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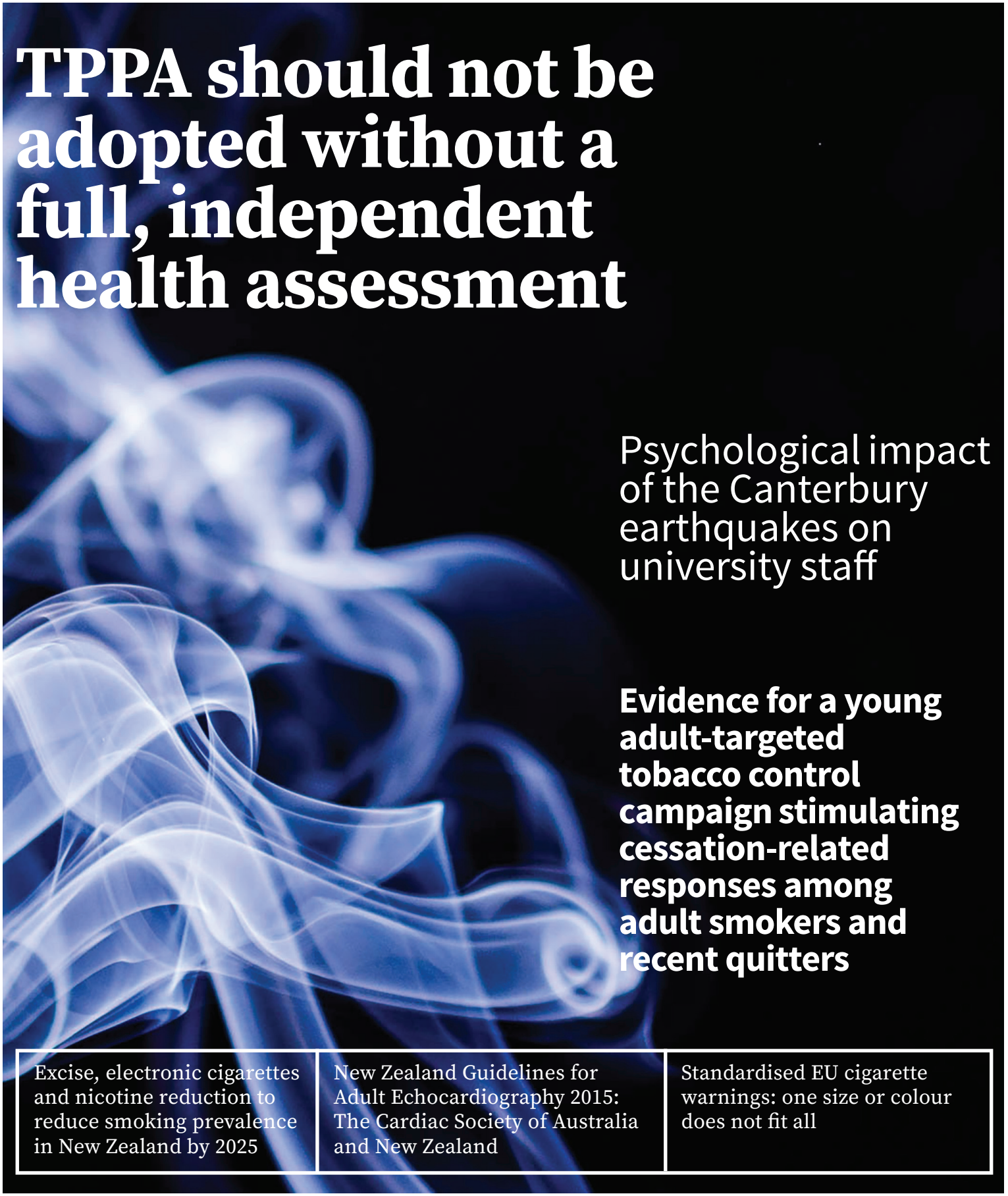
# TPPA should not be adopted without a full, independent health assessment



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## TPPA should not be adopted without a full, independent health assessment

Gay Keating, Josh Freeman, Alex Macmillan, Pat Neuwelt, Erik Monasterio

The secretive Trans-Pacific Partnership agreement (TPPA) was agreed in late 2015 and countries are now deciding whether or not they will formally join the treaty. The New Zealand Government's National Interest Analysis indicates that, in general, current health-relevant policies will continue; however, constraints will be placed on future governments developing new policies. Here we bring together several independent analyses of the released text of the TPPA, which reveal a concerning picture for health.

## Flexible sigmoidoscopy is the best approach for a national bowel screening programme

Brian Cox

A flexible sigmoidoscopy, done once in your life between 55 and 64 years of age, can reduce your risk of dying of bowel cancer by 33% and your chance of developing future bowel cancer by 43%. However, despite the very strong evidence that one-off flexible sigmoidoscopy screening is a much more effective screening test than the faecal occult blood test being used in the bowel screening pilot study, the Ministry of Health has failed to pursue this option. A national screening programme of one-off flexible sigmoidoscopy could be established within 12 months and recoup much of its initial cost within 10 years through savings in the total cost of treatment due to the reduction in bowel cancer incidence achieved.

## The role and potential of community-based cancer care for Māori in Aotearoa/New Zealand

Tania Slater, Anna Matheson, Cheryl Davies, Cheryl Goodyer, Maureen Holdaway, Lis Ellison-Loschmann

This is the first study to show how indigenous health providers contribute to cancer care and prevention in Aotearoa/New Zealand. A nationwide postal survey of Māori health provider organisations found that they deliver a wide range of cancer care programmes. These include cancer prevention services focussed on health promotion, as well as advocacy, information and support. The trust and long term relationships that Māori health providers have within their communities enables them to help people access mainstream cancer services such as screening, hospital care and cancer support services. This focus on supporting families rather than individuals is important throughout the cancer care journey.

## Trialling a shaken baby syndrome prevention programme in the Auckland District Health Board

Patrick Kelly, Kati Wilson, Aqeela Mowjood, Joshua Friedman, Peter Reed

Shaken baby syndrome is a cause of death and serious injury to a significant number of New Zealand babies every year. We describe a simple educational program, delivered routinely to parents or caregivers by health professionals in the first weeks or months of a baby's life, which may reduce the incidence of this condition. The program provides parents and caregivers with some simple strategies for coping with a crying baby as well as reinforcing the importance of never shaking a baby. The program was based on international scientific evidence, but modified significantly for the New Zealand context and trialled in the Auckland District Health Board over 18 months in 2010 and 2011.

 

## Assessing a hospital medication system for patient safety: findings and lessons learnt from trialing an Australian modified tool at Waitemata District Health Board

Jerome Ng, Penny Andrew, Marilyn Crawley, Wynn Pevreal, Jocelyn Peach

Medicines are one of the highest causes of preventable harm to patients. Improving medication systems is fundamental to making our hospitals safer for patients. The widely endorsed Medication Safety Self-Assessment (MSSA©) tool was used to compare local hospital medication systems against ideal medication safety practices (ie gap analysis). Information obtained from the review highlighted areas in need for further improvement.

## Evidence for a young adult-targeted tobacco control campaign stimulating cessation-related responses among adult smokers and recent quitters

Judy Li, Hayley Guiney, Darren Walton

Mass media campaigns are an effective tobacco control intervention. In New Zealand, smoking rates among young adults is higher than the rate among the overall adult population. In 2014, a new mass media campaign was launched, with young adults being the campaign's primary audience. Despite being a young adult-targeted tobacco control campaign, 'Stop Before You Start' had positive impact on adult smokers.

## Paediatric non-IgE mediated food allergy: guide for practitioners

Kahn Preece, Annaliesse Blincoe, Erik Grangaard, Genevieve Ostring, Diana Purvis, Jan Sinclair, Amin Sheikh, Robert Winkler and the Paediatric Allergy Special Interest Group, PSNZ

We present the current research on common childhood conditions that are, or thought to be, related to foods. Some rare conditions require food exclusion to prevent severe symptoms. Unfortunately, it is common for children to be placed on restrictive diets in an effort to alleviate symptoms such as colic or eczema. This is not supported by the scientific literature and has the potential to cause both physiological and psychological harm to children and their families.

## New Zealand Guidelines for Adult Echocardiography 2015: The Cardiac Society of Australia and New Zealand

Paul G Bridgman, Belinda Buckley, Mark Davis, Belinda Green, Alexander Sasse, David Tang, Niels van Pelt, Steve White

This is a national guideline for New Zealand provided by the Cardiac Society. It describes the standards for performing and reporting echocardiograms in New Zealand. All DHBs should be providing a digitally archived service with appropriately trained staff working with appropriate oversight and supervision. Regional networks should be developed to provide this where it is not currently in place.

## Psychological impact of the Canterbury earthquakes on university staff

Caroline Bell, Frances Carter, Joseph Boden, Tim Wilkinson, Jan McKenzie, Anthony Ali

This study shows that psychological symptoms following a disaster are common, but in a retrospective survey (completed 18 months after the earthquakes) most people report that these improve with time.A minority however continue to report difficulties which persist. The study gives insights into how different work roles for university staff were impacted and from this makes suggestions for how organisations may support staff over difficult times.

# TPPA should not be adopted without a full, independent health assessment

Gay Keating, Josh Freeman, Alex Macmillan, Pat Neuwelt, Erik Monasterio

The Trans-Pacific Partnership Agreement (TPPA) between 12 Pacific Rim countries (Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the US and Vietnam) was agreed and its text finally made available in late 2015.[1] The Agreement is long and complicated, and contains 30 chapters, many annexes and multiple side-letters. The National Interest Analysis released by the New Zealand Government indicates that while current health-relevant policies will continue, future governments will face constraints in developing new policies.[2] The New Zealand Medical Association, the World Medical Association and the Director General of the World Health Organization (WHO) have identified concerns about the health consequences of trade and investment agreements.[3–5] In this paper we synthesise some of the interim independent expert commentary on the released TPPA text.

## Global challenges for health and well being

Greater wealth usually goes along with greater health, dramatically so for least wealthy countries. But it's not a simple relationship. Health depends on the way increased wealth is shared and used, and if everyone benefits from technologies such as adequate housing, sanitation, nutrition, occupational health, education and medical treatments.[6]

So too with global trade and investment. Our lives are better for the import of vaccines, hip joint replacements, coffee, solar power and housing insulation technologies—but as with national wealth, more is not necessarily better. Indiscriminate imports can be appalling for health. Narcotics forced into China by the British (plus French and Americans) in the opium wars stands out.[7] This century, the World Trade Organization (WTO) insisted that Pacific countries import high-fat turkey tails and mutton flaps[8] and that the US take clove-flavoured tobacco products, with inevitable negative health consequences.[9]

In the same way that commerce is sometimes bad for health, measures to protect and improve health have at times forced commerce to adapt. When John Snow famously persuaded the authorities to close the pump that was making cholera–ridden water available on London's Broad Street in 1854, businesses that relied on this water had to find another water source or go broke.[10] Similarly, health regulatory measures on lead, laudanum and occupational health and safety have all saved lives, yet have also curtailed industry profits and closed businesses. Businesses and communities had to find healthier things in which to invest.

In this century, climate change caused by human greenhouse gas pollution looms as the greatest global health threat.[11] Tobacco, obesity and alcohol are huge global and national health issues.[12,13] In New Zealand, all are powerful drivers of inequality in health, especially for Māori.[13,14] Reduced carbon emissions, healthier foods, and decreased tobacco and alcohol use would all bring improved health, yet also lower sales, trade and profitability for some businesses.

The challenge for all countries is to transition to healthier commerce. Often regulations to protect or promote health have a cost to one industry while opening up commercial opportunities for others. Examples include regulations about worker safety, and reducing the burning of coal; the former creates opportunities for manufac-

turers of safety equipment, while the latter for innovators of clean, renewable technologies. We need trade and investment agreements to support these transitions, implementing WHO and United Nations (UN) Sustainable Development Goals, treaties and instruments, and ensuring governments respond to health threats as evidence emerges. The government's own National Interest Analysis and initial independent expert analyses all indicate that the TPPA fails to contribute to healthy trade in a number of important ways.

## Strengthening powers of global commerce

Almost all the TPPA chapters relevant to health expand on existing WTO provisions and these expanded provisions will become the new baseline. The New Zealand Government's analysis says:

> *The new obligations would, however, place new limitations on the Government's ability to modify New Zealand's policy settings to ensure they are appropriate for our domestic circumstances.*

The existing WTO rules on trade and investment give foreign countries opportunities to dispute and overturn government policies. Even threats of a dispute at the WTO can delay and limit government decisions. In 2010, New Zealand, Australia and others argued that Thailand's planned health warning labels for alcohol could pose an additional barrier for alcohol trade.[15] As a consequence, Thailand's alcohol warning labels were delayed by 5 years, and modified.[16]

The TPPA expands WTO dispute processes to further protect trade, investment, intellectual property monopolies and expectation of profit (Dispute Settlement Chapter 28). Disputes between countries are heard by off-shore panels. There is a requirement that dispute panel members have appropriate expertise when a dispute involves the labour, environment or anti-corruption chapters, but not health. Health advocates have no inherent right to make submissions; technical advice from health experts can be sought only if the complaining country agrees. If the panel rules against a health-protecting policy, the government is required to remove the policy or face financial or other sanctions.

In addition to these rights for foreign countries, the TPPA gives rights to foreign companies as soon as they take concrete action to invest (Investment Chapter 9). Investment is broadly defined to include brand names, logos, patents and more. Several TPPA chapters (such as Regulatory Coherence Chapter 25, Transparency and Anti-Corruption Chapter 26, Technical Barriers to Trade Chapter 8) give foreign companies greater influence in the formation, operation and review of regulation for the purpose of "facilitating increased trade".

Foreign companies also become entitled to dispute government actions via Investor-to-State Dispute Settlement (ISDS). Offshore *ad hoc* tribunals judge these disputes and can order the government to pay compensation. There is no right of appeal or review.

Many existing international agreements include ISDS provisions which have generated disputes. '*Eli Lilly* (a US pharmaceutical company*) versus the Canadian government*' is ongoing. The dispute arose after Canada declined to extend a medicine monopoly patent because the company's own data showed that the drug did not work for the claimed extended indications.[17] In the well-known '*Philip Morris versus the Australian government*', Australia reportedly spent over A$50 million in the first phase of defending tobacco plain packaging legislation. The case was closed on technical grounds, not because plain packaging was ruled a legitimate public health measure.[18] At the end of a long regulatory process, the US declined an application for the Keystone XL petroleum pipeline from Canada's tar sands on environmental grounds (particularly climate change). '*TransCanada versus the USA*' is beginning, with US$15 billion claimed in damages, using the ISDS provisions in the North American Free Trade Agreement.[19]

The TPPA text fails to meet the call of the World Medical Association for a prohibition on ISDS in relation to policies that promote or protect health.[4] However, some small concessions were made to the United Nations' suggested reforms to ISDS,[20] placing some limits on ISDS and prohibiting secrecy seen in the past. Further, the TPPA

does not meet the investment standard set by the European Parliament, to protect from ISDS any measures related to the Paris climate change agreement.[21]

New Zealand currently has some agreements that include ISDS. However, we have not previously had a trade agreement incorporating ISDS with the US, where companies are the most prolific in taking ISDS suits.[20]

## Generic protections for healthy public policy are fragmented, inconsistent and weak

The TPPA does contain a number of provisions that governments can use to defend healthy public policies against foreign country or foreign company disputes (see Technical Barriers to Trade Chapter 8, Investment Chapter 9 and Annex 9B, Intellectual Property Chapter 18, Exceptions Chapter 29, Annex II New Zealand). However, the defences for health are illogical, incoherent and incomplete. The following illustrate this incoherent picture.

Some clauses state a principle, some are for "protection", others for "preservation", others relate to "problems", or offer "sensitivity to objectives". Some are for "health", others for "public health". Human life, safety, nutrition and availability of medicines are sometimes named separately from health. While this messy terminology may reflect ignorance and piecemeal drafting, the vague wording of these health clauses contrasts with the precise language used in other areas of the Agreement (such as the explicit, extraordinarily broad definition of "investment" and the careful elaboration of other terms in the text to reduce doubt in interpretation). These ambiguous provisions could open governments to threats, delay tactics and disputes from foreign countries and foreign companies. It is far from clear how these unclear clauses would support, for example, the obesity and alcohol measures recommended by the New Zealand Medical Association.[22,23]

Each health-related protection applies to a select chapter or provision. There are appendices that permit specific existing country-specific policies and laws to continue. For example, a New Zealand appendix permits regulations on tobacco and alcohol wholesale and retail sales—but this protection does not extend to the regulation of advertising of tobacco and alcohol. The provision cannot be applied more widely (eg, to regulation on retail sale of junk food), or by other TPPA countries.

Other health protections are either weak or circular. Some follow WTO wording, despite the general failure of WTO protections to support governments' health or environmental policies. Judgements on WTO disputes to date have often decided that health-protecting regulations were not "necessary", as a more trade-friendly (but less health desirable) alternative could be found.[24] In other chapters, exceptions for government health measures are only defended from dispute if they are consistent with everything else in that chapter. Finally, some health protections may not apply in (undefined) "rare circumstances".

## Specific additional protections for pharmaceuticals and tobacco control

During the TPPA development, tobacco and pharmaceuticals were the health issues in greatest contention. It seems that even Trade Ministers agreed that there are holes in the generic protection for healthy public policies, because in these particular areas they negotiated extra protections.

Tobacco's prominence is a consequence of persistent and aggressive use of trade and investment treaties by the tobacco industry to delay, undermine and reverse governments' actions to implement the decade-old WHO treaty, the Framework Convention on Tobacco Control (FCTC). The TPPA does not recognise the existence of the FCTC. Foreign countries may use obligations in many different chapters to take a government to an international arbitration panel to reverse actions to implement the FCTC.[25] In direct opposition to the FCTC, in which countries have agreed to reduce the influence of tobacco companies on government policy, the TPPA expects

governments to include foreign companies in policy-making with no mechanism to exclude tobacco (see Transparency Chapter 8, Regulatory Coherence Chapter 25).

There is a significant tobacco control protection, thanks to the efforts of the Malaysian government negotiators and health professionals the world over. This provision (Exceptions Chapter 29.5) may limit the ability of foreign tobacco companies to sue a government for loss of profit because of smokefree policies. However, this protection is not automatic (a government has to explicitly invoke it) and the protection only applies to manufactured (not leaf) tobacco.

The focus on pharmaceuticals during the TPPA development arises from the long-standing pressure from patent-holding pharmaceutical companies to extend monopoly periods. Increased intellectual property provision threatens access to medicines (including biological medicines), particularly for developing countries. For wealthier countries, schemes such as PHARMAC that have successfully driven down medicines costs and progressively replaced brand-name medicines by cheaper generics (or biosimilars) have been opposed by brand name manufacturers and countries acting on their behalf.[26]

The TPPA brings longer exclusive monopoly periods for new medicines before a competitor's generic (or biosimilar) medicine can be made available (Intellectual Property Chapter 18 Subsection C). Additional intellectual property obligations will lead to delays for many countries in the availability of generics, with resulting increased medicines costs. There are complicated mechanisms to ensure market monopoly for biologics, a group of medicines never before given special protections in a trade agreement. For many countries these obligations will dramatically reduce access to affordable medicines. While the TPPA affirms parties' rights to take measures to protect public health as set out in the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health, some provisions in the intellectual property chapter actively undermine access to affordable medicines by extending and expanding monopoly rights.[27] It appears decisions on medicines subsidies will be protected from direct dispute.[28] Foreign countries cannot seek reversal of medicines subsidy decisions, nor can foreign companies directly seek compensation. However, they may be able to dispute the effect of those decisions on investments via other TPPA chapters.

For New Zealand, the TPPA provides increased opportunities for foreign pharmaceutical companies to question and seek review of PHARMAC's funding decisions. These provision concerning medicines are located in Transparency and Anti-Corruption Chapter 26. Some obligations are new, such as patent term extensions, patent linkage and aspects of biologic medicines market exclusivity. They will reduce future policy flexibility. The extent to which they will affect medicines costs for the government will depend on the ways in which the obligations are interpreted.

## Implications for other health threats

Evidence-based WHO and UN international agreements reflect the cooperation of many governments to limit disease by protecting the physical environment, and controlling hazardous products or behaviours. The only health-related international agreement explicitly supported in the TPPA is the Montreal Protocol on Substances that Deplete the Ozone Layer (Environment Chapter 20). Its inclusion is a 'win for health' (eg, skin cancer and cataracts), and demonstrates that the TPPA could recognise other health-related agreements. The text is totally silent on other health-protecting UN/WHO agreements, including the following:

- 1948 Universal Declaration of Human Rights (including the right to health —progressively attaining conditions which enable people to be healthy)
- 2010 WHO Global strategy to reduce harmful use of alcohol
- WHO Global action plan for the prevention and control of non-communicable diseases 2013–2020
- 1981 WHO International Code of Marketing of Breast-milk Substitutes
- 2007 UN Declaration on the Rights of Indigenous Peoples

- 1992 UN Framework Convention on Climate Change and subsequent international agreements
- 2015 UN Sustainable Development Goals.

The newly signed Paris Agreement under the UN Convention on Climate Change (UNCCC) has the potential to be a major global breakthrough in tackling climate change, and may be the most important agreement for public health this century. Climate change, greenhouse gases and the UNCCC do not rate a mention in the TPPA, although countries agree to "co-operate" on undefined "emissions".[29] It is difficult to see how countries that ratify the current text of the TPPA will translate the Paris Agreement into effective laws and policies.

The TPPA has many chapters relevant to both food and alcohol. Nutrition is mentioned once (Intellectual Property Chapter 18), but as separate from public health. It will take considerable time until independent analyses of the implications for these areas are available.

# Conclusions

Vital for 21st century healthy trade are investment agreements that support policies to underpin health, equity and human rights, the transition to a low-carbon economy and environmental protection. The New Zealand Medical Association and others have repeatedly called for independent health impact assessment of trade and investment deals,[3] in-line with concerns from the World Medical Association,[4] the Director General of the WHO[5] and many United Nations human rights experts.[30]

The TPPA is long, complicated, and interconnected. Comprehensive assessment is required of its broad impacts on health and equity. The initial independent health-focused analyses reported here indicate that the TPPA offers negligible support for implementation of UN and WHO health and human rights agreements, while enhancing the investment interests of foreign companies. While the TPPA appears to allow some regulatory freedom, the New Zealand Government's own analysis highlights that it places limitations on government's future policy options.

These concerns are sufficiently serious that decisions on implementation and ratification should be delayed until full and more comprehensive independent analysis of health impacts is available for public and Parliamentary scrutiny.

**Competing interests:**
Joshua Freeman, Gay Keating, Erik Monasterio and Pat Neuwelt are foundation members of Doctors for Healthy Trade. Joshua Freeman, Gay Keating, and Alexandra Macmillan are Executive Board members of OraTaiao: The New Zealand Climate and Health Council. Pat Neuwelt is a co-sponsor for the Public Health Association of New Zealand's Policy on Trade and Health.

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# Flexible sigmoidoscopy is the best approach for a national bowel screening programme

Brian Cox

The people of New Zealand rightly expect that the bowel screening method chosen will provide the greatest reduction in the risk of developing or dying of bowel cancer with minimal harm.

When the evidence suggests that one-off flexible sigmoidoscopy (FS) screening produces a greater reduction in bowel cancer incidence and mortality than faecal occult blood test (FOBT) screening, then the risks, benefits and resource requirements of a screening programme based on FS must be assessed. Despite calls for this,[1-3] and although New Zealand has the highest incidence of bowel cancer in the world, this has not happened. Opposition to one-off FS screening appears to have been based on a particular interpretation of the research results.[4]

In 2009, the first randomised controlled trial (RCT) of FS screening suggested that bowel cancer mortality may be reduced by the 7th year of follow-up.[5] The publication in May, 2010, of the results of the second RCT of one-off FS screening radically changed the health service options for bowel screening.[6] Participants in the trial who underwent one-off FS screening had a 43% reduction in the risk of dying of bowel cancer and a 33% reduction in future risk of developing bowel cancer. The results of these two studies were confirmed by two further RCTs of FS screening in 2011 and 2012.[7,8] These studies confirmed the magnitude of benefit from FS screening previously found in the well-designed observational studies[9-11] used to support options for colorectal cancer control in New Zealand.[12] Countries such as the UK that developed bowel screening programmes based on FOBT have been shifting to the more effective FS screening and initial participation in FS screening has been 43.1%.[13]

Instead of FS screening, general practitioners and DHBs are being asked to support a bowel screening programme based on 2-yearly immunohistochemical FOBT (iFOBT) and restricted to 60–69 years of age, a much narrower age range than the RCTs of guaiac FOBT (gFOBT) from which the effectiveness of iFOBT is imputed. This proposed 'slimmed-down' iFOBT programme can be expected to have lower effectiveness than the gFOBT trials that underpin it.

FS with an enema one hour beforehand takes about 15–20 minutes to complete and many family physicians in the US now provide FS screening. A one-off FS screening programme can be delivered by primary care organisations with appropriate gastroenterological or surgical support for the assessment of abnormalities detected. Surgical services already have experience in the provision of such support for the breast screening programme.

## What are the workforce requirements of a one-off flexible sigmoidoscopy programme?

There are currently an estimated 54,000 people who turn 60 years of age and 476,000 people 60–69 years of age annually in New Zealand. The results of the RCTs of FOBT and FS screening[14] provide estimates of the

**Table 1:** The expected screening, workload and effects on bowel cancer incidence and mortality for 4 bowel screening programmes.

| Characteristic | FOBT | FOBT | Flex-sig | Flex-sig |
|---|---|---|---|---|
| Age range (years) | 55-74 | 60-69 | 60 | 60 |
| Frequency | 2 | 2-yearly | once | once |
| Annual eligible pop | 464,185 | 237,940 | 53,745 | 53,745 |
| Participation | 55% | 60% | 43% | 50% |
| Number screened annually | 255,302 | 142,764 | 23,110 | 26,873 |
| Screens/week | 5,319 | 2,974 | 481 | 560 |
| Colonoscopy (%) | 5% | 5% | 5% | 5% |
| Colonoscopies with 30% surveillance | 16,595 | 9,280 | 1,506 | 1,747 |
| Annual number of cancers prevented | 30 | 10 | 222 | 309 |
| Annual number of cancer deaths prevented | 79 | 74 | 88 | 102 |

initial workload and long-term average annual number of bowel cancer cases and deaths prevented. Using this information, estimates for four screening scenarios are given in Table 1.

Assuming 50% participation, a full national FS screening programme would require 560 flexible sigmoidoscopies per week. In all, only about 20 flexible sigmoidoscopists, each performing an average of 28 flexible sigmoidoscopies each a week, would be required. Both screening modalities result in about 5% of participants being referred for colonoscopy.[15] With the addition of the likely surveillance colonoscopies required, the proportion requiring colonoscopy would initially be about 1,747 nationally per year (36 per week). The one-off nature of FS screening has major advantages, with greater impact on the bowel cancer burden, and a much more manageable increase in the colonoscopy workload. The proposed FOBT programme provided the poorest return of the four scenarios and a considerably greater requirement for colonoscopy.

These results suggest that for the Canterbury DHB for example, a region with an almost identical proportion of the national population 60–69 years of age as the Waitemata DHB (11.6%), a one-off FS screening programme would require about 200 extra colonoscopies per year (an average of just over 4 per week), and 69 flexible sigmoidoscopies per week. These resource requirements would appear manageable with appropriate organisation and a small increase in the support for existing gastroenterology or surgical services.

Staff to carry out FS screening would need to be trained and then perform a minimum number of tests per month to retain the skills and expertise to meet quality standards. Nurses and medical technicians were trained to conduct the FS screening of the UK randomised controlled trial.[1] Training at modest cost is available in several centres worldwide, such as the JETS programme of the RACP(UK) (www.jets.nhs.uk/CompareCourses.aspx?CourseCode=JAG_FDP2&CentreId=6&View=c).

Some supervision and follow-up of a number of video-reviewed FS procedures would be needed. With airfares and accommodation costs, an initial 20 flexible sigmoidoscopists could probably receive basic training in the UK and follow-up supervision back in New Zealand for less than $350,000. As the programme becomes established, ongoing quality assessment and video review might be managed by screening flexible sigmoidoscopists rather than endoscopists.

A FS screening programme could be based in, and run by, general practice organisations. A team of 2–4 trained flexible sigmoidoscopists in a region, with the appropriate sterilisation and video recording equipment, and a receptionist, visiting general practices 6-monthly, could provide a high quality FS screening service to the population. If suitable space or infection control facilities were not available, screening could be provided by suitably equipped mobile units such as has been done for other screening programmes.

## So what would such a national bowel screening service cost?

Several studies have suggested that one-off FS may be cost-neutral for the health service within 5-10 years because of the savings from the prevention of a large number of cases of bowel cancer, which iFOBT screening does not attain (Table 1).[15] Some studies suggest FS screening would produce net savings.[16] This will be more likely in populations with high incidence, such as New Zealand. It should be possible to fund the salaries, equipment and mobile facilities nationally for less than about $15 million a year. The cost would be offset within five years by the considerable savings from the treatment averted due to the reduced number of people developing bowel cancer.

