.0	100.0	0.0	0.0	0.0	100.0
<i>Canned vegetables</i>	263	23.2	76.8	44.1	55.9	0.0	100.0	0.0
<i>Frozen vegetables</i>	120	0.0	100.0	0.8	99.2	0.0	100.0	0.0
<i>Frozen potato products</i>	81	4.9	95.1	79.0	21.0	7.4	92.6	0.0

**Table 2:** Classification of New Zealand packaged foods (n=13,066) by each nutrient profiling system (continued).

Meat and meat products and alternatives	1,069	69.9	30.1	40.3	59.7	69.6	30.4	0.0
<i>Processed meat</i>	1,005	72.5	27.5	37.9	62.1	73.9	26.1	0.0
Non-alcoholic beverages	1,116	74.6	25.4	89.1	10.9	91.1	8.9	0.0
<i>Beverage mixes</i>	69	100.0	0.0	100.0	0.0	100.0	0.0	0.0
<i>Sugar-sweetened cordials</i>	71	98.6	1.4	95.8	4.2*	100.0	0.0	0.0
<i>Sugar-sweetened energy drinks</i>	69	100.0	0.0	100.0	0.0	100.0	0.0	0.0
<i>Fruit and vegetable juices</i>	361	38.2	61.8	100.0	0.0	88.4	11.6	0.0
<i>Sugar-sweetened soft drinks</i>	265	100.0	0.0	98.1	1.9**	100.0	0.0	0.0
<i>Sugar-free soft drinks</i>	54	100.0	0.0	96.3	3.7	90.7	9.3	0.0
<i>Waters, including flavoured</i>	158	63.9	36.1	32.9	67.1	67.1	32.9	0.0
Sauces and spreads	1,765	90.3	9.7	90.0	10.0	0.0	0.0	100.0
Snack foods	373	89.3	10.7	98.1	1.9	97.3	2.7	0.0
Sugars, honey and related products	162	97.5	2.5	100.0	0.0	14.8	15.4	69.8

R: Restricted; NR: Not restricted

O: Occasional foods; E/S: Everyday or Sometimes foods; N/A: Food groups not included in the FBCS system

\*3 blackcurrant fruit juice syrup products

\*\*5 carbonated juice drinks

**Table 3:** Classification of foods under the HSR and FBCS systems compared with WHO Model.

	N	% restricted (WHO)	% not restricted (WHO)
HSR nutrient profiling model			
Foods with HSR <3.5 stars	8,323	87.2	12.8
Foods with HSR ≥3.5 stars	4,743	42.3	57.7
MOH food and beverage classification system			
Occasional foods	5,415	87.9	12.1
Everyday/sometimes foods	5,140	47.3	52.7

gories, representing 79% of all foods meeting the criteria for all three systems.

In total 32% of packaged foods did not meet the criteria for all three systems.

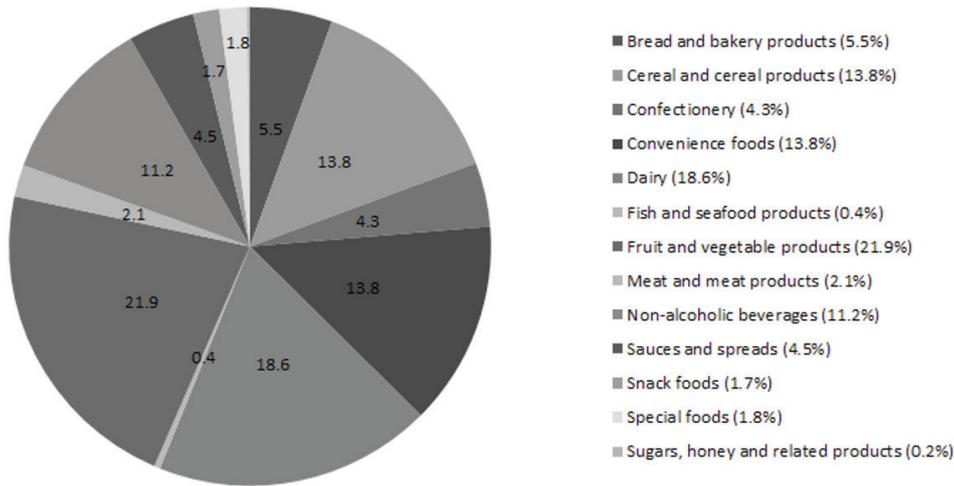
**Table 5** lists the top 10 categories, representing 66% of the foods that did not meet the criteria for any of the three nutrient profiling systems.

## Discussion

Under the three nutrient profiling systems assessed, approximately one-third (29-39%) of New Zealand packaged foods would be permitted to be marketed to children. The WHO Model would permit marketing

of 29% products; the HSR system (using a cut point of 3.5 stars) would permit 36%; and the FBCS system (everyday or sometimes foods only) would permit 39%. Food category differences between three systems were notable however; in particular HSR and FBCS systems would permit marketing of substantially more high-sugar breakfast cereals than the WHO model. HSR would also permit marketing of fruit bars and fruit juices, products largely not permitted by the two other systems. All three systems classified a number of food categories as inappropriate for marketing to children, including biscuits, confectionery, sugar-sweetened drinks and ice cream.

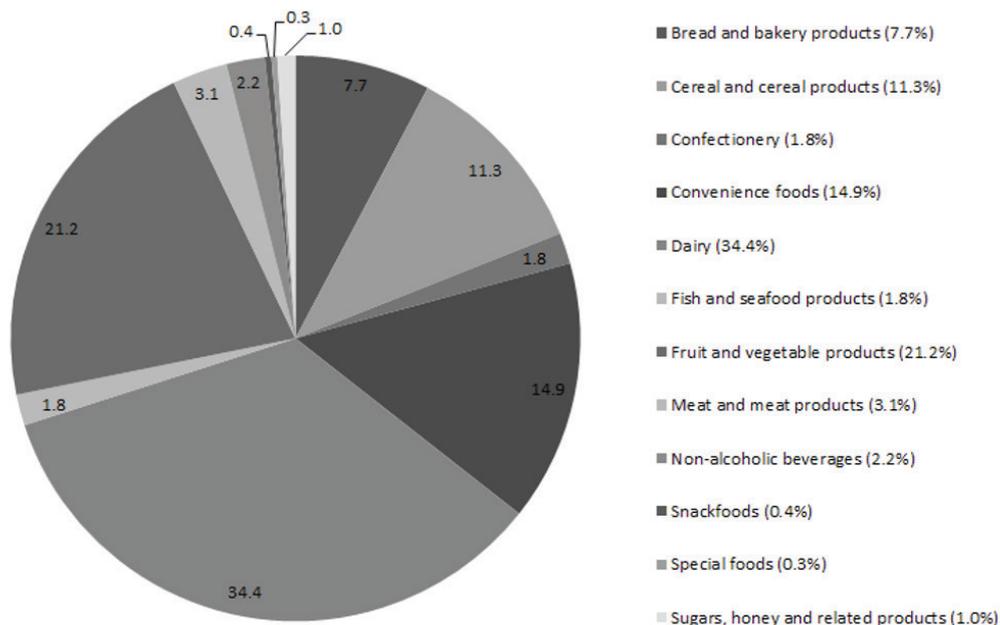
**Figure 2:** Types of products restricted by the WHO Model but receiving a HSR rating of  $\geq 3.5$  stars.



It is to be expected that the three nutrient profiling systems perform differently in some key food categories when they are underpinned by different nutritional criteria. All three systems consider nutrients or components to limit but there are differences in the number and types considered. The WHO Model considers total fat, saturated fat, total sugars, added sugars, non-sugar sweeteners, salt and energy; HSR considers energy, saturated fat, total sugars and sodium; and FBCS considers added fat, added salt and added sugar. The HSR system also takes into account nutrients or

components to promote (protein, fibre, and fruit, vegetable, nut and legume content) and these positive constituents can offset the negative components in the total score. The major food category differences observed between the systems (breakfast cereals, fruit bars, fruit/vegetable juices and dried fruit) appear to be due mainly to the different weighting that each system gives to sugar with HSR in particular and FBCS to a lesser extent, notably more lenient in classifying more high sugar products as eligible/permitted. There were also some notable differences in the convenience

**Figure 3:** Types of products restricted by the WHO Model but classified as everyday or sometimes foods by the FBCS.



**Table 4:** Products permitted under all three systems.

Type of food	N	%
Plain pasta, couscous, quinoa, noodles and rice	328	14.7
Mixed grain, white, wholemeal, flat and other bread	317	14.2
Canned fish and seafood	231	10.3
Fresh packaged and frozen fruit and vegetables	210	9.4
Canned and dried vegetables	176	7.9
Frozen and chilled fish and seafood	111	5.0
Unsalted nuts	98	4.4
Dairy milk, natural and fruit-based yoghurt	91	4.1
Canned and chilled soup	86	3.9
Frozen, canned, sliced and meat	107	4.8

foods and dairy categories with FBCS in particular and HSR to a lesser extent, classifying more products as eligible/permitted compared with the WHO model. This may reflect the FBCS greater emphasis on core food groups than nutritional composition, and the HSR and FBS classifying substantially more desserts, ice creams and yoghurts as eligible/permitted.

Our investigation has several strengths. It is the first to compare two well-known and accepted New Zealand nutrient profiling systems, HSR and FBCS, with an international system, the WHO Europe model that was developed for explicit purpose of restricting marketing to children. More than 13,000 packaged foods available for sale in major New Zealand supermarkets in 2014 were classified using each scheme and compared. Our study therefore provides a

comprehensive assessment of the potential of three nutrient profiling systems to protect New Zealand children from exposure to marketing of unhealthy foods and indicates that the best system for this purpose is the comprehensive WHO Europe model.

Some limitations should be considered. HSR and FBCS were not designed to limit marketing of unhealthy foods to children and are not ideally suited for this purpose. For example, HSR is a front-of-pack nutrition labelling system for packaged foods and has no accepted threshold to dichotomize foods as healthy or unhealthy although analysis suggests 3.5 stars is an appropriate cut point<sup>17</sup> and this threshold is being used to identify healthier packaged food options in the DHB National Healthy Food and Drink Policy. FBCS includes a broader range of food categories but was

**Table 5:** Products not permitted under any of the three systems.

Type of food	N	%
Sweet filled and unfilled, plain dry and savoury biscuits	586	14.1
Chocolate-based confectionery	424	10.2
Sugar-sweetened soft drinks, energy drinks and cordials	418	10.1
Ice cream and edible ices	270	6.5
Sugar-based chocolate and sweets	255	6.1
Potato crisps, pretzels, popcorn, corn chips	211	5.1
Cereal- and nut-based bars, and fruit bars	176	4.2
Cakes	146	3.5
Fruit juice	134	3.2
Pastries	131	3.2

designed for the school setting and classification of foods as “sometimes” foods depends on portion size in many cases and thus can be ambiguous.<sup>3</sup> Nevertheless both systems have been proposed as potential options for limiting the marketing of unhealthy foods to New Zealand children, in the ASA Consultation document itself and in submissions made by a number of bodies. Our analysis is therefore of direct relevance to current consideration of New Zealand marketing standards for children. Further, our database only included packaged foods so we were unable to compare the three nutrient profiling systems for fresh foods, fast foods and mixed dishes. Finally, our analysis could not take into account the frequency with which products in the Nutri-track database are actually marketed to New Zealand children because such data were not available, and some products included in the analysis might never be marketed to children. However, previous research has shown that the most common categories of food products promoted to children internationally are pre-sugared breakfast cereals, soft drinks, savoury snacks, confectionery and fast foods.<sup>3</sup> As such, implementation of any of the three systems examined should significantly limit the marketing of unhealthy foods to New Zealand children. All three prohibit marketing of soft drinks and confectionery, for example. The WHO system would also impose limits on types of breakfast cereals, savoury snacks and fast foods that could be marketed to children.

A limited number of other studies have compared nutrient profiling systems for restricting the marketing of foods and drinks to children. Brinsden and Lobstein compared two industry-led nutrient profiling schemes with three government-led schemes and found that government-led schemes were more restrictive than industry-led schemes, primarily due to more stringent sugar criteria.<sup>23</sup> The two industry-led schemes examined would permit 49% and 41% of products analysed to be advertised, compared with 37% under the UK Ofcom regulations, 14% under the US Interagency Working Group Proposals and 7% under the Danish Forum co-regulatory code.<sup>23</sup>

In 2013, Rayner et al provided an overview of some nutrient profiling models currently used or designed for regulation of the advertising of foods to children.<sup>24</sup> The 10 models summarised encompassed both industry pledges and government-led schemes, and emanated from a range of countries including Brazil, Denmark, Korea and the US. The authors highlight that the proliferation of nutrient models means that there is less of a need to develop models from scratch and that for the purposes of regulating marketing of foods to children it may be possible to adapt a model developed for a completely different application such as food labelling.<sup>24</sup>

Since publication in 2015, the WHO Model has stimulated debate and policy development in a number of European countries. In some countries exploring regulations (eg new broadcast advertising restrictions), the WHO Model has been used in national monitoring exercises to compare against existing industry voluntary pledges (eg Malta). Other countries, such as Turkey and Slovenia, have incorporated the WHO Model into national regulatory advertising codes with only minor adaptation. Most recently, Portugal in its new amendments to marketing legislation, made explicit reference to the WHO Model nutritional criteria.

We selected the HSR and FBCS nutrient profiling systems for comparison with the WHO Model because they are currently in use in New Zealand by various sectors of the food industry and have been suggested as potentially appropriate to classify foods as suitable/unsuitable for marketing to children. However, there are other nutrient profiling systems that also bear consideration including the Fuelled4Life school food classification system, which is based on FBCS but has adopted additional criteria to distinguish occasional, sometimes and everyday foods.<sup>19</sup> A disadvantage of the Fuelled4Life system in terms of its suitability for adaptation for marketing however is that it relies on serving size restrictions to distinguish between occasional, everyday and sometimes foods in some categories.

Another nutrient profiling system currently in use in the region that could be potentially adapted to limit children's exposure to unhealthy food marketing is

the Food Standards Australia New Zealand Nutrient Profiling Scoring Criterion (NPSC) system used to determine the eligibility of foods to carry health claims.<sup>25</sup> The NPSC system was based on the UK Ofcom model used to differentiate foods on the basis of their nutritional composition in the context of television advertising of foods to children. It also formed the basis for the HSR system but differs from HSR in using cut points to dichotomise foods as eligible or not eligible to carry health claims. A previous analysis of New Zealand packaged foods reported that 41% were eligible to carry health claims based on their NPSC categorization.<sup>26</sup> This suggests that the NPSC would be even more lenient than HSR or FBCS and thus unlikely to be an appropriate classification system in its current form for limiting marketing of unhealthy foods to children.

Our findings have important implications for the ASA review of its Children's Codes and the New Zealand Childhood Obesity Plan. Existing nutrient profiling systems need to be utilised or adapted to limit New Zealand children's exposure to marketing of unhealthy foods. The three systems we evaluated classified just 29% to 39% of New Zealand packaged foods as eligible

for marketing to children. Use of any of the three systems would provide an objective, evidence-based classification system to identify foods suitable for marketing to children. Our analysis demonstrates clearly however that the WHO Model is the most robust system because it restricts marketing of unhealthy foods more effectively than the other two systems evaluated. The HSR and FBCS systems would permit marketing of a number of food products of concern, particularly high-sugar breakfast cereals, fruit juices and ready meals.

Based on the findings of our analysis, we recommend that the WHO Regional Office for Europe Nutrient Profiling Model be used as the nutrient profiling system to underpin the new ASA Children's Code for Advertising Food. Given the recognised weak nutritional standards employed by industry for defining healthy foods and because many child-oriented food marketers do not participate in self-regulation,<sup>27</sup> the new Children's Code for Advertising Food should be subject to evaluation by an independent body. If the revised voluntary code still proves ineffective in reducing New Zealand children's exposure to the marketing of unhealthy foods and drinks, additional policy and regulatory actions will be necessary.

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# What's new with the flu? Reflections regarding the management and prevention of influenza from the 2<sup>nd</sup> New Zealand Influenza Symposium, November 2015

Nadia A Charania, Osman D Mansoor, Diana Murfitt, Nikki M Turner

## ABSTRACT

Influenza is a common respiratory viral infection. Seasonal outbreaks of influenza cause substantial morbidity and mortality that burdens healthcare services every year. The influenza virus constantly evolves by antigenic drift and occasionally by antigenic shift, making this disease particularly challenging to manage and prevent. As influenza viruses cause seasonal outbreaks and also have the ability to cause pandemics leading to widespread social and economic losses, focused discussions on improving management and prevention efforts is warranted.

The Immunisation Advisory Centre (IMAC) hosted the 2<sup>nd</sup> New Zealand Influenza Symposium (NZIS) in November 2015. International and national participants discussed current issues in influenza management and prevention. Experts in the field presented data from recent studies and discussed the ecology of influenza viruses, epidemiology of influenza, methods of prevention and minimisation, and experiences from the 2015 seasonal influenza immunisation campaign. The symposium concluded that although much progress in this field has been made, many areas for future research remain.

## Background

This paper presents a synopsis of the 2<sup>nd</sup> New Zealand Influenza Symposium (NZIS) that was hosted by the Immunisation Advisory Centre (IMAC) in November 2015. IMAC is a national organisation based at the School of Population Health at The University of Auckland. IMAC researches aspects of vaccines and vaccine-preventable diseases and is contracted by the Ministry of Health to provide immunisation technical advice and support, health professional training and input into policy development. The 2<sup>nd</sup> NZIS brought together national and international experts and service providers with the aim of improving the management and prevention of influenza. Building upon the inaugural symposium in 2014,<sup>1</sup> the topics discussed included: the ecology of influenza viruses, disease burden of

influenza, methods to minimise influenza transmission, effectiveness of influenza vaccines and experiences from the 2015 seasonal influenza immunisation campaign and local healthcare service providers.