Before DHBs agree to support the proposed 'slimmed-down' FOBT screening programme, they should consider the more effective and more cost-effective option that a one-off FS screening programme in their region would provide.

## How would such a programme work?

The general practice population lists could be used to identify individuals who had just had their 60th birthday. About 54,000 people turn 60 years of age each year in New Zealand. If each general practitioner serves about 5,000 people, a group practice of five general practitioners could expect, on average, to invite about 27 eligible people to screening in a 6-month period. If half accept the invitation, two flexible sigmoidoscopists could provide the screening required in a day. As a particular day may be unsuitable for some this might be carried out over two days. A two-day period may also cope with some of the variation in these estimates. The availability of FS screening in the evening or weekends increases participation and facilities may be more likely to be available at these times.

## What is the participation in one-off flexible sigmoidoscopy screening likely to be?

The only study of participation of the offer of FS in New Zealand was conducted through gastroenterological services in 1995.[17] This small study involved an invitation for screening sigmoidoscopy to a relative of someone who had recently undergone a colonoscopy. The subjects who were a relative nominated by a person who had a normal colonoscopy and no family history of adenoma or bowel cancer most represent the screening situation—where most people will know someone who has had a FS with whom to discuss their invitation. This small Dunedin study obtained 62% participation for the invitation for screening sigmoidoscopy.

Provision of FS screening through general practice would be expected to enhance participation.

## Conclusion

The failure to appropriately use all the available research evidence to develop a national bowel screening programme in New Zealand is of major concern. The one-off nature of the FS screening makes it ideal for introduction as a national programme without the necessity for a regional pilot study, but it would initially require monthly monitoring of progress and quality. The availability of FS screening training programmes overseas, and the small increased demand on current gastroenterological services, suggest that a national programme could be organised and begin within 12 months. The 'slimmed-down' iFOBT screening programme currently proposed by the Ministry of Health can not be expected to achieve the reduction in bowel cancer incidence and mortality of the RCTs. One-off FS is, on current evidence, the best practice of public health medicine for bowel cancer screening.

**Competing interests:** Nil

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# Psychological impact of the Canterbury earthquakes on university staff

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## ABSTRACT

**AIM:** To assess the impact of the Canterbury earthquakes on the psychological functioning of university staff, to identify predictors of adverse psychological functioning and to survey how different aspects of work roles (academic, teaching, clinical, administrative) were affected.

**METHODS:** Eighteen months following the most severe earthquake, 119 staff from the University of Otago based in Christchurch completed a retrospective survey. This included demographic information, a measure of earthquake exposure, standardised and self-rated measures to identify psychological distress and measures of how people perceived different aspects of their work roles were impacted.

**RESULTS:** A substantial minority of staff reported moderate-extreme difficulties on the Depression, Anxiety and Stress Scale (DASS) subscales 18 months following the most severe earthquake (Depression=9%; Anxiety=3%; Stress =13%). Predictors of distress were higher levels of exposure to earthquake-related stressors, neuroticism and prior mental health disorders. There was an association between impact and work roles that was hierarchical; academic and administrative roles were most affected, followed by teaching with the least impact on clinical roles.

**CONCLUSIONS:** This study shows that psychological symptoms following a disaster are common, but in a retrospective survey most people report that these improve with time. A minority however, continue to report difficulties which persist even 18 months post disaster. It also gives insights into how different work roles were impacted and from this makes suggestions for how organisations can support staff over difficult times.


In 2010 and 2011, the region of Canterbury, New Zealand, was struck by a series of powerful earthquakes and aftershocks. The first earthquake (4 September, 2010) measured 7.1[1] on the Richter scale[2] and resulted in relatively minimal physical damage to buildings and infrastructure. The second major earthquake (22 February 22, 2011) measured 6.3 on the Richter scale, but was situated closer to Christchurch city and had more devastating effects. Despite its relatively moderate magnitude, it generated some of the highest peak ground accelerations ever recorded,[1] and resulted in 185 deaths, multiple injuries and widespread damage to property and infrastructure.[3] There were further earthquakes in June 2011 (magnitude 6.3) and December 2011 (magnitude 6.0) which resulted in more damage, but no loss of life. In addition, there were more than 10,000 aftershocks over 2010–2011.[1]

As has been previously described after natural disasters, the earthquakes set off a train of complex adverse events for many people. Effects included not only exposure to the earthquakes and aftershocks, but also significant secondary stressors (damage to homes and workplaces, difficulties with insurance and delays in rebuilding).[4] Previous research has assessed the personal, emotional and social consequences of natural disasters, and has shown that exposure to a disaster, and the life events that follow, may lead to adverse consequences, including increased rates of mental health problems and psychological distress.[5,6] Studies which have focused particularly on the impact of disasters on working populations have reported similar findings with increased rates of mental health difficulties and distress.[7] These studies have also suggested that although being employed is often considered a


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measure of resilience, this may not actually be the case, and people at work may also have unmet mental health needs after a disaster. This research is important in order to inform employers of their staff's needs and for future disaster planning in order to support workers to continue to function.

This study aimed to assess the impact of the Canterbury earthquakes on the psychological functioning of university staff, to identify predictors of adverse psychological functioning and to survey how different aspects of work roles (academic, teaching, clinical and administrative) were affected. Staff in this study all worked at a medical school which was significantly damaged by the earthquakes. This resulted in the relocation of many facilities, with the main building remaining closed for almost 18 months after the February 2011 earthquake. In addition, clinical facilities, where many staff worked, also suffered damage resulting in loss of space and changing venues for teaching and clinical work.

# Methods

## Participants and survey administration

All 394 university staff at the Christchurch campus, University of Otago, were emailed inviting them to participate in an electronic survey asking about their experiences relating to the earthquakes. Surveys were sent in August 2012, which was 18 months following the most significant earthquake (February 2011). If staff did not respond, three email reminders were sent over the course of the next month. Staff were given relevant information about the study and gave consent to participate in the survey. The study was approved by the University of Otago Ethics Committee.

## Measures

The survey was designed to assess a broad range of variables to enable evaluation of the impact of the earthquakes on the psychological functioning of staff. This included demographic information, a measure of earthquake exposure, standardised and self-rated measures to identify psychological distress and symptoms, and measures of how participants perceived different aspects of their work roles had been impacted. It took 20-30 minutes to complete. The following outlines the information collected.

## Demographics

Age, gender, ethnicity (New Zealand European, Māori, Samoan, Chinese, Indian, Malay, Middle Eastern, other), relationship status (single, in a relationship, or married/de facto/civil union) and years spent living in New Zealand were reported by participants. The survey also asked about other factors that may have impacted on demands on staff, such as whether they had dependent children or others (such as elderly parents). Participants were asked to best describe their job (identifying one category from academic, joint academic/clinical, clinical, information technology, library, secretarial, other).

## Measure of exposure to earthquake-related stressors

The vast majority of earthquake-related stress was related to one event (the February 2011 earthquake) and the vast majority of respondents in the sample (>90%) had been present for this, with the result being that mere presence during the earthquake would not be an appropriate measure of exposure to this major earthquake. Furthermore, previous research has indicated that when attempting to measure exposure to a natural disaster such as an earthquake, it is necessary to take into account not only exposure to the event itself, but also exposure to the sequelae of the event including lingering disruption and difficulties related to repairs and rebuilding and effects on members of the individual's social network.[4] Previous studies have used different approaches to measuring exposure, such as the number of stressful exposures[8] as used in scoring for life stress scales,[9] or ordinal measures about the relative severity and impact of different components of a disaster.[10] In the current survey, earthquake exposure was measured using a method from a previous study of the effects of earthquake exposure on a longitudinal sample in which the general principles of the validity of using such a scale were established.[4] Participants were asked whether they were in Christchurch for each of the major earthquakes (yes/no) and also about their exposure to other stressors in order to assess stress burden.

This included questions such as whether they knew anyone who had been killed or seriously injured by the earthquakes, whether their home had been damaged and whether they had been affected by uncertainty about insurance issues in relation to this. The questions concerning home damage and insurance problems were rated on a five-point scale ranging from "not at all" to "a great deal", while the question concerning whether the respondent had known someone who had been killed or injured in the earthquake was answered using a dichotomous response format (yes/no). In order to examine associations between psychological distress and exposure to these issues arising from the earthquake sequence, questions about home and interpersonal issues were used to create an overall measure of exposure to severe stressors in the following manner. First, the two five-point measures (home damage, insurance difficulties) were converted into dichotomous measures in which those who endorsed the highest rating ("a great deal") were given a score of 1, while those who endorsed any lower level of rating were given a score of 0. These dichotomous measures were then summed along with the dichotomous measure of whether the respondent knew anyone who had been killed or injured in the earthquake. The result of this summation was a count measure of the number of different severe stressors reported by respondents, ranging from 0 to 3. Because only three participants received scores of 3 on this measure, the count measure was then altered such that scores ranged from 0 to 2+ severe stressors.

## Depression, Anxiety and Stress Scale

The Depression, Anxiety and Stress Scale (DASS) measures symptoms of depression, anxiety and stress in the past week.[11] The current study used the 21-item version of the scale, which produces comparable results to the longer version.[12,13] The DASS yields a total score indicating overall severity of symptomatology (all domains combined) plus subscale totals for depression, anxiety and stress. Subscale totals are categorised as normal, mild, moderate, severe and extreme. To ease interpretation, these categories were dichotomised as normal-mild and moderate-extreme. For the depression subscale, normal-mild was 0–13 and moderate-extreme 14–28. For the anxiety subscale, normal-mild was 0–9 and moderate-extreme 10–28. For the stress subscale, normal-mild was 0–18 and moderate-extreme 19–28.

## Work and Social Adjustment Scale

The Work and Social Adjustment Scale assesses current self-rated impairment attributable to an identified problem (earthquakes and aftershocks in this case).[14] Impact on five areas (work, home management, social leisure activities, private leisure activities and family and relationships) are rated on a 0 to 8 scale. Total scores range from 0–40.

## Eysenck Personality Questionnaire (Brief Version)

The Eysenck Personality Questionnaire (Brief Version) assesses self-rated personality characteristics in adults on a 1–5 scale (1=not at all, 5=extremely).[15] The scale consists of 24 items (12 extroversion, 12 neuroticism) and scores range from 12–60 for extroversion and 12–60 for neuroticism. In the current study, staff were asked to retrospectively rate their characteristics *prior to* the earthquakes. Scores for the extroversion and neuroticism subscales are reported here.

## Connor-Davidson Resilience Scale

The Connor-Davidson Resilience Scale assesses resilience over the past month.[16] The scale consists of 25 items rated on a 0–4 scale. The total score is a sum of the items with a range of 0–100.

## Other self-rated questions

### Health problems before and after the earthquakes

Participants rated the presence (yes/no) of health problems (mental and physical) prior to the earthquakes and currently.

### At worst and current ratings: symptoms and substance use

Participants rated the severity of impact of the earthquakes, both at their worst and currently, on the following variables which were not described above: sleep, concentration, alcohol, and cigarette use. Severity of impact was originally rated as being none, mild, moderate or severe. These

ratings were dichotomised as none-mild and moderate-severe.

### Impact on work roles

Participants rated on a 0–5 scale the extent that practical aspects of their job had been disrupted, for example by having to move offices or teach in unfamiliar venues. They also rated the severity of impact of the earthquakes, at worst and currently, on their ability to work in the following aspects of their jobs: academic, teaching, administrative and clinical, whichever were applicable to them. Many staff identified having multiple roles, including administrative and library staff, who identified as having roles in teaching, academic and clinical work. Degree of impact was rated as being none, mild, moderate or severe. These ratings were dichotomised as none-mild and moderate-severe.

Additional questions were asked about the impact on teaching and academic roles. Impact on teaching responsibilities were rated on a 1–4 scale (1=strongly agree, 4=strongly disagree) on questions about having less time to spend on teaching, the quality of their teaching, their accessibility and responsiveness as a teacher, the quality of the clinical experience they provided, the way in which the course was delivered and whether home/personal obligations had impacted. The impact on academic work was rated on a 1–4 scale on questions about writing papers, doing presentations, reviewing, taking on extra responsibilities, forming research collaborations, taking on studentships, taking on research students, attending meetings, participating in informal interactions with colleagues and continuing collection of data on existing projects.

### Positive outcomes

Participants were asked whether anything positive had come out of the earthquakes on a dichotomous variable (yes/no) and by a question asking them to describe these positive outcomes as a free text answer.

## Statistical analyses

Data were entered into the statistical analysis package SPSS (Version 20). Descriptive statistics were performed initially. In some cases, scales were converted into dichotomous measures because the distribution of responses were bimodal (almost none/a great deal) which meant that the use of full scales was superfluous and created difficulties for model estimation by inflating standard errors. Ratings before and after the earthquakes were compared using Chi-square and paired t-tests for categorical and continuous variables respectively.

Multiple regression models were fitted to the data for overall distress scores (DASS), earthquake exposure and covariate factors in two steps. In the first step, a model was fitted of the following form:

$$Y = B0 + B1X1 + e \quad (EQ1)$$

where Y was the overall measure of distress on the DASS, X1 was the count measure of exposure to severe earthquake-related stressors and e was an error term.

In the second step of the analyses, the covariate factors that were significantly ($p<.05$) related to the overall measure of distress (Eysenck neuroticism; prior mental health disorders) were entered into the model EQ 1 in order to examine whether the associations between earthquake exposure and overall distress could be accounted for by neuroticism and prior mental health disorders. This model was of the form:

$$Y = B0 + B1X1 + B2X2 + B3X3 + e \quad (EQ2)$$

where X2 was the continuous measure of neuroticism, and X3 was the dichotomous measure of prior mental health disorders. Model fitting was conducted using SAS V9.3.

## Results

### Response rate

119 of the 394 staff (30%) invited to participate gave consent and completed the survey either partially or fully.

### Participant characteristics

Participants were predominantly female (74%), with a mean age of 48.9 years (S.D 10.3, range 25–71 years). Most were of New Zealand European ethnicity (82%) with 5% identifying as Māori. The mean number of years lived in New Zealand was 38 years (S.D 17.9, range 1–71 years). Most were in a long-term relationship (77%), 45% had dependent children and 24% had others (such as elderly people) dependent on them. 36% of participants described their

**Table 1:** Mean, SD and range of DASS (and DASS subscales), Connor-Davidson Resilience Scale, Work and Social Adjustment Scale and Eysenck Personality Q: subscales and percentage in each dichotomous category for DASS subscales.

| Variable | Mean (SD), range or percentage in each dichotomous category |
|---|---|
| **DASS Total** | 14.7 (16.0), range 0–84 |
| **DASS Depression** | 5.2 (6.5), range 0–34 |
| Categories | |
| Normal-Mild | 90.8% |
| Moderate-Extreme | 9.2% |
| **DASS Anxiety** | 2.7 (4.3), range 0–20 |
| Categories | |
| Normal-Mild | 96.7% |
| Moderate-Extreme | 3.3% |
| **DASS Stress** | 6.9 (7.1), range 0–2 |
| Categories | |
| Normal-Mild | 87.5% |
| Moderate-Extreme | 12.5% |
| **Connor-Davidson Resilience Scale** | 68.9 (12.8), range 36–98 |
| **Work and Social Adjustment Scale** | 8.6 (8.7), range 0–36 |
| **Eysenck Personality Q: Extroversion** | 33.8 (7.6), range 19–49 |
| **Eysenck Personality Q: Neuroticism** | 23.1 (7.5), range 12–49 |

job as academic, 27% as secretarial, 18% as combined clinical/academic (doctors, nurses, psychologists, social workers with joint appointments with the University and District Health Board), 5% as either involved with the library or information technology and 13% as other. Demographic or other information was not available about staff who chose not to participate in the survey.

## Earthquake and other exposure

Most participants (92%) were in Christchurch for the most severe earthquake in February 2011 (78% for September 2010, 85% for June and 87% for December 2011). Fifty-nine per cent were in Christchurch for all four major earthquakes.

Thirty-four per cent of respondents knew somebody who had been killed or badly injured in the earthquakes. Most participants' homes had been damaged (92%), and in 28% this damage was rated as moderate (14%) or severe (14%). 40% reported being affected by uncertainty about house/land/insurance claims, and in 20% this was rated as being at least moderately affected.

## Psychological effects

Table 1 shows scores on the self-report psychological scales. Mean (SD) scores are presented for scale totals and for DASS subscales, total and category subscale scores and the percentage in each category.

## Depression, Anxiety and Stress Scale (DASS)

The mean DASS total score was 14.7 (SD 16.0, range 0–84). Nine per cent of participants reported moderate-extreme difficulties on the DASS depression subscale, 3% on the DASS anxiety subscale and 13% on the DASS stress subscale. The vast majority of staff were in the normal-mild category on all three subscales (87–97%).

## Work and Social Adjustment Scale

The mean score was 9 (SD 9, range 0–36: higher scores reflect more impairment). Ten per cent of participants scored above 20, suggesting moderate or severe impairment in functioning. Twenty-nine per cent of participants scored between 10 and 20, suggesting significant functional impairment.

## Connor-Davidson Resilience Scale

The mean score was 69 (SD 13, range 36–98: lower scores reflect lower resilience).

## Eysenck Personality Questionnaire (brief version)

The extroversion mean score was 34 (SD 8, range 19–49). The neuroticism mean score was 23 (SD 8, range 12–49).

**Table 2:** Associations between earthquake-related stressors and overall DASS Score, before and after adjustment for covariate factors (Eysenck neuroticism, prior mental health disorder).

| | **Model 1 (earthquake-related stressors only)** | | | | **Model 2 (earthquake-related stressors; Eysenck neuroticism; prior mental health disorder)** | | | |
|---|---|---|---|---|---|---|---|---|
| **Measure** | Unstandardised regression coefficient | SE | Standardised regression coefficient (β) | p | Unstandardised regression coefficient | SE | Standardised regression coefficient (β) | p |
| **Earthquake-related stressors** | 2.07 | 1.03 | 0.20 | <.05 | 2.29 | 0.91 | 0.22 | <.05 |
| **Eysenck neuroticism** | -- | -- | -- | -- | 0.43 | 0.09 | 0.40 | <.0001 |
| **Prior mental health disorder** | -- | -- | -- | -- | 5.53 | 2.15 | 0.22 | <.05 |

## Associations between exposure to earthquake-related stressors and overall distress

An overall measure of exposure to earthquake-related stressors was created. This was used in multiple regression models to examine the associations between earthquake-related distress and overall distress, as measured by the DASS. In the first step of the analysis, a regression model was used to estimate the bivariate association between exposure to earthquake-related stressors and overall DASS score. In the second step of the analyses—in order to examine the extent to which linkages between exposure to earthquake-related stressors and overall DASS score could be accounted for by statistically significant (p<.05) covariate factors—the regression model was extended to include terms representing: a) scores on the measure of Eysenck neuroticism; and b) the dichotomous measure of prior mental health disorder. Results of these analyses are shown in Table 2, which depicts the unstandardised regression coefficients, standard errors, standardised regression coefficients and tests of statistical significance for each model. Table 2 shows:

1. Before adjustment, there was a statistically significant (p<.05) association between exposure to earthquake-related stressors and DASS score, with those experiencing higher levels of stress having higher scores on the DASS measure.
2. Adjustment for Eysenck neuroticism and prior mental health disorder did not materially alter the association between exposure to earthquake related stressors and DASS score which remained statistically significant (p<.05). In addition, both Eysenck neuroticism and prior mental health disorder were independently related to DASS score, with those reporting higher levels of neuroticism having higher DASS scores, and those reporting prior mental health disorder having higher DASS scores. The overall $R^2$ for the final fitted model was 0.26.

Results of these analyses suggest that those individuals who reported higher levels of exposure to earthquake-related stressors also reported higher levels of distress on the DASS. This association could not be explained either by neuroticism, or by prior mental health disorders. However neuroticism and/or prior mental health disorders independently contributed to higher DASS scores alongside the earthquake-related stressors.

## Before and after the earthquakes: health problems, symptoms, substance use, mental and physical health problems

Participants reported an increase in mental health problems after the earthquakes (prior to earthquakes = 11 %; following the earthquakes = 16 %). Examples of mental health problems following the earthquakes included stress and other anxiety, mood or sleep-related difficulties. Participants also reported an increase in physical health problems following the earthquakes (prior to earthquakes = 27 %; following the earthquakes = 37 %). Examples of physical health problems following

**Table 3:** Severity of impact of earthquakes on symptoms, relationships and substance use at worst and currently (none-mild or moderate-severe), and whether treatment was received for these difficulties (percentage yes).

| **Variable** | **Severity percentage yes** | | **Treatment received** (either at worst or currently) **percentage yes** |
|---|---|---|---|
| | **At worst** | **Currently** | |
| **Sleep** | | | |
| None-Mild<br>Moderate-Severe | 39.3%<br>60.7% | 93.8%<br>6.2% | 10.6% |
| **Concentration** | | | |
| None-Mild<br>Moderate-Severe | 30.3%<br>69.7% | 92.9%<br>7.1% | 1.1% |
| **Alcohol Use** | | | |
| None-Mild<br>Moderate-Severe | 81.1%<br>18.9% | 96.4%<br>3.6% | 1.1% |
| **Cigarette Use** | | | |
| None-Mild<br>Moderate-Severe | 95.4%<br>4.6% | 98.2%<br>1.8% | 2.2% |

the earthquakes included a worsening of asthma and cardiac problems.

Table 3 shows the self-rated severity of impact of the earthquakes on a range of variables not covered in the psychological scales (sleep, concentration, alcohol and cigarette use) at worst and currently and whether treatment was received for these difficulties.

At worst, more than half of respondents reported moderate-severe effects on sleep (61%) and concentration (70%). A substantial minority also reported at worst moderate-severe effects on alcohol use (19%). There was no increase in cigarette use. Many of these impacts did not persist, ie were rated highly at their worst, but were lower by the time of the survey 18 months after the earthquakes.

# Impact on work

Fifty-four per cent of participants reported that practical aspects of their job (eg, having to move offices, working or teaching in unfamiliar venues) had been moderately to severely disrupted.

Different work roles were impacted differently. Eighty-seven per cent reported that at worst their ability in their academic role was moderately to severely affected. Eighty per cent reported that at worst their ability in their teaching role was moderately to severely affected. Seventy per cent reported that at worst their ability in their administrative role was moderately to severely affected. Sixty-one per cent reported that at worst their ability in their clinical role was moderately to severely affected. Many of these impacts were short lived, and at the time of the survey (18 months after the earthquakes) moderate to severe impacts were reduced. However, of those with academic roles, 53% reported that their ability to perform their academic role continued to be moderately to severely impacted, 40% their teaching roles, 33% their administrative roles and 19% their clinical roles.

Of participants with teaching responsibilities, the parts of their work identified as adversely affected were: having less time to spend on teaching (47%); the quality of their teaching (15%); their accessibility and responsiveness as a tutor (19%); the quality of the clinical experience they provided (11%); and their responsiveness as a clinical teacher (8%). Twenty-two per cent identified that the way the course was delivered had changed and 13% reported that home/personal obligations had impacted on their ability to teach. Twenty-six per cent of participants reported that they felt that their ability to meet students' needs had been moderately to severely affected. Of participants with

academic responsibilities, the parts of their work identified as adversely affected were: writing papers (46%); taking on extra responsibilities (46%); taking on research students (40%); doing presentations (39%); applying for grants (38%); taking on summer students (36%); forming research collaborations (31%); and reviewing papers (26%). Aspects of clinical and administrative responsibilities adversely affected were not asked about in this survey.

### Positive outcomes

66.7% of participants reported that positive things had come about from the earthquakes. These included themes involving: having a greater appreciation of the things that really mattered in life; having positive effects on relationships with colleagues, family and community; being less materialistic; and "living for the day".

## Discussion

The current study aimed to assess the impact of the Canterbury earthquakes on the psychological functioning of university staff, to identify predictors of adverse psychological functioning and to survey how different aspects of work roles (clinical, teaching, academic/research) were affected. The survey was completed approximately 18 months following the most severe Canterbury earthquake. This was at a time when secondary stressors, such as insurance difficulties and delays in rebuilding homes and workplaces, were a major factor. As described above, many participants reported having these issues in both their home and work environments.

Data were analysed for the 119 consenting respondents. This low response rate (30%) may limit the generalisability of the findings, but is similar to other surveys in post-disaster contexts.[7] Demographic characteristics of the survey participants were not able to be compared to the non-responders, and it is therefore not possible to comment on whether there was a difference between these groups. There may also have been a bias in those who completed the survey. For example, it could be that those who responded were likely to have the strongest motivation because they felt less positive about how they were coping. Conversely, those who were most affected may have been feeling under too much stress to respond.

As has been commonly reported in community surveys, it was relatively common for participants to report psychological symptoms from the earthquakes which often improved over time. For example, at worst participants rated themselves as being moderately to severely affected on concentration (70%) and sleep (61%), but by the time of the survey (ie, 18 months after the most significant earthquake) many of these symptoms had reduced. A minority (6–9%) however, continued to report moderate to severe difficulties with these issues.

Mean scores on the DASS showed that at the time of the survey, staff reported similar levels of depression, but lower levels of anxiety and stress than found in a previous study of the general population in Christchurch 6 months following the September 2010 earthquake.[17] Interestingly, a similar survey of medical students (although conducted 7 months after the earthquakes) showed similar results to those of the staff in our study.[18] Because work is seen as being good for mental health, it might be expected that an occupational and medical student group would score lower on measures of depression than a general population sample.[19] However, in the current study a minority of staff (9%) reported current moderate-extreme scores on the depression subscale of the DASS. These figures are higher than rates of major depression reported in the general population in New Zealand (3.7–5.2%)[20,21] and by a cross-sectional study in Christchurch at a similar time post-earthquake (7.5%).[22] This finding is similar to that from a previous study of university employees following Hurricane Katrina.[7]

Despite employment often being seen as a proxy measure for functioning, 10% of participants scored above 20 on the Work and Social Adjustment Scale, suggesting moderate or severe impairment in functioning, and 29% scored between 10 and 20, suggesting significant functional impairment.

Staff reported an increase in both mental and physical health problems after the earthquakes. Interestingly, no increase in smoking was reported by staff in the current study, which differs from findings from previous post-disaster studies, and by

a longitudinal study of a cohort of adults in Christchurch post-earthquake.[4] However, It is possible that medical school staff may have much lower rates of smoking than the general population.

The current study found that those who reported higher levels of exposure to earthquake-related stressors also reported higher levels of distress on the DASS. This association could not be explained, either by neuroticism or by prior mental health disorders, which was consistent with findings from a previous study.[4] The current study also found that neuroticism and prior mental health disorders independently predicted symptomatology. Interestingly, neuroticism and prior mental health did not seem to impact on the reporting of stressors (this may be because stressors were quite objective in nature). This is important because although these factors would not be confounded with actual exposure to stressors, they could theoretically be confounded by reports of stress exposure (because those who are more distressed generally could interpret the same events as being qualitatively worse than those who are less distressed). Other studies have also examined predictors of distress, and reported that prior mental health, neuroticism and not being of New Zealand European ethnicity predicted symptomatology independent of earthquake exposure.[17,18] Variation in the DASS score with the final model explained only about 25% of the variance. Other key factors, which were not assessed in the current study and which could be explored in further research, include the issue of prior exposure to traumatic stress and whether participants experienced other earthquake-related stress, for example, being in first responder or mental health roles providing vicarious exposure.[23]

The current study found that academic and teaching roles were the most impacted work roles, followed by administrative roles, with clinical roles being the least impacted. It may be that this is explained by a hierarchy of roles, such that when living with multiple stressors people prioritise their work according to their perceived immediate importance. That is, they prioritise clinical roles, whereas those roles seen as less immediately crucial, such as academic output, fall away. It may also be that academic and teaching roles require time and preparation and this may also be more difficult to protect from other demands. These findings may be informative for organisations in order to provide appropriate support to staff. For example, it may be helpful to recognise that academic or research writing, for example, is likely to fall off and employers may need to lower expectations for this. Positive initiatives by organisations are likely to be best targeted at areas providing increased academic support or, for example, taking over blocks of teaching. Unhelpful inputs are often unintentional, but relate to, for example, demanding increased reporting of activities that staff see as both less important and onerous. These findings support those recently summarised in a Red Cross report.[24]

Interestingly, two thirds of staff reported that positive experiences had also occurred as a result of the earthquakes. These included themes of greater appreciation of the things that really matter in life, positive effects on relationships with colleagues, family and community and being less materialistic. Similar post-traumatic growth descriptions of outcomes have been described previously by individuals and communities that have experienced adversity.[25]

Strengths of the current study are that it provided a unique opportunity to assess the impact of a natural disaster on a working population. The study included the use of standardised tests and Likert-type scales developed to assess aspects of impact/functioning of specific relevance to this population and a measure of earthquake exposure. Limitations of the study include the low response rate, although this is common in post-disaster survey work,[26-28] the reliance on self-report data (ie, no ratings from others, such as a clinician), the cross-sectional nature of the survey (that there are no comparisons pre-earthquake), and the retrospective nature of some of the assessments (personality, health problems and resilience prior to the earthquakes). Participants were not asked whether they had potentially high-risk roles, for example, as first responders or providing mental health treatment. These people may potentially be at increased risk of mental health effects,[23] although the number of

participants likely to have held that position would have been small, as only 18% of the survey identified as having a clinical role.

## Conclusion

Findings from the current study have potential implications for workplaces, and in particular educational institutions, in the event of a disaster. The current study's findings are consistent with existing research in showing that psychological symptoms following a disaster are common, but for most people these improve with time. They also show that a minority (up to 13%), continue to report moderate to severe difficulties which persist even 18 months post disaster. This highlights the need for organisations to recognise and plan for this in order to provide appropriate interventions for their workforce. In predicting who is most likely to have problems, clearly the extent of exposure to both the immediate disaster events and the adverse sequelae that often follow (for example, damage to home and work environments, difficulties with insurance) were found to play an important role. Other important factors were as previously reported, ie, neuroticism and prior mental health disorders. Organisations may be able to identify some (but not all) of these factors affecting their staff which may be helpful for offering interventions where they are required. The study also gives insights into how different work roles were impacted and how organisations may best support staff over difficult times.

**Competing interests:** Nil

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# The role and potential of community-based cancer care for Māori in Aotearoa/ New Zealand

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## ABSTRACT

**AIM:** To investigate the contribution to cancer care and prevention by Māori health provider organisations (MHPs) in Aotearoa/New Zealand.

**METHODS:** A nationwide postal survey of all MHPs (n=253) was undertaken in 2011. The response rate was 55%.

**RESULTS:** We found that MHPs are delivering a wide range of programmes including cancer prevention services focussed on health promotion, advocacy, information and support. MHPs identified financial hardship, transport difficulties, and lack of information as the greatest barriers to cancer care. Culturally safe care by mainstream providers would improve cancer service provision overall. The importance of trust and long-term relationships, with a focus on families rather than individual-based care, was highlighted.

**CONCLUSION:** These findings could lead to substantial improvements in quality of life for Māori cancer patients. This is the first study to show how indigenous health providers contribute to cancer care and prevention in Aotearoa/New Zealand.


There are stark differences in cancer incidence and survival across ethnic groups in Aotearoa/New Zealand (Aotearoa), with Māori carrying a disproportionate cancer burden.[1] Māori have an approximately 20% higher age-standardised incidence rate, and a 72% higher age-standardised mortality rate for cancer overall compared to non-Māori.[2] Additionally, quality of life differs between Māori and non-Māori from diagnosis through treatment, recurrence and survival.[2]

It is well established that there are challenges in accessing health care for Māori at all levels of service provision.[3-6] Access to care has a substantial impact on cancer outcomes,[7] yet the evidence suggests that mainstream systems of cancer care are substantially less responsive to Māori than non-Māori.[8]

Māori health providers (MHPs) were established in Aotearoa in the 1990s following radical public sector reforms. New funding models enabled MHPs to compete with other providers for health service contracts.[9] MHP values and ways of working were different to mainstream health providers and their services were available to all ethnic groups. One of the most important roles of MHPs was to enable people to access health services. MHPs used Māori models of wellbeing, positive Māori development and Māori philosophical and practical approaches.[10] However, health service contracts focussed on individuals and illness, which was inconsistent with Māori worldviews, emphasising holistic wellbeing and collective approaches to health for the whole whānau (family).[11] Despite these challenges, the number of MHPs has increased and their main focus is primary health care services relating to prevention and lifestyle issues.[12] Some MHPs offer general practitioner (GP) services and some do not, nonetheless MHPs play a major role in facilitating access for Māori into mainstream health care. This means that even if the MHP does not have its own GP service, regardless, appropriate onward referral (to primary health care

clinics/services in their areas), for those patients requiring this, is a core feature of the work that MHPs were set up to do. This facilitation remains important given that, as a diverse population, not all Māori access MHPs and all secondary care services are within the mainstream health care system.[13]

The establishment of MHP services coincided with the development of cultural safety education. Cultural safety programmes were developed in response to growing evidence of disparities in a range of health outcomes between Māori and non-Māori.[14] Cultural safety shifted responsibility back on institutions and health workers to address their performance in meeting the health realities of Māori, including access to care.[15]

The Medical Council of New Zealand and most District Health Boards (DHBs) have a cultural competency requirement, which is different to cultural safety. Cultural safety makes explicit the role of power in the nurse/midwife relationship with clients. Thus, the definition of 'good' care is placed in the hands of those receiving it. Cultural competency is less concerned with power and focuses more on the ability of clinical staff to engage respectfully and reflectively with people from different backgrounds.[16]

Primary care plays a key role in facilitating access to services, continuity of care and information that is person-centred throughout the cancer care journey.[17,18] As the first point of connection with the health system, primary care influences cancer prevention, early detection, access to specialist treatment and patient support following discharge from hospital.[19]

There is some research showing that as primary care providers, MHPs have a distinctive approach to cancer care.[20-25] The trust and rapport that MHPs have within their communities enables engagement with mainstream cancer care and support services. Additionally, these relationships enhance MHP driven cancer prevention activities (for example, smoking cessation). There is evidence that MHPs are effective at providing cancer screening[23] and support throughout cancer treatment.[22,25]

MHPs have been providing primary care services for decades, but information about of their services, particularly in relation to cancer, is scarce. There is evidence that MHPs have a wealth of local knowledge from their communities regarding the causes of disparities for Māori including access to and through cancer care.[23] This study aims to explore how MHPs facilitate access to cancer screening, diagnosis, treatment, support and palliative care services. Through identifying the services MHPs provide there is potential to build on strengths and help address unacceptable ethnic differences in cancer incidence, mortality and quality of life.

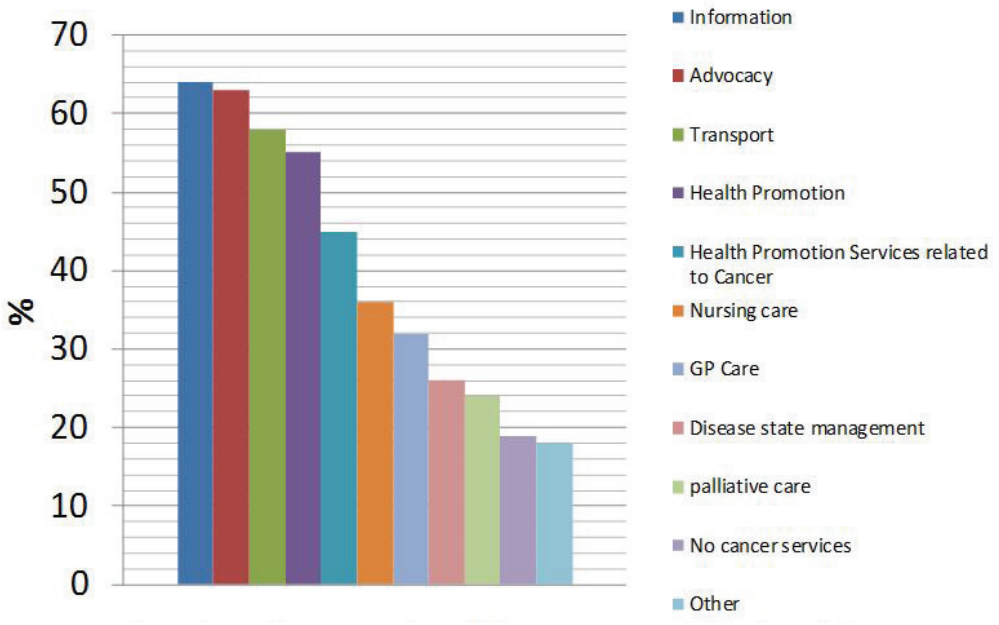
# Methods

This paper describes a survey of MHPs current role in cancer care. It examines the potential for further services, and explores MHP perspectives on what is impeding or assisting their communities in accessing services along the cancer journey. The study was approved by the Health and Disability Ethics Committee (MEC/09/11/131).

In 2011, we undertook a nationwide postal survey of all MHPs in Aotearoa. As discovered by other researchers,[25] there is no publicly available database of MHPs. MHPs can list their organisation on the Ministry of Health website, but this is not comprehensive with 66 MHPs listed at the time this paper was written.[26] For this study we therefore used publically available directories and networks in order to identify MHPs. Using this approach, 253 MHPs were identified.

The survey questionnaire was developed based on the Te Huarahi o Nga Tangata Katoa study, which investigated cancer service availability and experiences of patients and providers.[27] Our questionnaire explored services MHPs are currently delivering, including core services, types of support for cancer patients and whānau, and also health promotion, screening and other services which help with cancer prevention. Providers were asked to consider barriers to care for people who do not access cancer detection and diagnostic services, and what would help people with cancer and their whānau at all levels of cancer care and support. Finally, MHPs were asked if there were additional cancer care services that they could provide if funded.

**Figure 1:** Services for people with cancer and their whānau delivered by MHPs.




The questionnaires were sent to each provider together with a covering letter, information sheet and post-paid reply envelope. The information sheet outlined the aims of the study and explained that completion of the questionnaire implied consent. Non-responders were sent a follow-up survey, and contacted by telephone with a further survey sent on request. Data were entered into a Microsoft Access database. Analyses were undertaken using the statistical software package SAS and involved simple tabulations and percentages. No statistical tests were applied. Microsoft Access was used to group the data in the open text fields.

# Results

Of the 253 questionnaires sent out to MHPs, 119 (47%) were completed, 23 (9%) declined (of these, four organisations provided information about the services they provide), 37 (15%) were ineligible (return to sender, organisation no longer exists or is not a MHP). There were 74 (29%) non-responders. These included organisations that were sent the questionnaire and followed up with a telephone call, but did not complete the survey, and organisations that were sent the questionnaire twice but not able to be contacted by telephone. After subtracting the ineligibles, the overall response rate was 55%.

The survey was answered by people from a range of positions within the MHP organisations. Over half of the respondents were Kaiwhakahaere/Chief Executive Officers and managers (15% and 37% respectively), but the survey was also answered by nurses (10%), community health workers (8%), project/programme co-ordinators (8%), GPs (6%) and administrators (2%). Other respondents (9%) included team leaders, group responses, liaison positions and a counsellor. Six respondents did not provide their position within the organisation.

MHPs varied in size, ranging from individuals providing one health service, to large organisations with multiple premises, delivering up to 20 health service contracts. Respondents were asked to show the health services they offered, whether funded or not. Health promotion services were the most commonly provided health service. More than half of the respondents reported providing child/youth health, older people's health, community outreach, social services, infant health, mental health or nursing services. Services that were provided the least were disability support services and rongoā (Māori medicine).

## Cancer services

Respondents were asked about the services they provide for people with cancer and their whānau (Figure 1).

Information (64%), advocacy (63%), transport (58%) and health promotion (55%) were the most commonly reported cancer services, while health promotion services related to cancer (such as Aukati Kai

**Table 1:** Reasons for delay in accessing services for cancer detection/diagnosis.

| | Screening services | | Primary Care presentation with symptoms | |
|---|---|---|---|---|
| | (n) | % | (n) | % |
| Limited information | 88 | 74% | 73 | 61% |
| Financial barriers | 98 | 82% | 99 | 83% |
| Provider issues such as no GP or not registered with a Primary Health Organisation (PHO) | 57 | 48% | 54 | 45% |
| Lack of cultural safety | 59 | 50% | 57 | 48% |
| No Māori health workers | 52 | 44% | 49 | 41% |
| Fear of cancer diagnosis | - | - | 112 | 94% |
| Fear of misdiagnosis | - | - | 43 | 36% |
| Fear of treatment | - | - | 91 | 76% |
| Reluctance about talking to the doctor about other health issues | - | - | 83 | 70% |
| Delay in referral to specialist | - | - | 50 | 42% |
| Other reasons | 48 | 40% | 24 | 20% |

Paipa—a quit smoking programme) were reported by 45% of respondents. Respondents also reported provision of nursing care (36%), GP care (32%), disease state management (26%), and palliative care (24%). Almost 20% of providers reported no cancer service provision and 18% described other support and services including support for whānau, respite care, counselling and psychotherapy, support group programmes, funeral support, celebrations, rongoā (medicine) and accommodation (Figure 1).

In an open question, respondents were asked what services were of most benefit to people with cancer and their whānau. Most often, *by Māori for Māori* health and support services were described (33%). Specifically, respondents indicated the trust that people have in their MHP, cultural support, holistic healing, access to rongoā and mirimiri (massage), and wrap-around care that is often available after hours.

Advocacy and practical support were also outlined (27%), including transport and support for clinician and other appointments such as welfare agencies and electricity companies. Clinical services were identified (20%) including oncology departments, specialists and community nursing care. Palliative care was also noted (18%), with both palliative care and hospice care specified.

Respondents were asked to choose from a list of reasons why some people might delay accessing a service for early cancer detection or diagnosis. These included screening services and also primary care services such as a GP.

Findings related to delays in accessing cancer screening services indicate that financial barriers and limited information were the main reasons for delay. Half of respondents cited a lack of cultural safety by the screening provider, and provider issues such as not having a regular GP or not being registered with a PHO. Almost half of respondents thought an absence of Māori health workers at the screening provider contributed to delays. Other reasons were also described including: practical issues such as lack of transport and difficulty juggling childcare or time off work; and wider issues such as feeling whakamā (shy or embarrassed), denial and fear of diagnosis (Table 1). Information about accessing screening services due to fears of misdiagnosis, treatment or referral delay was not collected as it was seen as less relevant for asymptomatic people.

Findings with regard to delays in presenting at a primary care provider for

cancer detection or diagnosis, suggest that fear of diagnosis, financial barriers and fear of treatment were thought to be key reasons for delay. Additionally, many providers thought that reluctance about talking to the doctor about other health issues, such as diet or smoking, would contribute to delays. Limited information about cancer detection was also considered a factor. Almost half of respondents cited a lack of cultural safety by the primary care provider, while less than half thought that provider issues, such as not having a GP, a delay in referral to a specialist or no Māori health workers at the primary care provider, contributed to delays. Lastly, a fear of misdiagnosis was considered a contributor to delaying access to early cancer detection (Table 1). Just under a quarter of respondents listed other reasons. As with the delay in accessing screening services, these included practical issues, such as taking time off work, childcare and also worrying about the future, such as how to cope financially. Respondents also indicated that people might feel shy about seeing a doctor when they have symptoms, and fear of death, or fear of treatment based on the experiences of others.

In an open text question, providers were asked if they could identify any issues about, or barriers to, services for people with cancer. A quarter of respondents did not have any issues or barriers to identify. One respondent did not know, and data were missing for two respondents. Most respondents (70%) listed issues about, or barriers to services for people with cancer. Answers were similar to those shown for screening and presentation to primary care with symptoms in Table 1. Most commonly cited were transport and access issues. Additionally, a lack of appropriate information for people with cancer was described. This included information about diagnosis and treatment, and also information about support services available.

Financial costs were also reported as barriers to care, with time off work, childcare costs and accommodation adding financial pressure to whānau. Respondents also identified a lack of culturally appropriate services, for example cancer care staff pronouncing names correctly.

Respondents were asked if palliative care was readily available in their communities. Over half of the respondents (63%) thought it was, and 26% thought it was not. Eleven per cent of respondents did not know. Half of the respondents (n=60) identified issues or barriers to palliative care. Of these, location and travel were the main barriers, with many living in rural communities. Related to this were the responses of a smaller number of respondents who specified poor resourcing for community nurses in their area to provide palliative care services for whānau at home. A need for culturally safe palliative care services was described, and suggestions for improvement included acknowledging and improving cultural safety, having more Māori faces within palliative care service delivery, and a need for te reo Māori (Māori language), and karakia (prayer) to be available. A small number of respondents indicated reluctance by Māori to use hospice services due to associating the hospice with death.

Providers were asked if there were additional cancer care services that their organisation could provide, if funded. The question specified services that are currently not easily available or accessed in their communities. Over a quarter (32%) of respondents said there were no cancer care services that their organisation could provide. For many, this was due being a small provider with few contracts and resources. A small number (7%) of respondents did not know if there were cancer services they could provide, and over half (61%) answered positively. Of these, the services listed most were Māori-focussed cancer care services. These included support for whānau, Māori cancer support nurses, Māori focussed psychotherapy and counselling, and culturally appropriate home help. Respondents also listed 24-hour nursing support, mirimiri and rongoā, cancer resources and information specific to Māori.

In addition, the need for dedicated cancer navigator positions was highlighted. Support and advocacy, from diagnosis through to survival or palliative care, were emphasised. Respondents also listed provision of palliative care, appropriate funding for transport services rather than relying on volunteers and mobile nursing teams to access whānau in isolated areas.

# Discussion

This study is the first national survey of MHP cancer services. Four key areas were identified in our findings. The first is the largely unacknowledged, wide ranging cancer services that MHPs currently provide and the additional services that they would like to provide if adequately funded. Second, a number of barriers to and through cancer care for Māori were identified, such as financial and transport issues. Third, a continuing need was shown for culturally safe care by all services for Māori with cancer. Finally, the importance of trust and long-term relationships with a focus on families rather than individual-based care was highlighted.

Our list of MHPs was compiled from publicly available directories and networks. It is likely that in addition to our non-respondents, a small number of organisations were not surveyed, although it is impossible to count how many were missed. In 2009, the Ministry of Health estimated that there were approximately 275 MHPs,[28] but only a quarter of these are listed on their website.[26] This raises questions about why MHPs and their work are effectively invisible, with little information available about their contributions, and few evaluations of their work.

A response rate of 55% for this survey is acceptable. It is comparable to the 46% response rate yielded in a recent cross-sectional postal survey of GPs in Aotearoa.[28] Our efforts to increase the response rate included sending out the questionnaire up to three times and following up by telephone. We acknowledge that there may be non-response bias in this study with those organisations not providing cancer services feeling that the survey was not relevant and thus not completing it, however four declines provided information about the services they deliver and these did not differ markedly from the services reported by the respondents. Additionally, there may be some recall bias where MHPs have reflected on the services they offer or barriers experienced by those in their communities.

Results showed that MHPs contribute to cancer prevention, screening and care by delivering a wide range of programmes, including health promotion, advocacy, information and support alongside clinical care. In terms of contributing to cancer prevention, a high proportion of MHPs in our study provided health promotion services to their communities. The context of this work is important as Māori health promotion goes beyond delivering health and lifestyle messages. Ratima describes Māori health promotion as:

> *a process of enabling Māori to increase control over the determinants of health and strengthen their identity as Māori, and thereby improve their health and position in society.*[30]

In this way, the work that MHPs undertake in health promotion not only plays a central role in cancer prevention, but also contributes to positive Māori development.

Almost half of the MHPs in our study reported providing cancer screening services. Building trust, long-term relationships and practical assistance have been shown to increase cancer screening rates.[20,21,25] Our study demonstrated that many MHPs provide practical assistance, such as transport, advocacy and after hours care, but also link families with other services, such as the Cancer Society of New Zealand, hospice or Māori rongoā practitioners.

The coordination of care for Māori has been identified as a major area requiring further work.[20] Literature has shown that cancer navigator roles have succeeded in facilitating improved cancer care in Aotearoa,[21,31] and internationally—particularly for indigenous populations and those living in poverty.[32-34] The current study, and our previous work with cancer patients,[24] suggest that MHPs have been delivering informal cancer navigation for some time, but there is evidence that they are inadequately funded to do this work.[35-38]

Attempts to gather health funding information from Crown funding agencies have proven problematic.[35,36] Studies asking MHPs directly about their contracts have offered more insight. Lavoie found that MHPs were restricted by narrowly focussed contracts which did not reflect the work carried out.[37] Other studies have found limited scope for MHPs to negotiate with funders,[38] and MHP contracts to be short

term and audited with a heavy financial focus compared to their mainstream counterparts.[35] Indeed, the available evidence suggests that MHPs are underfunded and over regulated, but their process outcomes are under evaluated.[35-38] Without these issues being properly addressed by funders, it is difficult to see how the work of MHPs can be acknowledged and supported.

Financial struggles and travel featured consistently in our results as barriers to cancer screening, diagnosis and treatment. Health care reforms, beginning in 1999, aimed to improve primary care access in Aotearoa. By signing up to a PHO, the cost of GP consultations was reduced and some services were free.[38] However, findings from this study suggest that in addition to many Māori not having a regular GP or being signed up to a PHO, other barriers, such as the cost of travelling to appointments, still remain.

A lack of appropriate information was also a barrier to cancer services for the communities served by MHPs. This finding is consistent with work by Walker et al, who encourage more information and resources tailored to whānau and MHPs,[21] and Cormack and colleagues, who recommend Māori-specific resource material about cancer and cancer service options for individuals, whānau and communities.[20]

Our results suggest that fear is a major contributor inhibiting access to primary care services and potentially a cancer diagnosis. Fear of cancer, particularly by indigenous populations, has been documented internationally.[40-42] Our previous work found that having a trusted community health worker, nurse or GP can help alleviate these fears.[24] Further, persistence by MHPs in contacting and encouraging Māori to attend primary care services has been shown to ease fears about cancer screening,[22] diagnosis and treatment.[21]

Despite 66% of respondents believing that palliative care is available to Māori with cancer, and 24% of the MHPs delivering palliative care services, our results showed that MHPs are not confident their communities can always access the palliative care services they need. For some, this was due to living in remote locations. For those in areas where palliative care services are available, more Māori staff and improved cultural safety in hospices to encourage access was suggested. This aligns with findings from Frey et al, who additionally found a lack of awareness amongst Māori and other groups around palliative care service availability.[43]

MHPs in our study considered that shyness, or reluctance to discuss other health issues, impacted on Māori with cancer symptoms consulting a doctor. This finding suggests a current gap in comfort and rapport with mainstream primary health care providers which has also been described in other studies.[25,44-46] There is more work to be done within mainstream health systems and those who work in them to improve cultural safety. Approximately half of the MHPs who took part in this study consistently reported a lack cultural safety as a barrier to all cancer services, from prevention through to screening, primary, and hospital care.

Progress is being made. Our study supported previous findings that whānau play a critical role in relation to facilitating Māori access to cancer care services.[20,27,47] Whānau Ora, a new interagency approach to providing health and social services in Aotearoa, may offer better outcomes. The Whānau Ora initiatives encompass a philosophical approach, model of practice and measurable outcomes for health and social services.[48] At the time of this survey, Whānau Ora provider collectives were being established and early reports on Whānau Ora progress are scarce but positive. Boulton et al, for example, have shown how as a Māori-centred framework, Whānau Ora has positively changed ways of working and integration of contracts for a Māori health and social service provider.[49] Although not all MHPs will be part of Whānau Ora collectives (at the time of writing there were 34 Whānau Ora collectives),[50] Whānau Ora represents an opportunity to be appropriately resourced for the wide range of MHP services that overlap across sectors. Thus, the Whānau Ora approach should be considered as central to any framework for an integrated cancer care journey for Māori.

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Tania Slater, Maureen Holdaway, Anna Matheson and Lis Ellison-Loschmann report grants from Health Research Council of New Zealand, during the conduct of the study.

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# Trialling a shaken baby syndrome prevention programme in the Auckland District Health Board

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## ABSTRACT

**AIM:** To describe and evaluate a shaken baby prevention programme trialled in the Auckland District Health Board from January 2010, to December 2011.

**METHOD:** Development and implementation of the programme, telephone survey of a sample of caregivers and written survey of a sample of providers.

**RESULTS:** At least 2,592 caregivers received the trial programme. 150 (6%) were surveyed by telephone a median of 6 weeks later. 128 (85%) remembered at least one key message, unprompted; most commonly "It's OK to walk away" (94/150, 63%). When asked, 92% had made a plan for what to do when frustrated and 63% had shared the information with others. Only 98/150 (65%) watched the programme DVD. Many said they already knew about the risks of shaking a baby, but still found the programme highly relevant.

Thirty-one nurses were surveyed. There was a high degree of agreement that the programme was relevant. Barriers to programme delivery included time, workload and the documentation required.

**CONCLUSION:** A shaken baby prevention programme adapted to New Zealand can be introduced in a District Health Board and is acceptable to caregivers and health professionals. Further research is needed to evaluate the content, mode of delivery and effectiveness of this programme.


Shaken Baby Syndrome (SBS) is a well-known term for the most common cause of head injury in infancy, with a peak incidence under six months.[1-3] It usually results from a violent response to crying,[4] and many more infants may be shaken than diagnosed.[5] In New Zealand, the diagnosed incidence is 22–31/100,000 infants,[3] and may be increasing.[6-7]

Most infants with SBS suffer permanent effects.[8] The lifetime cost to New Zealand exceeds one million dollars per child, including health and ACC costs, educational costs and the costs of statutory intervention. There is a clear economic argument for an injury prevention programme.[9]

In 2005, Dr Dias (a paediatric neurosurgeon from New York State) described an apparently successful SBS prevention programme, introduced in December 1998, using a brief intervention targeted at the parents of newborns.[10,11] This consisted of a conversation between a health professional and caregivers in hospital soon after birth, written materials, posters and the option to watch a DVD.[10] It included a signed "commitment statement" confirming caregivers' understanding that "violent shaking is harmful and potentially deadly to a baby", and suggested ways to handle "persistent infant crying". A similar Canadian programme focusing primarily on education about crying[12] has recently been investigated in a large prospective trial, with mixed results.[13]

The Ministry of Social Development funded the Auckland District Health Board (ADHB) to trial a SBS prevention programme from 1 January 2010 to 31 December 2011. The purpose of this study was to evaluate that trial.

## Method

### Setting

The ADHB manages approximately 8,000 live births per year. The demographics of that population are described in the results.

## Programme structure

The basic structure (a perinatal conversation with supporting materials) was modelled on the Dias programme, with two key differences.

Firstly, early discharge meant that any New Zealand programme must often be delivered outside postnatal wards. Secondly, there was no commitment statement. In New York State, this also enrolled the child in prospective research linking programme delivery with cases of SBS. In New Zealand, this would require a separate process of informed consent to participate in research. Furthermore, a commitment statement was opposed at all stages of a 6-month consultative process and by almost all those consulted, including focus groups. Feedback was adamant that it would antagonise New Zealanders and be an insurmountable barrier to programme implementation. It was therefore not included.

## Programme materials

Dias used a leaflet from the American Academy of Pediatrics and a DVD (*Portrait of Promise*; Midwest Children's Resource Center, St Paul, MN), both produced in 1995.

We developed new materials, beginning with two pamphlets by an ADHB midwife, based on current literature and already in use (*Never shake a baby* and *Coping with a crying baby*). These were revised in a widely-consultative iterative process over a period of 6 months, including new and teen parents, Māori and Pasifika, interest groups and healthcare providers. This process identified six key messages (Figure 4).

Feedback consistently requested a local DVD, but in its absence *Portrait of Promise* was used. A bottle-feeding clip was removed to comply with the Baby Friendly Hospital Initiative (BFHI),[14] a WHO strategy to promote breastfeeding, which is mandatory in New Zealand maternity services.

## Programme delivery

After materials were developed, and before the trial began, co-ordinators trained staff on 'a train-the-trainers' model, supported by a clinical champion in each unit.[15] Training was designed for delivery in 20 minutes (the minimum time available), but could be expanded to 60 minutes. Content was highly standardised, and clinical champions reinforced it in daily practice. Trainees received a comprehensive 'educator's guide' and ongoing access to the clinical champion and co-ordinators for advice and support.

The programme, delivered by nurses or midwives, comprised: a) a face-to-face conversation with caregivers, following an 8-minute script, one-to-one or in a small group (less than 10); b) supporting materials—educational posters on the walls, pamphlets in English and the option (offered to all) to view *Portrait of Promise*.

The programme began in the neonatal unit (NICU) on June 1 2010, delivered before discharge. When disseminated (to community health, Starship inpatients and midwifery), the timing changed. Starship delivered it up to one year after birth. Community midwives introduced key messages in antenatal clinics, then followed up at postnatal home visits.

## Evaluation

The evaluation objectives were:

1. Was the programme structure acceptable?
2. Were the materials appropriate?
3. Did caregivers retain the information?

The evaluation had two arms: a telephone survey of caregivers (approved by the Health and Disability Ethics Committee and conducted by two co-ordinators), and a survey of NICU nurses delivering the programme.

## Participants

Programme delivery was recorded by a tick box in the clinical record and on a simple *pro forma*. Co-ordinators entered data into an Access database, including infant date of birth, prioritised ethnicity (mother's if antenatal), date and location, deprivation index (NZDep, a scale based on residential address)[16] and who participated (including relationship to the child and if they viewed the DVD).