## Ecology of influenza viruses and the impact on humans

Influenza is a contagious respiratory illness caused by influenza viruses, of which there are three types (ie influenza A, B and C) that all belong to the *Orthomyxoviridae* family.<sup>2</sup> Influenza A viruses are comprised of eight separate strands of ribonucleic acid (RNA) that contain their genetic information and high mutation rates while replicating can lead to the creation of novel viruses.<sup>3,4</sup> Influenza viruses constantly evolve via antigenic drift and occasionally via antigenic shift enabling these viruses to evade host immune memory from the

last influenza infection by creating variants with different antigenic composition.<sup>5</sup> These constantly changing viruses require surveillance to identify predominant circulating strains and make recommendations for annual vaccine formulation and pandemic preparation. Many novel type A viruses are currently circulating with pandemic potential, including highly pathogenic avian influenza (HPAI) H5N1 and H7N9 subtypes.<sup>6</sup>

Wild aquatic birds are the natural hosts of all known influenza A virus subtypes although influenza viruses have adapted to infect many species including humans, pigs and other animals.<sup>7</sup> Most avian influenza viruses (AIVs) have generally remained stable and are usually non-pathogenic to birds.<sup>8,9</sup> Varying prevalence rates and wide genetic diversity of influenza virus subtypes have been found among animal and environmental reservoirs worldwide.<sup>10,11</sup> Despite the abundance and diversity of AIVs, these viruses are generally inefficient in infecting humans.<sup>8</sup> Moreover, many different management interventions appear to aid in reducing the risk of zoonotic infections in identified hot spots; for instance, implementing market rest days, banning overnight markets and separating species in live poultry markets in Asia.<sup>12,13</sup>

However, it is important to note that AIVs have successfully crossed the species barrier to infect humans and cause disease outbreaks.<sup>14,15</sup> Most notably, hybrid viruses containing portions of animal viruses have caused the past four influenza pandemics.<sup>16,17</sup> Thus, continual and coordinated surveillance and management efforts are required to detect and prepare for potential pandemic threats. Evaluative tools, like the influenza risk assessment tool (IRAT) and efforts of the FLURISK Consortium play important roles in helping prioritise efforts towards those influenza viruses currently circulating in animals with the greatest potential pandemic risk.<sup>18,19</sup>

### Influenza epidemiology globally and in New Zealand

Influenza spreads from close personal contact between humans via infectious respiratory droplets and by touching infected surfaces.<sup>20</sup> Infection with influenza viruses can cause asymptomatic, mild or severe illness in humans and the main

burden arises from the secondary complications of infection. Influenza type A and B viruses cause seasonal epidemics estimated to cause 250,000 to 500,000 deaths per year worldwide.<sup>20</sup> While most of those infected will experience common signs and symptoms (eg high fever, cough, myalgia and sore throat), some may experience more severe complications particularly young children, the elderly and those with chronic medical conditions.<sup>20</sup> Recent literature has noted an increased risk of influenza-associated deaths among adults with certain medical conditions, such as acquired immunodeficiency syndrome (AIDS) and pulmonary tuberculosis (PTB), highlighting the importance of prioritizing at-risk groups for influenza vaccination.<sup>21,22</sup>

In New Zealand, seasonal influenza is not a notifiable condition and influenza surveillance comprises of sentinel general practice surveillance and non-sentinel laboratory-based surveillance. Since 2012, the sentinel influenza surveillance network has been enhanced by the additional surveillance capabilities of the Southern Hemisphere Influenza Vaccine Effectiveness Research and Surveillance (SHIVERS) project (2012–2016), enabling the collection of robust data to better understand the national disease burden of influenza. Data collected from the 2015 winter season showed that influenza-like illness (ILI) consultation rates were within the normal activity range with most infections due to A(H3N2) viruses for the majority of the season until type B strains (B/Victoria and B/Yamagata) predominated in the later portion.<sup>23</sup> Identified risk factors for severe influenza included a range of host, socio-economic, healthcare, environmental and behavioural factors.<sup>24</sup> The importance of demographic and socio-economic risk factors were highlighted as the disease burden is consistently highest among young children, the elderly, those of Māori and Pacific peoples ethnicity and those living in socio-economically deprived areas.<sup>23,25</sup> In addition, the higher risk of getting influenza among pregnant women was noted; between 2012 and 2014, cumulative incidence data reveals that pregnant women were 4.88 times (95% confidence interval [CI] 3.14–7.36) more likely to get influenza compared to non-pregnant women.<sup>23</sup>

## Prevention and minimisation of influenza

Non-pharmaceutical (eg isolation, quarantine) and pharmaceutical (eg vaccine, antiviral drugs) interventions can mitigate the effects of influenza outbreaks.<sup>26</sup> Several non-pharmaceutical interventions limit the spread of influenza and are commonly recommended. Some measures, such as respiratory and hand hygiene, are effective in reducing influenza transmission<sup>27,28</sup> and are viewed as acceptable, familiar and socially responsible methods.<sup>29</sup> The effectiveness of mask wearing has been highlighted, as a recent study reported that surgical face-masks worn by influenza-infected patients resulted in an overall 3.4 fold (95% CI 1.8–6.3) decrease in viral aerosol shedding.<sup>30</sup>

The best way to prevent seasonal influenza is annual influenza vaccination with an inactivated influenza vaccine (IIV) or a live attenuated influenza vaccine (LAIV), although it is noted that LAIVs are not yet licensed or available in New Zealand. Much research is being dedicated towards estimating vaccine effectiveness (VE) to evaluate the public health benefit of immunisation campaigns and accuracy of vaccine strain selection. Recent research has indicated that the level of protection offered by IIVs used in seasonal influenza vaccination campaigns varies each year and by age group, but generally offers a moderate level of protection for most people.<sup>31,32</sup>

Starting in 2012 in New Zealand, the SHIVERS project has provided robust and timely estimations of VE of the trivalent IIV and the protection offered in community and hospital settings using a test negative study design.<sup>33–35</sup> Most recently, during the 2014 influenza season, VE was 42% (95% CI 16%–60%) for preventing laboratory-confirmed influenza hospitalisations and 56% (95% CI 35%–70%) against influenza cases among general practice patients in the community.<sup>35</sup> In contrast to New Zealand data, studies from the northern hemisphere reported suboptimal overall VE of the 2014/2015 seasonal influenza vaccine due to a poorly matched A(H3N2) component of the vaccine.<sup>36,37</sup> One study reported that low VE levels were linked to mutations in the egg-adapted A(H3N2) vaccine strain introduced during the manufacturing process instead of due to antigenic drift of

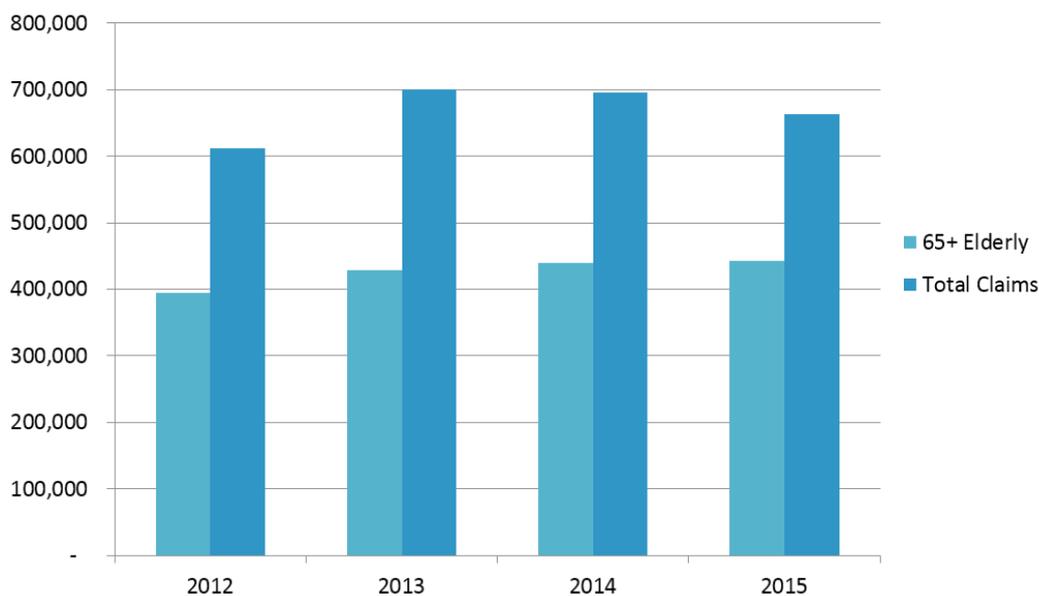
the circulating virus.<sup>38</sup> Despite offering only moderate levels of protection, vaccination still prevents influenza-related illness and complications (eg hospitalisation, death) and is recommended for all of those who do not have a contraindication.<sup>39</sup>

Literature has generally reported LAIVs to have similar or superior vaccine efficacy and effectiveness in children compared to that of IIVs, which supports the long-standing recommendation of LAIVs for this age group.<sup>31,32,40</sup> However, two recent studies revealed that the quadrivalent LAIV was not effective against the 2009 pandemic influenza A(H1N1) virus (A[H1N1]pdm09) while the trivalent/quadrivalent IIV was effective among children aged 2–17 years old during the 2013/2014 season in the US.<sup>41,42</sup> The ineffectiveness of the LAIV against the A(H1N1)pdm09 strain in children underscores the need for constant monitoring to ensure the most appropriate type of vaccine is recommended to provide optimal protection.<sup>41</sup>

## Influenza immunisation programme and service delivery in New Zealand

In 2015, the Ministry of Health's (MOH) seasonal influenza immunisation campaign achieved its target of distributing 1.2 million doses, despite experiencing a late start to the programme. Delays in vaccine availability occurred as a result of adding two new strains to the vaccine.<sup>43</sup> Particularly important was the addition of a new A(H3N2) strain as it was noted that A(H3N2) had been responsible for significant disease burden in the older age groups.<sup>23</sup> Pertaining to specific programme goals, provisional data on the funded influenza vaccines given to those aged 65 years and older indicates a steady increase in coverage since 2012, although room for improvement remains (Figure 1).<sup>43</sup> Furthermore, progress was made in terms of improving immunisation coverage for healthcare workers (HCWs) (Figure 2).<sup>43</sup> The role of pharmacists in the seasonal influenza immunisation campaign was also highlighted as a recent reclassification now allows pharmacists to administer the non-funded influenza vaccine.<sup>44</sup> The MOH continues to work on enabling pharmacist vaccinators to record immunisations on the National Immunisation Register (NIR).

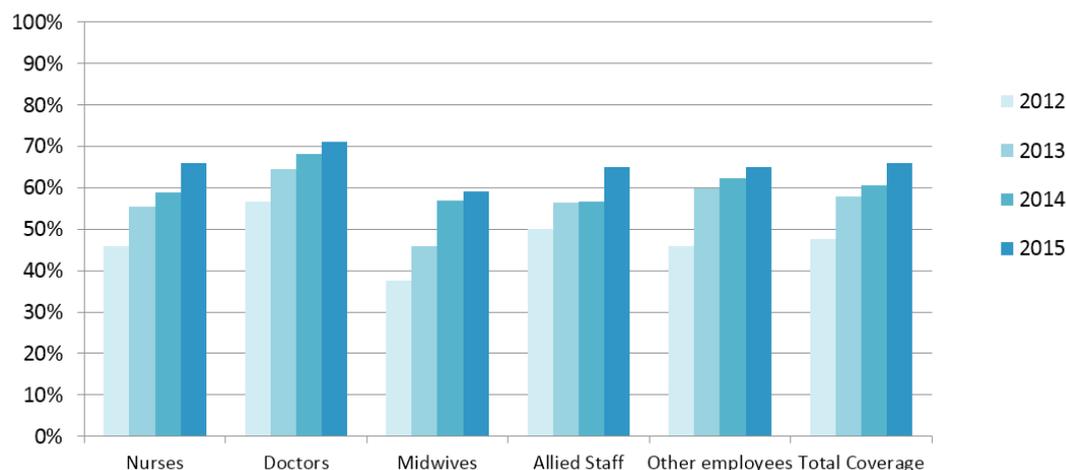
**Figure 1:** Immunisation benefit claims for funded influenza vaccines among the elderly (65 years and older) in New Zealand, 2012–2015 (provisional data, 11 November 2015).



In 2015, a new multifaceted ‘blue dust’ promotional campaign was introduced to raise public awareness about influenza and the influenza vaccine.<sup>45</sup> Evaluation of the promotional campaign revealed that the campaign reached 50% of people eligible for the funded vaccination, 41% of the elderly and 80% of pregnant women.<sup>45</sup> The most commonly reported motivators to immunise were the perceived severity and susceptibility of influenza, social concern of preventing influenza transmission and being offered the funded vaccine.<sup>45</sup> On the other hand, commonly reported barriers included needle phobia, concern of side effects and preference of building natural immunity.<sup>45</sup> Results highlighted the critical role HCWs play in recommending influenza vaccinations and the need for high-risk groups in particular (eg the elderly and pregnant women) to understand the associated benefits and risks of vaccination.

During the influenza season, a range of strategies were used to control and manage the spread of influenza at the local level. To provide a service delivery perspective on the influenza programme in 2015, healthcare planners and providers shared their experiences and lessons learnt. In addition to experiencing challenges due to delays in vaccine availability and extending the immunisation programme dates, issues related to the different types of vaccine offered in the funded programme compared with those available for private purchase were reported; in particular some people were requesting the quadrivalent IIV when only the trivalent one was available as part of the funded programme.<sup>46</sup> Methods used to improve immunisation coverage rates included offering specific immunisation clinics, extended hours, opportunistic vaccinations, and off-site vaccinations (eg residential, home and workplace visits).<sup>46,47</sup>

**Figure 2:** Influenza immunisation coverage for District Health Board healthcare workers in New Zealand, 2012–2015.



In preparation for the 2016 influenza season, the need for a team-based approach in planning, improved immunisation education, better reporting and rapid point-of-care testing were noted.<sup>46,48</sup>

The international debate about whether seasonal influenza vaccination should be mandatory for HCWs was raised. Outbreaks of nosocomial (hospital-acquired) influenza can lead to severe morbidity and mortality and HCWs are at an increased risk of acquiring influenza and subsequently transmitting the disease to vulnerable patients.<sup>49,50</sup> Increased vaccination of HCWs has been shown to reduce patient mortality rates.<sup>51-53</sup> All District Health Boards (DHB) in New Zealand offer funded voluntary influenza vaccination to their staff. In 2015, Waikato District Health Board (WDHB) became the first DHB in New Zealand to implement a 'Vaccinations for Health Care Workers' policy. The policy aimed to increase seasonal immunisation coverage rates among HCWs and reduce influenza transmission in healthcare settings. Similar to a policy introduced in British Columbia, Canada,<sup>54</sup> it required that employed HCWs receive the season influenza vaccination or don a mask while at work until the end of the season. The CEO of the WDHB reported that the programme was generally successful with 81% of HCWs receiving the vaccination and only 3% claiming medical or religious exemptions, despite some resistance from unions and a few staff members.

## Conclusion and recommendations for future work

Overall, the NZiS 2015 concluded that much progress has been made regarding the management and prevention of influenza although many unanswered questions remain. The key areas discussed and recommendations for future work related to research, strategic planning and service delivery are summarised in Table 1.

As many viruses pose a potential pandemic threat, it is important that continued effort is directed towards influenza surveillance and identifying effective management interventions to reduce the incidence of zoonotic infections globally. In New Zealand, the SHIVERS project has established robust surveillance capabilities and identified groups that experience a higher disease burden. Future research should be directed towards reducing these identified inequities based on age, ethnicity and socio-economic deprivation. Moreover, research is needed to improve the vaccine effectiveness of influenza vaccinations and better understand what type of vaccine is best suited for particular age groups. To improve vaccination coverage rates, shared experiences indicated that future campaigns should consider extending the programme dates and improving educational efforts. There also appears to be growing interest for strengthening policies related to influenza vaccination of HCWs.

**Table 1:** Summary of key issues and suggested areas for future work identified by participants attending the 2<sup>nd</sup> New Zealand Influenza Symposium, November 2015.

Ecology of influenza viruses	<ul style="list-style-type: none"> <li>• Surveillance of avian influenza viruses with pandemic potential</li> <li>• Identification of effective management interventions to reduce influenza transmission from animal sources to humans</li> </ul>
Influenza epidemiology	<ul style="list-style-type: none"> <li>• Surveillance of circulating influenza viruses</li> <li>• Reduce inequities of influenza disease burden</li> <li>• Understand the extent and implications of asymptomatic influenza</li> </ul>
Influenza vaccines	<ul style="list-style-type: none"> <li>• Improve vaccine effectiveness and level of protection of influenza vaccine</li> <li>• Improve A(H3N2) vaccine component and manufacturing process</li> <li>• Understand effectiveness of LAIV versus IIV in young children (in particular for protection against A[H1N1]pdm09 strain)</li> <li>• Value of trivalent versus quadrivalent IIV</li> <li>• Public's perception of trivalent versus quadrivalent IIV</li> <li>• Understand intra-seasonal waning immunity</li> <li>• Understand the impact of repeat immunisations (improves overall protection or not)</li> </ul>
National influenza immunisation programme	<ul style="list-style-type: none"> <li>• Methods to reach people eligible for funded vaccines to improve vaccination coverage rates (focus on identified motivators and barriers to immunise)</li> <li>• Improve vaccination rates of the elderly population and pregnant women (need to target educational efforts to understand risks and benefits)</li> <li>• Explore ways to better utilise pharmacist vaccinators</li> </ul>
Healthcare service delivery	<ul style="list-style-type: none"> <li>• Explore evidence to support the implementation of mandatory seasonal vaccination or mask policy for HCWs</li> <li>• Improve influenza vaccine service delivery by allowing registered nurses to vaccinate without a prescription or a standing order (similar to pharmacist vaccinators)</li> </ul>

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The Immunisation Advisory Centre and Regional Public Health are funded by the Ministry of Health to promote the delivery and uptake of influenza immunisation as part of the national immunisation programme. Dr Mansoor reports my current employer, RPH is funded to promote influenza vaccine. I have undertaken work on maternal influenza immunization or WHO. Dr Turner reports other from SHIVERS study: CDC funded, outside the submitted work.