## Telephone survey of caregivers

Programme recipients were invited to participate in a 10-minute follow-up telephone survey 6 weeks later. Those interested were contacted by a co-ordinator for consent. The timing was chosen to correlate (for newborns) with the peak age of infant crying, a key trigger to shaking.[4,17] This was similar to the Canadian programme,[12,18] but

**Figure 1:** Questionnaire for telephone survey.

**SHAKEN BABY SYNDROME PREVENTION PROGRAMME**

**FOLLOW-UP PHONE SURVEY**

**PROGRAMME NUMBER:** **DATE OF PHONE CALL:**

**INTERPRETER USED** **YES / NO**

**PARTICIPANT'S RELATIONSHIP TO THE BABY:** _____
**PARTICIPANT'S DATE OF BIRTH:** _____

**DO YOU REMEMBER BEING GIVEN PAMPHLETS ABOUT COPING WITH A CRYING BABY?**

**YES / NO**

| WHEN GIVEN THIS MATERIAL, DID YOU FEEL THAT… | SD | D | N | A | SA | n/a |
|---|---|---|---|---|---|---|
| You were treated with respect | | | | | | |
| The person knew what they were talking about | | | | | | |
| The conversation took place at a convenient time | | | | | | |
| The conversation took the right amount of time | | | | | | |
| The content of the conversation was right for you | | | | | | |
| The written materials were easy to understand | | | | | | |
| The DVD was helpful | | | | | | |

**WHAT DO YOU RECALL FROM THE INFORMATION YOU RECEIVED**

Crying is how babies communicate ☐
It's okay to walk away ☐
Never, ever shake a baby ☐
Never leave baby alone with anyone who you think may lose control ☐
Share this information with everyone who is looking after your baby ☐
If you ever think that your baby has been injured, seek medical help at once ☐

Other (specify) _____

**HAVE YOU SHARED THIS INFORMATION WITH ANYONE?** **YES/NO**

_____

**HAVE YOU MADE A PLAN FOR WHAT TO DO IF YOUR BABY CRIES AND YOU ARE NOT ABLE TO SOOTH BABY?** **YES/NO**

_____

**WAS THERE ANYTHING YOU FOUND ESPECIALLY HELPFUL?**

_____

**WAS THERE ANYTHING YOU FOUND ESPECIALLY UNHELPFUL?**

_____

**IS THERE ANYTHING YOU WOULD SUGGEST THAT WE COULD DO DIFFERENTLY?**

_____

**ANY OTHER COMMENTS?**

_____

SBS Prevention Programme Follow-up Phone Survey December 22 2010 Version 3 Page 1

**Figure 2:** Questionnaire for nurse survey.

**EVALUATION OF THE ADHB SHAKEN BABY PREVENTION PROGRAMME**

**First, a couple of questions about yourself…**

1. How many years have you worked in NICU for? 0-3 years 4-6 years 7-10 years > 10 years

2. What is your job title? Senior Nurse Staff Nurse Bureau Nurse Other_____

3. Did you attend a training session in May 2010? Yes No

4. If you did NOT attend a training session, did you receive training any other way? Yes No

5. If you said 'Yes' to Q.4, please specify who you received the training from:…….

| | **Strongly Disagree** | | | | | **Strongly Agree** |
|---|---|---|---|---|---|---|
| 1. The Shaken Baby Prevention Programme is relevant to my work place | 1 | 2 | 3 | 4 | 5 | 6 |
| 2. I have the knowledge and skills to educate caregivers about Shaken Baby Syndrome | 1 | 2 | 3 | 4 | 5 | 6 |
| 3. At present, I feel sufficiently supported by senior nursing staff to deliver the programme | 1 | 2 | 3 | 4 | 5 | 6 |
| 4. I feel comfortable discussing the content of the programme with caregivers | 1 | 2 | 3 | 4 | 5 | 6 |
| 5. All programme materials are readily available | 1 | 2 | 3 | 4 | 5 | 6 |
| 6. The process of completing and returning the associated documentation (e.g. the programme record) is convenient | 1 | 2 | 3 | 4 | 5 | 6 |

In your opinion, what are the challenges that limit effective programme delivery?

What are the benefits of the programme to your professional development?

Are there aspects of the programme you would like to change or improve?

earlier than in New York state, where caregivers were rung at 7 months, the median age of diagnosed SBS.[10]

Two cohorts were recruited using convenience sampling: Cohort One from NICU (June to October 2010), and Cohort Two from NICU, community midwifery and Starship (March to July 2011). All programme recipients were told about the survey and invited to take part.

Surveys were in English or by interpreter at a time of the participant's choosing and the study bore the cost of the call. Participants were asked "Do you remember being given pamphlets about coping with a crying baby?" and their level of agreement to seven statements (Figure 1). They were then invited to recall, unprompted, key messages in their own words. The interviewer recorded these in the order remembered.

In Cohort One, those who watched the DVD were asked whether a local DVD should be produced. Cohort Two were not asked, because production had already begun. Unprompted, few in Cohort One recalled "Share this information". To clarify whether this was forgotten, or merely less likely to be volunteered, we added a specific question for Cohort Two. Another question ("Have you made a plan for what to do if your baby cries and you are not able to soothe baby?") was added because of anecdotal reports that this was a common strategy.

Four questions were designed to encourage broad feedback. All free text responses were written down by the interviewer, but not audio recorded for transcription. All answers were recorded on a survey form, then transferred to the database.

### Survey of health professionals

In December 2010, nurses in NICU (the only unit where the programme had been fully implemented) were also invited to participate in a survey. (Figure 2) This was to evaluate staff response early enough to be able to modify the programme if necessary before wider dissemination.

### Data analysis

Quantitative data were analysed using JMP 10.0 software (SAS Inc., US). Medians and interquartile ranges (IQR), or mean and standard deviation (SD) are provided as appropriate. Comparisons of survey participants to non-participants, and to all mothers of live births, were undertaken using the two sample t-test (for mother's age) or Fisher's exact test (for NZDep and ethnicity). The telephone surveys had nearly identical results and were combined. Qualitative data was analysed with thematic analysis. Briefly, this is a widely used qualitative method that reduces a dataset into key, recurring themes.[19] The researcher takes an active role in the identification of themes. In this study, the dataset was read on multiple occasions and recurring ideas were highlighted by the researcher. Across multiple readings, the researcher gradually condensed them into the themes that best described patterns and trends in the dataset.

## Results

### Participants

Eighteen hundred programme sessions were recorded as delivered. A *pro forma* was completed in 1,524 (85%), with 2,316 participants. In these 1,524 sessions, only one caregiver was present in 901 (59%). The mother was present in 1,500 (98%). The father (or mother's partner) was present in 522 (34%). There were at least 276 participants in recorded sessions with no *pro forma*: a minimum total of 2,592 participants.

Where location was recorded, 790/1800 (44%) occurred at home, 392 (22%) in NICU, 332 (18%) in Starship, 221 (12%) in antenatal clinics, 44 (2%) on postnatal wards and 21 (1%) in other locations. In 1,274 postnatal sessions where the child's age was recorded, it ranged from 0 to 22 months (median 17 days, IQR 6–50 days).

### Telephone survey of caregivers

Participants: Figure 3 depicts the numbers of programme recipients and survey participants in each cohort. The survey occurred 4–13 weeks after programme delivery (median 6 weeks, IQR 5 to 8). Participation was recorded against the child's NHI on the database so no-one was surveyed twice.

Difficulties in obtaining the return of written consent forms for programme recipients in the community were anticipated but could not be overcome.

### Comparison of demographics

Table 1 compares the mothers of all live births from 1 June 2010 to 31 December 2011, programme recipients and survey participants.

**Figure 3:** Programme recipients and survey participants.

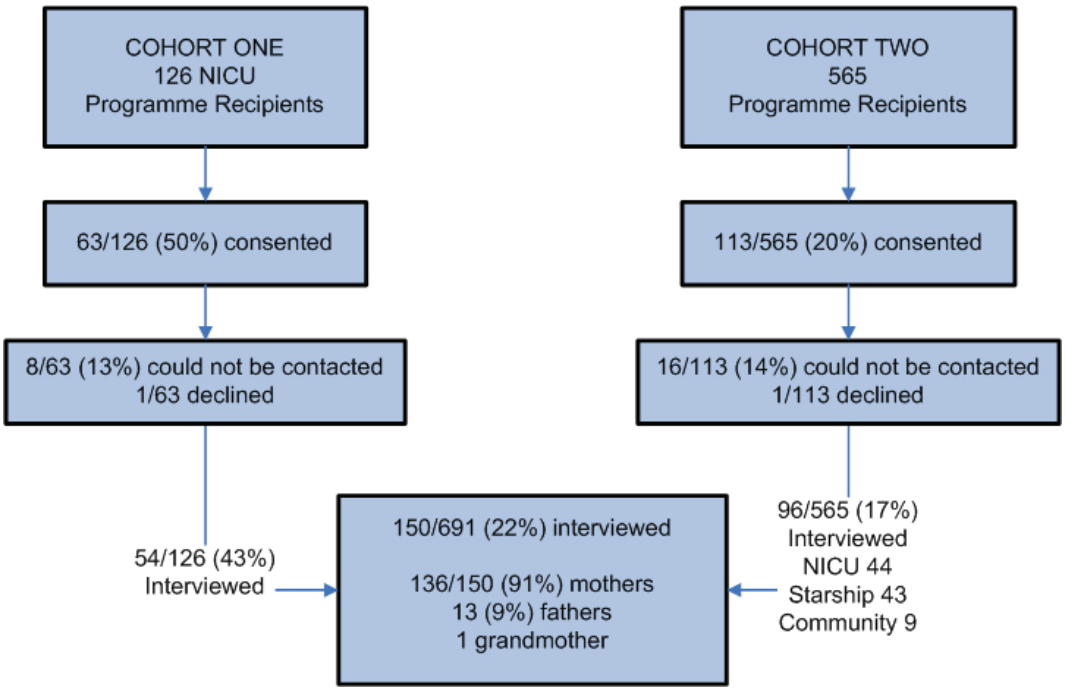



**Table 1:** Comparison of demographics.

| | Mothers of live births N=11,943 | Programme sessions N=1,800 | Survey participants N=150 | Survey compared to programme sessions | Survey compared to mothers of live births |
|---|---|---|---|---|---|
| **Age of mother (years)** | 14–55<br>Mean 31, SD 5.7 | 14–45†<br>Mean 29, SD 6.3 | 14–44†<br>Mean 29, SD 6.6 | t=0.72<br>p=0.5 | t=15.05<br>p<0.001 |
| **NZ Dep 1–3*** | 3,388 (29%) | 286 (16%) | 39 (26%) | p=0.002 | p=0.14 |
| **NZ Dep 4–7*** | 4,634 (39%) | 596 (33%) | 51 (34%) | | |
| **NZ Dep 8–10*** | 3,847 (32%) | 903 (51%) | 60 (40%) | | |
| **European** | 5,695 (48%) | 583 (32%)‡ | 81 (54%) | p<0.001 | p<0.001 |
| **Pasifika** | 1,626 (14%) | 479 (27%)‡ | 17 (11%) | | |
| **Asian** | 3,275 (27%) | 377 (21%)‡ | 29 (19%) | | |
| **Māori** | 930 (8%) | 278 (15%)** | 21 (14%) | | |
| **Other** | 417 (3%) | 79 (4%)** | 2 (1%) | | |

* NZDep available for 11,869 live births and 1,785 programme sessions. 1 = least deprived, 10 = most deprived

† Age recorded for 650 mothers in programme sessions and 133 in survey

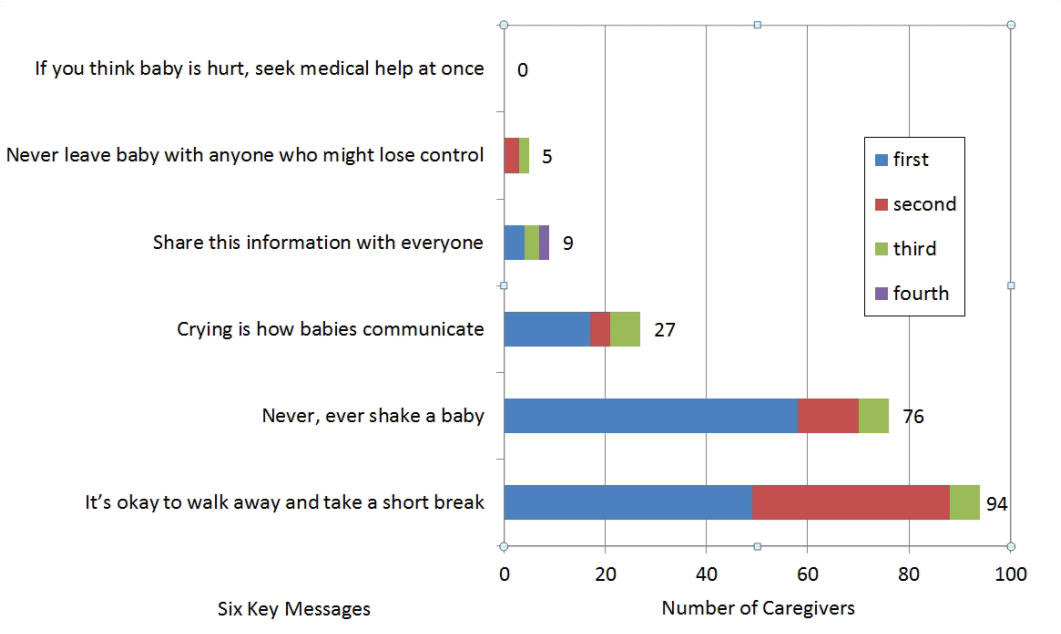
‡ Ethnicity recorded for 1,796 programme sessions

**Table 2:** Caregiver responses to statements about the programme.

| Statement | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | No response | Mean score out of 5 (SD) |
|---|---|---|---|---|---|---|---|
| You were treated with respect. | 0 | 0 | 4 | 58 | 83 | 5 | 4.5 (0.6) |
| The person knew what they were talking about. | 0 | 0 | 3 | 54 | 88 | 5 | 4.6 (0.5) |
| The conversation took place at a convenient time. | 0 | 4 | 5 | 62 | 70 | 9 | 4.4 (0.7) |
| The content of the conversation took the right amount of time. | 0 | 2 | 5 | 67 | 69 | 7 | 4.4 (0.6) |
| The content of the conversation was right for you. | 0 | 6 | 11 | 63 | 62 | 8 | 4.3 (0. 8) |
| The written materials were easy to understand | 0 | 2 | 5 | 43 | 92 | 8 | 4.6 (0.6) |
| The DVD was helpful | 0 | 0 | 8 | 32 | 58 | 52* | 4.5 (0.7) |

* Refers to those who did not watch the DVD

**Figure 4:** Messages recalled and the sequence in which they were recalled.



Survey participants tended to come from less deprived areas (NZDep 1–3) than programme recipients, but were similar in this respect to the mothers of all live births. Survey participants were marginally younger than the mothers of all live births and more often European compared to both programme recipients and the mothers of all live births (Table 1).

### Recollection of key messages

All but one (149/150, 99%) remembered the pamphlets. Responses to the statements are shown in Table 2.

Fifty-two of 150 (35%) did not watch *Portrait of Promise*. We did not ask why, and no free comment was made. However, anecdotal reports were that many caregivers chose not to. Most who did found it helpful, but in Cohort One, 29/32 who viewed it still wanted a local DVD.

Asked what they recalled, 128/150(85%) volunteered at least one key message, 65/150 (43%) two messages, 22/150 (15%) three and 2/150 (1%), four (Figure 4). Only 15/150 (10%) volunteered "Share this information with everyone", but when Cohort Two was asked whether they had shared the information, 60/96 (63%) had. Making a plan for what to do if frustrated was in the pamphlet, but not a key message. However, 88/96 in Cohort Two (92%) had made such a plan.

### Qualitative analysis of caregiver responses

Theme One: The programme was a useful reminder. Many already knew about the risks of shaking a baby, but valued a refresher. "Good reminder to tell others of the danger".

Theme Two: The content was highly relevant. "Grateful for the opportunity, using the information"; "The numbers for the helplines for people that don't have family"; "Have phoned Plunket line twice"; "Now getting support"; "Used the walk away technique"; "Baby is safe". The DVD was particularly memorable "Seeing physically what could go wrong was shocking and so that was helpful, I think about it more"; "How they demonstrated… so everyone can understand". Others appreciated the manner of programme delivery: "Nurse made it very real—talked about a case she had known".

Theme Three: *Portrait of Promise* was ineffective due to its style. "Use local people as we can associate better with them"; "Overdramatised, exaggerating due to being American"; "Good to share stories from New Zealand".

### Survey of NICU nurses

Thirty-one of 114 nurses (27%) completed the survey. Thirteen (42%) had worked there for over 10 years and 10 (32%) for 4–6 years. Twenty (65%) were staff nurses, five (16%) senior nurses and six (19%) "other" (bureau or enrolled nurses).

Twenty-four (77%) had attended training. Seven had not—of whom four (13%) were trained by a champion, and three (10%) received no training.

Mean responses to the six statements are shown in Table 3.

### Qualitative analysis of nurse responses

One theme was time and workload: "Time! Another task to do in the day." "Time constraints, suitable timing when parents not feeding baby so have their undivided attention". Others mentioned environment: "Level Two room, with four babies, parents and visitors and not time alone with parents."

Another theme was professional development: "Increases my skills in teaching parents"; "Building rapport with parents"; "A new focus, widening scope for discussion—a community focus rather than just hospital focus"; "It adds more knowledge on how I can care for the babies as a whole not just their illness."

Themes for improving the programme were a local DVD and alternative settings for programme delivery (ante-natal classes, training for midwifery and nursing students and parenting workshops).

### One pamphlet or two?

Throughout the trial, pamphlets on *Coping with a crying baby* disappeared much more quickly than *Never shake a baby*. In consultation with staff and caregivers after 2011, both pamphlets were simplified into one called *Power to Protect: Coping with a Crying Baby*.[20]

## Discussion

The first objective was to determine whether the structure of this programme (a perinatal conversation with supporting materials) was acceptable to caregivers and health providers.

**Table 3:** Nurse responses to questions about the programme.

| Survey statement | Mean rating out of 6 (SD) |
|---|---|
| The Shaken Baby Prevention Programme is relevant to my workplace. | 5.6 (1.0) |
| All programme materials are readily available. | 5.2 (0.9) |
| I have the knowledge and skills to educate caregivers about Shaken Baby Syndrome. | 4.9 (1.3) |
| I feel comfortable discussing the content of the programme with caregivers. | 4.8 (1.4) |
| At present, I feel sufficiently supported by senior nursing staff to deliver the programme. | 4.7 (1.4) |
| The process of completing and returning the associated documentation (eg, the programme record) is convenient. | 4.5 (1.3) |

Most caregivers surveyed responded positively to the manner, timing, duration and content of the programme. Similarly, providers reported that it was relevant and they felt competent to deliver it. Although community recipients were not well represented in our survey, and providers outside NICU were not formally surveyed, both constituencies participated in focus groups and there was close communication throughout the trial between co-ordinators, champions and providers. A wide range of health professionals, including community midwives, adopted the programme enthusiastically and gave similarly positive feedback.

However, there were barriers to implementation. NICU nurses described constraints of time and paperwork, evidenced by the fact that a *pro forma* was not completed for 15% of programme sessions. After the trial, the *pro forma* was discontinued, both from lack of resource to maintain a database and from concern that it hindered staff engagement. We now use 'tick boxes' in clinical records audited for compliance, similar to the approach for auditing family violence screening.[21]

Our second objective was to determine whether programme materials were appropriate. Survey participants found the pamphlets easy to understand. There were no comments about the posters, so their value is unknown. Thirty-five percent of those surveyed did not watch the DVD. For some, this may have been for technical reasons, or because it was not offered (in the Dias study, less than 2/3 of hospitals regularly showed the DVD).[10] For most, it was by choice, perhaps reflecting reluctance to watch material anticipated to be upsetting. Those who did watch *Portrait of Promise* generally found it helpful, but inappropriate for our population, so a new DVD, produced in partnership with tangata whenua, was launched in December 2011.[22]

Our third objective was to evaluate whether caregivers retained the information. Unprompted, most could only recall one or two messages, but these were arguably the most important ("It's OK to walk away" and "Never, ever shake a baby"). Many told others, even though they did not recall that as a key message. Many made a plan, though that was not a key message. Future research could explore whether further programme modification would aid recall. It is interesting that an evident preference for the *Coping with a crying baby* pamphlet was not expressed in surveys. In-depth qualitative research may be required to capture the full range of responses to programme language.

# Limitations

Dias' is the only programme shown to reduce the incidence of SBS, yet our programme differed in two respects. Firstly, it was mostly delivered outside hospital. This was unavoidable and there is no obvious reason why this would reduce efficacy. Secondly, there was no commitment statement. Dias hypothesised that this "may be a very important (perhaps even the most important) component of the program's success",[10] but provided no specific evidence for this.[23] It is therefore unknown what (if any) effect the absence of a commitment statement has on efficacy.

The most serious methodological limitation was that our formal surveys had small samples and were not fully representative. In particular, the low community response rate raises the possibility of a non-response bias, which may affect the validity of our findings. The caregiver survey relied on telephone calls, with all their limitations,[24] and the 10-minute time-frame seriously constrained the depth of qualitative data. Nevertheless, the programme evolved through a process of wide consultation and formal and informal feedback was consistent over time (two cohorts 9 months apart), location (hospital or community) and role (caregivers and a variety of health professionals). To address the problem with written consent forms, future evaluations could consider reducing the burden on community participants by collecting a recorded oral statement of consent, and sending a record of this to participants.

Most importantly, this study cannot answer the central questions (notoriously difficult to study): does the programme change behaviour or reduce the incidence of SBS? Although some authors describe an effect on caregiver behaviour, this is based on self-report, not observation,[12,18] and a reduction in incidence has not been shown outside New York State. Our trial, involving only 15% of births in the ADHB, had no power to show an effect on incidence. In addition, the absence of a database will hinder ongoing thorough evaluation of the programme and its efficacy. The 'gold standard' trial (a prospective RCT) is probably impossible to conduct for a condition of low prevalence in our small and mobile population, and may be difficult to justify for a programme that is intrinsically low-risk.

# Conclusion

This study has shown that a SBS Prevention Programme is received positively by New Zealand parents, caregivers and health professionals and can be introduced into a New Zealand DHB. Further research is needed to evaluate content, mode of delivery and effectiveness. In particular, this would include face-to-face qualitative research with community recipients and providers.

**Competing interests:**
Aqeela Mowjood was awarded a student research scholarship by the Child Injury Prevention Foundation of New Zealand to undertake the mid term evaluation of the shaken baby prevention programme.

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# Evidence for a young adult-targeted tobacco control campaign stimulating cessation-related responses among adult smokers and recent quitters

Judy Li, Hayley Guiney, Darren Walton


## ABSTRACT

**AIMS:** Young adults are an important group for tobacco control interventions because of their high smoking prevalence. In 2014, New Zealand launched a young adult-targeted tobacco control campaign: 'Stop Before You Start'. The evaluation undertaken with young adults (aged 18 to 24 years) showed that the campaign exerted positive impacts on this age group. This study aimed to investigate the collateral effects of this campaign on older adults.

**METHODS:** Data were collected from a fortnightly survey of adult smokers and recent quitters, where respondents were maintained on a panel and interviewed every fortnight, up to six times. This paper reports on data collected over three consecutive fortnights (540 interviews). Ten measures were used to assess campaign effectiveness (eg, felt regret, tried to quit).

**RESULTS:** After adjusting for recent quit attempt status and socio-demographic characteristics, age differences were not found in any of the outcome variables (aged 25–44 years and 45+ years were compared against 18–24 years).

**CONCLUSIONS:** Internationally, little is known about the effectiveness of young adult-targeted tobacco control campaigns. Alongside data from the campaign evaluation with young adults, findings from the current study suggest that this young adult-targeted campaign also created a desirable impact on older adults.


The World Health Organization's Framework Convention of Tobacco Control Article 12 requires parties to raise public awareness of tobacco control issues through different communications tools, including mass-media campaigns.[1] Implementation of tobacco control mass-media strategies is evidenced in many developed countries, including Canada, the US, the UK and Australia.[2–5] However, the majority of mass-media campaigns to date have focused either on youth initiation or cessation among adult smokers. While some of these campaigns have included young adults as part of broader target audiences, young adults have typically not been the focus. Consequently, those broadly-targeted campaigns might not have recognised and reflected the smoking experiences unique to young adults.

Not until recently have campaigns that specifically target young adults begun to emerge (eg, 'My smoking' and 'If you smoke, your future's not pretty' were launched in Queensland in 2011 and 2014, and 'Quit the denial' was launched in Canada in 2013). The development of these young adult-targeted campaigns was in response to the: a) high smoking prevalence in that age group;[6,7] and b) recognition that smoking serves different social functions for young adults and therefore different messages are required for this audience.[8]

As in other countries, smoking prevalence among young adults (aged 18–24 years) in

**Figure 1:** A still image from one of five television adverts.

New Zealand is higher than average (24%, compared with 17% of adults aged 15 years or over).[9] In response to the high smoking prevalence in this age group, a new mass-media campaign called 'Stop Before You Start' was launched in June 2014. This national campaign targeted young adults specifically and aimed to discourage specific groups of young adults from progressing to more frequent smoking: *never smokers* from taking up smoking, and *experimenters* and *social smokers* from progressing to regular smoking. Previous research on young adults' smoking behaviours and their construction of identity suggests that young adults do not fit neatly into 'smoker' and 'non-smoker' categories.[10] Young adults are also more likely than older adults to smoke infrequently and identify themselves as 'social smokers'.[11] Since many social smokers do not consider themselves to be 'real' smokers, they are likely to resist mainstream tobacco control messages that they see as being for regular smokers.[12] In light of this diversity and the importance of developing personally relevant messages in persuasive communications,[13–15] the 'Stop Before You Start' advertisements purposely did not highlight a specific smoking frequency. Rather, they showed how smoking can develop in an insidious way, beginning in social situations and later leading to nicotine dependence.

Television advertising, comprising five advertisements, was the main media channel at the initial stage of the campaign (can be viewed at www.stopbeforeyoustart.org.nz).[16] This was supported by radio and online advertising, and communications through social media. All five television advertisements featured a personified cigarette (a middle-aged man dressed as a cigarette) that looked disgusting and unattractive (see Figure 1). The rationale for personifying cigarettes was to distance the unattractive characteristics associated with smoking from the young smokers and to represent the young smokers as being manipulated by the cigarette man. In this way, the advertisements could portray the unattractiveness of smoking without stigmatising or victimising people who smoke. A qualitative study of young adult smokers in New Zealand revealed a general disbelief among this group that smoking is addictive. They also had a strong sense that they could stop smoking if, and when, they wanted to.[17] These findings were supported by the international literature.[18–20] By representing young smokers as being manipulated by the cigarette man, the campaign provided an opportunity to educate its audience on how addictive smoking is. The campaign also highlighted the health, social, and financial impacts of smoking, and asked young adults to think about the relationship they have with tobacco. These messages were intended to provide reasons for young people to resist tobacco. It did not contain any overt cessation messages as this type of message could reduce the perceived relevance of the campaign to non-smokers, experimenters, and social smokers.

To assess the short-term impact of 'Stop Before You Start' on young adults, a cohort of 353 17 to 24-year-olds was surveyed via computer-assisted telephone interviewing (CATI) just prior to the campaign launch and again six months later.[21] The results showed that campaign exposure was high (85% prompted recall) and that the campaign was targeted effectively (86% agreed that 'the ads are relevant to people my age'). There were also positive cognitive and behavioural responses to the campaign. For example, in response to the advertisements: 42% of daily smokers said they had thought about their relationship with tobacco; 45% had regretted started smoking; 25% had talked to someone else about the advertisements; 33% deliberately didn't smoke when they were with others; and 28% tried to stop smoking completely. Finally, the evaluation showed that implementation of the campaign was associated with positive changes in young adults' smoking-related attitudes. For example, there were significant reductions in agreement that smoking is 'attractive' (13% at benchmark and 5% at follow-up) and 'social' (75%; 65%), and significant increases in agreement that smoking is 'disgusting' (65%; 74%). Together, these findings indicate that the campaign had a positive impact on its target audience.

The purpose of the current research was to understand the collateral effects of this young adult-targeted campaign on segments of the population other than the target audience: specifically, the extent to which 'Stop Before You Start' affected the attitudes and behaviours of the wider adult smoker population. Two previous studies reported by White and colleagues found such collateral effects of tobacco control campaigns, but they related to the impact of adult-targeted tobacco control campaigns on adolescents.[22] No studies have examined the effects of young adult-targeted campaigns on the wider population. The current paper fills this information gap by investigating adult smokers' and recent quitters' responsiveness to a young adult-targeted campaign implemented in New Zealand. As tobacco control mass-media spend in New Zealand had dropped remarkably over time,[23] this assessment is particularly important and would have important implications for the coordination of national tobacco control campaigns in New Zealand.

It should be noted that data collection for the current study commenced immediately after the campaign was launched and it was aired at a low intensity (at 350 targeted audience rating points/TARPs). Previous studies showed that tobacco control advertising needs to have sufficient reach, intensity, and duration for audience to receive and process the message.[24,25] Therefore, it is important to emphasise that this study only reported on the impact of the early phase of 'Stop Before You Start'. It is conceivable that better overall outcomes could be achieved once the campaign is more established.

# Methods

## Instruments

The New Zealand Smoking Monitor (NZSM) is a fortnightly monitor implemented since 2011, and fieldwork is delivered using CATI.

## Participants

Responses were gathered from a sample of New Zealand adult smokers or recent quitters (aged 18 years or over) who took part in the NZSM. Ethics approval was obtained from the New Zealand Health and Disabilities Ethics Committee (Ref: 13/CEN/99).