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# Improved compliance with the World Health Organization Surgical Safety Checklist is associated with reduced surgical specimen labelling errors

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## ABSTRACT

**Aims:** A new approach to administering the surgical safety checklist (SSC) at our institution using wall-mounted charts for each SSC domain coupled with migrated leadership among operating room (OR) sub-teams, led to improved compliance with the Sign Out domain. Since surgical specimens are reviewed at Sign Out, we aimed to quantify any related change in surgical specimen labelling errors.

**Methods:** Prospectively maintained error logs for surgical specimens sent to pathology were examined for the six months before and after introduction of the new SSC administration paradigm. We recorded errors made in the labelling or completion of the specimen pot and on the specimen laboratory request form. Total error rates were calculated from the number of errors divided by total number of specimens. Rates from the two periods were compared using a chi square test.

**Results:** There were 19 errors in 4,760 specimens (rate 3.99/1,000) and eight errors in 5,065 specimens (rate 1.58/1,000) before and after the change in SSC administration paradigm ( $P=0.0225$ ).

**Conclusions:** Improved compliance with administering the Sign Out domain of the SSC can reduce surgical specimen errors. This finding provides further evidence that OR teams should optimise compliance with the SSC.

The World Health Organization (WHO) introduced the Surgical Safety Checklist (SSC) with the intent of improving communication and preventing errors or omissions in the operating room (OR).<sup>1</sup> The SSC is composed of three domains: 'Sign In' (administered when the patient arrives in the OR); 'Time Out' (administered immediately prior to the first incision); and 'Sign Out' (administered before the patient leaves the OR). In the most common administration paradigm the SSC is initiated and administered by the OR circulating nurse reading from a paper copy of the checklist.

Adoption of the SSC has been shown to reduce surgical complications and mortality.<sup>2</sup> Perhaps not surprisingly there

is accumulating evidence that better compliance with the administration of the SSC items is associated with a greater likelihood of improved patient outcomes.<sup>3-6</sup> With the aim of increasing compliance and engagement with the SSC in our institution we eliminated the paper SSC and developed large posters (one for each domain) to display our adapted version of the SSC on the OR wall. In addition, we allocated responsibility for leadership of each domain to the OR sub-team most central to the processes occurring at the time; thus, the Sign In, Time Out and Sign Out domains were led by anaesthesia, surgery and nursing respectively. This paradigm change has resulted in many significant improve-

ments in compliance and engagement of OR sub-teams in SSC administration including vastly improved compliance with administering the SSC Sign Out domain (from 22% to 84% of cases).<sup>7</sup>

One of the SSC items administered in the Sign Out domain requires a review of any surgical specimens and their labelling (the words are “specimen description, quantity and patient identification correct”). We therefore hypothesised that improved compliance with the Sign Out phase of the checklist would reduce errors in the labeling of specimens, and undertook an evaluation of specimen labelling errors before and after the roll-out of the new SSC administration paradigm to investigate whether the improved compliance with Sign Out was associated with error reduction.

## Methods

This retrospective audit was approved by the Auckland District Health Board (ADHB) Research office (Reference: A+ 7093). The SSC administration paradigm change was sequentially rolled out across five OR suites (A-E, see Table 1) within the ADHB, a large tertiary health service provider for the greater Auckland region. The roll-out process is described in more detail elsewhere.<sup>7</sup> OR staff were not made aware of plans to audit specimen labelling errors after roll-out of the new checklist administration paradigm. Specimen labelling error data were collected for each OR suite over a six month period prior to, and a six month period after each suite’s SSC administration paradigm change date (Table 1).

## Data collection

In the OR, each surgical specimen is placed in a specimen pot and labelled with patient identifying details and specimen details. A specimen analysis request form is also completed, which includes patient, specimen and laboratory analysis details. This is performed by one of the OR team members, usually a nurse. Confirmation of completion and details of the specimen pot and labelling is supposed to occur as part of the Sign Out domain, before the specimen is sent to the laboratory for analysis.

We defined a specimen labelling error as any error in the labelling or completion of the specimen pot or the specimen laboratory request form identified by the laboratory after receipt of the specimen. These errors were prospectively recorded on specimen labelling error forms by laboratory staff who followed up with the OR team to clarify details and/or anomalies. For each suite we identified specimen labelling error forms that pre-dated and post-dated that suite’s roll-out date for the new SSC administration paradigm for up to six months.

This prospectively maintained file of specimen labelling error forms was the source of all data. We included only the specimen labelling errors occurring in the five OR suites. Any errors occurring in a clinic or ward environment where the SSC was not a mandated part of standard practice were excluded. In addition, OR specimens that were sent to the laboratory prior to the completion of Sign Out (such as frozen sections) were excluded. The total number of relevant specimens received by the laboratory from the five OR suites

**Table 1:** OR suites in the ADHB health service included in the current audit.

OR suite	Number of ORs	Surgical specialties	Date of SSC paradigm change
A	13	general, orthopaedics, vascular , urology, neurosurgery	24/11/2014
B	7	paediatric surgery	27/1/2015
C	7	cardiothoracic surgery, otorhinolaryngology	9/2/2015
D	4	obstetrics and gynaecology	10/3/2015
E	8	Day stay unit for general surgery, oral health, otorhinolaryngology, gynaecology, urology, orthopaedics, ophthalmology	16/3/2015

**Table 2:** Rates of specimen labelling errors for all OR suites for the 12 month study period (All errors), then separated into the six month periods before (PRE) and after (POST) the SSC paradigm change. Rates are per 1,000 cases. Raw error numbers are also given in brackets.

Error type	All errors N=27	PRE N=19	POST N=8
Specimen—incorrect patient identifying details	0.712 (7)	1.050 (5)	0.395 (2)
Specimen—no patient identifying details	1.120 (11)	1.682 (8)	0.592 (3)
Specimen form—no patient identifying details	0.712 (7)	0.840 (4)	0.592 (3)
Specimen form—incorrect completion	0.102 (1)	0.210 (1)	0 (0)
Specimen—empty specimen pot	0.102 (1)	0.210 (1)	0 (0)

during the study period was obtained from the clinical records department of the laboratory.

### Statistical analysis

The primary endpoint was a comparison of the rate of specimen labelling errors for the periods before and after the introduction of the new SSC administration paradigm. Error rates were calculated as the number of specimen labelling errors divided by the total number of specimens received by the laboratory in each of the six month study periods, and were reported as errors per 1,000 specimens. Rates were compared using the Chi-square test, or Fisher's exact test where rates were low. A p-value  $\leq 0.05$  was considered statistically significant. Analyses were conducted using IBM SPSS version-22.

## Results

A total of 9,825 specimens was received by the laboratory from the ORs in the full 12-month period: 4,760 of these were in the six-month period preceding the SSC paradigm change (PRE-period), and 5,065 were in the six-month period after SSC paradigm change (POST-period).

A total of 27 specimen labelling errors was recorded over the 12-month period, giving a total error rate of 0.275% (2.75 errors per 1,000 specimens). There were 19 specimen labelling errors in the PRE-period, giving an error rate of 0.399% (3.99 errors per 1,000 specimens). There were eight specimen labelling errors in the POST-period, giving an error rate of 0.158% (1.58 errors per 1,000 specimens). The difference between the error rates in the PRE and POST-periods was statistically significant ( $p=0.0225$ ). The sub-types of specimen labelling errors recorded during the study period, along with error distri-

bution in the PRE and POST periods, are reported in Table 2.

## Conclusions

A modified SSC administration paradigm in which the checklist appears on large wall-mounted posters, and where leadership of each domain is allocated to a different OR sub-team has been introduced to our institution. A recently published study undertaken in one of the five OR suites (Suite A in Table 1) demonstrated that this initiative resulted in dramatic improvements in compliance and engagement in checklist administration.<sup>7</sup> One of the notable improvements was an increase in the frequency of administration of the Sign Out domain (from 22% to 84% of cases). That study did not, however, measure patient outcomes or other indicators of patient safety that might be influenced by the improvement in SSC compliance.

In the present study we found that the rate of surgical specimen labelling errors more than halved in the six months following introduction of the new SSC administration paradigm. Although we cannot definitively attribute this error reduction to the change in SSC paradigm, the related improvement in compliance with administration of the Sign Out domain does provide a compelling explanation. Sign Out contains a checklist item which requires explicit review of the number, nature and labelling of specimens. The fact that this is now administered in the vast majority of cases as opposed to the vast minority likely underpins the reduction in errors, especially as there were no other process interventions or educational initiatives over the same period that might account for or have contributed to the change.

This is an important finding for several reasons. First, specimen labelling errors may have serious consequences in the provision of medical and surgical care, having the potential to delay, impede and/or misdirect management options.<sup>8</sup> Minimising these errors is clearly desirable and their rate is an important quality measure in patient safety.<sup>9</sup> Complying with the Sign Out domain of the SSC is a simple, cheap intervention that, on the basis of these findings, may have significant impact on this quality measure. Second, if we accept that improved compliance with Sign Out was the explanation for the reduction in specimen errors, this study lends further weight to the assertion that adopting a checklist “in name” is not sufficient to reap its potential benefits. The checklist actually has to be used; ideally with all OR staff paying full attention to the process. This point was emphasized in a recent editorial which stated: “The obvious point here is that checklists do not work by themselves: they must be used, and used in an engaged fashion with the mind focused on the issues at hand”.<sup>10</sup>

There are several limitations of this study that must be acknowledged.

First, we did not conduct a parallel evaluation of a control hospital or group of OR suites where the checklist paradigm changes did not occur. This could have provided some reassurance that the observed reduction in specimen labelling errors in our suites after converting to the new paradigm was not due to some other unanticipated factor. Nevertheless, we believe that the association between a dramatic improvement in compliance with sign out under the new paradigm and a concomitant reduction in specimen labelling error rates is plausibly explained by the prescription of a specimen check during Sign Out.

Second, the number of specimen errors was relatively small. Nevertheless, the rates are congruent with those reported from other institutions,<sup>11</sup> and the denominator is large.

Third, the data demonstrating improvement in Sign Out compliance after introduction of the new SSC administration paradigm published by Ong et al<sup>7</sup> came from one (albeit the largest) of the five OR suites that contributed data to the present

study. We therefore cannot be certain that the improvement in compliance with Sign Out was equivalent across all suites. It may not have been as substantial in other suites, but equally, it may have been even greater; anecdotally, Sign Out was virtually never done in several locations before the paradigm change. Thus it seems very likely that there was an improvement in other suites similar to that demonstrated in Suite A (Table 1); especially given that the change to SSC practice was rolled out in a standardised fashion across all suites.

Fourth, we have assumed that all specimen labelling errors are both detected and reported. This assumption may not be valid, but any inaccuracy in this regard would probably be equally distributed across the two periods examined.

Fifth, our audit methodology was not capable of capturing all errors relating to specimen labelling that might have been affected by improved Sign Out compliance. For example, errors relating to the description of a specimen detected at Sign Out and corrected before despatch of the specimen to the laboratory would not be captured. It follows that the beneficial effect of the SSC on this quality measure may be greater than we have demonstrated here.

A final point which is an observation rather than a limitation is that we did not attempt to subdivide the individual errors according to the risk they represented to the involved patients. To do so would have divided the numerator into sizes too small to be meaningful, and would have substantially missed the point; all of these errors are indicative of an imperfect process that could ultimately result in patient harm given the right circumstances. Prevention of even minor errors will almost certainly result in a milieu in which major errors are also less likely.

We conclude, therefore, that an improvement in compliance with the Sign Out domain of the WHO SSC was associated with a significant reduction of specimen labelling errors in our hospital. These findings lend weight to the Health Quality and Safety Commission’s current advocacy for adoption of the SSC administration paradigm described by Ong et al<sup>7</sup> by all New Zealand District Health Boards.

**Competing interests:**

Dr Merry reports that he is Chair of Board of Health Quality and Safety Commission in New Zealand.

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# The uses of mental health telephone counselling services for Chinese speaking people in New Zealand: demographics, presenting problems, outcome and evaluation of the calls

Christine Yang Dong

## ABSTRACT

**Aim:** This study aimed to investigate the call profiles of a Chinese-speaking mental health counselling helpline service in New Zealand (Chinese Lifeline provided by Lifeline Aotearoa) and to evaluate the calls and explore the possible factors influencing the outcome of the calls.

**Method:** A random sample of 151 answered calls was involved. Descriptive analysis with appropriate statistical tests was used to analyse the client profile and outcome data.

**Results:** The majority of the calls were made by female callers, aged between 21–60 both single and married. Top three presenting problems were: 1) mental health issues (82.1%); 2) family/partner relationship issues (47.0%) and 3) communication and related difficulties (45.0%). The majority of the calls (65%) ended after a clear decision in overcoming the issues made by the caller, with the help from the counsellor. Discussing mental health issues, grief and loss issues, and communication and related difficulties were shown to have influenced length of calls ( $p < 0.05$ ). Caller's age, frequency of calls, discussing relationship problems with family/partner, and physical problems were shown to have influenced the helpline counsellors' satisfaction of the helpfulness of the calls ( $p < 0.05$ ).

**Conclusion:** The service receives calls from callers with a wide range of demographics and a large variety of presenting issues. This study identified several important factors which influenced counsellors' satisfaction of the calls and the length of the calls.

In New Zealand, the Chinese population is on a constant increase. In the recent census in 2013, it was shown that Chinese people make up 3.8% of all New Zealand residents; the largest sub-ethnic group within the Asian ethnic group ('Asian' as defined by Statistics New Zealand in 1996.) in New Zealand.<sup>1</sup> Additionally, if we take into account the Chinese people who live in New Zealand without permanent residency (eg, international students), then the Chinese

population or the Chinese speaking population would be even larger.

As Ho et al<sup>2</sup> pointed out, previous research findings have suggested that the mental health level among Asians does not differ significantly from those of the general population; there was also evidence of high rates of depression among Chinese older migrants. Furthermore, new or second generation Chinese migrants may face more emotional stresses and issues compared

to local people, such as issues related to cultural differences, language and communication issues, unemployment, traumatic experiences prior to migration, migration expectations not being met and regrets about coming to New Zealand.<sup>2,3</sup>

Since its establishment in 1993, Chinese Lifeline has provided confidential helpline services to people who would like to talk through their issues in Mandarin or Cantonese. The service has around 50–60 Chinese volunteer helpline counsellors. All of the counsellors need to have a counselling or related qualification or studying toward a degree in this area when they apply for the roles. When they are accepted, a six-week well-designed training program would be provided by Lifeline. It has several unique strengths compared to other mental health/emotional health services such as no language barriers and no cultural differences between the provider and the client.

Internationally, although there are a number of research studies in the field of Asian mental health issues, as Kumar et al<sup>4</sup> pointed out, most research focused on the Asian ethnic group in general and did not break it down to sub-ethnic groups (eg, Chinese). In New Zealand, literature on mental health issues around the Chinese population is even scarcer, and to the best extent of our knowledge we are not aware of any existing research that studied the client profile and presenting issues of a Chinese specific service in New Zealand. Thus, the aim of the current study is to investigate the demographic and presenting problems of the callers of a Chinese speaking counselling helpline service in New Zealand (Chinese Lifeline). It also aims to evaluate the calls using the length of the calls, and the counsellor's satisfaction of the calls, and explore the possible factors that influence these.

## Methods

This study is a cross-sectional descriptive study. All call files of Chinese Lifeline that fell into the financial year (FY) 2013/4 (ie, 1 July 2013–30 June 2014) were obtained from Lifeline Aotearoa. There were several exclusion criteria: 1) the call was a test call; 2) wrong number; 3) a hoax call. Then a 20% random sample, stratified by the month of the calls, was pulled out from all the eligible calls in the FY 2013/4.

All the relevant call data were then entered into a standardised Excel database, which was set up for this study from the paper files. Data was carefully cleaned and validated before data analysis. Data was then analysed using SAS 9.3.

Descriptive analysis was used to analyse the client profile and the presenting problems. Chi-square tests were used to investigate the differences in the presenting problems among different demographic variables.

For the outcome and evaluation of the calls, three outcome variables were used: length of a call (up to 30 minutes vs. longer than 30 minutes), immediate outcomes of the calls and self-rated helpline counsellors' satisfaction on the helpfulness of a call (dissatisfied vs. satisfied; ie, whether the counsellor thought that the telephone counselling was helpful to the caller or not). The length of a call provides an indication of the efficiency of the service, while the immediate outcomes and the counsellors' satisfaction of a call gives an indication of the effectiveness of the service. Two separate binary multiple logistic regressions were undertaken to investigate factors associated with the length of calls being longer than 30 minutes and the helpline volunteers' satisfaction. The covariates were callers' demographic variables and the common presenting problems. Observations with missing data were excluded from the regression analyses. There were a few missing data of different variables which were excluded from all analysis.

## Results

In total, there were 890 call files obtained from the call centre during the study period. Of these, 160 calls were excluded from the study due to the exclusion criteria. In the end there were 728 eligible calls for the study and the final sample size was 151 (ie, 20% random sample stratified by the month of the call).

### Callers' demographics

Table 1 presents the callers' demographics and the main characteristic of the calls. The majority of the calls were made by female callers (90.5%). More than 40% of the calls were from young adults 21–30

years, 28% of the calls were made by callers from the 31–40 years age group and 23% of the calls were made by callers from the 41–60 years age group. In addition, most of the calls were made by either never-married singles (41%) or married people (43%). Frequent callers (classified as those who called more than 10 times per month for at least six months) made up just over one-third of the calls, while 27% of the calls were from first time callers.