A quota system is in place to ensure the sample consisted of three groups (n=60 per group, per fortnight), differentiated by participants' current and past three-month quitting behaviours:

1. 'non-attempters': daily smokers who had not made a quit attempt lasting 24 hours or longer in the past three months;
2. 'recent quit attempters': daily smokers who had made a quit attempt lasting 24 hours or longer in the past three months;
3. 'serious quitters': previously daily smokers who had not smoked daily in the past 30 days, and intended to be completely smokefree in the next three months.

To determine if a respondent had made a quit attempt lasting 24 hours or longer,

**Table 1:** Socio-demographic characteristics by recent quit attempt status.

| | Recent quit attempt status | | | Comparison by recent quit attempt status |
|---|---|---|---|---|
| | Non-attempters n=51 | Recent quit attempters n=55 | Serious quitters n=64 | Pearson chi-square test |
| **Gender** | | | | |
| Male | 51.0 | 30.9 | 40.6 | $X^2$ (167, 1) = 4.42, p=.11 |
| Female | 49.0 | 69.1 | 59.4 | |
| **Ethnicity** | | | | |
| Māori | 23.5 | 34.6 | 34.4 | $X^2$ (167, 1) = 1.99, p=.37 |
| Non-Māori | 76.5 | 65.5 | 65.6 | |
| **Age group** | | | | |
| 18–24 years | 5.9 | 1.8 | 10.9 | $X^2$ (167, 1) = 5.64, p=.22 |
| 25–44 years | 58.8 | 58.2 | 45.3 | |
| 45+ years | 35.3 | 40.0 | 43.8 | |
| **Household equivalised income** | | | | |
| Low (NZ$0–$34,600) | 19.6 | 32.7 | 32.8 | **$X^2$ (167, 1) = 17.97, p=<.01** |
| Med (NZ$34,601–$66,500) | 35.3 | 32.7 | 23.4 | |
| High (NZ$66,501+) | 45.1 | 20.0 | 26.6 | |
| Unspecified | 0.0 | 14.6 | 17.2 | |

*Household equivalised income was calculated using an established formula that took into account the number of adults and the number and the age of children (0–18 years) residing in the household.[30,31]

they were asked, "In the last three months, have you deliberately stopping smoking cigarettes or tobacco for 24 hours or more because you were trying to quit smoking?" The 24-hour definition for a quit attempt was adopted from the 2008 and 2009 Tobacco Use Survey.[26,27]

The NZSM uses a self-refreshing panel design. Respondents are maintained on the panel and interviewed fortnightly up to six times. Those who drop-out from the sample (either because they withdrew or had completed six interviews) are replaced by new respondents. Because the NZSM uses a within-subjects design, 277 respondents completed a total of 540 interviews. The current analysis was restricted to those who had reported exposure to the campaign in the past two weeks, reducing the number of cases to 170 unique respondents.

## Sampling procedure

Respondents were recruited through two methods. Non-attempters and recent quit attempters were recruited from a telephone-based omnibus survey, where a nationally-representative sample of New Zealand adults aged 18 or over were recruited via random digit dialling. Respondents who were eligible to take part in the NZSM were asked for permission to be re-contacted and they were then invited to take part at a subsequent phone call.

Serious quitters were recruited through the national Quitline client database, due to the small incidence of serious quitters at a population level. Each fortnight, a random sample of Quitline callers was invited to take part in the NZSM. Callers must have given prior consent for releasing their names and contact details. Potential respondents were contacted over the phone; the interviewers asked for their informed consent and screened for eligibility. Despite the different recruitment methods, all participants were interviewed by the same fieldwork company.

## Questionnaire

The NZSM questionnaire focuses on smoking-related behaviours (self-reported),

**Table 2:** Cognitive responses to the campaign - proportions, adjusted odds ratio and 95% confidence intervals.

| | Thought about the relationship they had with cigarettes ('yes') | | Thought about quitting smoking ('yes')* | | These ads make me regret I have ever started ('strongly agree' or 'agree') | |
|---|---|---|---|---|---|---|
| | % | AOR (95% CI) | % | AOR (95% CI) | % | AOR (95% CI) |
| **Overall** | 56.5 | - | 59.2 | - | 62.9 | - |
| **Gender** | | | | | | |
| Male | 56.5 | 1 | 61.5 | 1 | 58.0 | 1 |
| Female | 56.4 | .91 (.47–1.75) | 57.5 | .55 (.23–1.30) | 66.3 | 1.39 (.70–2.75) |
| **Ethnicity** | | | | | | |
| Māori | 54.7 | 1 | 68.4 | 1 | 58.5 | 1 |
| Non-Māori | 57.3 | 1.23 (.61–2.49) | 55.2 | .74 (.29–1.86) | 65.0 | 1.59 (.76–3.34) |
| **Age group** | | | | | | |
| 18–24 years | 63.6 | 1 | 40.0 | 1 | 45.5 | 1 |
| 25–44 years | 57.1 | .67 (.17–2.73) | 64.8 | 5.03 (.59–42.94) | 62.6 | 3.46 (.84–14.17) |
| 45+ years | 54.4 | .54 (.13–2.25) | 53.1 | 2.08 (.24–17.68) | 66.2 | 3.58 (.85–15.04) |
| **Household equivalised income** | | | | | | |
| Low | 53.1 | 1 | 76.5 | 1 | 71.4 | 1 |
| Med | 52.9 | 1.16 (.51–2.67) | 47.5 | **.23 (.07–.74)** | 64.7 | .71 (.29–1.76) |
| High | 61.8 | 1.93 (.80–4.64) | 56.1 | .38 (.12–1.22) | 51.0 | **.39 (.15–97)** |
| Unspecified | 57.9 | .92 (.30–2.83) | 60.0 | .20 (.04–1.06) | 68.4 | .57 (.16–1.95) |
| **Recent quit attempt status** | | | | | | |
| Non-attempters | 43.1 | 1 | 39.2 | 1 | 47.1 | 1 |
| Recent quit attempters | 58.2 | **2.39 (1.03–5.56)** | 70.2 | **4.52 (1.66–12.32)** | 63.6 | 1.61 (.69–3.76) |
| Serious quitter | 65.6 | **3.11 (1.36–7.09)** | 77.8 | **6.60 (2.06–21.15)** | 75.0 | **3.49 (1.47–8.28)** |

*Base = those who were smoking in the past two weeks

knowledge, attitudes and beliefs about smoking and quitting, and awareness of tobacco control activities. The questionnaire also has a non-core module to address emerging issues in tobacco control. This paper reports on responses to non-core questions related to 'Stop Before You Start', including exposure to, and reactions elicited by, the campaign (see Appendix 1). These non-core questions were created to evaluate the impact of these advertisements specifically, and covered a range of desirable cognitive and self-reported behavioural responses that were commonly assessed in tobacco control campaign evaluations.[22,28,29]

## Statistical analyses

The analysis was undertaken using STATA IC 13.1. Five out of ten questions used a five-point agreement scale, whereby "agree" and "strongly agree" responses were combined to indicate agreement with the statements. The remaining questions required a "yes" or "no" response. For all questions, participants who could not form an opinion or refused to answer were excluded from the analysis for that particular question (=< 1% of responses). Proportions and adjusted odds ratios (AOR) were computed to assess the relationship between each of the outcome variables and participants' socio-demographic and past 3-month quit attempt status.

# Results

## Sample characteristics

Socio-demographic characteristics of the sample, stratified by their recent quit attempt status, are described in Table 1. The household equivalised income report by non-attempters, recent quit attempters and serious quitters was statistically different. It should be noted that the proportion of non-attempters who had a low household

**Table 3:** Behavioural responses to the campaign - proportions, adjusted odds ratio and 95% confidence intervals.

| | Talked to someone about these ads ('yes') | | Browsed the campaign website ('yes')+ | | Deliberately did not smoke when they were with others ('yes')* | | Made a quit attempt ('yes')* | |
|---|---|---|---|---|---|---|---|---|
| | % | AOR (95% CI) | % | AOR (95% CI) | % | AOR (95% CI) | % | AOR (95% CI) |
| **Overall** | 28.2 | - | 3.0 | - | 33.6 | - | 27.2 | - |
| **Gender** | | | | | | | | |
| Male | 24.6 | 1 | 2.9 | 1 | 30.6 | 1 | 25.0 | 1 |
| Female | 30.7 | 1.29 (.63–2.64) | 3.0 | .41 (.03–5.76) | 35.7 | 1.04 (.44–2.48) | 28.8 | .95 (.37–2.46) |
| **Ethnicity** | | | | | | | | |
| Māori | 32.1 | 1 | 5.7 | 1 | 45.7 | 1 | 31.6 | 1 |
| Non-Māori | 26.5 | .76 (.36–1.60) | 1.7 | .19 (.02–1.85) | 28.6 | .54 (.22–1.31) | 25.3 | 1.00 (.37–2.68) |
| **Age group** | | | | | | | | |
| 18–24 years | 27.3 | 1 | 18.2 | 1 | 50.0 | 1 | 20.0 | 1 |
| 25–44 years | 27.5 | 1.14 (.26–5.05) | 0.0 | - | 29.4 | .31 (.03–3.04) | 29.6 | 1.61 (.12–21.28) |
| 45+ years | 29.4 | 1.27 (.28–5.76) | 4.5 | .23 (.01–4.40) | 38.3 | **.44 (.04–.41)** | 24.5 | .93 (.07–12.76) |
| **Household equivalised income** | | | | | | | | |
| Low | 30.6 | 1 | 4.1 | 1 | 46.9 | 1 | 35.3 | 1 |
| Med | 23.5 | .77 (.31–1.92) | 2.0 | 1.44 (.09–23.81) | 23.7 | .48 (.16–1.44) | 22.5 | .63 (.20–2.02) |
| High | 27.5 | 1.06 (.42–2.66) | 0.0 | - | 30.8 | .88 (.29–2.65) | 22.0 | .62 (.18–2.10) |
| Unspecified | 36.8 | 1.31 (.41–4.17) | 10.5 | 4.37 (.33–57.57) | 40.0 | .66 (.14–3.04) | 40.0 | .72 (.15–3.53) |
| **Recent quit attempt status** | | | | | | | | |
| Non-attempters | 19.6 | 1 | 0.0 | - | 17.7 | 1 | 5.9 | 1 |
| Recent quit attempters | 34.6 | 1.93 (.75–4.96) | 1.8 | 1 | 43.5 | **3.74 (1.32–10.63)** | 31.9 | **7.08 (1.76–28.53)** |
| Serious quitter | 29.7 | 1.54 (.61–3.87) | 6.3 | 1.90 (.14–25.04) | 50.0 | **4.84 (1.50–15.69)** | 59.3 | **23.85 (5.68–100.12)** |

*Base = those who were smoking in the past two weeks
+Some categories did not have any observations

equivalised income was remarkably lower than the other two groups, and that the proportions of recent quit attempters and serious quitters who did not provide information on their household income and/or household composition were remarkably higher than the proportion of non-attempters.

## Cognitive responses

Three measures were used to assess the cognitive responses elicited by the campaign (see Table 2). Over half of the respondents indicated that the campaign had made them think about the relationship they have with cigarettes, and about the same proportion of respondents thought about quitting smoking because of the campaign. Just over 60% of respondents agreed with the statement that "these ads make me regret I ever started smoking."

After adjusting for gender, ethnicity, age group and household equivalised income, statistically significant differences were found by recent quit attempt status for all three measures. Compared with non-attempters, recent quit attempters and serious quitters had higher odds of reporting cognitive responses. Differences by household equivalised income were found in one measure only: those with a high income were less likely than those with low income to agree that the ads had made them regret starting.

While the difference did not reach statistical significance (possibly due to the small cell size), it is important to point out the higher proportion of Māori respondents (68%) who thought about quitting smoking as a result of exposing to the campaign, when compared with non-Māori

(55%). However, responses to the other two measures were more similar.

### Behavioural responses

Four specific self-reported behavioural responses were measured (see Table 3). The results showed that over one-quarter of respondents had talked to someone about the campaign; one-third indicated that as a result of seeing the campaign, they had made a conscious decision to not smoke when they were with other people; and 27% had made a quit attempt in the last two weeks. However, only 3% of them had browsed the campaign website as a result of exposure to the campaign.

The AORs indicate that after adjusting for a range of socio-demographic variables, recent quit attempt status was a predictor for two (out of four) behavioural measures. Specifically, compared with non-attempters, recent quit attempters and serious quitters had increased odds of: a) making a conscious decision to not smoke when they were with others; and b) making a quit attempt. While the difference did not reach statistical significance, the proportion of non-attempters (20%) who had talk to someone about the advertisements was lower than recent quit attempters (35%) and serious quitters (30%).

### Interpretation of the campaign

Overall, 35% felt the advertisements were "disturbing", and 65% thought the main character in the advertisements (the 'cigarette man') was "creepy" (see Table 4). Three-quarters of respondents (75%) believed the advertisements were relevant to them. The multivariate logistic model showed that when compared with those with a low household equivalised income, respondents with a medium income had reduced odds of perceiving the 'cigarette man' as creepy. Apart from this sub-group difference, responses to these three measures did not differ significantly.

## Discussion

### Collateral effects on other audiences

Despite being a young adult-targeted campaign, 'Stop Before You Start' had collateral effects on older smokers and recent quitters. After adjusting for recent quit attempt status and socio-demographic characteristics, age was not a predictor for any of the outcome variables. This finding indicates that the campaign had exerted positive impacts on its target audience, as well as older smokers and recent quitters.

Previous studies on campaign development have demonstrated the importance of developing personally relevant messages.[13–15] The findings regarding the personal relevance of this campaign show that young adults (aged 18–24 years) and their older counterparts (25–44 years and 45+ years) were equally likely to "recognise something of my [their] story" in the adverts. Even though the campaign was deliberately aimed at young adults, the depiction of young people starting to smoke might remind older smokers of their personal experience with cigarettes and how experimentation had progressed into daily smoking. The perceived relevance of the campaign could have contributed to the cognitive and behavioural responses reported by the respondents.

Another plausible explanation for the collateral effects we found on older adults is the campaign eliciting regret. Regret is known to be positively associated with quit intention,[32] and our data show that 63% of respondents felt regret after seeing the campaign. This matches with the equally high proportion of respondents (59%) who reported thinking about quitting smoking because of the campaign.

### Other key findings

A number of other important findings emerged from this study. Recent quit attempt status was the only variable that consistently predicted engagement with the campaign. Using a wide range of indicators to assess the cognitive processing and self-reported behavioural responses that were elicited by the campaign, we found significant differences in five out of seven measures. Previous research indicated that making a quit attempt is a strong predictor for future quit attempts.[33] Considering non-attempters were those who indicated at their first interview that they had not made a deliberate quit attempt in the past three months, it is probably not surprising that they were also less likely to think about quitting or to make a quit attempt after seeing the campaign. Other than the reduced impact on cessation-related thoughts and

**Table 4:** Interpretation of the campaign—proportions, adjusted odds ratio and 95% confidence intervals.

| | These ads are disturbing ('strongly agree' or 'agree') | | The man who dresses as a cigarette is creepy ('strongly agree' or 'agree') | | I recognise something of my story in these ads ('strongly agree' or 'agree') | |
|---|---|---|---|---|---|---|
| | % | AOR (95% CI) | % | AOR (95% CI) | % | AOR (95% CI) |
| **Overall** | 35.1 | - | 64.5 | - | 75.3 | - |
| **Gender** | | | | | | |
| Male | 29.0 | 1 | 58.0 | 1 | 73.9 | 1 |
| Female | 39.4 | 1.57 (.78–3.17) | 69.0 | 1.49 (.74–2.98) | 76.2 | 1.19 (.56–2.50) |
| **Ethnicity** | | | | | | |
| Māori | 47.2 | 1 | 67.9 | 1 | 83.0 | 1 |
| Non-Māori | 29.6 | .53 (.26–1.08) | 62.9 | .87 (.41–1.86) | 71.8 | .56 (.23–1.32) |
| **Age group** | | | | | | |
| 18–24 years | 45.5 | 1 | 54.55 | 1 | 72.7 | 1 |
| 25–44 years | 32.6 | .84 (.21–3.30) | 70.0 | 3.10 (.74–13.09) | 72.5 | 1.47 (.32–6.68) |
| 45+ years | 36.8 | 1.06 (.26–4.27) | 58.8 | 1.78 (.42–7.57) | 79.4 | 2.14 (.45–10.17) |
| **Household equivalised income** | | | | | | |
| Low | 44.9 | 1 | 75.5 | 1 | 81.6 | 1 |
| Med | 36.0 | .86 (.37–2.01) | 50.0 | **.29 (.12–.72)** | 76.5 | .85 (.31–2.35) |
| High | 28.0 | .66 (.27–1.61) | 60.8 | .52 (.21–1.32) | 72.6 | .69 (.25–1.92) |
| Unspecified | 26.3 | .45 (.13–1.51) | 84.2 | 1.61 (.38–6.91) | 63.2 | .40 (.12–1.39) |
| **Recent quit attempt status** | | | | | | |
| Non-attempters | 24.0 | 1 | 54.0 | 1 | 70.6 | 1 |
| Recent quit attempters | 36.4 | 1.58 (.64–3.91) | 74.6 | 1.90 (.77–4.65) | 72.7 | 1.03 (.41–2.61) |
| Serious quitter | 42.9 | 2.22 (.93–5.30) | 64.1 | 1.20 (.52–2.74) | 81.3 | 1.84 (.71–4.77) |

behaviours, the campaign was also less likely to motivate non-attempters to reflect on the relationship they have with cigarettes or to feel regret about their smoking.

The differential levels of responses reported by non-attempters, compared with recent quit attempters and serious quitters, highlights a challenge in tobacco control. Despite being exposed to a message that was emotionally engaging (ie, 54% agreed the 'cigarette man' was creepy) and seen as personally relevant (interpretation of the campaign did not differ by recent quit attempt status), people who had not made a recent quit attempt continued to show resistance to the campaign messages. Previous analyses of the NZSM data showed that non-attempters were also less responsive to increases in tobacco excise,[34] and were more resistant to tobacco control policies, such as display bans at point of sale.[35] A population-based survey in 2012 showed that one-half of current smokers and recent quit attempters in New Zealand had not made any serious quit attempts in the past year, and the rate did not differ significantly by age, gender, educational or deprivation levels.[36] Given the high proportion of non-attempters among the smoker population, the inability to motivate them to make a quit attempt poses a threat to New Zealand achieving the Smokefree 2025 goal. More in-depth research with non-attempters might be required in future to explore their perception of smoking and motivators that might encourage them to try quitting.

## Implications and future research

Despite being a young adult-targeted campaign, the current study provides evidence for the flow-on effects it had on adult smokers and recent quitters. More research is required in the future to investigate whether young adult-targeted campaigns in general resonate with adult smokers, and to unpack the elements of the 'Stop Before You Start' campaign that help draw in adult smokers. Future studies should also investigate the potential flow-on effects the campaign had on adolescents.

## Strengths and limitations

This study used a wide range of measures to capture responsiveness to the campaign. However, our findings are based on a small sample of smokers and recent quitters (n=170). Furthermore, the sample is not meant to be representative of the overall adult smoker population in New Zealand. However, as responses did not differ significantly by gender, ethnicity, age or household equivalised income for most measures (eight out of ten measures), the use of an unrepresentative sample became a less salient issue.

# Conclusions

This study provides new information on the collateral effects of a purposefully developed, young adult-targeted campaign to adult smokers and recent quitters. Despite not being the target audience, the findings suggest that the campaign appealed to adults and elicited a range of cessation-related attitudes and behaviours. Our findings suggest that young adult-targeted campaigns can reach both young adults and older adults, and therefore create positive unintended consequences for both the priority audience and the broader audience group.

# Appendix: Survey questions

INTRO: There is a series of advertisements called "Stop Before You Start". All of these ads feature the same middle-age man who dresses as a cigarette but he is with a different young person each time. In some ads, the young person talks about the relationship he has established with the man who dresses as a cigarette, while in other ads the young person shows no interest in him.

**1.** In the last 2 weeks (since we last spoke to you), have you seen any of these ads on TV?
- Yes
- No
- Don't know
- Refused

**2.** Again, in the last two weeks (since we last spoke to you), have you seen or heard these ads anywhere else?
- Yes
- No
- Don't know
- Refused

INTRO: Now, I am going to ask you a few more questions about these ads.

**3.** As a result of seeing these ads, did you do any of the following in the last two weeks? Did you…
- **a.** Talk to someone about these ads
- **b.** Make a conscious decision to not smoke when you were with other people
- **c.** Think about quitting smoking
- **d.** Make a quit attempt
- **e.** Think about the relationship you have or had with cigarettes
- **f.** Go to the "Stop Before You Start" website….
  - Yes
  - No
  - Don't know
  - Refused

INTRO: I am going to read out a set of statements about the ads. Again, please indicate whether you strongly agree, agree, neither agree nor disagree, disagree or strongly disagree with it.

RANDOMISE Q4-7

**4.** I recognise something of my story in these ads.
- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know
- Refused

**5.** These ads are disturbing.
- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know
- Refused

6. These ads make me regret I have ever started smoking.
   - Strongly agree
   - Agree
   - Neither agree nor disagree
   - Disagree
   - Strongly disagree
   - Don't know
   - Refused

7. The man who dresses as a cigarette is creepy.
   - Strongly agree
   - Agree
   - Neither agree nor disagree
   - Disagree
   - Strongly disagree
   - Don't know
   - Refused

**Competing interests:** Nil

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# Assessing a hospital medication system for patient safety: findings and lessons learnt from trialling an Australian modified tool at Waitemata District Health Board

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## ABSTRACT

**AIM:** To undertake a review of Waitemata District Health Board's (WDHB) hospital medication system for patient safety assessment and improvement purposes.

**METHODS:** A multidisciplinary group rated current WDHB hospital medication systems against the Medication Safety Self-Assessment for Australian Hospitals (MSSA®-AH) criterion of 247 aspirational practices using a five point scale ("no" to "fully implemented"). Items with a lesser extent of implementation represented practice gaps. The MSSA®-AH database and weighted adjustment scoring system generated an overall hospital score.

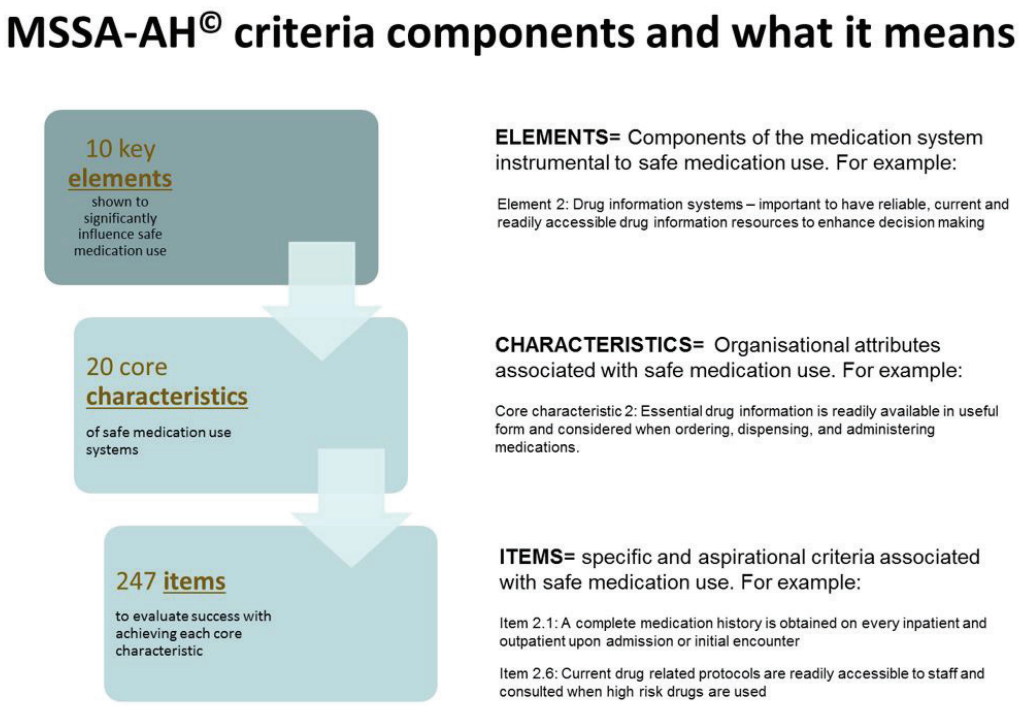
**RESULTS:** Of the maximum possible score that could be obtained had all MSSA®-AH practices been implemented, WDHB scored 63% and this was comparable to other demographically similar hospitals in Australia. Lowest scoring practices needing improvement related to staffing. Conflict resolution was a previously unidentified practice gap. Previously identified gaps, such as those relating to electronic medication systems suggested ongoing implementation was required.

**CONCLUSION:** This was the first documented use of the MSSA®-AH's in a New Zealand hospital setting and helped WDHB identify areas in need of further improvement. The unique generation of a percentage score helped simplify understanding for non-technical stakeholders. Future repeated assessments would help WDHB track progress. Implicit benefits, such as stakeholder engagement, were observed. The MSSA®-AH may be useful in other hospital settings.


Medicines are the most common medical interventions used in healthcare. Of all unintended injuries caused by medical management, the largest proportion relate to medications.[1] Injuries resulting from the wrong medicine or dose being given could have been prevented through safer medication practices.[1-3] Medication safety practices, such as the implementation of electronic prescribing and administration with clinical decision support (ePA), or clinical pharmacy involvement in medical care, can help reduce medication errors and harm.[4-8] The enhancement of medication systems is fundamental for any organisation committed to making their hospitals safer for patients.[1]

Standards to help hospitals assure medication systems for patient safety, such as those set by Medsafe and the Health and Disability Services (NZS8134.1:2008), have been used as part of certification for a number of years in New Zealand.[9,10] An important but commonly missed point, however, is that standards only provide minimum acceptable levels of practice. In

**Figure 1:** Medication Safety Self-Assessment for Hospitals® criteria components, their meaning and examples.




contrast, assessing a hospital's medication system against an aspirational criterion of ideal medication safety practices can help identify potential gaps for further enhancement.[11]

A widely endorsed tool to assess medication systems has been the Medication Safety Self-Assessment for Hospitals (MSSA®).[11-22] Consistent with current professional knowledge and evidence, the MSSA® and its modified version for Australian Hospitals (MSSA®-AH), contains a criteria list of 247 items of ideal and aspirational medication safety practices. The MSSA®-AH has apparent good face and construct validity having been tested across several Australian hospitals and promoted for use by the Australian Quality and Safety Commission.[23] Despite international widespread use, no published research of MSSA®-AH use in New Zealand was identified.[11,15,16]

Waitemata District Health Board (WDHB) comprises several large healthcare facilities, of which North Shore (595 beds) and Waitakere (269 beds) are its largest hospitals. WDHB's promise to its community is best care for everyone. It aims to provide healthcare that is safe, continuously improving and among the best in the world. To help fulfil WDHB's promise, a systematic assessment of hospital medication systems was needed to inform how safe systems were, identify areas for further improvement, track and demonstrate progress over time.

With a view to determine the utility of the MSSA-AH® for New Zealand hospital settings, and obtain specific information for WDHB purposes, an assessment of local hospital medication systems using the tool was undertaken. The findings obtained will be described for illustrative purposes, and the utility of the tool for WDHB explored. Lessons learnt, limitations and implications of the findings on New Zealand policy, practice and research will be discussed.

# Method

After consultation with the Institute for Safe Medication Practice (ISMP), and due to perceived similarities between New Zealand and Australian hospital systems, the Clinical Excellence Commission's (CEC) MSSA®-AH version was selected for use. Permission for the use of the CEC electronic database was obtained and a nominal subscription fee paid. No commercially sensitive or patient information was collected, and thus

**Table 1:** Demographic information of Waitemata DHB using the MSSA®-AH categories.

| Demographic information categories listed in the MSSA®-AH | Waitemata DHB demographic information |
|---|---|
| Number of inpatient beds | More than 500 beds |
| Type of organisation for establishing policy for the overall operation of hospital | Public sector |
| Best description of service that the hospital provides to the majority of its admissions | General medical and surgical |
| Specific services provided at the hospital as defined within the MSSA®-AH | Oncology, Paediatrics, Neonatal intensive care unit, trauma services, maternity, psychiatric, Ear Nose and Throat (ENT) and Ophthalmology |
| No. of hospitals comprised within a larger healthcare organisation with common ownership and/or governance | Two to five hospitals (ie, North Shore and Waitakere) |
| Location of hospital(s) | Metropolitan |
| Pharmacy services management | Internally |
| Clinical pharmacy services availability | Yes |
| State or territory hospital is located | New Zealand |

was not deemed to be an organisational or privacy risk. A review of WDHB's medication systems using the MSSA-AH® tool for patient safety was sought and endorsed by WDHB's medication safety group (MSG) in late 2014. MSSA®-AH instructions recommend the assessment of one hospital at a time.[12] The differences in medication systems at both North Shore and Waitakere were deemed negligible by members of the MSG group and so a decision was made to review the entire WDHB.