**Table 1:** Callers' demographics and characteristic of the calls.

Demographic	n (%)
<b>Gender (N=147)</b>	
Male	14 (9.5)
Female	133 (90.5)
<b>Age Group (N=126)</b>	
20 or below	2 (1.6)
21–30	53 (42.1)
31–40	35 (27.8)
41–60	29 (23.0)
Over 60	7 (5.6)
<b>Marital Status (N=118)</b>	
Never married	48 (40.7)
Married	51 (43.2)
Separated	8 (6.8)
Divorced	4 (3.4)
Widow/widower	7 (5.9)
<b>Type of callers (N=105)</b>	
First time callers	28 (26.7)
Several times callers	40 (38.1)
Frequent callers	37 (35.2)

## Presenting Problems

Reasons for calls have been classified into 13 categories as shown in Table 2. Top five presenting problems were: 1) mental health issues (82.1%; 95% CI [75.9%, 88.3%]); 2)

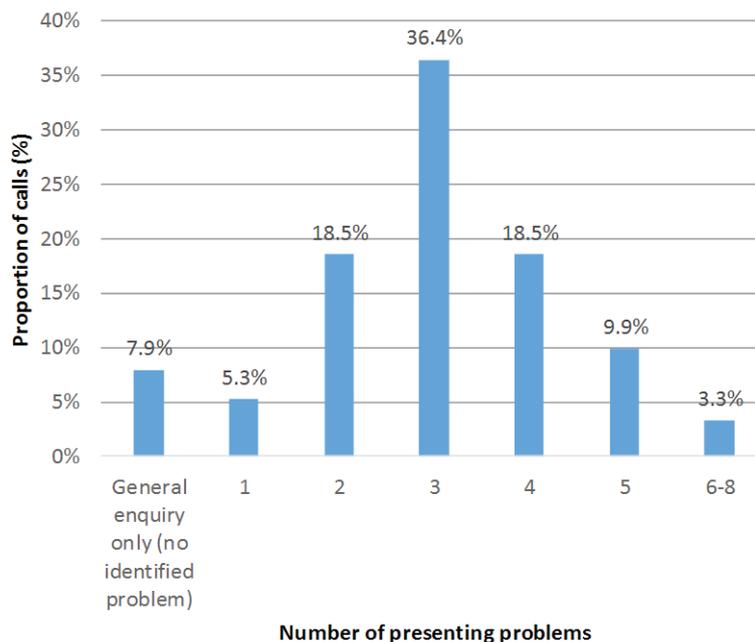
family/partner relationship issues (47.0%; 95% CI [39.0%, 55.1%]); 3) communication and related difficulties (45.0%; 95% CI [37.0%,53.1%]); 4) peers/friends/employer/employee and other relationship issues (33.1%); and 5) work and education related concerns (26.5%). With the mental health and family/partner relationship issues, a more detailed account was captured by the counsellors. Overall, the most common mental health issues were “stress” (43.1%), “depression” (31.1%), “loneliness” (28.5%), and “anxiety” (27.2%). There was also 15.2% (n=23) of the calls where psychiatric/mental health issues (eg, bipolar, schizophrenia) were identified. With family/partner relationship issues, the biggest group was “issues with extended family and in-laws” (31.1%). The risk level for most callers' issues were low to moderate; however, there were occasional high risk calls (eg, suicide-related issues).

Only 7.9% (n=12) of the calls were general enquiry calls with no presenting problems identified (ie, non-counselling calls; see Figure 1). Furthermore, of the remaining 92.1% of counselling calls, only 5.3% (n=8) were of single presenting problem calls, and 86.7% were of multiple presenting problem calls. In fact, more than half of the calls (54.9%) were subjected to three to four presenting problems. Significant negative correlations were found between having family/partner relationship issues and having peers/friends/employer and other relationship issues ( $r=-0.41$ ,  $p<0.0001$ ), and significant positive correlations were found between having family/partner relationship issues and having mental health issues ( $r=0.30$ ,  $p=0.0002$ ).

In addition, the age groups of over 30 years were significantly more likely to have discussed family/partner relationship issues (65% vs. 33%,  $p=0.0004$ ) and were significantly less likely to have discussed work and education related concerns than the age groups of 30 years or younger (19.7% vs. 41.8%;  $p=0.007$ ). On the other hand, first time and several time callers were significantly more likely to have discussed grief and loss issues in the calls compared to frequent callers (34% vs. 8%,  $p = 0.004$ ).

**Table 2:** Presenting problems of callers in descending order (N=151).

<b>Presenting problem categories</b>	<b>n (%)</b>
Mental health issues	124 (82.1)
Family/partner relationship issues	71 (47.0)
Communication and related difficulties	68 (45.0)
Peers/friends/employer and other relationship issues	50 (33.1)
Work and education related concerns	40 (26.5)
Grief and loss	34 (22.5)
Physical health concerns (eg, diabetes, obesity etc.)	29 (19.2)
General enquiries	29 (19.2)
Practical help/requests	19 (12.6)
Abuse and violence	8 (5.3)
Drug and alcohol and other addictions	3 (2.0)
Suicide related issues	2 (1.3)
Sexual health concerns	2 (1.3)
<b>Details of Mental health issues</b>	<b>Proportions of calls (%)</b>
Stress	43.1
Depression	31.1
Loneliness	28.5
Anxiety	27.2
Lack of confidence	22.5
Psychiatric/mental health problems	15.2
Self image	11.9
Phobia/fear	5.3
Disordered anger/violence	2.0
<b>Details of Family/partner relationship issues</b>	<b>Proportion of calls (%)</b>
Family (extended and in-laws)	31.1
Relationship breaking up	12.6
Marital/de facto	9.3
Parent/child	8.6
Romantic/emotional/sexual	7.3
Divorce/separation	6.6
Boy/girlfriend	5.3
Extramarital relationship	2.7
Single parent	0.7
Blended family	0.0
Former spouse	0.0
Adopted parent/child	0.0

**Figure 1:** Proportion of number of presenting problems identified in a call conversation (N=151).

## Outcome and evaluation of the calls

### Outcome of the calls

Counsellors were asked to record the immediate outcomes of the calls. Overall, the majority of the calls (n=92, 65%) ended after a clear decision in overcoming the issues was made by the caller, with help from the counsellor. Out of these, only five calls were transferred/referred to other mental health or counselling services (including the two suicide-related issues calls); whereas the rest of the callers came up with a detailed self-care plan. However, the remaining 35% of calls had no clear decisions made by the end of the calls; and the reasons were either because the calls were interrupted by somebody else from the caller's end and ended unexpectedly, or the caller did not feel like discussing the care plans at that moment in time.

### Helpline counsellors' satisfaction of the helpfulness of the calls and associated factors

Helpline counsellors' satisfaction ratings with the effectiveness of the calls were captured in 141 out of the 151 calls in the sample. In total, they were satisfied with 109 (77.3%) of these calls. There were several factors identified, which influenced their satisfaction (see Table 3). In particular, the helpline counsellors were more likely to be satisfied with the helpfulness of the call if the caller's age was between 30 years or

younger compared to if the caller was older than 30 years (p=0.002); and if the caller was a first time or several times caller, compared to if the caller was a frequent caller (p=0.02). They were less likely to be satisfied with their part of the call if relationship problems with people other than family/partner were discussed during the conversation (vs. if not) (p=0.008); and if physical problems were discussed during the conversation (vs. if not) (p=0.004).

### Length of calls and factors associated with it

Overall, half of the calls were between 5–30 minutes (50.7%; n=73). There were 11.8% (n=17) of very short calls (ie, 0–5 minutes) and 10.4% (n=15) of very long calls which were over 60 minutes.

Table 4 presents the results of logistic regression of factors associated with length of calls being more than 30 minutes. Length of call was more likely to be longer than 30 minutes if mental health issues were discussed during the conversation (vs. if not) (p=0.04); and if grief and loss issues were discussed (vs. if not) (p=0.01). Length of call was less likely to be longer than 30 minutes if communication and related difficulties was discussed during the conversation (vs. if not) (p=0.01). On the other hand, callers' gender, age, frequency of contact and the existence of any other common presenting problems were not shown to significantly influence the length of a call (p>0.05 for each of these).

**Table 3:** Multiple logistic regression for factors associated with helpline counsellors' satisfactions with the helpfulness of the Chinese Lifeline calls (N=80).

Factors	OR (95% CI)	p-value
<b>Gender</b>		0.27
Female	Ref	
Male	7.55 (0.17,334.01)	
<b>Age group</b>		0.002
14–30 years	Ref	
30+ years	0.04 (0.003, 0.47)	
<b>Frequency of contact</b>		0.02
First/several times	Ref	
Frequent caller	0.08 (0.009, 0.77)	
<b>Mental health issues</b>		0.35
No	Ref	
Yes	0.31 (0.02, 3.97)	
<b>Family/partner relationship issues</b>		0.45
No	Ref	
Yes	0.46 (0.06, 3.40)	
<b>Communication and related difficulties</b>		0.10
No	Ref	
Yes	0.22 (0.03, 1.48)	
<b>Grief and loss</b>		0.16
No	Ref	
Yes	0.24 (0.03, 1.76)	
<b>Physical health concerns</b>		0.004
No	Ref	
Yes	0.03 (0.002, 0.46)	
<b>Practical help/requests</b>		0.06
No	Ref	
Yes	NA	

## Discussion

Firstly, the results indicated that Chinese Lifeline is heavily dominated by female clients (90%). This finding is quite similar to the mainstream or English speaking helpline services. For example, in 2008, Lifeline Australia found that 76% of their callers were women,<sup>5</sup> and Coveney et al<sup>6</sup> found that 78% of the callers to a national

suicide prevention helpline in UK were female. However, according to the Mental Health and Addiction: Service use 2011/12 data,<sup>7</sup> the overall age-standardised access rates to secondary mental health services was actually higher in males (3851.5 per 100,000 population) than females (3076.2 per 100,000 population) in New Zealand. For the Asian population, the access rate is quite similar between females (938.5 per 100,000

**Table 4:** Multiple logistic regression for factors associated with length of calls with Chinese Lifeline (N=88).

Factors	OR (95% CI)	p-value
<b>Gender</b>		0.69
Female	Ref	
Male	0.68 (0.11, 4.38)	
<b>Age group</b>		0.62
14–30 years	Ref	
30+ years	1.45 (0.35, 6.01)	
<b>Frequency of contact</b>		0.37
First/several times	Ref	
Frequent caller	0.51 (0.12, 2.25)	
<b>Mental health issues</b>		0.02
No	Ref	
Yes	12.79 (1.02, 160.73)	
<b>Family/partner relationship issues</b>		0.15
No	Ref	
Yes	3.21 (0.64, 16.02)	
<b>Communication and related difficulties</b>		0.007
No	Ref	
Yes	0.19 (0.05, 0.70)	
<b>Grief and loss</b>		0.007
No	Ref	
Yes	6.88 (1.48, 31.98)	
<b>Physical health concerns</b>		0.20
No	Ref	
Yes	0.33 (0.06, 1.89)	
<b>Practical help/requests</b>		0.40
No	Ref	
Yes	1.94 (0.41, 9.24)	

population) and males (969.0 per 100,000 populations). Further, in the most recent Mental Health Annual report, released by the Ministry of Health in 2014,<sup>8</sup> it highlighted that “approximately 3.3 times as many males as females died by suicide in 2011. Of those service users who died by suicide in 2011, 24 percent were female and 76 percent were male.”<sup>8</sup> All of the data above suggests a need for males of any ethnic group to

receive support from mental health services. However, males appear to be reluctant in approaching primary or community health services, such as counselling helplines, in the early stages of their presenting issues. As a result, these issues, if not dealt with, become more severe until they have to seek help from secondary health services, or in some cases, results in suicide attempts. For community helpline services, such as

Chinese Lifeline, the providers need to consider how to promote the service to males so that appropriate early interventions can be put in place, which is likely to reduce the need for secondary health services further down the track.

Secondly, our study shows that the callers of Chinese Lifeline often have multiple and complex issues with their lives. Mental health and family relationship issues are the top presenting problems and are likely to be present at the same time. Interestingly, compared to English speaking helpline services, Chinese lifeline has a much higher proportion of callers who are married (43.2%), while only 24% for Australia Lifeline.<sup>5</sup> Furthermore, McNeil found that people who are married experienced better mental health than all other marital status groups in Australia for both men and women.<sup>9</sup> However, the present study found that the most common problem with family/partner relationship issues of Chinese callers was, in fact, around extended family and in-laws, and most of these callers were married. This indicated that, compared to Europeans, Chinese people, and perhaps other Asian sub-ethnic groups, often face much more complicated family dynamics. Based on observations from the helpline services, and due to cultural reasons, many Chinese people live with their parents and other extended family members, even after getting married. Therefore, when problems arise within the family, it is often multi-dimensional, involving many people from different generations. As Chan and Parker pointed out, what is very important to the Chinese society is the collective sense of wellbeing, rather than an individual's.<sup>10</sup> Family (including extended and in-laws) is often considered the basic unit within a society. Especially given the service is for those people who would like to receive tele-counselling in Chinese, it is believed that the callers were more likely to be the first generation of immigrants who grew up in China and therefore tended to have more traditional beliefs and values. On the other hand, their children might have grown up in New Zealand and therefore were more embedded with western culture. Thus, it adds more complexity to the family issues of these Chinese families. The mental health service providers need to be fully aware of

these cultural differences in order to provide appropriate and responsive cultural support.

Next, although the study showed that the helpline counsellors were satisfied with the calls most of the time, the study provides useful findings that are worth further investigation. The study indicated that the helpline counsellors may be less confident in dealing with callers who are over 30 years, frequent callers or if the presenting problems were related to relationship issues with people other than family/partner or physical health issues. More work should be undertaken in how to manage these cases more effectively. Recently, there have been quite a few research studies looking at regular/frequent callers.<sup>11,12</sup> However, most research focused on exploring the characteristics of frequent callers, rather than finding a solution in managing such callers more effectively.

Finally, the length of a call was more likely to be longer than 30 minutes if mental health issues or grief and loss were discussed. At Lifeline, the service sets the standard of ideal maximum call length to 20 minutes, the red flag length being 30 minutes or longer. This is the standard brief intervention timeframe used across helplines internationally, which increases efficiency and helps focus a call on the presenting issues. While it is important to make sure that the counsellors are able to guide the callers to focus on the present issues, it is also important to be aware that in Chinese cultures, people tend to avoid talking about mental health concerns. This is because the expression of emotions and any deviation from social norms are markers of incorrect social behaviour and could impact negatively on social harmony, hence stigmatised and shunned.<sup>10,13</sup> This meant that Chinese callers may find it difficult to express their true mental health issues in the first instance, but go around circles. Thus, it may be pertinent for the service to consider more flexibility in call length given the complex issues present within the Asian cultural context, especially where risk is present or complex mental health issues are involved.

There were a few limitations to this study. First, the study did not include any measurement of the effectiveness of the service from the callers' perspective because it was not collected as part of the practice. Also, given the service is strictly anonymous, it is not possible to send a survey to the

callers either. Second, some of the calls in the sample might come from the same people, so there might be some clustering effects. However, again due to the nature of the service, it is not possible to identify callers and thus interpretation of the findings should be based on calls rather than callers/individuals. With appropriate ethic approvals obtained, further research could be done to incorporate clients' satisfactions or client's self-ratings of effectiveness by inviting the callers to participate in a research study at the end of calls and also explore better management of the regular callers.

In conclusion, this is one of the first studies in New Zealand, or perhaps internationally, to investigate the client profile, presenting issues and evaluating the

service of a Chinese-specific tele-counselling service in a Western country. The service receives calls predominately from female callers (which is very common in similar helpline services), with a wide range of other demographics and with a large variety of presenting issues. The majority of the calls ended with a definite decision made by the callers in solving their problems. Additionally, the helpline counsellors were satisfied with the helpfulness of the calls most of the time. There were several important factors which influenced the counsellors' satisfaction of the calls and the length of the calls. It is believed that the implications of this study should not be unique to Chinese Lifeline and it is generalisable to other similar Chinese-specific helpline services.

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**Competing interests:**

Nil.

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# Overview of the 2015 American Thyroid Association guidelines for managing thyroid nodules and differentiated thyroid cancer

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## ABSTRACT

The last few years have witnessed numerous publications addressing the management of thyroid nodules and differentiated thyroid cancers. The purpose of this review is to provide a simplified summary of the newly released guidelines by the American Thyroid Association. A systematic approach has been recommended to evaluate a thyroid nodule through clinical assessment, measurement of serum Thyroid Stimulating Hormone, neck ultrasonography and Fine Needle Aspiration where appropriate. This is followed by cytology analysis using the Bethesda scoring system to detect malignancy. Once diagnosed, thyroid cancers need to be staged and risk stratification needs to be applied to develop further treatment plans. Lastly, several recommendations have been presented to assure proper follow-up and support for thyroid cancer patients regardless of the treatment received.

Thyroid nodules are common clinical presentations. The purpose of assessing and evaluating them is to detect the presence or absence of malignancy, which occurs in approximately 10% of all nodules.<sup>1</sup> The American Thyroid Association (ATA) has recently published clinical guidelines for the management of thyroid nodules and differentiated thyroid cancer (DTC) in adult patients.<sup>2</sup> This extended document consists of 101 recommendations that span over more than 400 pages. ATA has implemented in these guidelines an evidence based approach in an attempt to answer the variety of the clinically challenging questions related to this topic. Sixteen expert persons were involved in interpreting and analysing the up-to-date information available on this subject over the course of two years. When compared to the previously published guidelines in 2009, it appears that there have been significant changes with a number of new recommendations added and others modified. This

review will aim to provide an overview on the main points of the 2015 guidelines using similar sections and recommendations posed in the novel article.