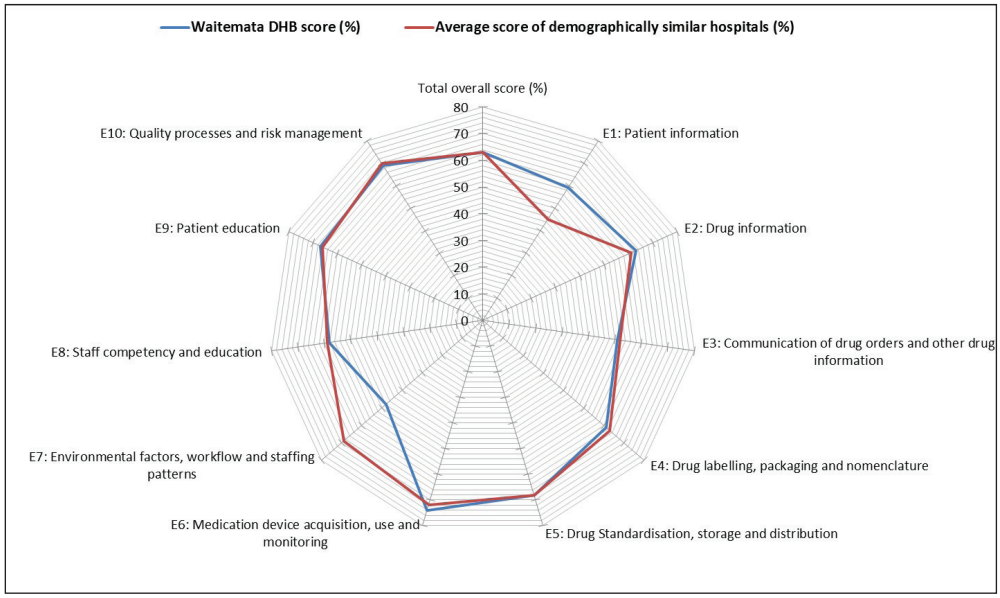
The instructions for conducting the review and methodology behind the MSSA® tools have been described in-depth elsewhere,[11-13] so a brief outline is provided. The MSSA®-AH comprised 247 medication safety practice items which can be grouped into 20 core characteristics and 10 key elements (see Figure 1). Items referred to medication safety practices. Characteristics referred to organisational attributes associated with safe medication use (see Appendix 3 for the list and their explanations). Elements referred to components of the medication use system instrumental to safe medication use (see Appendix 2).

Each item in the MSSA®-AH had a maximum possible weighted score based on their impact on medication safety. The maximum possible weighted scores for each item were 16 (highest impact), 12, 8, 4 or 2 (lowest impact). Items with the heaviest weighting were those which have demonstrated long-lasting effectiveness in reducing serious medication errors, that target the system and not just the workforce and which safeguard high-risk patient groups.[12]

In accordance with MSSA®-AH instructions, a multi-disciplinary medication safety review (MSR) group representing those with intimate knowledge of WDHB's medication systems were purposively selected to undertake the review (see Appendix 1). A team leader was responsible for coordinating the review. MSR members were not aware of the weighting for each item when completing the assessment. MSR members considered current WDHB practice and rated the extent of implementation of each aspirational item using a five point scale ("no" to "fully implemented").

Items with less extensive implementation represented practice gaps and scored the lowest, while items with a greater extent of implementation scored the highest. When consensus of the MSR group was reached for the item's rating, the result was recorded on paper by the team leader. As part of the initial briefing, participants were reminded that this was a formative exercise aimed at better understanding of existing gaps in practice. Where there were different opinions about the level of implementation for a certain item, the most conservative rating score was selected. Field notes on the relevance and limitations of particular items in local settings,

**Figure 2:** MSSA-AH® scores (%) across each of the 10 key elements safe medication use for Waitemata DHB compared with demographically similar hospitals across Australia (n=24 hospitals).




suggestions or comments were also captured to help inform the refinement of the tool for future and New Zealand specific use. In total, the MSR group met once weekly for three consecutive weeks, with each meeting taking 90 minutes.

At the completion of assessing all MSSA®-AH items, the data was entered into the CEC secure and confidential online electronic database. Rated scores for each item and the overall hospital were calculated as a percentage of the total possible maximum weighted scores. The MSSA®-AH database and weighted adjustment scoring system automatically generated WDHB's result. To help prioritise the 247 items for improvement, the results generated from the CEC database was exported to Microsoft Excel 2010. Items were then ranked according to:

1. Weighted scores, which represented the item's impact on medication safety (from highest to lowest impact in descending order), then by;
2. Items with the largest gap in score between the maximum possible score and actual score (from largest to lowest gap in descending order), then by;
3. Items specifically flagged by MSR members as being important to WDHB for improvement.

The ranked items provided a basic framework for discussion and theme generation. Using a general inductive approach, each item was further coded and categorised according to the common subject theme.[24,25] Item 9.2, for example, was "Doctors and other prescribers routinely educate patients about recommended drugs before initial dose received", and was rated a "C" (partially implemented) by the MSR group. Item 9.2 was categorised under the subject label of "patient education" and this represented an area for further improvement because it was not fully implemented. Emergent key themes were presented to the MSG for the consideration of impact, difficulty in implementation and priority for improvement at WDHB.

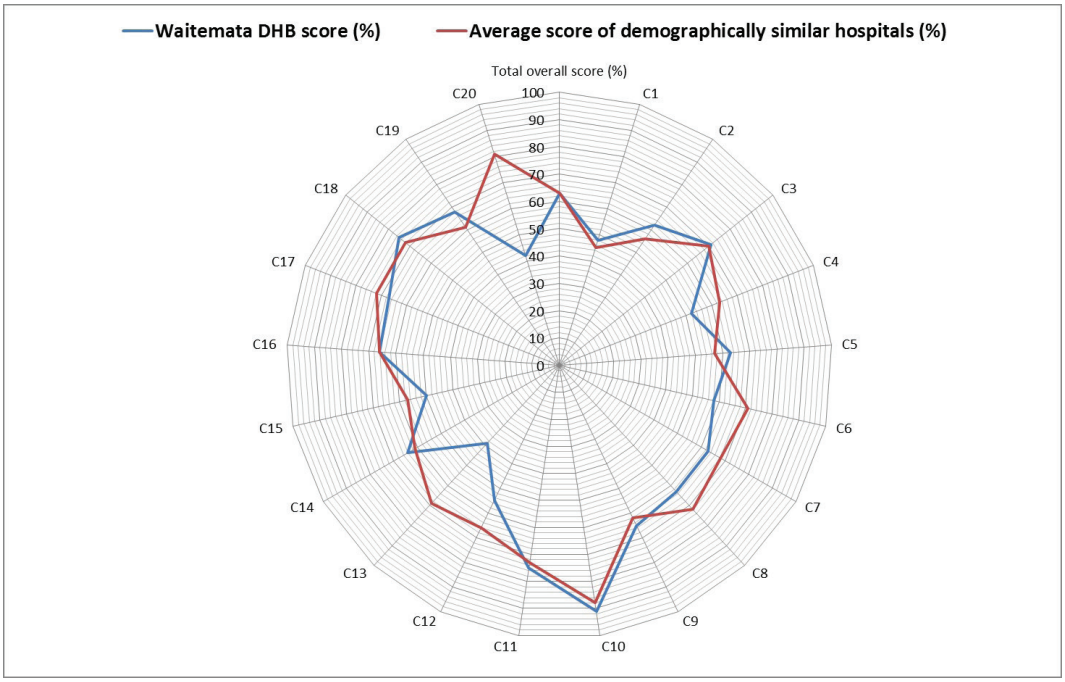
# Results

Waitemata DHB's demographic information has been outlined in Table 1.

In Australia, a total of 370 hospitals have used the MSSA®-AH tool. Using the MSSA®-AH criteria listed in Table 1, 24 Australian hospitals were categorised as being demographically similar to WDHB, and the results from these hospitals formed the basis for comparison. The results were analysed according to the 10 key elements and graphically displayed in Figure 2.

The radar chart in Figure 2 provides WDHB's self-assessed score against each of the ten key elements of the MSSA®-AH. WDHB scores have been expressed as a percentage of the total maximum possible score for each of the ten key elements. Of the maximum possible score that could be obtained through the full implementation of all medication safety practices listed in the MSSA®-AH, WDHB's overall score was 63%. WDHB's

**Figure 3:** MSSA-AH® scores (%) across each of the 20 core characteristics of safe medication use for Waitemata DHB compared with demographically similar hospitals across Australia (n=24 hospitals).




**Legend**

**C1:** Essential patient information is obtained, readily available in a useful form and considered when prescribing, dispensing and administering medication.

**C2:** Essential drug information is readily available in useful form and is considered when prescribing, dispensing, and administering medications.

**C3:** A controlled drug formulary system is established to limit choice to essential drugs, minimise the number of drugs with which PRACTITIONERS must be familiar and provide adequate time for designing safe processes for the use of new drugs added to the formulary.

**C4:** Methods of communicating drug orders and other drug information are standardised and automated to minimise the risk of error.

**C5:** Strategies are undertaken to minimise the possibility of errors with drug products that have similar or confusing manufacturer labelling/ packaging and/or drug names that look and/or sound alike.

**C6:** Readable labels that clearly identify drugs are on all drug containers and drugs remain labelled up to the point of actual drug administration.

**C7:** IV solutions, drug concentrations, doses and administration times are standardised whenever possible.

**C8:** Medications are provided to patient care units in a safe and secure manner and available for administration within a timeframe that meets essential patient needs.

**C9:** Unit-based ward or imprest stock is restricted.

**C10:** Hazardous chemicals are safely sequestered from patients and not accessible in drug preparation areas.

**C11:** The potential for human error is mitigated through careful procurement, maintenance, use and standardisation of devices used to prepare and deliver medications.

**C12:** Medications are prescribed, prepared, dispensed and administered in a physical environment that offers adequate space and lighting and allows PRACTITIONERS to remain focused on medication use without distractions.

**C13:** The complement of qualified, well-rested PRACTITIONERS matches the clinical workload without compromising patient safety.

**C14:** PRACTITIONERS receive sufficient orientation to medication use and undergo baseline and annual competency evaluation of knowledge and skills related to safe medication practices.

**C15:** PRACTITIONERS involved in medication use are provided with ongoing education about medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused.

**C16:** Patients and/or their parents/ carers are included as active partners in their care through education about their medications and ways to avert errors.

**C17:** A non-punitive, systems-based approach to error reduction is in place and supported by management, senior administration, and the Governing Body.

**C18:** PRACTITIONERS are stimulated to detect and report errors, and multidisciplinary teams regularly analyse errors that have occurred within the organisation and in other organisations for the purpose of redesigning systems to best support safe PRACTITIONER performance.

**C19:** Simple redundancies that support a system of INDEPENDENT DOUBLE CHECKS or an automated verification process are used for vulnerable parts of the medication system to detect and correct serious errors before they reach patients.

**C20:** Proven infection control practices are followed when storing, preparing and administering medications.

**Table 2:** Top 10 key themes for medication safety improvement at Waitemata DHB based on MSSA®-AH tool weighted scores, practice gaps and perceived priority areas by the Medication Safety Review (MSR) team.

| **Priority themes for medication safety improvement at Waitemata DHB and MSSA-AH® items as targets for implementation related to the following areas:** |
|---|
| **1. Electronic and automated medication systems**<br>• Item 3.2A: ePA system warns prescribers about unsafe orders (eg, overdoses, interactions) and guides appropriate use.<br>• Item 3.1: ePA directly interfaced with pharmacy computer system.<br>• Item 1.17: ePA directly interfaced with lab system to guide appropriate prescribing.<br>• Item 2.16: All inpatient prescriptions are screened for appropriateness before being administered.<br>• Item 3.9: ePA system shares a common database with pharmacy to facilitate drug administration.<br>• Item 1.14: Barcoding is used to verify patient identity during drug administration.<br>• Item 10.44: Barcoding used to verify correct drug administered.<br>• Item 10.42: Barcoding used to verify drug picked for dispensing.<br>• Item 6.13: Infusor pumps with clinical decision support are in use with full functionality. |
| **2. Staff shortages and high workload**<br>• Item 2.11: Pharmacists regularly work directly in outpatient care units.<br>• Item 2.9: Pharmacists regularly work directly in inpatient care units.<br>• Item 7.12: Contingency plan established when short staffed.<br>• Item 7.13: Pharmacy perceives staff shortages pose a risk to providing safe pharmaceutical care.<br>• Item 8.8: Staff are not pulled from their usual areas without adequate training and orientation.<br>• Item 7.11: Schedules and workload permit staff to take at least one 15-minute break and one 30-minute break per shift (NB: focused on medical doctors). |
| **3. Medication safety measurement and surveillance system**<br>• Item 10.24: e-triggers are used to enhance detection of potential adverse drug events (ADE).<br>• Item 10.1: One or more staff dedicated to enhance detection of medication errors, over-see analysis of their causes, and coordinate an effective error reduction plan.<br>• Item 10.29: med safety measurement and surveillance system in place (past, present, future). |
| **4. Patient safety and learning culture with communication**<br>• Item 8.16: Staff regularly receive information about medication errors and high risk situations.<br>• Item 10.3: All known med errors disclosed to patient and families.<br>• Item 10.23: MDT routinely analyses errors to proactively target areas for improvement.<br>• Item 10.4: no disciplinary action against slip/lapse errors.<br>• Item 3.11: conflict resolution policy and pathway when pharmacist and nurse safety concerns differ to those by prescribers.<br>• Item 10.2: Staff report and openly discuss errors without fear of reprisal from hospital.<br>• Item 10.22: "Near misses" are given the same high priority for analysis and error prevention strategies as errors that actually cause harm.<br>• Item 10.30: Strategies are in place to allow staff, regardless of rank, to raise concern without fear or intimidation. |
| **5. High-risk drugs (IV) to be independently double checked and unit dose**<br>• Item 5.20: 1st dose of high-alert drugs reviewed by pharmacist before being available.<br>• Item 6.4: Every new change or infusion of high alert drugs in paediatric patients is independently checked before use.<br>• Item 4.14: Labelled, ready-to-use unit doses dispensed. |
| **6. Standardised insulin sliding scale**<br>• Item 5.7B: Standardised sliding scale protocol in place (alternative is to NOT use sliding scale). |
| **7. Environment and equipment supporting drug administration**<br>• Item 5.6: Dosing windows established to help nurses safely administer most medications at established standard times.<br>• Item 6.3: All tubing for admin lines are labelled adjacent to the injection port(s).<br>• Item 7.3: Pharmacies and ward medication rooms have adequate space for storage of drugs.<br>• Item 7.4: IV preparation area is isolated to minimise distractions.<br>• Item 7.7: Nurses select meds for admin in areas relatively free of distractions and noises. |
| **8. Organisational wide plans and downstream effects communication and consideration**<br>• Item 7.16: Hospital plans are well communicated to affected staff and downstream effects considered.<br>• Item 10.11: Specific med safety objectives are included in the hospital strategic plans and celebrated when met. |
| **9. Patient education**<br>• Item 9.2: Doctors and other prescribers routinely educate patients about recommended drug before initial dose received. |
| **10. Analgesia and sedation complications monitoring and management**<br>• Item 1.13: Monitoring of analgesia complications.<br>• Item 5.13: Antidotes (for opioids, sedatives) and guidelines for emergency use readily available near point of use. |

score was the same as other demographically similar Australian hospitals (63%).

Of note, WDHB self-assessed to have implemented more extensively than other Australian hospitals medication safety practices related to patient information (ie, Element 1: 59% vs 45%). However, medication safety practices related to environmental factors, workflow and staffing patterns were self-assessed to have been less extensively implemented compared with other similar Australian hospitals (ie, Element 7: 48% vs 69%) and this represents a gap for improvement for WDHB.

WDHB scores analysed by the core characteristics of a safe medication system were graphically presented in Figure 3.

Compared with other Australian hospitals, WDHB self-assessed to have implemented to a similar extent many medication safety practices and characteristics. Core characteristics where WDHB self-assessed to not have implemented medication safety practices as extensively as other hospitals were C4 (52% vs 63%), C6 (58% vs 71%), C12 (55% vs 66%), C13 (39% vs 63%) and C20 (42% vs 81%). The themes of these relate to "medication order communication", "better labelling of medicines", "the provision of distraction free physical environments where medicines are used", and "staffing and workload" issues, respectively.

The key themes of identified gaps for improvement at WDHB are outlined in Table 2. Of the highest impact medication safety practices, the most common theme identified for improvement related to "electronic and automated medication systems". Specific items relating to electronic systems which were highly ranked are listed in Table 2 as examples of areas for further implementation. Consistent with the analysis using the elements and core characteristics in and respectively, "staffing and workload" issues appeared to be a key area for improvement. The themes of medication safety practices requiring further implementation at WDHB related to "medication safety measurement and surveillance system", "high risk drugs which are independently double checked" and "patient safety learning and communication".

# Discussion

## Benefits obtained from the use of MSSA®-AH

The information obtained from, and the process of, assessment using the MSSA®-AH was meaningful for WDHB for a number of reasons. Firstly, previously unidentified medication safety practice gaps were discovered and highlighted areas for intervention. For example, it was identified that WDHB did not have a formal process "that can be followed by nurses and pharmacists to resolve conflict when prescribers do not agree with their expressed concerns about the safety of an order" (Item 3.11).[17] Disrespectful behaviours towards staff who question the safety of an order may lead to unsafe medications being administered to the patient.[26] Interventions, such as the development of a formalised escalation pathway coupled with behaviour change management, may thus help resolve such conflicts and prevent unsafe orders from ever reaching the patient. Practice gaps for improvement will be addressed and incorporated within the WDHB Medication Safety Strategy for action in the 2015–2018 periods.

A second benefit was derived from MSSA®-AH's weighting system and unique generation of an overall hospital score as a percentage. This helped simplify the complexity of the results and interpret, for non-technical stakeholders, the significance of the findings. Similar to school reports, WDHB's score of 63%, which could be approximately equated to a C+, resonated with stakeholders as being passable, but further improvement was required. MSSA®-AH scores helped to reinforce engagement among management and senior staff, and continue the support of improvement initiatives. Coupled with the ability to now compare against other hospitals—and for an organisation which aims to provide care that is among the best in the world—the results promulgated the need for further improvement. Having established baseline scores for the overall system and individual items, WDHB can now track its progress over time with repeated assessment.

Beyond the utility of the information obtained for measurement purposes, a third, and arguably most important observed benefit, was the generation of engagement from undertaking the assessment process and the nurturing of a shared belief in the importance of patient safety. Applying the MSSA®-AH forced staff to critically reflect on existing medication systems, whether in a ward, hospital or entire organisation, for patient safety and motivated individual action and system development in their respective areas to support and inform priorities. Research previously published in this journal suggests many patients admitted into New Zealand hospitals are inadvertently harmed by the medications intended to help them, and this emphasises the importance of conducting assessments such as the MSSA®-AH to help evaluate progress and further improve medication safety practices.[27,28]

## Limitations and lessons learnt for future MSSA®-AH use

Some of the recommended practices within the MSSA®-AH have strong evidence supporting their implementation to reduce errors and harm, but many do not.[4, 5] Even if all recommended medication safety practices contained in the MSSA®-AH were implemented, there may be no demonstrable change to adverse medication-related incident trends. Research suggests that medication systems are complex and good systems are not always causally linked to desired health outcomes. In fact, unintended adverse consequences can occur[29-33] and there are well-known methodological difficulties in establishing correlation between implemented interventions and improved patient safety outcomes.[34,35] MSSA®-AH cannot be used in isolation to measure medication safety within a hospital. In order to holistically assess medication safety, other tools and approaches—such as data obtained from trigger tools or observation—need to be used concurrently.[36-40]

Recently published evidence suggests that inpatients at hospitals with full quality accreditation were associated with a lower 30-day mortality risk than admissions at partially accredited hospitals.[41] Because many of the recommended practices in the MSSA®-AH, such as electronic prescribing and barcoding, have been empirically shown to reduce medication errors and harm, high and improving scores may provide a proxy indicator for safe outcomes. Despite apparent good face and construct validity[23] however, no published research was identified which examined the correlation between MSSA®-AH scores with adverse medication incidents. Further research into the association of MSSA®-AH scores with safety outcomes would help determine its suitability as a proxy indicator. At this stage, the MSSA®-AH is probably more useful as a formative indicator of activity, effort and progress for the implementation of safer practices than a definitive and summative measure for improved safety outcomes.

Correspondence with ISMP, and previous publications, suggest that weightings for each medication safety practice item was assigned based on the strength of evidence, sustainability and system effect.[11,12,42] It is not easily apparent, however, the exact approach on how these weightings were assigned or whether they were applicable for New Zealand settings. Default weighting have been accepted for the purpose of trialling the MSSA-AH® tool in WDHB. Further research into testing the effectiveness of implementing different recommended practices at reducing medication errors and harm in New Zealand hospitals may help to substantiate the content validity of weightings. Qualitative Delphi approaches, by way of expert focus group consensus or questionnaires, may help further assess the face and construct validity of the weightings in the New Zealand setting.

Because the assessment was conducted by staff members, it was important to note the rated scores were subjective and there was the possibility of bias. Bias was possible, but thought to be unlikely. Throughout the assessment process, it could be clearly observed that staff undertook the exercise with a mind-set aimed at learning and improvement. Furthermore, the overall score of 63% suggested that even if bias was present, practice gaps were still being identified for improvement. In-depth investigation into medication-related injuries which occur in the organisation support the practice gaps identified from the MSSA®-AH for improvement.

It is important to note that self-assessment items in the MSSA®-AH tool cover broad concepts, but they do not always detail the exact definition. Take, for example, Item 8.14: "Practitioners are educated about new drugs added to the formulary..." This medication safety practice appears straightforward, logical and common-sense. However, how should the level of education be defined? For an organisation who uses the MSSA®-AH to self-assess, 'education' may be interpreted as the development of a newsletter, while for another 'education' may refer to one-on-one tutorials with prescribers. Subjectivity in interpretation among assessors may limit the ability to compare MSSA®-AH scores between organisations.

For New Zealand hospital practice requirements, it appeared that the MSSA®-AH can be customised to make it more fit for purpose. For example, questions about the hospital formulary (eg, Item 2.23: "The hospital formulary contains almost no duplication of generic equivalents"), and related questions were less relevant for the New Zealand setting. In New Zealand, there is a national hospital formulary which is managed via the preferred medicines list controlled by PHARMAC; a national government agency for medicines funding.[43] Duplicates of generic equivalents are not generally available and individual hospitals have limited control to obtain alternative agents.

Certain weighted scores were difficult to make sense of. For several items where services were not provided at WDHB, the "not-applicable" category was chosen; however, the MSSA®-AH weighting gave such scores a zero. For example, Item 10.47 did not apply because no intravenous admixtures were prepared, but WDHB was scored as zero out of eight. This may have meant that WDHB's overall score of 63% underestimated the extent of medication safety practices implemented. Several assessment items appeared to be duplicates. For example, Item 1.5 "Prescribers and nurses can easily and electronically access laboratory values for both inpatients and outpatients while working in their respective inpatient and outpatient locations" was similar to Items 1.1 and 1.3, with the only difference being that the latter items focused on prescribers and nurses individually.

## Implications of findings for research, policy and practice

This is the first documented case of MSSA®-AH use in New Zealand hospitals. The findings have significantly added to the body of research on how New Zealand hospital medication systems can be assessed for patient safety. The information obtained from the use of the MSSA®-AH is relevant and meaningful for at least one DHB and can be used to better understand deficiencies in hospital medication systems and help refine improvement initiatives. Further research on the correlation of scores obtained from the use of MSSA®-AH with the incidence of adverse medication-related incidents would help determine its predictive value and its suitability as a proxy measure. Intra- and inter-rater reliability testing were not undertaken, but would have helped determine if the ratings were consistent among different groups.

The experiences and lessons learnt from the use of MSSA®-AH in the hospitals of a New Zealand DHB have implications for policy. The Health Quality and Safety Commission (HQSC), a national organisation charged with identifying key measures to inform and monitor improvements in safety, has struggled to find a suitable indicator relating to medication safety.[44] Only as recently as September 2014, has an indicator for quality and safety related to medicines use been introduced.[45] This 'measure' asked DHBs whether eMedicines Reconciliation had been implemented or not. While medicines reconciliation is an important process in contributing to safe medicines use, it is only one part of a complex system.[46] The information that can be obtained from the MSSA®-AH provides a more rounded view, which includes medicines reconciliation but importantly, extends to other key elements of medication safety, such as drug labelling and packaging, and patient education. Coupled with the standardised and systematic approach used for assessment in MSSA®-AH, it may be useful tool which fulfils HQSC requirements.

## Conclusion

Using the MSSA®-AH tool has helped WDHB to examine its medication safety system in a rigorous way. MSSA®-AH's unique generation of an overall hospital score helped simplify understanding for non-technical stakeholders. Resources required were nominal, and additional benefits, such as stakeholder engagement, were observed. The intended aim of undertaking the MSSA®-AH was to provide aspirational goals in order to facilitate learning, prioritise and guide improvement.[11-13,16] Future repeated assessments would help WDHB track progress. Used for identifying and informing improvement priorities the MSSA®-AH offers a pragmatic and relevant approach. The use of MSSA®-AH and information obtained was of utility to WDHB and may be applicable for other New Zealand hospitals to assess its medication systems for patient safety.

## Appendix 1: Medication System Review (MSR) team members and their roles

| Recommended personnel or equivalent by MSSA-AH® | Staff member | Role in hospital |
|---|---|---|
| Team Leader and patient safety officer | Dr Jerome Ng | Lead for Clinical Quality improvement and Informatics |
| Senior Hospital administrator | Dr Penny Andrew | Clinical Leader Quality |
| | Dr Jocelyn Peach | Director of Nursing and Midwifery |
| At least two staff doctors from different specialty areas | Dr Jonathon Christiansen | Consultant Cardiology |
| | Dr Ian Wallace | Consultant Gastroenterology/General Medicine |
| | Dr Robert Wakuluk | Renal registrar |
| At least two staff nurses from different specialist areas | Ms Janine Quiding | Child Health Nurse Educator |
| | Ms Sylvie Dombroski | Nurse Educator – New Graduates |
| | Mr Brian Leaman | Charge Nurse Manager Taharoto Mental Health Unit |
| Director of Pharmacy | Ms Marilyn Crawley | Chief Pharmacist |
| Information Technology (IT) representative | Mr David Ryan | eMedicines Project Lead, Pharmacy Operations Manager |
| At least two staff pharmacist | Ms Nicola Williams | Team leader |
| | Ms Jenny Young | Team leader |
| | Mr Wynn Pevreal | Medication safety pharmacist |
| Additional staff co-opted for the review of particular items | Mr Bill MacDougall | Clinical Engineering |
| | Ms Julie Bromley | Charge Anaesthetic Technician |
| | Dr Remy Lim | Consultant radiologist |
| | Dr David Cranefield | Clinical Director – Radiology |
| | Ms Jenny Crawford | Paediatric pharmacist |
| | Ms Kim Rogers | Dispensary manager |

# Appendix 2: The ten key elements of safe medication use contained in the MSSA®-AH tool (reproduced from [12])

| Components of a safe medication system | Description and rationale for why the element is fundamental to safe medication use |
|---|---|
| **Element 1: Patient information** | Obtaining the patient's pertinent demographic (age, weight) and clinical (allergies, lab results) information that will assist practitioners in selecting the appropriate medications, doses and routes of administration. Having essential patient information at the time of medication prescribing, dispensing and administration will result in a significant decrease in preventable adverse drug events (ADEs). |
| **Element 2: Drug information** | Providing accurate and usable drug information to all healthcare practitioners involved in the medication-use process reduces the amount of preventable ADEs. Not only should drug information be readily accessible to the staff through a multitude of sources (drug references, formulary, protocols, dosing scales…), it is imperative that the drug information is up to date as well as accurate. |
| **Element 3: Communication of drug information** | Miscommunication between physicians, pharmacists and nurses is a common cause of medication errors. To minimise the amount of medication errors caused by miscommunication it is always important to verify drug information and eliminate communication barriers. |
| **Element 4: Drug labelling, packaging and nomenclature** | Drug names that look-alike or sound-alike, as well as products that have confusing drug labelling and non-distinct drug packaging significantly contribute to medication errors. The incidence of medication errors is reduced with the use of proper labelling and the use of unit dose systems within hospitals. |
| **Element 5: Drug storage, stock, standardisation, and distribution** | Standardising drug administration times, drug concentrations, and limiting the dose concentration of drugs available in patient care areas will reduce the risk of medication errors or minimize their consequences should an error occur. |
| **Element 6: Drug device acquisition, use and monitoring** | Appropriate safety assessment of drug delivery devices should be made both prior to their purchase and during their use. Also, a system of independent double-checks should be used within the institution to prevent device related errors such as, selecting the wrong drug or drug concentration, setting the rate improperly, or mixing the infusion line up with another. |
| **Element 7: Environmental factors** | Having a well-designed system offers the best chance of preventing errors; however, sometimes the environment in which we work contributes to medication errors. Environmental factors that often contribute to medications errors include poor lighting, noise, interruptions and a significant workload. |
| **Element 8: Staff competency and education** | Staff education should focus on priority topics, such as: new medications being used in the hospital, high- alert medications, medication errors that have occurred both internally and externally, protocols, policies and procedures related to medication use. Staff education can be an important error preventions strategy when combined with the other key elements for medication safety. |
| **Element 9: Patient education** | Patients must receive ongoing education from physicians, pharmacists and the nursing staff about the brand and generic names of medications they are receiving, their indications, usual and actual doses, expected and possible adverse effects, drug or food interactions, and how to protect themselves from errors. Patients can play a vital role in preventing medication errors when they have been encouraged to ask questions and seek answers about their medications before drugs are dispensed at a pharmacy or administered in a hospital. |
| **Element 10: Quality processes and risk management** | The way to prevent errors is to redesign the systems and processes that lead to errors rather than focus on correcting the individuals who make errors. Effective strategies for reducing errors include making it difficult for staff to make an error and promoting the detection and correction of errors before they reach a patient and cause harm. |

# Appendix 3: The 20 core characteristics of a safe medication system contained in the MSSA®-AH tool (reproduced from [12])

| Core characteristic: | |
|---|---|
| 1 | Essential patient information is obtained, readily available in useful form, and considered when prescribing, dispensing, and administering medications. |
| 2 | Essential drug information is readily available in useful form and considered when ordering, dispensing, and administering medications. |
| 3 | A controlled drug formulary system is established to limit choice to essential drugs, minimise the number of drugs with which practitioners must be familiar, and provide adequate time for designing safe processes for the use of new drugs added to the formulary. |
| 4 | Methods of communicating drug orders and other drug information are standardised and automated to minimise the risk for error. |
| 5 | Strategies are undertaken to minimise the possibility of errors with drug products that have similar or confusing manufacturer labelling/packaging and/or drug names that look and/or sound alike. |
| 6 | Readable labels that clearly identify drugs are on all drug containers, and drugs remain labelled up to the point of actual drug administration. |
| 7 | Intravenous (IV) solutions, drug concentrations, doses, and administration times are standardised whenever possible. |
| 8 | Medications are provided to patient care units in a safe and secure manner and available for administration within a time frame that meets essential patient needs. |
| 9 | Unit-based floor stock is restricted. |
| 10 | Hazardous chemicals are safely sequestered from patients and not accessible in drug preparation areas. |
| 11 | The potential for human error is mitigated through careful procurement, maintenance, use, and standardisation of devices used to prepare and deliver medications. |
| 12 | Medications are prescribed, transcribed, prepared, dispensed, and administered in a physical environment that offers adequate space and lighting, and allows practitioners to remain focused on medication use without distractions. |
| 13 | The complement of qualified, well-rested practitioners matches the clinical workload without compromising patient safety. |
| 14 | Practitioners receive sufficient orientation to medication use and undergo baseline and annual competency evaluations of knowledge and skills related to safe medication practices. |
| 15 | Practitioners involved in medication use are provided with ongoing education about medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused. |
| 16 | Patients are included as active partners in their care through education about their medications and ways to avert errors. |
| 17 | A non-punitive, system-based approach to error reduction is in place and supported by management, senior administration, and the Board of Trustees/Directors. |
| 18 | Practitioners are stimulated to detect and report errors, and interdisciplinary teams regularly analyse errors that have occurred within the organisation and in other organisations for the purpose of redesigning systems to best support safe practitioner performance. |
| 19 | Simple redundancies that support a system of independent double checks or an automated verification process are used for vulnerable parts of the medication system to detect and correct serious errors before they reach patients. |
| 20 | Proven infection control practices are followed when storing, preparing, and administering medications. |

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# Paediatric non-IgE mediated food allergy: guide for practitioners

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## ABSTRACT

**AIM:** Food avoidance in children is increasingly common due to concerns about allergy. We aim to review the current literature on paediatric non-IgE mediated food allergy including what is known about pathophysiology, diagnosis, management and prognosis of common and severe presentations. Considerations regarding appropriate formula selection are also presented.

**METHODS:** Common non-IgE mediated conditions were searched through common medical databases. Thorough review of available literature was then synthesised and critically appraised.

**RESULTS: C**urrent understanding of immunological mechanisms of most non-IgE mediated conditions remains elusive. Most conditions are outgrown in childhood and have a good prognosis. Dietary modification for some conditions is important to ensure safety. They are not recommended in all situations due to potentially harmful consequences.

**CONCLUSION:** Assessment of children with concerns regarding non-IgE mediated conditions requires a thorough history and is generally not supported by reliable diagnostic tests. Caution is warranted when advising families to undertake dietary exclusions unless well supported by the evidence and ensuring benefits outweigh any potential harm.

Childhood food allergy is an increasingly common problem presenting to both primary care providers and paediatric services. IgE-mediated food allergy has been estimated to affect more than 10% of one year olds in Australia,[1] and has recently been reviewed in this journal.[2] Perceived adverse reactions to foods is generally much higher, affecting up to 30% in some studies. For these additional cases, non-IgE based mechanisms are often considered. Presentation is often in young, preverbal children with symptoms and signs non-specific, vague, inconsistent and subjective, making assessment and management challenging. The absence of any reliable testing further adds to diagnostic uncertainty.

A trial of elimination and re-challenge of the proposed culprit food is often considered best practice. However this can have limitations. Merras-Salmio et al recently undertook a double-blind placebo-controlled food-challenge for cow's milk protein (CMP) associated complaints, with outcome assessed by a paediatrician.[3] Symptoms were attributed to placebo in 46% (18/39) of challenges, and in half of these patients the parents felt reaction on placebo milk was more severe than on CMP. Furthermore, exclusion of a staple food protein in children has considerable negative effects. Growth and micronutrient deficiency have been well shown in children on exclusion diets[4,5] and food avoidance can contribute to family anxiety, adversely affecting mother-baby interactions.[6]

According to the World Allergy Organization (WAO), a reaction to food can only be referred to as an allergy if related to the immune system.[7] In this article, we review the commonly considered non-IgE mediated food allergy presentations. This includes Food Protein-Induced Enterocolitis Syndrome (FPIES), food-protein induced proctocolitis, eosinophilic oesophagitis (EoE), eczema and gastroesophageal reflux/colic. We also look at the best practice

**Table 1:** Summary of Non-IgE mediated food allergies in children.

| | FPIES | Eosinophilic Oesophagitis | Colic / reflux | Proctocolitis | Eczema | Immediate Food Allergy |
|---|---|---|---|---|---|---|
| **Manifestations** | Repetitive vomiting<br>Lethargy<br>Diarrhoea<br>Pallor<br>Floppiness<br>Sepsis-like | Infants<br>• Irritable<br>• Feeding difficulty/ refusal<br>• FTT<br>Older children<br>• Food impaction<br>• Dysphagia, chest pain | Excessive crying<br>Inconsolable<br>Thriving | Low level blood and mucous in stools<br>Generally well | Itch and dry skin<br>Papulovesicular inflammation<br>Infants<br>• cheeks, trunk, extensors<br>Children<br>• flexures, face, eyelids | Vomiting, diarrhoea<br>Urticaria, pruritus<br>Angioedema<br>Wheeze<br>Cardiovascular collapse |
| **Time to reaction** | Vomiting 2–4hs<br>Diarrhoea 5–10hs | Days | N/A | Hours to days | Hours to days | Minutes–2 hours |
| **Age of onset (predominant)** | 6-12 months<br>Median 15 months (8–36) | Variable | 6–12 weeks | 6 weeks to 6 months | ~70% in infancy (3–6 months) | Infancy–childhood |
| **Foods implicated** | Any<br>Milk most common<br>• 60% one food<br>• 30% two foods<br>• 9% three foods | Milk most common<br>Wheat, egg, soy frequently implicated | Controversial | Milk<br>Occasionally soy | Controversial<br>Likely minimal role | Any<br>>90% due to milk, soy, egg, wheat, peanut, tree nut, fish, shellfish |
| **Occurrence in breast feeding** | Case reports | No | Yes **(unrelated to maternal diet)** | Yes (most common >60%) | Yes **(unrelated to maternal diet)** | Possible but rare |
| **Pathology (if known)** | Possibly T-cell mediated | Uncertain | None<br>Physiological variant of normal | Uncertain<br>Eosinophils predominate if biopsied | Epidermal barrier dysfunction | IgE mediated mast cell degranulation |
| **Investigations** | Clinical<br>OFC usually unnecessary<br>Up to 20% have ssIgE<br>Patch test unhelpful | Endoscopy<br>IgE / patch testing probably unhelpful | None | None | Swab for culture if evidence of infection<br>No role for IgE testing to manage eczema | ssIgE<br>Skin prick testing |
| **Differential diagnosis** | Septic shock<br>Intussusception | GORD<br>Infectious oesophagitis (candida)<br>Crohn's disease<br>Oesophageal achalasia | GORD<br>Malrotation<br>Urinary tract infection | Constipation (fissure)<br>Infectious colitis<br>Meckel's diverticulum<br>Chronic granulomatous disease | Wide differential includes: seborrheic dermatitis, psoriasis, ichthyosis, scabies, tinea, immune deficiency, GVHD, nutritional and others | Idiopathic/viral induced urticaria |
| **Treatment** | Avoidance<br>Adrenaline NOT indicated | PPI trial<br>Empiric elimination diets<br>Swallowed steroid | Parental support (association with SBS) | Avoidance<br>Can consider no treatment | Emollients<br>Topical steroid<br>Avoidance of triggers | Avoidance<br>Emergency adrenaline for anaphylaxis if indicated<br>Ongoing research into desensitisation |
| **Association** | Atopy (60% atopic background)<br>Sensitisation may progress to IgE mediated food allergy | Male predominance<br>Atopic dermatitis<br>IgE mediated food allergy | Nil reproducible | Nil | IgE mediated food allergy (~30%)<br>Other atopic disease | Atopic dermatitis<br>Other atopic disease |
| **Natural history** | Resolve 3–5years<br>OFC at least 12 months after last reaction | Unknown and unpredictable | Generally resolves by 6 months | Benign with spontaneous resolution before 12 months | Infantile eczema may clear by 2 years<br>Most outgrown by teens<br>Adult eczema in 2–10% | Food dependant: Many outgrown by adolescence<br>Milk, egg: 70–80%<br>Peanut: 20%<br>Tree nuts: 10% |
| **Home challenge** | No | Yes (unless suggestion of IgE mediated allergy) | Yes | Yes | Yes (unless suggestion of IgE mediated allergy) | Food and history dependant |

FPIES, Food protein-induced Enterocolitis Syndrome; IgE, immunoglobulin E; ssIgE, serum specific IgE; FTT, failure to thrive; GORD, gastroesophageal reflux disease; PPI, proton pump inhibitor; OFC, observed food challenge; SBS, shaken baby syndrome

guidelines for dietary modification in infants with presumed CMP-related symptoms and information is summarised in Table 1. Finally, appropriate dietary modification is outlined including the vital role of a paediatric dietitian.

## Food Protein-Induced Enterocolitis Syndrome (FPIES)

FPIES is a rare condition characterised by severe gastrointestinal symptoms generally presenting in young infants.[8] First described in 1967 due to cow's milk,[9] a wide variety of foods have now been implicated in triggering FPIES. Pathogenesis remains uncertain however antigen specific T cells are thought to be important[10] and other atopic conditions (atopic dermatitis, asthma) are commonly seen in affected children.

Recent large cohorts of FPIES patients in the UK,[11] the US[12] and Australia[13] have helped outline the common characteristics of the condition and also variations among different populations. In all studies, the most common symptom was vomiting (81–100%). Classically, this is profuse, and begins 1–4 hours after ingestion. Hypotension is well recognised and is documented in almost 20% of patients at supervised challenge.[12] The presentation of severe vomiting, abdominal pain and shock can lead to extensive investigation and empiric management for sepsis or intra-abdominal pathology.[13] In general, cow's milk is the most common trigger; however rice was more common in the Australian cohort.[13]

The diagnosis of FPIES is made on clinical grounds and centres on a thorough history. Repeated exposure causing symptoms consistent with FPIES are required by some experts.[14] Laboratory investigations are generally unhelpful, with a raised white cell count (peaking at 6 hours after exposure) often adding to clinical confusion. Acute inflammatory markers are generally not increased. Skin prick and patch testing are not useful in the identification of causative foods. Challenge, if required, should be done under medical supervision in hospital. Sopo et al reported fluid resuscitation was required in more than 40% of patients at food challenge.[15]

Management requires specific food avoidance. Most patients (67–83%) react to a single food.[12,13,15] In cases where more than one causative food is identified, data is discrepant regarding associations and subsequently, firm recommendations are difficult. As an example, different series report coincident cow's milk and soy FPIES affecting from 0%[13,15] to 35%.[12] The prognosis for FPIES is good, with half of affected children outgrowing the condition by 3 years of age. Resolution is delayed in some children, particularly with solid food triggers.

## Eosinophilic oeophagitis

Eosinophilic oesophagitis (EoE) is a chronic immune/antigen-mediated disease, associated with symptoms of oesophageal dysfunction. It is characterised by eosinophil predominant inflammation of the oesophageal mucosa and is generally classed as an allergic condition, as clinical and histological improvement are often seen with antigen avoidance.[16] The incidence and prevalence of EoE range from 0.7–10/100,000 per person year and 0.2–43/100,000 respectively, and appears to be increasing.[17] Caucasian males are most commonly affected, with a reported male to female ratio of 3:1.[18] With increasing recognition it is also the subject of many recent reviews, and some confusion remains around pathophysiology, investigations and treatment strategies.[16,19,20]

The clinical presentation varies, depending on the age of presentation. Infants and young children usually present with irritability, feeding difficulties, abdominal pain, vomiting and failure to thrive. Older children and adolescents present with dysphagia, abdominal or chest pain, food impaction and, rarely, symptoms similar to those of gastro-oesophageal reflux disease.[21] A personal or family history is common and research continues into determining firm genetic or HLA associations.

Diagnosis requires endoscopy and the histological presence of ≥15 eosinophils per high powered field (eos/hpf) in at least one oesophageal mucosal biopsy, with or without the presence of other microscopic features of eosinophilic inflammation. Upper gastrointestinal endoscopic findings are variable, ranging from normal oesophageal mucosa

to longitudinal furrows, white plaques, oesophageal trachealisation, and strictures. Clinical differential diagnoses include gastro-oesophageal reflux disease (GORD), infectious oesophagitis, oesophageal achalasia, Crohn's disease, and connective tissue disorders. This is generally resolved on endoscopy and biopsy.

Uncertainty remains about the best choice of management strategies and balancing treatment effectiveness, side effects and patient quality of life. Use of acid suppression (omeprazole for 6–8 weeks prior to endoscopy) is generally suggested to resolve any reflux associated eosinophilic infiltration/inflammation (PPI-responsive oesophageal eosinophilia).[21] Topical anti-inflammatory therapy is an effective treatment option. Swallowed fluticasone or budesonide slurry (not available in New Zealand) is effective at achieving histological remission in ~80% of patients that are able to comply.[22]

Dietary modification is the alternative mode of therapy. Cow's milk is thought to be the most common food trigger. Transition to exclusive amino acid formula feeding is effective at achieving remission in >90% of patients. Unfortunately, for many patients this is not sustainable and may be unnecessary. For targeted allergen elimination, possible causative foods are identified by skin prick or patch testing and removed from the diet. While CMP is the most common trigger in EoE, it is also the food allergen for which the testing is least helpful. Alternatively, empiric elimination diets have been suggested, where commonly implicated food allergens are removed. Six-food elimination diet (SFED) (milk, soy, wheat, egg, peanut/tree nuts and fish/shellfish), a four-food elimination diet (FFED) (milk, soy, wheat, egg) and milk avoidance alone have all been assessed with 74%, 72% and 62% histological disease remission, respectively.[23] Multiple endoscopic procedures may be required to monitor response to treatment; however, there are no consensus guidelines to recommend timing and duration of these dietary restrictions.

Not all patients have clinical or histological remission on elemental diet suggesting that factors other than diet play a role. Environmental allergens (eg, grass pollens, house dust mites) may cause some of the fluctuations in histological disease seen on surveillance. Oral immunotherapy to environmental allergens is a well-recognised cause of EoE, with 2.7% of patients affected.[24] With the variable response to current therapeutics and uncertainty about the long-term consequences of uncontrolled EoE, 'best practice' is still yet to be defined.

## Gastro-oesophageal reflux disease/colic

Colic is a common presentation to both primary care and paediatricians. For research purposes, a definition of colic is paroxysms of crying for more than 3 hours a day, more than 3 days in a week, for at least 3 weeks.[25] Several population questionnaires have identified normal crying patterns in infancy. In 1962, Brazelton found the median crying time in a 3-month-old infant was 3 hours a day,[26] with similar results found by other groups.[27,28] Above this is considered excessive crying. Importantly, excessive crying does not equate to disease.

A large population study of >76,000 one-month-old infants in the UK demonstrated that colic affected 18%.[29] This study suggested that bottle feeding (standard formula) was protective (OR 0.74 (95% CI: 0.70–0.78)) when compared to sole breast feeding. Risk factors identified were higher socioeconomic status, increased maternal age and higher levels of parental education. Multiple community studies were compiled by Lucassen et al.[30] The type of feed was unrelated to the diagnosis in most studies, as was parental atopy. Exposure to household smoking was an associated risk factor. The lack of any clear association to feeds in multiple, large, population-based cohorts make the type of feed an uncommon and unlikely cause of excessive crying in the first 3 months of life.

Gastro-oesophageal reflux (GOR), defined as passive regurgitation of stomach contents in to the oesophagus, is extremely common in infancy. The prevalence reaches a peak affecting ~40% of infants at 3–4 months of age, declining to <5% at 13–14 months of age.[31] It is also a common cause for medical review. A large, population-based, Melbourne study found 14% of families

had sought medical review for perceived GOR related symptoms.[32] With such similar chronological co-association, it is common for parents and physicians to consider a causative role of reflux and gastrointestinal contents (feed) in excessive crying.

Gastro-oesophageal reflux disease (GORD) refers to the disease state, thought to be secondary to retrograde movement of stomach contents into the oesophagus. The symptoms may include crying and/or irritability, poor appetite, vomiting, wheezing, stridor, apparent life-threatening event (ALTE), abdominal and/or chest pain, chronic cough, hoarseness, and Sandifer syndrome. Many of these are interchangeable with physiological reflux in the setting of a baby with excessive crying, and can make diagnosis difficult. Failure to thrive, feed refusal or respiratory involvement should prompt further investigation or referral for review by a paediatrician. Medications are frequently prescribed for infants with suspected GOR. However, their role is controversial, as meta-analyses have failed to demonstrate benefit in symptom control and GOR is generally self-limiting.

There is no good evidence for dietary modification to treat colic, reflux or GORD. For the vast majority of infants, this is a physiological transition that requires support and understanding for families who are stressed, sleep deprived and desperate to find a 'solution'.

## Food protein-induced proctocolitis

Colitis in infancy due to cow's milk protein ingestion has been described for more than 30 years. While other foods have been identified as precipitants, milk is by far the most common trigger. Infants usually present with low-grade rectal bleeding and mucous stools, but are otherwise healthy and thriving. Histopathology of rectal biopsies taken from affected infants reveal a high proportion of eosinophils (>60/hpf), suggesting a possible allergic inflammatory process.[33]

Cow's milk protein proctitis is the only food allergic condition that is frequently seen in exclusively breastfed infants. Low levels of food proteins have been demonstrated in human milk.[34] Amounts vary considerably from person to person, with only about 50% of lactating women having food proteins detectable.[34,35] Excretion can vary over time and can be independent of the amount of daily consumption.[35]

Differential diagnoses include necrotising enterocolitis, chronic granulomatous disease, intussusception, infectious colitis, perianal fissure, bleeding Meckel diverticulum or bleeding secondary to thrombocytopenia. Children generally respond promptly (within 2 weeks) to dietary exclusion of the culprit food. This may include maternal milk avoidance if exclusively breastfed. Maternal soy avoidance can also be considered if there is no improvement with dairy avoidance. Transition to extensively hydrolysed formula may be required if formula fed or if symptoms are severe, prolonged or associated with failure to thrive. More severe features should prompt thorough investigation for other differential diagnoses. Monitoring of haemoglobin and iron may be warranted if bleeding is protracted or refractory. Home-based challenge (maternal dairy ingestion or CMP based formula) can be considered from 6 months of age and the vast majority of children will have outgrown symptoms by 12 months.

## Eczema

Eczema is a common inflammatory disease of the skin that affects 15–30% of New Zealand children. Eczema is characterised by itch, chronic, relapsing skin inflammation, epidermal barrier dysfunction, and immunological changes including IgE-mediated sensitisation to food and environmental allergens. In infants, eczema typically affects the cheeks, trunk and extensor surfaces of the limbs. In older children, flexural eczema is seen, often with facial and eyelid dermatitis. Only 2–10% of adults have eczema, typically affecting the head and neck, hands and flexures.

There are two main theories of the pathogenesis of eczema. The first proposes that the primary cause is an immunological defect, resulting in IgE-mediated sensitisation and local inflammation which causes the epidermal barrier dysfunction. The second proposes that abnormalities of epidermal barrier function are the

primary cause, with immunological changes occurring as a consequence of local inflammation and abnormal antigen presentation. This second hypothesis is supported by the fact that early onset eczema is often seen in the absence of IgE-mediated sensitisation, and many individuals with eczema never develop IgE sensitisation. Interestingly, loss of function mutations in FLG (a gene that encodes filaggrin, an important protein in skin barrier function) are more common in people with eczema, and are also associated with immediate hypersensitivity to peanut, independent of eczema. This suggests that skin barrier dysfunction may be a common cause underlying both conditions.[36]

One of the hypothesised mechanisms of food allergy development is via transdermal antigen exposure in children with atopic dermatitis.[37] It is estimated that 35–45% of children with severe eczema have immediate hypersensitivity reactions to foods on double-blind, placebo-controlled food challenge.[38] However, Cochrane review of the benefit of food exclusion for treating eczema found little evidence to support this as a management strategy.[39] The quality of studies was generally poor. One randomised controlled study found a small, but just statistically significant, benefit (reduced body surface area affected) from egg exclusion in children with eczema and egg sensitisation.[40] Numbers were small (~25 in each group) and both groups are stated as having 'hidden' egg in foods, such as pasta and cakes. There is no evidence to support widespread indiscriminate food exclusions for the treatment of eczema.[39]

Epidemiology of childhood eczema and prevention strategies have recently been reviewed.[41] With regard to preventing the onset of eczema, current advice is that there is no benefit from exclusion of foods from the maternal diet during pregnancy or breastfeeding to prevent eczema. There is also no evidence for dietary supplementation during infancy. Partially or extensively hydrolysed formulas (eg, HA formulas, PeptiJr®) have also not consistently been shown to significantly reduce onset of eczema, but these remain the recommendation of the American Academy of Allergy, Asthma & Immunology[42] and the European Society of Asthma, Allergy and Clinical Immunology[43] in high-risk babies unable to breastfeed in the first 4–6 months of life. Application of emollients to the skin of high-risk newborns before the onset of eczema may reduce rates by up to 50% and may prove a simple and low-risk alternative to dietary manipulation, as demonstrated in two small studies.[44,45]

There is mounting evidence that food avoidance in high-risk atopic infants and children is associated with loss of tolerance and increased food allergy risk. These effects may be lifelong. Good skin care remains the cornerstone of eczema management.

# Dietary manipulation

Firstly, it must be stated that if breast feeding is intended by the mother, then this is the feed of choice regardless of the presenting complaints. If maternal dietary restrictions are recommended by the treating practitioner, it is important that maternal diet is assessed to ensure adequate micro- and macronutrient intake.

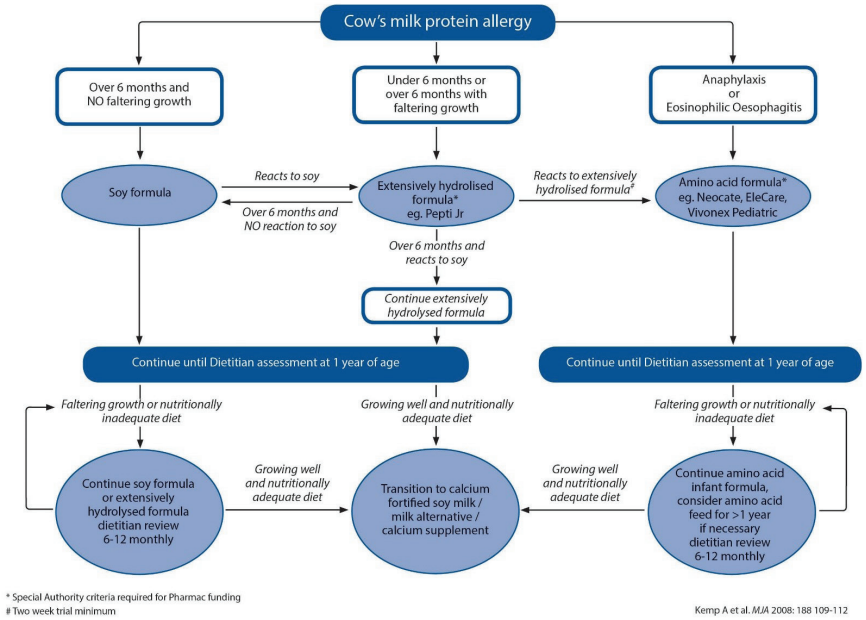
Despite the lack of scientific evidence supporting dietary manipulation as management for many of these conditions, it is often initiated by patients/families and physicians. When prescribing a dietary restriction for a child, we must provide families with information to do this effectively while preventing unnecessary harm. Nutritional deficiency and growth impairment is well documented in patients with dietary restrictions associated with IgE mediated allergy.[5,46] Enlisting the help of a dietician is highly recommended and often vital in the setting of multiple food avoidances.

If dietary restriction is being considered as treatment for non-IgE mediated allergy it is vital a plan for a clear trial period of single food elimination (most often 2 weeks, maximum 4 weeks) followed by re-introduction. This timing is sufficient to demonstrate effective change if the condition is immune mediated, with symptoms returning after re-exposure.

# Cows' ilk alternatives

A flow-diagram for alternative formula is presented in Figure 1. In New Zealand, there are strict requirements for the prescription of extensively hydrolysed and amino acid formulae for children. These are

**Figure 1:** Algorithm for formula use in cows' milk protein allergy.




aimed at ensuring appropriate use of these expensive formulae. Prescription of amino acid formula requires any of the following:

- Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance, allergy or malabsorption;
- Cows' milk anaphylaxis;
- Eosinophilic oesophagitis.

This means a trial of extensively hydrolysed formula is required for all clinical indications other than CMP anaphylaxis or EoE. Most clinical guidelines recommend soy milk as a cows' milk alternative in infants over the age of 6 months where breast feeding is not possible.[47,48] Soy formulas have been used for more than 100 years in the western world. Vandenplas et al conducted an extensive literature review on the use and safety of soy formula in children.[49] In all, 156 studies were identified and 35 were included in their meta-analysis. This study examined markers of nutrition (growth, weight gain, bone density), neurological effects (IQ, behavioural problems, learning) and reproductive function (more than 30 outcomes assessed) with no difference demonstrated between soy and other milks (human milk, cows' milk or alternate formula).[49]

# Risks

Food avoidance in children to manage non-IgE mediated conditions has the potential to alter the natural history of IgE mediated food allergy. There is now good evidence that early exposure to food allergens in high-risk infants decreases the risk of food allergy. The LEAP study, conducted in the UK, demonstrated both primary and secondary prevention of peanut allergy by incorporating peanut into the diet of infants prior to 11 months of age.[50] 640 infants (4–11 month of age) with eczema or egg allergy were randomised to complete avoidance or regular consumption of peanut until 5 years of age. In skin-test negative infants, a reduction in peanut allergy from 13.7% (avoidance group) to 1.6% (consumption) was seen. In those who were already peanut skin test positive (1–4mm) on enrolment, peanut allergy was diagnosed in 35.3% (avoidance), compared to 10.6% (consumption) at 5 years. In another randomised-controlled trial focusing on egg allergy, a trend to allergy reduction was also seen with early egg introduction. However, results did not quite reach significance.[51] Milk allergy reduction has been demonstrated (OR 19 (95% CI, 6–62) in a large Israeli prospective cohort, if milk is introduced before 15 days of age.[52]

Allergen avoidance in atopic high-risk children has been shown to allow loss of tolerance and development of severe reactions, including a fatal reaction to food that had previously been tolerated.[53]

Recent evidence also suggests dietary restriction of milk due to real or perceived allergy can lead to reduced growth percentiles in children and the effect was most pronounced in children younger than 2 years.[46] Older children with >2 food restrictions had BMI reductions similar to children with coeliac disease[46] and seems unrelated to caloric intake.[5]

As well as potential health costs, the costs of living have been recently shown to be increased in patients avoiding milk, egg and/or wheat. Children and adolescents with these dietary restrictions have approximately €4,000 (NZD 8,000)/year increased household expenditure compared to their peers.[54]

# Conclusion

Non-IgE mediated food allergy is a common presenting complaint, with some conditions causing significant morbidity and family stress. Availability of specialised formulae has allowed complete avoidance for cow's milk allergic infants, ensuring safety and facilitating adequate growth and nutrition. Dietary modification is not without harm and should be reserved for patients where it is clinically indicated and necessary. It should also be undertaken with the assistance of a dietitian wherever possible. When appropriately managed, paediatric non-IgE mediated food allergy has an excellent prognosis.