## Thyroid Nodule guidelines

This section illustrates the steps in management of thyroid nodules that have been detected through palpation or incidentally while investigating for other illnesses. After careful history and clinical examination, serum Thyroid Stimulating Hormone (TSH) and ultrasonography should be considered first when assessing a thyroid nodule.<sup>3</sup> No role for serum Thyroglobulin measurement and no evidence to support the use of calcitonin serum levels at this stage.<sup>2</sup> Nodules with low TSH should proceed to have thyroid scan (Iodine 123 or Technetium 99m). Hot nodules are generally not cancerous and need evaluation for hyperthyroidism while cold nodules have 5% chance of being cancerous.<sup>3</sup> Cold nodules and nodules

**Table 1:** ATA sonographic patterns of thyroid nodules with associated risk of malignancy and the recommendations for FNA.#

Sonographic pattern	Sonographic features	Risk of malignancy	Recommendation for FNA
High suspicion	Solid hypoechoic nodule or solid hypoechoic component of a partially cystic nodule with one or more of the following features: irregular margins, microcalcifications, taller than wide shape.	70–90%	FNA of nodules more than 1 cm in largest dimension otherwise repeat US in 6–12 months (Strong recommendation)
Intermediate suspicion	Hypoechoic solid nodule without high suspicion features	10–20 %	FNA of nodules more than 1 cm, otherwise repeat US in 12–24 months (Strong recommendation)
Low suspicion	Isoechoic or hyperechoic solid nodule, or partially (>50%) cystic nodule, with eccentric solid area without high suspicion features	5–10 %	FNA of nodules more than 1.5 cm, otherwise repeat US in 12–24 months (Weak recommendation)
Very low suspicion	Spongiform or partially cystic nodules without high or intermediate suspicion features	<3 %	<ul style="list-style-type: none"> <li>FNA or observe nodules more than 2 cm in largest dimension.</li> <li>1–2 cm nodules need repeat US in 2 years.</li> <li>Less than 1 cm nodules require no intervention and no follow-up (Weak recommendation)</li> </ul>
Benign	Purely cystic nodules	<1 %	No FNA required but consider aspiration for comfort or cosmesis (Strong recommendation)

# adapted from the 2015 American Thyroid association guidelines<sup>2</sup>

with Normal or elevated TSH results should have a neck ultrasound (US) which involves thyroid and cervical lymph nodes assessment (Strong recommendation).

Fine Needle Aspiration (FNA) is the procedure of choice in diagnosing thyroid cancer. Non-palpable, posterior thyroid nodules or nodules with high cystic components should have FNA done under US guidance. Table 1 illustrates the interpretation of sonographic patterns, with estimated risk of malignancy and the recommendations for FNA associated with each.<sup>1,2,4</sup> Multi-nodular thyroid should be assessed in the same manner with consideration to each nodule being a separate entity in the clinical evaluation.<sup>2,5</sup> This is also true for assessment of thyroid nodules in pregnancy with the exception of the Iodine radionuclide scan being contraindicated.<sup>2,6</sup>

Once FNA done, the results should be interpreted using the Bethesda cytology reporting system. Management action post cytology is listed below:<sup>2,7</sup>

1. Non-diagnostic cytology: (1–4% risk of malignancy). Repeat FNA,

US guided, with preference to have on-site cytology interpretation (Strong recommendation). Repeatedly non diagnostic with high suspicion US, clinical risks for malignancy or growth in size of nodule requires surgical excision; otherwise close observation can be considered (Weak recommendation).

2. Benign cytology: (0–3% risk of malignancy). No treatment or further immediate investigations (Strong recommendation). Follow-up with US and FNA in one year for high suspicion group, US only in 1–2 years for intermediate suspicion group and US only in more than two years for low suspicion group. If repeated US/FNA is benign then no further follow-up will be required. Adequate dietary iodine intake advised.
3. Atypia of Undetermined Significance or Follicular Lesion of Undetermined Significance cytology (AUS/FLUS): (5–15% risk of malignancy). Surveillance, molecular testing or surgery

can be considered on a case-by-case basis (Strong recommendation).

4. Follicular Neoplasm/Suspicious for Follicular Neoplasm cytology (FN/SFN): (15–30% risk of malignancy). Surgery or molecular testing in low suspicion groups and carefully selected low risk patients (Weak recommendation).
5. Suspicious for Malignancy cytology (SUSP): (60–75% risk of malignancy). Surgery is strongly recommended. Considering molecular testing only if it may change decision making regarding surgery (Weak recommendation).
6. Malignant cytology: (97– 99% risk of malignancy). Surgical approach is strongly recommended.

The introduction of molecular testing, such as BRAF mutation, in the diagnosis and prognosis of thyroid cancer is considered to be a relatively new approach.<sup>8</sup> ATA made two strong recommendations which highlight the importance of patient's counselling and the consistency in laboratory techniques when molecular testing being utilised.<sup>2</sup> However, due to the lack of sufficient evidence and the limited availability of this approach in New Zealand and Australia, it will not be explored any further in this article.

For cytologically indeterminate nodules (3, 4, 5 groups above), and when the decision has been made for surgical approach, lobectomy is the surgery of choice.<sup>2,9</sup> This is usually true unless the patient is at high risk for thyroid cancer where total thyroidectomy maybe preferential (large nodules more than 4 cm in any dimension, sonographically suspicious, radiation exposure history, familial thyroid cancer, positive molecular testing for cancer). It is also relevant here that for this group of patients, clinical assessment is the main stem for decision making and further investigations, particularly with FDG-PET, are not rendered to be of benefit.<sup>10</sup>

### Initial management of Differentiated Thyroid Cancer

Operative intervention is the gold standard for management of Differentiated Thyroid Cancer (DTC).<sup>9</sup> Multiple pre-operative measures should be considered. Neck US and FNA sampling of sonographically

suspicious lymph nodes that are more than 8 mm in diameter is strongly recommended.<sup>2,9</sup> Thyroglobulin (Tg) washout analysis of the FNA samples may provide additional information in certain cases (inconsistent sonographic and cytologic features, inadequate cytologic evaluation or cystic lymph nodes) (Weak recommendation). Cross sectional imaging (CT or MRI) with intravenous contrast should also be considered. However, FDG-PET and serum Tg or Tg antibodies testing are not routinely needed prior to the surgery (Strong and weak recommendations respectively).<sup>2,10</sup> Appropriate surgical consent and preoperative examination and assessment of voice should be performed.<sup>11</sup> Laryngeal exam (to detect vocal cord paralysis) should be considered when voice abnormalities noticed, thyroid cancer with posterior extra thyroidal extension or extensive central nodes involvement, or previous history of neck or upper chest surgery and where the recurrent laryngeal or vagus nerves could have been damaged (Strong recommendation).

When it comes to decision making regarding the surgical approach to DTC, ATA makes the following recommendations:<sup>2</sup>

- I. Patients with cancer more than 4 cm in size, gross extrathyroidal extension or clinical metastases to nodes or distant sites, should have total or near total thyroidectomy. When the cancer is 1–4 cm in size, unifocal, without extrathyroidal extension or metastasis, then lobectomy should be considered.<sup>12</sup> However, patients with advanced age (>45), high surgical risk, previous history of head and neck radiation exposure or family history of thyroid cancer, are strongly recommended to have total thyroidectomies. Finally, for cancerous nodules less than 1 cm, lobectomy is the recommended approach (Strong recommendation).
- II. Completion thyroidectomy should be offered for patients who underwent lobectomy if the histopathological diagnosis suggests the need for it (Strong recommendation).<sup>13</sup> Radioactive Iodine ablation cannot be considered as a substitute to surgery in this instance (Weak recommendation).

- III. Therapeutic central node dissection should be performed for all patients with central nodal involvement (Strong recommendation). Similar principle applies for biopsy proven malignant lateral lymph nodes since lateral compartment lymph node dissection is needed. Prophylactic central node dissection is not routinely recommended where no clinical lymph nodes involvement present. However, weak evidence suggests that this should be done for patients with papillary thyroid carcinoma, where there is lateral lymph nodes involvement or advanced primary tumour, ie clinical T3 or T4.
- IV. Identification and preservation of Recurrent Laryngeal nerve, External branch of superior laryngeal nerve and parathyroid glands with their blood supply (Strong recommendation).<sup>11</sup> Nevertheless, only weak evidence support the use of intra-operative neural stimulation where feasible.

Post-operatively, staging and risk stratification should be done in order to guide further management and predict disease outcome and prognosis. ATA guidelines endorse the use of the AJCC (American Joint Committee on Cancer) TNM staging and the 2009 ATA Initial Risk Stratification Systems.<sup>2,14</sup> The latter provides additional advantage of predicting disease recurrence or persistence. In the 2015 guidelines, ATA suggests the addition of new prognostic variables such as mutational status of cells when molecular testing applied, degree of lymph nodes invasion and extent of vascular involvement to produce a “modified” initial stratification system (weak recommendation with moderate level of evidence). This information should be accounted for in the histopathology report and according to that, ATA risk stratification system divides patient into three tiers: low, intermediate and high risk. Table 2 illustrates the main features of each group, taking in consideration the modifications introduced in the 2015 guidelines, with the associated risks of disease abstinence or recurrence that applies to each tier.<sup>2</sup> When applying this risk stratification system, it is key to appreciate that these three tiers

represents a continuum, rather than a clear cut points, of disease recurrence values ranging from 1% in low risk to more than 50% in high risk individuals. Therefore, individualised approach for interpreting patient results, using the three tiers as a general guide, is highly recommended when management decisions have been made. Also, the initial risk estimates for each patient needs continuous modification and re-application throughout the follow-up period as new clinical materials arise.

Following surgery for thyroid cancer, it is essential to monitor disease status. To do so, multiple investigations should be considered such as serum thyroglobulin (Tg), neck ultrasound and radioactive iodine (RAI) whole body scan. In majority of patients, Serum Tg levels should be lowest 3–4 weeks post-operatively.<sup>2,15</sup> In general, Serum Tg levels less than 1 ng/ml are associated with more favourable prognosis and further intervention may not be needed. This is particularly true for Low and Intermediate risks groups. On the other hand, value more than 10 ng/ml is usually associated with worse outcome and further treatment will likely be needed. RAI whole body scan with or without SPEC-CT can be used when facing difficulties to establish the extent of thyroid residual disease.<sup>16</sup>

RAI therapy (remnant ablation or adjuvant) and TSH suppression (using thyroid hormone therapy Levothyroxine L-T4), are considered the main treatment modalities after surgery.<sup>2,14</sup> Despite the inconsistency of the evidence evaluated, ATA has made multiple recommendations about the target levels for serum TSH. This has been summarised in Table 3.

RAI therapy has been the topic for many studies over the last decade.<sup>16</sup> ATA suggests that RAI therapy is not necessary for low-risk patients but strongly recommended for high-risk group. Prior to RAI therapy or scanning, thyrotropin stimulation by levothyroxine withdrawal has been the gold standard method as it improves the uptake of iodine. The recommended TSH level prior to RAI therapy is more than 30 mIU/L (weak recommendation due to results based on observational studies).<sup>2</sup> Withdrawal protocols suggest stopping Levothyroxine 3–4 weeks prior to RAI therapy. However, if it was to be stopped for more than four weeks, Liothyronine (L-T3) should be used

**Table 2:** The 2015 ATA risk stratification system.\*

ATA Risk Tier	2009 Features	2015 Modifications	Risk: 1. NED§ 2. SI†
LOW	Papillary Thyroid Carcinoma (PTC) with complete resection, no local invasion or distant metastasis, no aggressive histology AND no RAI avid metastases on the first post-operative whole body RAI scan (when performed)	<ul style="list-style-type: none"> <li>For PTC, same features as 2009, AND no vascular invasion AND Clinical N0 or pathologic N1 with 5 or less lymphnodes (LN) involvements that are less than 0.2 cm in largest dimension</li> <li>Intrathyroidal, encapsulated follicular variant of PTC.</li> <li>Intrathyroidal well differentiated Follicular Thyroid Carcinoma (FTC) with capsular invasion and No or minimum vascular invasion (less than 4 foci)</li> <li>Unifocal or multifocal BRAF mutated intrathyroid PTC less than 1 cm in size with No extrathyroidal involvement</li> </ul>	78–91% 2–7 %
INTERMEDIATE	FTC or PTC with local microscopic invasion, Aggressive histology, vascular invasion AND/OR RAI avid metastasis in the neck	<ul style="list-style-type: none"> <li>PTC with Clinical N1 or Pathologic N1 with more than 5 LN involved of less than 3 cm in largest dimension</li> <li>BRAF mutated PTC that are 1–4 cm in size OR has extrathyroidal involvement</li> </ul>	52–63 % 21–34 %
HIGH	Gross extrathyroidal invasion Incomplete resection Distant metastasis (clinical or when Tg results suggestive of that)	<ul style="list-style-type: none"> <li>FTC with 4 or more foci of vascular invasion</li> <li>Pathologic N1 with LN size of 3 cm or more in largest dimension</li> </ul>	14–31 % 56–72 %

# adapted from table 12 of the 2015 American Thyroid association guidelines<sup>2</sup>

§ NED = No Evidence of Disease detected, † SI = Structurally Incomplete response to initial therapy

with the aim to stop the latter two weeks prior to therapy (strong recommendation).<sup>17</sup> Patients with any ATA risk category who have significant physical or psychological illness that would be exacerbated by hypothyroidism or could not illicit appropriate endogenous thyroid stimulation response, should have recombinant human thyrotropin (Thyrogen or rhTSH) used as an alternative to Levothyroxine withdrawal, in preparation for RAI therapy (strong recommendation).<sup>16,17</sup> ATA also suggests that

Thyrogen can be used in low and intermediate risk groups with no evidence of distant metastases. However, no recommendations were made regarding high risk group due to lack of evidence.<sup>2</sup> Patients should be advised to have low iodine diet 1–2 weeks prior to therapy.<sup>16</sup> The dose of RAI recommended should correspond to the physiological status of patients (age, renal function, etc.) and the extent of disease. Low risk groups should have doses as low as 30 mCi while high-risk groups may dictate the use of a

**Table 3:** ATA recommendation of appropriate TSH suppression levels for each risk group during the initial treatment phase.#

Risk group	TSH level (mIU/l)	Quality of evidence
High	Less than 0.1	Moderate (Strong recommendation)
Intermediate	0.1–0.5	Low (Weak recommendation)
Low, post RAI ablation and serum Tg undetectable	0.5–2	Low (Weak recommendation)
Low with low level serum Tg, with or without RAI ablation	0.1–0.5	Low (Weak recommendation)
Low post lobectomy	0.5–2	Low (Weak recommendation)

# adapted from the 2015 American Thyroid association guidelines<sup>2</sup>

dose as high as 200 mCi.<sup>2,16,17</sup> A post therapy RAI scan is strongly recommended. Apart from RAI therapy and TSH suppression, there is no role for other adjuvant systemic therapy, neck radiotherapy or chemotherapy in the initial management of DTC.<sup>14</sup>

### Long-term cancer management guidelines

The aim of long term follow-up of thyroid cancer after the initial treatment phase is to detect recurrence and monitor TSH suppression. This is usually done by periodic measurement of serum Tg, Tg Antibodies and TSH.<sup>6,13,15</sup> This ideally should be done using the same laboratory assay technique that is calibrated against CRM457 standards.<sup>2,14</sup> The use of imaging modalities is governed by the clinical and biochemical findings of each patient. The frequency of performing those tests depends on the ATA risk and the response to treatment categories. Table 4 and the following points illustrate the ATA recommendations in this regard.<sup>2,14</sup>

a. In ATA low and intermediate risk groups who show excellent response to treatment: Serum Tg (stimulated or suppressed), Tg Antibodies and TSH testing in the first 6–12 months then every 12–24 months thereafter with no need to repeat stimulated Tg testing. Neck ultrasound in the first 6–12 months then every five years thereafter.<sup>18</sup>

- b. In all the other groups (indeterminate response, incomplete response or High risk): More frequent neck ultrasound, serum suppressed Tg, Tg antibodies and TSH testing with regular consideration of stimulated Tg analysis, cross sectional imaging, Whole body RAI scanning with or without SPEC-CT and FDG-PET where appropriate.
- c. When new lymph nodes detected on ultrasound, those that are more than 8 mm in size and suspicious should undergo FNA biopsy for cytology and Tg assay (Strong recommendation). When positive for cancer, surgical dissection should be considered. Non-suspicious or small nodes can be monitored conservatively (Weak recommendation).
- d. In patients with structural or biochemical incomplete response, TSH levels should be kept below 0.1 mIU/l long term, unless significant contraindications present (Atrial fibrillation for instance).
- e. Patients with excellent or indeterminate response to therapy who were in the low ATA risk group can have TSH levels at 0.5–2 mIU/L (strong recommendation). However, patients in the high ATA risk, then TSH level should be maintained at 0.1–0.5 mIU/l (weak recommendation).

**Table 4:** Clinical response of differentiated thyroid cancer following initial therapy with thyroidectomy, with or without RAI therapy.<sup>#</sup>

Category	Excellent	Indeterminate	Biochemical incomplete	Structural incomplete
Definition	No evidence of disease	Cannot confidently rule disease presence in/out	No localisable disease but suspicious biochemistry	Persistent or newly diagnosed disease
Imaging	negative	Non-specific/negative	Negative	Positive
Suppressed Tg	<0.2 ng/ml	<1	>1	any
Stimulated Tg	<1 ng/ml	<10	>10	any
Tg trend	Persistently low	Declining	Persistent or rising	any
Tg Antibodies level	absent	Absent or declining	Persistent or rising	any
Prognosis: Recurrence and Disease specific death	1–4% recurrence <1% death	15–20% recurrence <1% death	20% recurrence <1% death	11–50% death dependent on metastasis and extent of disease

<sup>#</sup> adapted from table 13 in the 2015 American Thyroid association guidelines<sup>2</sup>

The ATA guidelines acknowledge the presence of different treatment options for recurrence and metastasis such as Radiofrequency and thermal ablation, ethanol injection of lymph nodes, Stereotactic radiotherapy and using lithium as an adjunct to iodine in RAI therapy.<sup>2,14</sup> However, surgical resection where possible and RAI therapy remain the gold standard.<sup>13,16</sup> Patients who undergo RAI therapy should have appropriate counselling with particular emphasis on potential complications, limitations and the need for ongoing treatment.<sup>18,19</sup> Those patients should have baseline blood count and renal function tests and pregnancy testing for women at child bearing age. Breastfeeding women should not receive RAI and men receiving high doses should be counselled for potential sterility. Since the risk for developing secondary primary malignancy from undertaking RAI therapy is small, additional measures for secondary cancer screening is not needed apart from what is appropriate for that patient's age. Surgical correction for problems arising from RAI therapy, such as nasolacrimal duct obstruction, should be offered where appropriate.<sup>2</sup>

RAI refractory DTC is defined as: 20 cases when the disease tissue does not accumulate iodine, loses the ability to accumulate iodine, some parts accumulate iodine while others do not, or metastasis continues to progress despite adequate RAI dosages. In those instances, continuing to use RAI therapy is strongly not recommended and the prognosis is considered unfavourable. Treatment options include:<sup>2,20</sup>

1. Monitoring: mainly for cancers that have slow progress rate, aggressive monitoring can be considered (Weak recommendation).
2. Directed therapy with surgery or alternatives such as thermal ablation or stereotactic radiotherapy (Weak recommendation).
3. Referral for clinical trial, particularly when considering using toxic agents in which efficacy hasn't been established. (Strong recommendation).
4. Systemic therapy such as kinase inhibitors and cytotoxic chemotherapy with adequate patient counselling and appropriate surveillance for potential adverse effects.

5. In cases with bone metastasis, bone-directed therapy with bisphosphonate or Denosumab can be considered (Strong recommendation).

### Outline of the differences between the new (2015) and the old (2009) guidelines

When looking back at the 2009 guidelines, we can see that ATA had generated 80 recommendations, 103 subrecommendations and utilised 437 references.<sup>14</sup> In 2015, 101 recommendations were published, 175 subrecommendations and 1,078 references were utilised.<sup>2</sup> Numerous new recommendations were associated with pre-operative communication and voice check, and the management of RAI refractory DTC. Furthermore, new questions were answered such as the role of FDG-PET and Cross sectional scanning in thyroid nodule assessments and the manner of histopathologic reporting of samples. A comment has also been made regarding the lack of evidence to justify screening in people with familial follicular thyroid cancer. On the other hand, several parts have undergone significant changes. Reporting each section in the new guidelines using the strength of recommendation and the quality of associated evidence, where as in the 2009 version, they used rating from (A) to (I). Sonographic evaluation of nodules to the different subgroups, the use of FNA and the associated cytology interpretation have been substantially changed. A more conservative approach has been adapted in 2015 towards smaller nodules (less than 1 cm) and in surgical approach in general (lobectomy rather than thyroidectomy for low risk cancers) when compared to 2009. The modified ATA stratification system had a number of features introduced as previously mentioned. Target and diagnostic values for TSH and Tg assay respectively have also been revised.

## Conclusion

The American thyroid association has published new guidelines in the management of thyroid nodules and differentiated thyroid cancer. These guidelines are evidence based and have been generated after careful consideration of variety of experts' opinions and current literature. Following the discovery of a thyroid nodule,

multiple steps should be considered to appropriately assess the nature of this nodule. This should eventually lead to an appropriate management plan to be put in place with realistic yet effective follow-up

regimen. One should always keep in mind that these guidelines were found to aid the clinician in decision making, not as a replacement since treatment strategies must be tailored for each individual patient.

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**Competing interests:**

Nil.

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# Amniotic fluid embolism after intrauterine fetal demise

Karl Kristensen, Fali Langdana, Howard Clentworth, Chu Hansby, Paul Dalley

## ABSTRACT

We present a case of the successful treatment of severe amniotic fluid embolism in a 41-year-old woman undergoing emergency caesarean section at 36 weeks of gestation for placental abruption and intrauterine fetal demise. The treatment included prolonged cardiopulmonary resuscitation, emergency hysterectomy, re-operation with intra-abdominal packing and intra-aortic balloon pump insertion. The patient made a remarkable recovery and to date has minimal residual morbidity.

Amniotic fluid embolism syndrome (AFES) is a rare and often fatal obstetric condition that remains one of the main causes of maternal mortality in developed countries. The incidence varies from 2 to 6 per 100,000 and suggested mortality rates exceed 60%.<sup>1-2</sup> The classic triad of sudden hypoxia, hypotension and coagulopathy with acute onset during labour or immediately after delivery forms the hallmark of the AFES diagnosis, however AFES is primarily a clinical diagnosis of exclusion.

We present a case of successful maternal outcome following severe amniotic fluid embolism after placental abruption and intrauterine fetal demise.

## Case Report

A 41 year-old well woman (TM), gravida 5 para 4, was admitted with a small antepartum haemorrhage at 36 weeks of gestation.

She also had severe hypertension of 180/110 mmHg and mild tachycardia of 100 beats per minute (bpm). On examination her uterus was tender and firm. A bedside ultrasound scan revealed intrauterine fetal demise with an anterior placenta clear of the cervix and a retro-placental haematoma. On vaginal examination the presenting part was high and the cervix was posterior and closed. Initial bloods showed creatinine 150 µmol/L (normal range 55–73 µmol/L) and subtle signs of coagulopathy with fibrinogen 1.5g/L (normal range 3–6.9g/L).

This diagnosis was made of a placental abruption with renal failure and coagulopathy and warranted urgent delivery. An emergency caesarean section under regional anaesthesia was favoured based on the urgency of the situation. Intra-operative findings included a Couvelaire uterus. A stillborn female infant of 2.5 kg was delivered with findings of a complete placental abruption.

Following closure of the uterus, the patient went into sudden cardiac arrest with pulseless electrical activity (PEA) on the electrocardiogram (ECG). She was intubated and cardiopulmonary resuscitation (CPR) commenced.

After around 28 minutes of CPR, TM regained circulation but the uterus remained hypotonic despite uterotonic treatment and B-Lynch sutures and it was decided to perform a subtotal hysterectomy. Haemodynamic instability persisted and due to rapid availability, an intra-aortic balloon pump (IABP) was inserted by the cardiothoracic surgeon with immediate significant improvement in cardiac function.

At around 90 minutes, TM developed severe disseminated intravascular coagulation (DIC) and required re-operation with pelvic-abdominal packing, Flow-Seal administration, and aggressive treatment with blood products (12 units packed red cells, 3 units platelets, 12 units FFP, 6 units cryoprecipitate) including recombinant factor VIIa as per recommendation from the transfusion medicine specialist.

TM was transferred to ICU with the DIC resolving in the ensuing 10 hours. The

intra-abdominal packs were removed on day three and TM was extubated on day five. In total, TM was in hospital for five weeks with acute renal failure requiring dialysis, mild residual left ventricular failure but no residual neurological or cognitive morbidity.

## Discussion

The treatment of AFES is mainly supportive and associated with a high mortality rate.

This case demonstrates that with effective CPR combined with aggressive treatment with IABP and blood products, a favourable outcome with minimal degree of morbidity is possible even in a situation with prolonged CPR and DIC.

We have found one previous report of the successful use of IABP for AFE although it is a well-known and accepted treatment for acute cardiogenic shock.<sup>3</sup> The use of recombinant factor VIIa for management of DIC is controversial and recommended for AFE when the haemorrhage cannot be stopped by massive blood product replacement.<sup>4</sup> Intra-abdominal packing has proven safe and effective in controlling major obstetric haemorrhage and should be considered when there is refractory massive bleeding from raw surfaces or suture-lines in complicated obstetric or gynaecological operations.<sup>5</sup>

We would also like to highlight the importance of a multidisciplinary approach for managing complicated clinical situations and multiple specialty involvement was key in this woman's remarkable recovery.

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### Competing interests:

Nil.

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# Stroke Family/Whānau pilot project

Roslyne McKechnie, Sylvia Hach, Dianne Roy, Allanah Harrington, Victoria Andersen

We read with interest the report of an audit carried out at North Shore Hospital's stroke services by Yeo, Zhou and Ratnasabapathy (Vol 129, No 1431, 11 March 2016), which contributes valuable data with respect to acute and inpatient care. This retrospective examination of case notes from 72 patients looked at five domains of care: case-mix, processes of care in the first 72 hours, discharge results, therapy intensity and post discharge community cares.

The audit highlights changes in acute care delivery. Despite dedicated stroke beds at North Shore Hospital increasing by 150% since the last audit carried out in 2009/10, an important deficiency in ongoing treatment and rehabilitation of stroke survivors, particularly after discharge, was identified. There were significant delays in access to community rehabilitation, especially for physiotherapy and occupational therapy when compared with Australian and UK post-discharge stroke services.

We hope to add to this emerging discussion by signalling some recent work undertaken as a trial of a stroke navigator service. There are two points to consider from the published audit. Firstly we note the lack of ethnicity data. This represents a problem in light of New Zealand health statistics showing that incidence rates are increasing, particularly for Māori.<sup>1,2</sup> The inclusion of ethnicity data in audits such as this is important in understanding service provision and the design of targeted services. Secondly, qualitative data about patient experience and satisfaction regarding communication, partnership, care coordination and physical and emotional needs<sup>3</sup> are required in order to provide a complete picture of service provision. The gap we may be able to fill is in addressing these two points.

Both ethnicity and the provision of qualitative data about patient experience have

been the focus of a pilot project run in collaboration with the Waitemata District Health Board (DHB). The Stroke Family/Whānau project has been ongoing since 2010. Phase one (2010–2011) surveyed health professionals and family/whānau of stroke survivors to ascertain information and education needs through identifying current practice and resources, the appropriateness, accessibility, timelines and information/knowledge gaps.<sup>4</sup> Phase two (2011–2015) was a longitudinal qualitative study of the experience of living as a stroke family/whānau and aimed to provide new understandings of the long-term experiences and needs of extended family/whānau. Preliminary findings<sup>5,6</sup> align with other research completed both in New Zealand and overseas, and data analysis is currently being completed.

As a result of the preliminary findings from phases one and two, which indicated that improving education, support and outcomes for family/whānau will reduce the burden of stroke on individuals and the community, Phase three (2014–2017) of the project was initiated. The overall hypothesis was that provision of a stroke navigator service would improve outcomes and quality of life for stroke survivors and their family/whānau. Phase three included the development of the stroke navigator role in consultation with various stakeholders. Following this, the stroke navigator role was trialled in a small participant sample (n=7) who received the intervention compared with a comparison group (n=4) over a six-month period. Consistent with the recommendations of our Māori stakeholder group, we aimed to recruit 50% Māori, and we used a Māori stroke navigator supported by the He Kamaka Waiora team who are part of the Waitemata DHB.

Preliminary analysis of the recently completed pilot has shown that the stroke

navigator intervention provided support for rehabilitation and focused on individual family/whānau needs. During initial consultation, health professionals expressed concern that the navigator role could overlap with other roles within the stroke team. However this was not the case; the navigator filled identified gaps in service provision for stroke families in both inpatient and community services.

We anticipate that ongoing research within the Stroke Family/Whānau project will supplement the data gained from the Yeo et al audit. An emphasis on individual and family needs and preferences in accordance with commonly agreed guidelines for the continuation of rehabilitative services are crucial to ensure that the stroke survivor maintains the gains achieved through inpatient rehabilitation.

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**Competing interests:**

Nil.

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# Riding in cars with boys, and girls, while smoking...in New Zealand

Frank Houghton, Bruce Duncan, Diane O'Doherty

Tobacco control has clearly been identified by the Governments of both New Zealand<sup>1</sup> and Ireland<sup>2</sup> as major national priorities. Given the significant toll on both morbidity and mortality arising from cigarettes,<sup>3-8</sup> 'the deadliest artifact in the history of human civilisation',<sup>7</sup> such attention is to be commended. Such a focus is particularly laudable given the often successful subversive tactics routinely employed by Big Tobacco to undermine tobacco control.<sup>9-10</sup> Both countries have set broadly similar targets for becoming smoke free (ie having a smoking rate of less than 5%) with Ireland's official target for this achievement being 2020,<sup>2</sup> with New Zealand following shortly behind with a target date of 2025.<sup>1</sup>

There are many similarities between Ireland and New Zealand including population size, English as the dominant spoken language (both countries also have other official languages as well), an economic focus on both agriculture and tourism and historic links with Britain as well as other cultural similarities and sporting interests.

It has been suggested that although New Zealand has received significant

international praise and recognition for being a global leader in tobacco control,<sup>11</sup> Ireland's similar achievements have been largely overlooked.<sup>12</sup> Ireland's entrance onto the global stage of tobacco control occurred in 2004 when it became the first country in the world to implement a national workplace smoking ban. New Zealand followed suit approximately nine months later.

As can be seen from the examples of tobacco control activities introduced by New Zealand and Ireland outlined in Table 1, the two countries have often been relatively matched on this issue, with New Zealand having led the field in earlier years.

Both Ireland<sup>14</sup> and Aotearoa/New Zealand<sup>15</sup> are also currently in the process of introducing plain packaging for cigarettes, an issue fraught with legal challenges from the tobacco industry.

Although there are encouraging trends, smoking remains an issue in both countries. Results from the 2014/15 New Zealand Health Survey indicate a current smoking rate in the 15 years and over total population of 16.6% (18.2% among males and

**Table 1:** Sample of comparable tobacco control activities in Aotearoa/New Zealand and Ireland by year.

Aotearoa/New Zealand <sup>13</sup>	Ireland <sup>12</sup>
1963—Cigarette advertising banned on radio and television	1971—Tobacco Advertising banned on television 1978—Tobacco Advertising banned on radio
1974—Health warning introduced on cigarettes	1979—Health warnings on cigarettes introduced (3 rotating warnings)
1988—Ban on tobacco sales to anyone under 16 years	1988—Ban on tobacco sales to anyone under 16 years
1997—Ban on sales of cigarettes in packs of less than 20	1988—Ban on sales of cigarettes in packs of less than 20
1997—Ban on sales of tobacco products to anyone under 18 years	2002—Ban on sales of tobacco products to anyone under 18 years (implemented 2007)
2004—Workplace smoking ban introduced	2004—Workplace smoking ban introduced

15% among females), with notably higher rates among Maori (38.1% overall) and Pacific (24.7%) populations, and noticeably lower rates in Asian groups (6.4% overall).<sup>16</sup> Ireland's smoking rate in 2014 was 21%, although this rate may have continued to drop. Between 2012 and 2014 Ireland experienced the highest reduction in the smoking rate of any country in the European Union, from 29% to 21%.<sup>17</sup>

Despite manifold similarities in tobacco control between Ireland and New Zealand one glaring difference evident relates to smoking in cars with children. Ireland introduced a law (the Protection of Children's Health [Tobacco Smoke in Mechanically Propelled Vehicles] Act) banning smoking in cars with children on 1st January 2016,<sup>18</sup> just three months after England and Wales introduced such a ban. New Zealand currently has no such ban in place and does not overtly appear to be in the process of introducing such legislative protection for children.

This absence is glaring given that the negative impact of secondhand smoke is now widely accepted and the impact of smoking in cars well researched. It is perhaps ironic that some of the research supporting the ban on smoking in cars with children used internationally in campaigns by groups such as Tobacco Free Kids actually originates in New Zealand.<sup>19</sup> There would be popular support for such legislation: 97% of respondents in the New Zealand Health and Lifestyle Survey in 2014 agreed with the statement "smoking in cars should be banned where children are in them".<sup>20</sup>

Looking elsewhere internationally, it is perhaps notable that smoking in cars with

children is already illegal in Australia and a number of other countries. In 2007 the American Academy of Pediatrics adopted a resolution calling for all State and local bodies to "support and advocate for changes in existing and local laws and policies that protect children from secondhand smoke exposure by prohibiting smoking in any vehicle while a legal minor (under 18 years of age) is in the vehicle".<sup>21</sup>

Interestingly, although Ireland has introduced a legal ban on smoking in cars with children, it is notable that key stakeholders explain the impact of the law in non-confrontational,<sup>22</sup> moral, normative<sup>23</sup> and educational terms.<sup>24</sup> It could perhaps be argued therefore that New Zealand's current educational strategy to combat this issue is broadly similar to Ireland. While educational strategies are undoubtedly important, given the significant volume of evidence detailing the adverse effects and the vulnerability of the population involved, the addition of a robust and immediate legislative approach will underline societal attitudes to the protection of health in our children.

It is notable that wearing front seat belts became a legal requirement in New Zealand in 1975. From 1979, back seat belts had to be fitted in cars in New Zealand, with their use becoming mandatory a decade later in 1989.<sup>25</sup> Few, if any, would now question the wisdom of such legislation. Similarly now is the time for action on the issue of smoking in cars with children in New Zealand. The moral/ethical, health and economic arguments behind such a move are unequivocal. A decade from now New Zealanders will undoubtedly ask "Why did it take so long?"

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**Competing interests:**

Nil.

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# A continuation of 10% annual tobacco tax increases until 2020: Modelling results for smoking prevalence by sex and ethnicity

Frederieke Sanne van der Deen, Nick Wilson, Tony Blakely

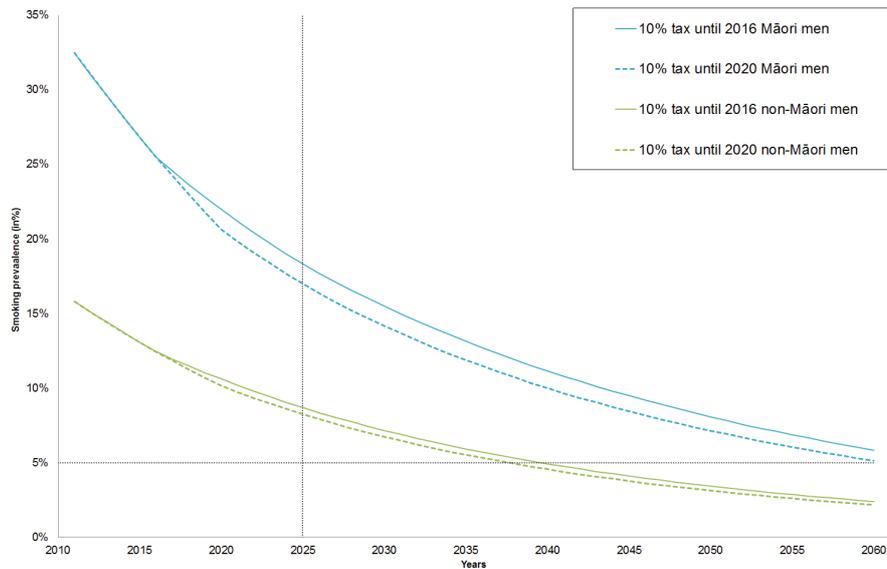
On 26 May 2016 the New Zealand Government announced it would continue its programme of annual 10% tobacco tax increases from 2017 to 2020 inclusive. Since 2010, the Government has increased tobacco tax by 10% each year, albeit with a higher increase in 2010 (all above a routine annual inflation adjustment). Tobacco tax is the single most effective tool used by governments to prevent young people from taking up smoking and reducing current smoking rates, while simultaneously benefiting population health and generating large savings on healthcare spending.<sup>1-3</sup> Given this background we aimed to project future smoking prevalence for Māori and non-Māori men and women under the four additional years of tobacco tax compared to no continuation of this programme (ie, tax increases to January 2016 only). This letter extends previous work reported in an online blog, that projected smoking prevalence under the scenario of tax increases until 2020 for specific ethnic groups only.<sup>4</sup> In addition, in this letter, we also aimed to discuss how such a programme could be enhanced by using collected tobacco tax revenue to fund tobacco control activities, and the need for the NZ Government to explore more novel (and substantive) measures to increase the chances of achieving its Smokefree Nation 2025 goal.

## Methods

We used a peer-reviewed dynamic tobacco forecasting model<sup>5,6</sup> that itself was initially derived from a published Australian model.<sup>7</sup> This model was used

to project future smoking prevalence for a continuation of annual 10% tobacco tax increases until 2020 compared to the business-as-usual trends (albeit with the tax increases that have occurred to January 2016). Briefly, this model is built in Microsoft Excel and includes a base and forecasting model using demographic and mortality data for New Zealand. In the base model recent annual trends in smoking uptake and cessation by sex, age and ethnicity were 'solved' by using smoking prevalence data from the 2006 and 2013 censuses. To project future smoking prevalence in New Zealand by sex and ethnicity under a series of annual 10% tax increases, these baseline trends in prevalence were tweaked by using age group-specific tobacco price elasticities (ie, responsiveness to tax increases as observed in the past). We used the following age group-specific tobacco price elasticities derived from previous BODE<sup>3</sup> tobacco tax modelling work: -0.38 (15–20 years), -0.29 (21–24 year olds), -0.19 (25–34 years), and -0.10 (35+ years).<sup>2</sup> The applied tobacco price elasticities were scaled up by 20% for Māori as done in previous BODE<sup>3</sup> tobacco tax modelling work.<sup>1</sup> There is some international evidence suggesting greater tobacco price elasticities among low-income populations,<sup>3</sup> and as such one would expect higher price elasticities among Māori. While there is no direct evidence of greater responsiveness to tobacco price increases among Māori, there is some indirect evidence from an experimental study,<sup>8</sup> and some parallel evidence from a study suggesting greater sensitivity to food pricing policies among Māori.<sup>9</sup>

**Figure 1:** Daily adult smoking prevalence projections for Māori and non-Māori men under two tobacco taxation scenarios (annual tobacco tax increases until January 2016 only and also ending in January 2020).



## Results

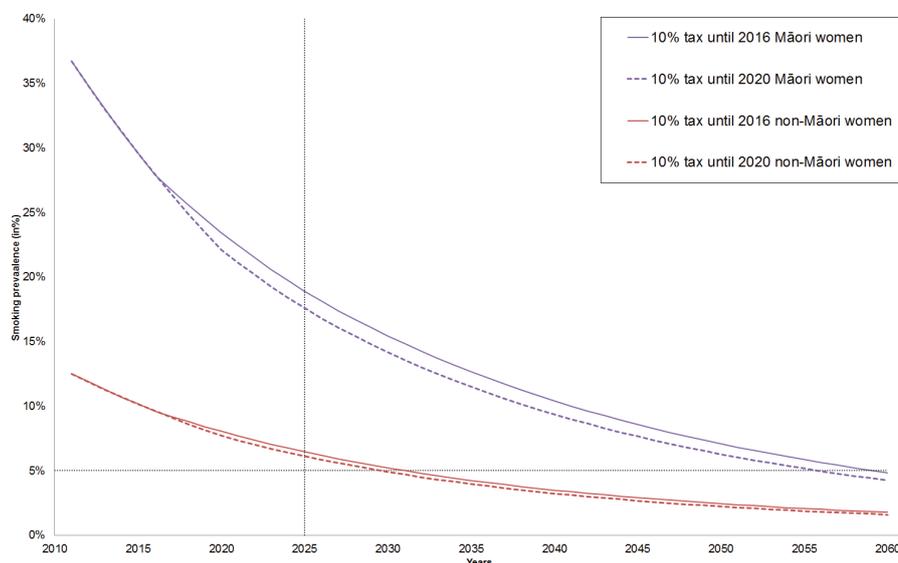
Our model projects that a continuation of 10% tax increases from 2017 to 2020 inclusive will see daily adult smoking prevalence rates reduce to 20.7% and 22.1% for Māori men and women and to 10.2% and 7.7% for non-Māori men and women by 2020 (see Figures 1 and 2). These compare to projected smoking rates of 22.0%, 23.5%, 10.6% and 8.0% for Māori and non-Māori men and women respectively if such a programme had not continued beyond January 2016. Assuming a continuation of baseline trends in smoking uptake and cessation after 2020 was projected to

produce further reductions in smoking rates to 17.0% and 17.6% for Māori men and women by 2025 and to 8.3% and 6.1% for non-Māori respectively. Furthermore, the additional four rounds of tax increases have the potential to reduce the absolute ethnic gap in smoking prevalence observed in New Zealand by nearly one percentage point in 2025 (eg, from 9.6% to 8.7% for men and from 12.4% to 11.5% for women).

## Discussion

A continuation of the programme of 10% annual tobacco tax increases was predicted to see tobacco smoking rates reduce further, but not sufficiently to achieve a below 5%

**Figure 2:** Daily adult smoking prevalence projections for Māori and non-Māori women under two tobacco taxation scenarios (annual tobacco tax increases until January 2016 only and also ending in January 2020).



smoking prevalence for Māori or non-Māori men and women by 2025. Yet there is uncertainty around the stability of tobacco prevalence elasticities into the future as they may increase with tobacco reaching higher prices, or increase with changes in access to nicotine-containing electronic cigarettes (both of which would probably favour larger smoking reductions than we project). There may also be various tipping points for higher quit rates as smoking becomes more denormalised in New Zealand society or psychologically significant prices are achieved (eg, the “\$30” per pack threshold). Conversely, others have argued that the effect of tobacco taxation may be undermined by a growing illicit tobacco market. But in our past modelling we have shown that even a substantial growth in the illicit market had little impact on overall population-wide prevalence of tobacco smoking.<sup>2</sup>

While a continuation of the 10% annual tobacco taxation programme is a solid step forward towards the NZ Government’s Smokefree 2025 goal, such a programme could be enhanced by dedicating some of the collected tobacco tax revenue to fund tobacco control activities. This revenue could particularly fund additional cessation support services and mass media campaigns targeting low-income smokers who may be disproportionately affected by tax rises if they continue to smoke. Earmarking tobacco tax for tobacco control is already common practice in various jurisdictions overseas (eg, Iceland, California, Switzerland,

Vietnam).<sup>10,11</sup> Indeed, it seems unethical for the New Zealand Government to not provide smokers with more motivation to quit and more direct support to quit when it is dealing with a highly addictive substance. (The argument about smokers paying their way or not is not directly relevant when a democratically-elected government has opted for a Smokefree Nation goal. Also the issues are very complex and not all are easily quantifiable: health costs from smokers and non-smokers harmed by second-hand smoke (SHS), superannuation costs, nuisance impacts from SHS and environmental impacts such as tobacco-related litter and fires.)

Also this and past New Zealand modelling work<sup>2,6,12</sup> strongly suggest that the need for further intensification of existing tobacco control measures or completely novel measures remains. More incremental measures such as the proposed law on plain packaging, expansion of smokefree areas (including a law for smokefree cars) and more mass media campaigns (especially targeted at Māori and Pacific audience) remain worthwhile. Novel measures, and potentially more substantive in terms of reducing smoking, that the New Zealand Government could explore include the tobacco-free generation idea (thereby essentially preventing new generations from becoming addicted to tobacco<sup>13</sup>) or a substantive reduction in the number of tobacco retail outlets (which is currently estimated at around 6,000 outlets<sup>12</sup>).

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**Competing interests:**

Nil.

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# Perspectives of New Zealand health professionals and smokers on e-cigarettes

Trish Fraser, Nigel Chee, Murray Laugesen

Using an e-cigarette (vaping) that contains nicotine (nicotine e-cigarettes) is estimated to be 95% safer than smoking<sup>1</sup> and can help people stop smoking.<sup>2</sup> However, in New Zealand the Ministry of Health does not recommend nicotine e-cigarettes to quit smoking<sup>3</sup> and e-cigarette users (vapers) can only purchase nicotine for e-cigarettes online.

Vaping has grown rapidly in New Zealand<sup>4</sup> with most smokers trying e-cigarettes out of curiosity (49%) and desire to quit smoking (37%).<sup>5</sup> Low socio-economic smokers (mainly Māori and Pacific) are interested in nicotine e-cigarettes as a stop smoking aid.<sup>6</sup>

Public health researchers and advocates in New Zealand and around the world are divided in their views of the likely impact of nicotine e-cigarettes, for example, will they re-normalise smoking, be a gateway to smoking and continue addiction?<sup>7-8</sup>

The rationale for combining health professionals and smokers in this study was to seek both groups' views of nicotine e-cigarettes, as health professionals have a key role helping smokers stop smoking.

## Methods

This qualitative study was conducted in 2014 in Wellington, Otago and Southland.

We conducted in-depth, semi-structured interviews with 12 health professionals from a range of health professions involved in helping patients or clients stop smoking, and held three focus groups with a total of ten smokers. Focus groups were our preferred method of interviewing but due to perceived difficulties recruiting health professionals to these groups, we conducted interviews with them. We also had to interview six smokers to reach our required number for the study. Budgetary constraints and researchers' past experience determined sample sizes. Among

the smokers, Māori were the priority group because of high smoking rates.<sup>9</sup>

Table 1 shows the characteristics of participants.

**Table 1:** Characteristics of participants (N=28)

Health professionals		Number
Occupation	Aukati Kai Paipa* providers	3
	General Practitioners	3
	General Practice Nurses	2
	Quitcard* Providers	2
	Quitline Advisers	2
Gender	Female	10
	Male	2
Ethnicity (multiple response)	Māori	3
	NZ European	8
	Indian	1
	British	1
Age range	26-35	5
	36-50	3
	51-60	4
Smokers		
Gender	Female	12
	Male	4
Ethnicity (multiple responses)	Māori	9
	Pacific	2
	NZ European	7
Age range	16-35	9
	41-55	4
	61-70	3

\* Aukati Kai Paipa—a Māori smoking cessation programme

\* Quitcard—prescription for subsidised nicotine replacement therapy

Interview schedules guided interviews and focus groups beginning with the distribution of participant information sheets, consent forms and questions seeking gender, age, ethnicity and knowledge of nicotine e-cigarettes. Sample e-cigarettes and bottles of liquid (with and without nicotine) were shown to the participants. The lead researcher then demonstrated how to vape using an e-cigarette without nicotine.

Data collected were transcribed. A general inductive approach was utilised to analyse the data because it allows themes to emerge and can produce reliable findings.<sup>10</sup> Content analysis was carried out.

The Ministry of Health, Health and Disability Ethics Committee received our application for ethics review but determined further consideration was not required for this study.

## Results

Emergent themes on nicotine e-cigarettes were: lack of knowledge, less harmful than smoking, helpful for quitting, some personal and population health concerns, support use if smoker chose them and better access with some restrictions.

Most participants (health professionals and smokers) in this study self-reported not knowing much about e-cigarettes. All, except one health professional, agreed nicotine e-cigarettes would probably be helpful as a quit smoking aid, and all thought they would be less harmful than smoking.

“You’ve got to add it up... I’m sure you would be better off smoking an e-cigarette [than a cigarette].” Smoker.

Vaping with nicotine to stop smoking was more acceptable to several of the health professionals than as an activity to replace smoking. Some health professionals had concerns about continuing addiction to nicotine and re-normalisation of smoking due to increased vaping and the uptake of nicotine e-cigarettes by young people and non-smokers. Smokers did not generally share these concerns.

Most health professionals would be hesitant to recommend nicotine e-cigarettes to their patients or clients as a first option to stop smoking, however they would support those who wished to use them.

“I would probably inform them of other ways of stopping smoking... start with something else, then move onto them [nicotine e-cigarettes].” Quitcard (prescription for subsidised nicotine replacement therapy) provider.

Most participants wanted better access to nicotine e-cigarettes albeit with a range of restrictions.

## Discussion

Concerns and contested evidence about nicotine e-cigarettes are reflected in this study, particularly among health professionals.<sup>7</sup> However, there is little evidence that any of these concerns have much validity.<sup>1</sup> Accurate information about nicotine e-cigarettes would help health professionals and smokers make informed decisions about their use.

Smokers wanting to try nicotine e-cigarettes to quit smoking may not be getting clear advice from health professionals. Reasons could be a combination of a lack of knowledge about them, mixed messages in the media and medical journals, and cautionary advice from the Ministry of Health<sup>3</sup> and the World Health Organisation.<sup>8</sup>

This was a small qualitative study and does not purport to represent the views of all health professionals and smokers in New Zealand. A strength of the study is that it was the first time health professionals’ views of nicotine e-cigarettes have been studied in New Zealand.

We recommend that the Ministry of Health review personal and population benefits of nicotine e-cigarettes and any regulations that might be required if nicotine for e-cigarettes were to be made available in New Zealand.

**Competing interests:**

Nil.

**Acknowledgements:**

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# Does smoking cessation prior to elective spinal surgery lead to long-term smoking abstinence

Bruce Hodgson, Chris Hanrahan, Vivian Cuthbertson

Smoking is a major health hazard.<sup>1</sup> It is well known that there is a significant link between smoking and surgical complications.<sup>2,3</sup> The rate of complications are twice as high in patients who continue to smoke post-operatively. Of importance, those patients that stop smoking before surgery are more likely to maintain abstinence post-operatively.<sup>2</sup>

In 1996 our group noted that clinical outcomes following elective spinal surgery were inferior in those patients who continued to smoke despite being advised not to. We therefore commenced an enforced smoking cessation programme for elective spinal surgery. The Australian and New Zealand College of Anaesthetists recommended cessation of smoking six weeks prior to elective surgery to reduce peri-operative complications.<sup>5</sup> We chose this time interval to be consistent with their guidelines.

At the time of the consultation to decide about surgery, patients were counselled about smoking and associated complications. They were informed smoking cessation was required a minimum of six weeks prior to their surgery. Patients were advised that if they were smoking at the time of hospital admission, their surgery would be cancelled. Patients were instructed to seek help for smoking cessation with their general practitioner or other agency.<sup>11</sup> The consultation to confirm surgery, as well as the six-week smoking cessation requirement, included oral and written informed consent. Copies of these notes were sent to referring general practitioners, colleagues and other agencies where applicable.

While the short term benefits of smoking cessation and surgical outcome have been well documented in the literature,<sup>2,3,4,5,6,7</sup> little is known about long-term cessation rates in patients required to stop smoking before major elective spinal surgery.

It was for this reason that the current audit was carried out. The project received full approval from the Ethics Committee, Mercy Hospital, Dunedin.

The senior author's medical records from 2008 to 2012 (inclusive) were used to identify those patients that were smoking when the decision was made to proceed with surgery.

We decided to review patients that had been discharged from follow up for a minimum of 12 months in order to reduce the possible impact of the surgeon's influence and the enforced requirement to stop smoking.

An initial request to take part in the audit was mailed to selected patients informing them of a telephone interview within two weeks.

In the five years outlined (2008 to 2012 inclusive), 1,161 patients underwent elective spinal surgery of which 180 (15.5%) were noted to be smokers. These patients were sent the letter of survey request; 106 patients responded. Of those, 16 refused to participate in an interview.

90 patients were interviewed by telephone (55 males/35 females).

60 (40 males/20 females) had recommenced smoking.

30 (15 males/15 females) had remained abstinent.

Thus, of the group interviewed, one third (33%) of patients remained abstinent following surgery (28% if those that refused the interview were presumed to be smokers). We noted females rather than males had a greater tendency to remain abstinent (43% vs 27%).

Long-term cessation rates referred to by the New Zealand Ministry of Health (MoH) web site as published by the Cochrane Library extend to six months duration.<sup>4,10</sup> In our study, we noted 72% of the smoking group had recommenced within the first year post-surgery. By two years 89% had returned to their habit.

We therefore consider six-month follow up of smoking cessation rates to be too short and of little relevance. Long-term follow up to confirm sustained smoking abstinence should, at the very least, be a minimum of two years.

Cahill et al<sup>4,10</sup> indicates long-term cessation is best achieved with “combined therapy”, namely medication and supportive counselling sessions. This approach has been shown to improve six month cessation rates

to 25–30%. Of interest, in our study, only 52% of patients stated they sought help with smoking cessation.

The MoH web site notes, on average, smokers have 14 attempts at cessation before success. It is clear then that the enforced requirement to stop smoking before elective spinal surgery in our study was a powerful “one off” motivator.

Elective spinal surgery in New Zealand is usually funded by ACC, health insurers or in public hospitals by the Crown. It is important that tax-payer funded surgery is carried out to avoid complications, reduce costs and enable the greatest utilisation of scarce public resources. It is our belief that an enforced smoking cessation programme before elective surgery should become a standard of care for admission to hospital. A determined, unrelenting approach is important. “If you don’t stop smoking, you don’t get surgery”.

While smoking is a person’s freedom of choice, smoking cessation prior to surgery is not a moral or ethical dilemma but one of patient safety.<sup>9</sup>

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**Competing interests:**

Nil.

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## Long-term aromatase-inhibitor therapy in breast cancer

Treatment with an aromatase inhibitor for five years as up-front monotherapy or after tamoxifen therapy is the treatment of choice for hormone-receptor-positive early breast cancer in postmenopausal women. This study was designed to evaluate the benefits of extending treatment with letrozole to ten years.

1,918 women were randomised in this double-blind, placebo-controlled trial to receive 2.5 mg of letrozole or placebo for a further five years.

The extension of treatment with an adjuvant aromatase inhibitor to 10 years resulted in significantly higher rates of disease-free survival and a lower incidence of contralateral breast cancer than those with placebo. Bone-related toxic effects were more frequently seen in those receiving letrozole.

*N Engl J Med* 2016;375:209–19

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## Migraine and cardiovascular disease

Is there an association between migraine and risk of cardiovascular disease in women? That is the question addressed in this prospective cohort study which reviews data from US Nurses Health Study.

A total of 115,541 women aged 25 to 42 at baseline and free of angina and cardiovascular disease were included. The primary outcome sought was the incidence of major cardiovascular disease. 15.2% of the women had physician-diagnosed migraine. The conclusions reached were that migraine was associated with an approximately 50% increased relative risk of major cardiovascular disease and an approximately 37% increased relative risk of cardiovascular disease mortality.

An accompanying review notes the findings and speculates whether treatments decreasing the frequency and severity of the migraine would reduce the cardiovascular outcomes. The question also arises—should women with migraine be treated with statins or aspirin?

*BMJ* 2016;353:i2610 and *BMJ* 2016;353:i2806

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## Effects of aspirin on risk and severity of early recurrent stroke after transient ischaemic attack and ischaemic stroke

Aspirin is recommended for secondary prevention after transient ischaemic attack (TIA) or ischaemic stroke on the basis of trials showing a 13% reduction in long-term risk of recurrent stroke. However, several non-randomised observational studies have reported much higher reduction rates. This meta-analysis was planned to elucidate the issue.

The researchers have pooled data for 15,778 participants from 12 trials of aspirin versus control in secondary prevention. They found that the risk of recurrent ischaemic stroke at six weeks was reduced by about 60%. This benefit continued up to 12 weeks but not after 12 weeks. The addition of dipyridamole to the aspirin did not improve results within 12 weeks but did reduce the risk after 12 weeks.

The conclusions reached were “that medical treatment substantially reduces the risk of early recurrent stroke after TIA and minor stroke and identify aspirin as the key intervention. The considerable early benefit from aspirin warrants public education about self-administration after possible TIA.”

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# The therapeutics of cancer

August 1916



Large rabbit being held by unidentified man. Whites Aviation Ltd :Photographs. Ref: WA-21625-G. Alexander Turnbull Library, Wellington, New Zealand. <http://natlib.govt.nz/records/23209273>

The "Medical Record" of April 8, 1916, points out that the renewed interest in cancer which followed the discovery that malignant growths can be transplanted from one animal to another has extended from the domain of experimental pathology to that of therapeutics, and no sooner is a report issued from the laboratory than the procedure is tried at the bedside. It is right that this should be so, provided only inoperable cases are chosen, for in our efforts to control this dreadful scourge nothing must be left undone; the immediate and blind application of a method, however, is not right. The attitude of the therapist toward the laboratory should be as critical as he can make it, in order that he may be in a position to select the most reliable results for his clinical investigations; an experiment, said a great investigator once, is not necessarily scientific because it has been performed on a rabbit.

But even more important than this critical attitude should be one of endeavour to

discover exactly what it is that the laboratory is trying to bring about. For example, while it has been discovered that mice can be immunised with normal mouse tissues against the inoculation of tumors, it has been expressly stated by those best qualified to know that such treatment has no effect upon transplanted tumors already established. Now, as these are under relatively unfavourable conditions compared with spontaneous neoplasms, being composed of the cells of an animal other than that in which they are proliferating, while the latter consists of cells of the animal itself, it is evident that transplantable growths should be much more easily cured than spontaneous; and yet even these inoculable neoplasms cannot be healed at present. Nevertheless, many attempts have been made to cure spontaneous tumors in man, in spite of this distinction, by the injection of normal human tissues, generally in the form of extracts, although the laboratory has definitely explained that living and intact cells are necessary for the production of

immunity; and not only have normal tissues been tried, but emulsions of living tumor cells have been introduced, which, in several instances, have led to the production of new tumors at the point of inoculation.

All this is not so much the fault of the clinician, perhaps, as it is his misfortune, for he is no better able to judge between conflicting laboratory reports than the experimental pathologist would be to choose between two rival therapeutic methods. On the other hand, pathologists do not differ so greatly in opinion as the contradictory nature of much of their writing would suggest; a great deal of the apparent disagreement is due to the fact that it was not realised in the first few years of cancer research that transplantable tumors vary remarkably in such characteristics as type of growth, susceptibility to, immunity, etc., and that in some of them even complete spontaneous disappearance is not an unusual occurrence in untreated animals. Frankel and Furer ("Wiener klin. Wochenschr.," 1915, xxviii, 1433, and 1916, xxix, 63) have, therefore, performed a work of great value to both clinician and pathologist in reviewing some of these earlier conflicting findings in the light of our more recent knowledge. They have carefully investigated the question whether cell-free juices from the tumors of rats and mice have any immunising or therapeutic action in these animals, and have found that they possess neither.

Their second paper is devoted to a discussion of the effect of foreign sera upon growing tumors, it having been assumed by various writers that the serum of a normal individual differs from that of the

cancerous organisms in the possession of some substance injurious to the cancer cell, or that it contains a ferment with the power of dissolving tumor cells. Frankel and Furer very wisely divorced themselves from all theory, and set themselves the task of finding out simply whether foreign serum would or would not influence the growth of transplantable neoplasms. Mice bearing carcinoma or sarcoma were inoculated intravenously one or more times with horse, goat, sheep, goose, rabbit, and guinea-pig serum, but in no case was the tumor definitely affected, although amounts of from one-fortieth to one-twentieth of the body weight were introduced. In a few of the animals the rate of proliferation was somewhat retarded; but a similar occurrence was noted in some of the untreated controls. The experiments have an important bearing upon the many attempts that have been made to influence new growths in the human subject by the injection of serum from adults or from infants, the procedure being based, in the latter instance, upon the false assumption that because infants do not have cancer there must be some protective substance in their blood.

In conclusion, it is necessary to point out only that no authoritative cure of either transplantable or spontaneous neoplasms in animals has yet been published, even the selenium cure, from which so much was looked for in some quarters, having been proved a complete failure. In man, therefore, the surgeon still may, with more or less apparent justification, claim that the only hope of relief lies in early and complete surgical removal.

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# Proceedings of the 233rd Otago Medical School Research Society, Summer Research studentship meeting

2016

## Effect of DNA methylation on expression of genes related to PD-L1 expression in melanoma.

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Melanoma, a significant cancer in New Zealand, expresses the PD-L1 gene to activate immune checkpoints such as the PD-1 pathway to downregulate immune system activity. While anti PD-L1 therapy has been promising, some patients do not respond well to treatment. Currently, it is not understood how PD-L1 expression is regulated. Some melanoma cells naturally express PD-L1 (constitutive), while some require a stimulus such as interferon gamma (inducible). This report examines if alteration in the DNA methylation of specific genes, which may increase or suppress the expression of PD-L1, could explain this. If so, such genes could be used as positive biomarkers for PD-L1 treatment.

Four *PD-L1* inducible cell-lines were compared with four *PD-L1* constitutive cell-lines obtained from melanoma patients. A genome-scale methylation sequence was used to select six genes that had significant methylation differences between inducible and constitutive cell-lines. A further six genes that

commonly influenced methylation (including *DNMT3A* *TET1*) were also investigated. The expression of the selected genes was measured using quantitative real-time PCR and analysed using qPCR data analysis software. Gene expression between cell-line types was compared for any significant difference. It was also seen whether there was a relationship between the methylation level and expression of the genes.

Genes *GATA4* ( $P=0.039$ , paired t-test), *GNA14* ( $P=0.055$ ), *TET1* ( $P=0.019$ ) and *DNMT3A* ( $P=0.049$ ) showed clear differences between inducible and constitutive cell-lines. While *GATA4* and *GNA14* are genes that regulate *PD-L1* expression from the gene body and promoter region, *TET1* and *DNMT3A* are genes that regulate DNA methylation outside of the gene. There was no significant relationship between the methylation level and relative expression of *GATA4* and *GNA14* although this is likely due to the small sample size.

These results suggest the changes in DNA methylation of genes *DNMT3A*, *TET1*, *GATA4* and *GNA14* may influence the expression of the *PD-L1* gene and may be possible candidates for predictive biomarkers for PD-L1 treatment response.

*Supported by the Maurice and Phyllis Paykel Trust Summer Scholarship.*

## The effects of bacterial components on colonic stem cell proliferation.

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The colon contains trillions of commensal microbes, which are restricted to the lumen by the epithelial barrier. Balancing stem cell proliferation and the apoptosis of mature cells, results in the turnover of the epithelium every 3–5 days, which is important in barrier maintenance. Alterations in these processes can result in bacteria passing into the underlying tissue, potentially causing disease. This project aimed to better understand colonic stem cell proliferation and how it is influenced by its environment.

Human colonic organoids, a 3D *in vitro* model of the epithelium, were used to investigate proliferation via 5-ethynyl-2'-deoxyuridine (EdU) incorporation into proliferating cells under normal conditions, without the growth factors Wnt3A or LY2157299 and SB202190, with the addition of the  $\gamma$ -secretase inhibitor N-[(3,5-Difluorophenyl)acetyl]-L-alanyl-2-phenylglycine-1,1-dimethylethyl ester (DAPT, 10 $\mu$ M) or in the presence of bacterial components including lipopolysaccharide (LPS), muramyl dipeptide (MDP), lipoteichoic acid (LTA) and flagellin (all 20 ng ml<sup>-1</sup>).

Findings showed immature spheroids consisted of 36% (n=21) proliferating cells, while in mature enteroids only 6% were proliferating (n=6,  $P<0.0001$ ). Spheroids were significantly affected by the removal of Wnt3A or LY2157299 and SB202190, both decreasing proliferation to 8% (n=6,  $P<0.05$ ) and 4% (n=7,  $P<0.01$ ), respectively. The addition of DAPT, reduced spheroid proliferation to 3% (n=6,  $P<0.001$ ). Finally, proliferation in spheroids decreased to 7% (n=12,  $P<0.00001$ ) when treated with LPS, 8% (n=8,  $P<0.001$ ) with the addition of MDP, 9% (n=13,  $P<0.01$ ) with the inclusion of LTA and to 6% (n=7,  $P<0.001$ ) with the addition of flagellin. In contrast, no changes in the enteroids were seen upon environmental alterations. This helps to better understand stem cell proliferation in the human colon, and how the epithelium reacts to environmental change.

*Supported by a summer research scholarship from the Southern Victorian Charitable Trust and administered by the Otago Medical Research Foundation.*

### **Investigating *Candida albicans* Cdr1p dimerisation with NanoBRET™ technology.**

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*Candida albicans* is a significant cause of opportunistic infections which can become life-threatening in immunocompromised patients. Clinical isolates that are resistant to treatment with the widely-used antifungal fluconazole often have resistance conferred by overexpression of multidrug efflux pump Cdr1p. Despite the significance of Cdr1p in the development of new antifungal drugs and combination therapy to combat *C. albicans* drug resistance, little is known about the structure and function of this efflux pump. This study aimed to investigate potential Cdr1p homo-dimerisation in live yeast cells, using the novel NanoBRET (bioluminescence

resonance energy-transfer) technology (developed by Promega Corporation, Wisconsin, US) which had not previously been tested in one of the best-studied eukaryotic model organisms *Saccharomyces cerevisiae*.

The experimental approach was to clone plasmids in *Escherichia coli*, and then isolate these plasmids and confirm their sequence. The plasmids encoded Cdr1p expression cassettes with Cdr1p being tagged either with the novel light-emitting bioluminescent enzyme, NanoLuc luciferase, or with the acceptor fluorophore, HaloTag-618. Expression cassettes were excised and used to transform *S. cerevisiae*. Yeast transformants were confirmed by DNA sequencing and Cdr1p dimerisation was investigated by measuring energy transfer between NanoLuc and HaloTag, with each tag fused to a separate Cdr1p molecule. Detection of energy transfer would indicate Cdr1p dimerisation, as the close proximity of the tags is required for signal detection. The pump function of tagged Cdr1p constructs was characterised by measuring the minimum inhibitory concentrations of fluconazole required to inhibit the growth of *S. cerevisiae* strains.

Functional over-expression of the positive control construct, Cdr1p tagged with a NanoLuc-HaloTag fusion, in *S. cerevisiae* was achieved, with strong BRET signals being detected, demonstrating for the first time that the novel NanoBRET technology can be used successfully in *S. cerevisiae* to study protein-protein interactions.

*Supported by a summer studentship from the Southern Victorian Charitable Trust, administered by the Otago Medical Research Foundation.*

### **Water bath effectively dilates veins to improve prediction of suitability for arteriovenous fistula.**

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Arteriovenous (AV) fistula, formed by connecting a vein to an artery, allows vascular access for haemodialysis in patients with kidney failure. Vein suitability is determined by a patient's vein diameter and vein's ability to dilate, therefore current protocol uses venous tourniquet to dilate veins prior to measurement. There is some evidence to suggest that interventions other than tourniquet may be more effective. This project aimed to determine whether 1) warm water bath, 2) Bair Hugger (warm air through a jacket), or 3) handgrip exercise, was most efficient at dilating the cephalic vein, compared to current practice in the Otago Vascular Lab (tourniquet).

All three interventions were tested on 12 participants recruited from the dialysis unit, on three separate days. They were compared with baseline after rest, baseline tourniquet, and the intervention with tourniquet to determine the most effective mechanism. Baseline tourniquet (current protocol) and tourniquet following the intervention was 50 mmHg for 1 min.

Water bath was the most efficient and effective method of dialing the cephalic vein, 16% ( $P<0.0001$ , repeated measures two-way ANOVA) after 40 min with 1 min tourniquet compared to current protocol of 1 min tourniquet. Water bath also caused 50% of participants with <3 mm with the current protocol to reach threshold diameter after 10 min, and 75% after 40 min. These participants would not have been put forward for AV fistula with current protocol. Hand exercise did not cause a significant increase in vein diameter compared with current protocol, while Bair Hugger caused 16% ( $P<0.0001$ ) after 40 min with tourniquet.

If water bath was used in clinical practice to measure vein suitability before surgery, the results suggest it would increase the number of patients put forward for AV fistula. AV fistula has a lower rate of complications than other forms of haemodialysis therefore the water bath

could improve overall outcomes if these patients go on to form successful fistulae.

*Supported by a Summer Student Scholarship from the Otago Medical Research Foundation.*

### Expression, purification and preliminary characterisation of a plant cysteine dioxygenase.

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Cysteine dioxygenase (CDO) is a non-heme, mononuclear-iron enzyme responsible for the addition of molecular oxygen to the thiol of cysteine residues. In plants this oxidation leads to decreased protein stability, promoting degradation of proteins that are required only when the environment is depleted of dioxygen. This facilitates both submergence-tolerance and seed development, contributing to enhanced crop yield. In mammals CDO is involved in cysteine catabolism. Therefore, determination of its mechanistic activity may have clinical relevance in a number of cysteine related disorders including Alzheimer's and Parkinson's disease. Bioinformatic analysis shows that the active site of plant CDO differs from mammalian CDO even more so than that of bacterial CDO. Given this, plant CDO offers a unique perspective on the minimal requirements for CDO activity. This study aimed to determine expression and purification protocols to enable plant CDO characterisation and comparative studies.

Two plant CDO genes (*PCO1* and *PCO2*) were expressed from a pGS-21a vector in *Escherichia coli* strain BL21(DE3). Optimal temperature and expression times for amount of expressed protein were established for

each of the genes. Solubility of expressed protein was determined using sonication followed by centrifugation and sodium dodecyl sulfate polyacrylamide gel electrophoresis. Expressed protein was purified by strep-tag affinity and identified by mass spectrometry. Enzymatic assays were completed using a colorimetric based assay, and preliminary crystallisation trials performed.

Optimal expression and solubility of *PCO1* and *PCO2* was achieved at 18°C and 37°C, respectively. Under nearly all conditions investigated, an expression time of six hours was as effective as an expression time of 20 hours. *PCO1* was purified to homogeneity and this isoform was used for enzymatic characterisation. Enzymatic assays supported a  $K_M$  of 11±2 mM for cysteine. Crystallisation trials of *PCO1* showed extensive precipitation without crystal growth. Reducing protein concentration may lead to the production of a crystal suitable for x-ray diffraction.

Overall, parameters for both expression and purification were obtained and preliminary characterisation of the enzyme was achieved. These results give a basis for further experimentation and characterisation.

*Supported by a summer research studentship from the Department of Biochemistry.*

### Determining the role of tumour infiltrating IL-2 producing T cells in patients with colorectal cancer.

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Colorectal cancer (CRC) is one of the most common causes of cancer death in New

Zealand. A high infiltrate of T cells within colorectal tumours is associated with positive patient outcomes; however, the immune cell infiltrate has yet to be incorporated into traditional staging methods of CRC, which rely solely on tumour size and spread. The Immunoscore is a recently established method which quantifies the infiltrate of T cells within the tumour and has been proven to be a better predictor of patient prognosis than current staging methods. Preliminary experiments from our lab have identified that T cells producing IL-2, a cytokine important for T cell function, may have a prognostic role in CRC. This study sought to validate the predictive role of IL-2-producing T cells in additional patients with CRC.

Immunofluorescence was used to quantify the frequency and number of tumour infiltrating IL-2-producing T cells (CD3+IL-2+) from formalin fixed, paraffin embedded tumour samples from early stage (II) CRC patients with recurrent (n=13) and non-recurrent disease (n=18) at the invasive margin and centre of the tumour.

CRC patients with a high frequency (above median) of IL-2-producing T cells in the invasive margin were associated with poor disease free survival compared to patients with a low frequency (below median) of IL-2-producing T cells (Log rank test P=0.0456). However, the frequency of IL-2-producing T cells in the centre of the tumour was not associated with disease free survival.

These results validated previous findings from our lab and indicate that the presence of IL-2-producing T cells in the invasive margin of colorectal tumours may be predictive of disease relapse in patients with CRC.

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