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# Sweet outcome for a rare inflammatory condition

Salah Abdel Jalil, Owais Abdul-Kafi, James Smith, Ala' Abdel Jalil


## ABSTRACT

Sweet syndrome is a rare inflammatory condition that was first described by Douglas Sweet in 1964 as an acute febrile neutrophilic dermatosis.[1] It can be associated with infections, inflammatory conditions, pregnancy, drugs, and malignancy. It is usually divided into three subtypes based on etiology: classical (idiopathic); malignancy-associated; and drug-induced.

We describe a patient with classical Sweet syndrome who had a dramatic response to corticosteroids. Our patient met the major criteria for diagnosis (positive histopathology and an abrupt onset of a painful rash), along with 4 minor criteria (fever, preceding upper respiratory tract infection, dramatic response to steroids, and leukocytosis).


## Presentation

A 47-year-old Caucasian female with an unremarkable past medical history presented to the emergency room with a chief complaint of fever and chills for 2 days. On the morning of her presentation, she developed a non-pruritic, tender rash over her extremities that started as papules and plaques and rapidly progressed into pseudovesicular lesions. She also had cough and malaise over the preceding three weeks. She denied any antibiotic or non-steroidal drug exposure before her illness. She also denied anorexia, weight loss, abdominal pain, blood in her stool, or changes in bowel habits.

Although she was allergic to penicillin, this rash was not similar to the macular rash she developed after penicillin. She smoked cigarettes, and admitted to occasional marijuana and cocaine use.

## Assessment

On physical exam, she had a temperature of 38°C, blood pressure of 162/87 mmHg, pulse rate of 120 beats per minute, and was in no apparent distress. Skin exam revealed tender, erythematous papules and plaques (Figure 1), along with pseudovesicular lesions with raised edges and central pallor resembling 'targetoid- lesions' of different stages (Figure 2). Some lesions developed eschar formation over the upper and lower extremities. The rash notably spared the trunk, palms and soles. She did not have any lymphadenopathy or organomegally. The rest of her physical exam was unremarkable.

She was admitted for further evaluation. Laboratory tests revealed a white blood cell count of 12,400/Ul with 80% neutrophils and evidence of mild iron deficiency anaemia.

Chest x-ray was negative for pneumonia. Collagen vascular disease antibodies, HIV, cryoglobulins, and serum immunoglobulin levels were all within the normal limits. Hepatitis C antibody was positive, but PCR and genotype testing were negative and liver enzymes were within normal limits. Occult malignancy work-up with a mammogram and upper and lower endoscopy was negative, and she did not have manifestations of a lymphoproliferative disease. Hematologic malignancy was felt less likely, so bone marrow biopsy was deferred. A skin biopsy was obtained, which demonstrated dense neutrophilic dermatosis without evidence of leukocytoclastic vasculitis, suggestive of Sweet syndrome, (Figure 3).

## Management

The patient was started on prednisone 40 mg daily and had a dramatic improvement in her skin lesions within the first few days (Figure 4). The precipitating aetiology of this patient's Sweet syndrome was felt to be a preceding upper respiratory tract infection.


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**Figure 1:** Lower extremities image shows erythematous papules and plaques bilaterally.

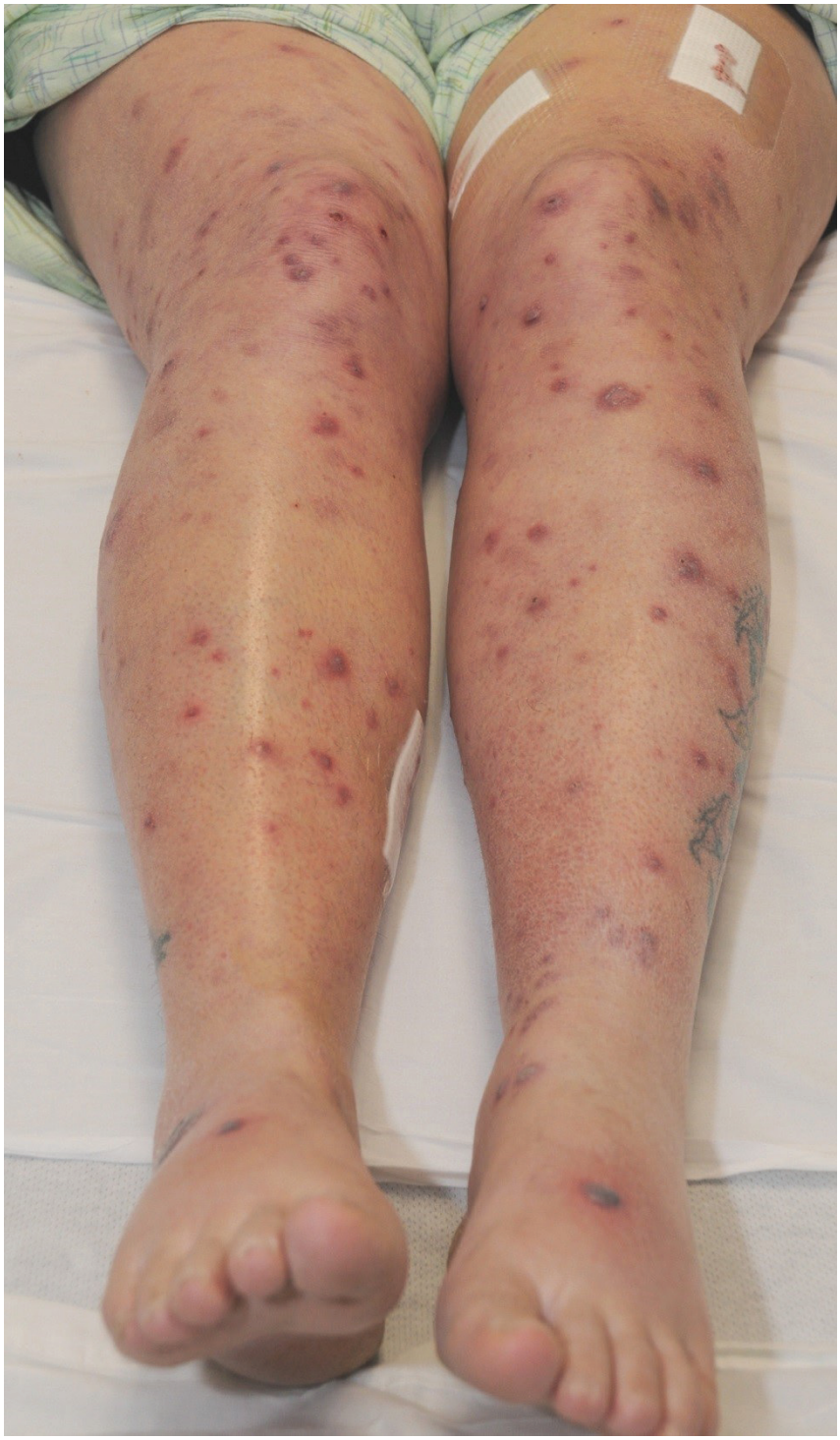


**Figure 2:** Bullous lesions on lateral aspect of right hand and forearm.

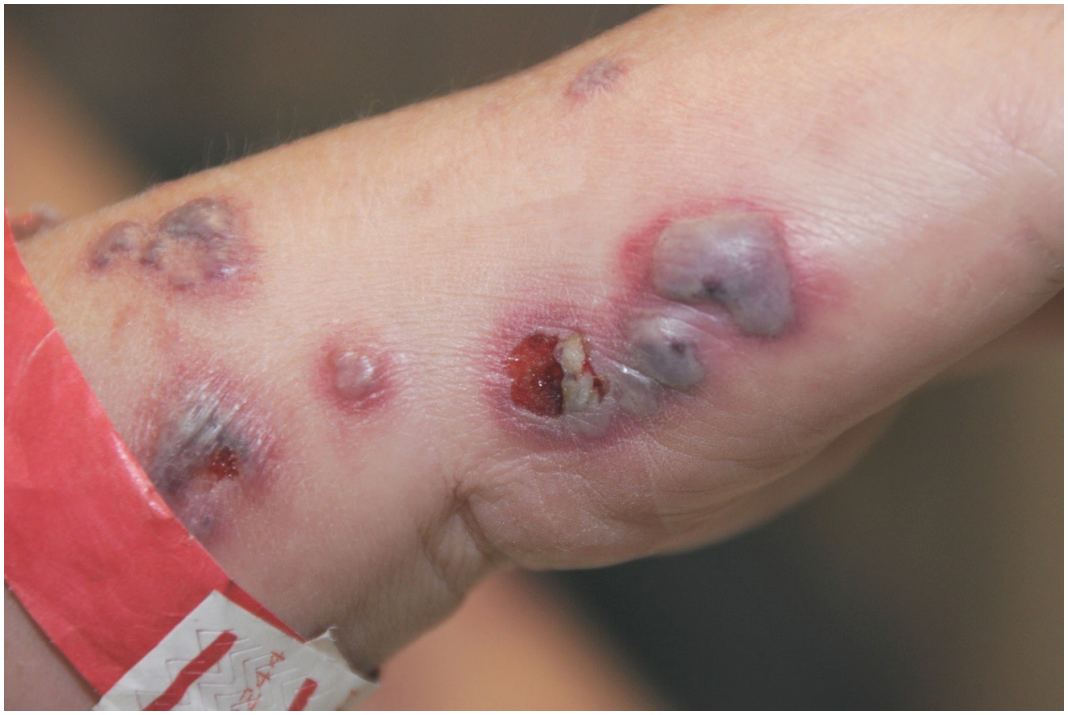


**Figure 3:** Hematoxylin & eosin stain microscopy (100X), showing dense neutrophilic infiltration of dermis, without evidence of leukocytoclastic vasculitis.

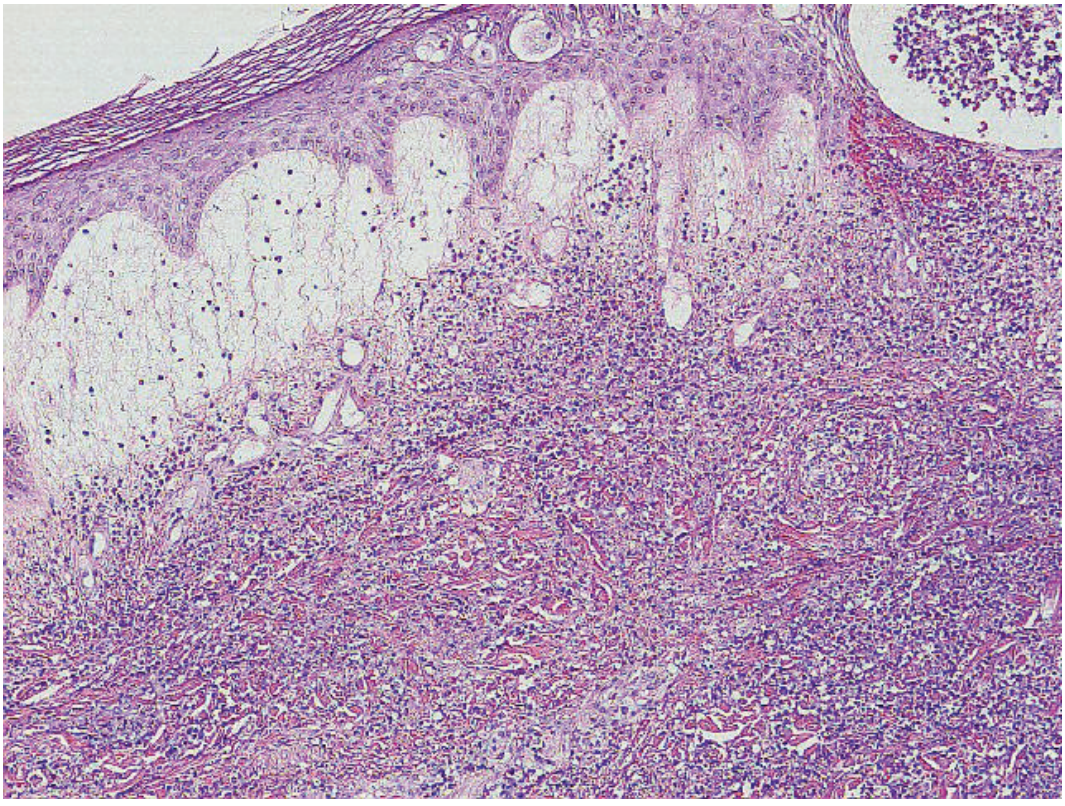
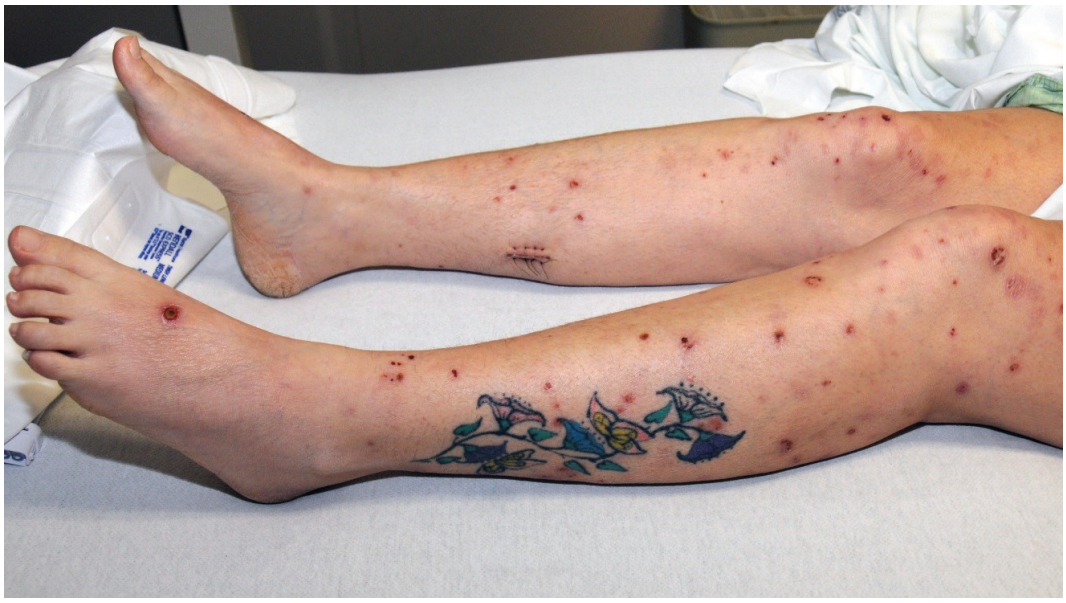


**Figure 4:** Lower extremities few days after treatment with corticosteroids was started, showing dramatic healing of skin lesions.



# Discussion

Sweet syndrome is characterised by an abrupt onset of painful skin papules, plaques, or nodules. Fever and leukocytosis usually accompany the cutaneous lesions. Sweet syndrome has been observed in association with different conditions and has been classified into classical, malignancy-associated, and drug-induced.[2]

Classical (idiopathic) Sweet syndrome is most frequently preceded by a gastrointestinal, upper respiratory tract, or other infection. It might also be associated with inflammatory conditions like inflammatory bowel disease, pregnancy, and, less frequently, other autoimmune diseases.[2]

Malignancy-associated Sweet syndrome, which constitutes 20–25 % of cases, is more common in older patients, and is most often associated with a haematological malignancy, especially acute myelogenous leukaemia (AML) and the myeloproliferative disorders.[3] The rash could precede, accompany, or follow the malignancy diagnosis. Drug-induced Sweet syndrome has a temporal relation with certain medications, including non-steroidal anti-inflammatory medications, colony-stimulating factors, antibiotics, contraceptives, and other medications. The skin lesions usually resolve after the offending medication is discontinued.[4]

According to the screening procedure originally suggested by Su and Liu in 1986, and modified by Von Den Driesch in 1994,[5,6] the diagnosis of classical Sweet syndrome requires both major criteria: a) an abrupt onset of painful erythematous skin papules or nodules; and b) histopathologic evidence of dense neutrophilic infiltrate without evidence of leukocytoclastic vasculitis. In addition, the diagnosis requires meeting at least two of the four minor criteria: a) fever >38°C; b) association with an underlying haematologic or solid malignancy, pregnancy, inflammatory condition (eg, IBD), or preceding upper respiratory or gastrointestinal infection; c) excellent response to treatment with corticosteroids or potassium iodide; and d) at least three of the four abnormal laboratory values (ESR >20mm/hour, elevated CRP, WBC count >8,000/Ul, neutrophils >70% of WBC count).[4]

Characteristic skin lesions of Sweet syndrome are in the form of tender erythematous papules or nodules which can develop into erythematous plaques with a characteristic papillomatous surface.[1] Bullous Sweet syndrome and subcutaneous Sweet syndrome are less common manifestations.[7] A skin biopsy should be performed whenever possible. A punch biopsy is usually obtained for histologic examination, and microbial stains should also be performed to rule out an infectious aetiology.[7]

Systemic corticosteroids therapy is the first-line treatment for Sweet syndrome, and usually results in dramatic clinical improvement.[8] Colchicine, Dapsone, and

potassium iodide are additional effective therapies. Symptoms often begin to improve within 48 hours and skin lesions usually resolve within one to two weeks. Relapse may occur after tapering or discontinuation of glucocorticoids, and may be more likely to occur in patients with malignancy-associated disease.[9]

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# Excise, electronic cigarettes and nicotine reduction to reduce smoking prevalence in New Zealand by 2025

Murray Laugesen, Randolph C Grace

We thank Edwards, Blakely and van der Deen for their comments on our recent letter. Because of space limitations we could not discuss the important work their group has carried out with population-based modelling (eg,[1-3]). They are concerned that our assumptions are over-optimistic and could "skew debates about how best to achieve the Smokefree 2025 goal." Although our approach was simpler and did not include uncertainty estimates, our major implication was fully consistent with the conclusions of their recent simulation study:[1] Current excise policy alone is insufficient and further measures are needed if the 2025 goal is to be reached (p. 4).

In our letter we emphasised three main methods to achieve the 2025 goal:

1. *Increasing excise by 20% annually*. Our estimate of the reduction in prevalence is more favourable (3.7% compared to 7.6%[1] ), but this should be a key component in the overall strategy. Cost for heavy smokers could be severe, but nicotine reduction in point 2 (below) could provide financial relief while lessening dependence.
2. *Reducing nicotine content of cigarettes*. We draw attention to a review in the area,[4] three ground-breaking studies,[5-7] and a recent public survey showing wide support for very low nicotine content (VLNC) cigarettes.[8] This method could (over 2017–2020) be used to reduce excise on VLNC cigarettes by 20% to 2014 levels, making these the preferred price alternative. These cigarettes are available from 22nd Century (US). Nicotine in VLNC tobacco would reduce by 90% or more,[6] smoking would greatly reduce, and many would quit:
   a. In 2009/10 Walker et al undertook a pragmatic, community-based, randomised trial (n=1,410) in New Zealand, in which Quitline callers were randomised to receive either VLNC cigarettes to use whenever they had an urge to smoke for up to 6 weeks after their quit date, in combination with usual Quitline care (8 weeks of NRT patches and/or gum or lozenges, plus behavioural support) or to usual Quitline care alone. Participants in the intervention group were more likely to have quit smoking at 6 months compared to those in the usual care group, and were less likely to relapse back to smoking.[5]
   b. In 2014, Walker et al undertook a pragmatic, community-based, randomised trial (n=33) in Central Otago among cigarette smokers unmotivated to quit. Among those smoking VLNC cigarettes (<0.7 mg tobacco) they reduced cigarette consumption, reduced nicotine exposure, and increased quitting.[6]
   c. In 2015, Donny et al[7] conducted a randomised trial within the US with 780 smokers unmotivated to quit. They showed that those randomised to smoke very low VLNC cigarettes (0.4 mg–2.4 mg per cigarette) rather than standard-nicotine cigarettes (5 mg–15 mg of nicotine per cigarette), reduced their nicotine exposure, nicotine dependency, and cigarettes per day (from 20 to 15). They reported little evidence of

any negative effects (including compensatory smoking) and that participants were more likely to try to quit during follow up.

d. On 8 January 2016, the Health Promotion Agency reported that adults (n=2,594) showed wide support (81% of those surveyed, 63% of smokers, and all age, sex and ethnicity groups) for the concept that "nicotine content of cigarettes should be reduced to very low levels so that they are less addictive".[8] A policy along these lines has the support of the New Zealand public.

3. *Nicotine-containing e-cigarettes*. E-cigarettes, if legal to sell, provide an alternative source of nicotine if nicotine content of cigarettes was lowered as in point 2 above. We have reported evidence that e-cigarettes are partially substitutable for tobacco cigarettes in a simulated demand study, although population-level effects are uncertain[9]. Bullen et al (University of Auckland) have a trial under way to test a New Zealand-sold, tank-filled, e-cigarette for smoking cessation.

Many have asked for steps to help us reach the 2025 target of 5% smoking. We wish to ask that the Ministry of Health in the next few months should issue a Discussion Paper to all parties in the tobacco industry and the tobacco control sector to ascertain everyone's views, and from there proceed to action.

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# Reporting risk-adjusted outcomes for surgical procedures in New Zealand

Harry Alexander, Adam Bartlett, Garth Poole

Tools to assess and compare surgical outcomes have been developed in many centres overseas. These have proven to be useful in monitoring performance, as well as enhancing transparency between health-care providers and the public. However, such systems are complex and a number of issues need to be addressed before they can be successfully implemented. In New Zealand, we have a valuable opportunity to take ownership of our surgical outcomes by leading the development of a fair, universally-applicable surgical scoring system.

New Zealand is ideally placed to lead this process. We have a relatively homogenous DHB- based public health service. We have good collegiality, along with well-organised government and college supervision. Our medico-legal system, especially the Accident Compensation Corporation (ACC) and the Health and Disability Commissioner (HDC), is envied by most countries. Our private sector is dominated by a single insurer with sound structure in the billing models.

Firstly, we must decide on an appropriate scoring system. Variations in surgical volume, physiological risk, operative risk, and the type and severity of complications must be taken into consideration. There must be a compromise between the accuracy of surgical scoring systems and the simplicity of their use. We require a system which accurately accounts for variations in case-load, but is user-friendly and widely implementable. The outcomes to be reported, and to who they are released, will also dominate the discussion.

The outcomes of a scoring system must be risk-adjusted. Surgeons who take on complex cases should not be the victims of a scoring system publishing crude, unadjusted mortality rates favouring those taking on low-risk operations. Implementing an unadjusted system could discourage surgeons from taking on these complex cases. However, accurate risk adjustment is complex and requires the collection of many factors pre-operatively. A number of risk prediction tools exist, and we must decide the most appropriate tool to adjust surgical outcomes for operative risk. Along with calculators of physiological risk, such as the ASA, it is also crucial to predict and grade the predicted operative difficulty of a case. This requires input from surgeons.

Adverse outcomes from surgery include mortality, morbidity and patient dissatisfaction. The chosen outcomes of the scoring system must be capable of accurately representing surgical performance over time.

Therefore, we suggest that surgical performance should be measured by a mathematical formula, which takes into account the:

1. number of cases in surgical career
2. preoperative physiological risk of patients
3. technical challenge of the operative procedures
4. size and outcome of surgeon-specific complications.

With these considerations, we propose adopting a surgical scoring system based on the 'Surgical Risk Scale'. This tool was developed for the purposes of comparative surgical audit and accounts for both physiological and operative risk. Three variables make up this scoring system: ASA grade; a 5-point score for operative difficulty; and a 4-point score for operative urgency.[1] This system is easy to use and interpret and has been multiply validated as an accurate predictor of mortality in general surgical patients.[2] A recent systematic review of


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surgical risk predictors showed it to be the most consistently accurate system, along with P-POSSUM.[2] Its ease of use is a clear advantage over P-POSSUM. All of the inputs into this scoring system are pre-operative factors, so it can also be used to counsel patients about risk.

We must also consider whether the outcomes will be compared between individual surgeons or between surgical units and hospitals. History has shown that outlier performance can occur at the level of institutions as well as individuals.

Clearly defining the purpose of a surgical scoring system will help with consideration around the distribution of outcomes data. Overseas, the public release of surgical outcome data has been acknowledged as leading a new era of transparency between surgeons and the public. Corresponding calculations and awareness of pre-operative risk can lead to more open discussions with patients around informed consent. The release of outcome data by surgeons could be a bold statement of ownership of surgical outcomes to the New Zealand public.

However, there are complexities to the public release of outcomes data. There is concern overseas that the public release of outcomes data for an individual surgeons can lead to irrevocable career damage. The public release of data could also lead to 'gaming' of the system by encouraging risk-averse behaviour.

These issues require the careful attention and collaboration of New Zealand surgeons in order to create a surgical system which is fair and accurate. In leading this process, we have an opportunity to take ownership of our surgical outcomes. Such a system has the potential to be a powerful tool for monitoring performance, detecting outliers and enhancing transparency in healthcare. By driving this process from within, we have the chance to create a user-friendly system which does not punish surgeons and their patients unfairly.

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# Standardised EU cigarette warnings: one size or colour does not fit all

Frank Houghton, Edward Hopkins

Tobacco use continues to be the world's leading preventable cause of death, killing approximately 6 million people annually.[1] Estimates suggest this will rise to 8 million by 2030.[1] Governmental responses to this threat include taxation, controls relating to sales and advertising, as well as the mandatory inclusion of anti-smoking warnings. Attention recently has focused on the introduction of anti-smoking graphics[2] and standardised packaging.[3] The EU has worked hard to introduce and standardise anti-smoking legislation, such the 42 anti-smoking graphic images and 14 warning messages adopted by the 25 EU countries in 2005.[4]

However, such standardisation resulted in less uniformity than might be assumed. Examination of the textual warnings reveals subtle differences that may result in differential impacts. To explore this in more depth, the EU warnings related to cancer for the 25 EU states in 2005 were examined. Each warning is associated with one of three images, all of which feature the phrase "Smoking causes fatal lung cancer" underneath.[4] Although all of the textual warnings are written in MyriadPro Bold font, there are differences in font size. Font size is reduced in warnings featuring more than one language. Although 20 countries included warnings in just one language, the warnings in the five other countries are reduced in size. Malta, Luxembourg, Finland, and Ireland include such warnings in two languages, and Belgium includes warnings in three languages. The size and prominence of warnings are important in terms of reader impact.[5-6]

Differences were also noted in font colour. Evidence demonstrates that people have particular cultural associations with certain colours.[7] In Europe, red is linked to passion, danger, blood, fire, and war. Phrases demonstrating such shared associations in English include to "see red" (a description of anger and volatility), and the infamous Cold War slogan, "Better Dead Than Red". It is no surprise, therefore, that red font was used extensively in the textual warnings.

Given the connotations of the colour red, one might expect warning labels to feature red font exclusively. However, this is not the case. In 19 countries, the first word or two of the warnings are in white font, with the remainder in red. This pattern is not uniform in officially bilingual and trilingual countries. In Finland, Luxembourg, and Malta, the second/final warning was in red font (Swedish, French, and English respectively), with the first warning in white font (Finnish, German and Maltese respectively). In Belgium, the first and third warnings are in white font (German and Dutch), with the middle warning in red font (French). Ireland's warning labels, in both Gaelic and English, feature all white font.

Even in officially monolingual countries, the proportion of red to white text varies. In Slovakia, 50% of words included in the warning are in red font, whereas in Portugal and France the figure is 86%. The average proportion of the words in red font is .75, with a standard deviation of almost 0.1.

It is clear that the standardisation of EU anti-smoking warnings has not, as one might have assumed, resulted in uniformity. Further research is required to explore the impact of these differences in both font size and colour. How, for example, have differences in font colour affected the different peoples of Belgium, namely first-language Dutch or German speakers, who read warnings in white font, compared to first-language French speakers, who read their warnings in red? Similarly, what has been the impact of textual warnings in

Slovakia, where only half of the words are depicted in red, compared to France, where 86% are in red? Alternatively, what is the impact of the smaller font and language order on warnings in officially bilingual and trilingual countries?

It is a little over 50 years since the US led the world by requiring warnings on cigarette packets following the 1964 Surgeon General's report.[8] In the rush to explore the impact of graphic images and standardised packaging, it is important to remember the importance of textual warnings. These warnings remain a vital element of both pictorial and standardised packaging, especially in a number of countries, including the US, which have still not managed to introduce graphic images, and are thus still substantively reliant on textual warnings to convey anti-smoking messages.

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# We respond to Dr Gordon Purdie's Viewpoint, 20 November 2015

Mary Wyatt, on behalf of the Faculty of Occupational and Environmental Medicine, RACP

Dr Purdie makes a number of points[1] about information in the Health Benefits of Work[2] position statement and subsequent publications. We respond to his points in turn.

Dr Purdie raised concerns that we have misinterpreted or misrepresented the survival curves. We concur, in retrospect, that we have not interpreted the survival curve correctly. We thank Dr Purdie for drawing this to our attention. The curve does indicate that the longer someone is off work the lower the chance of the individual returning to work, however the percentages quoted are not accurate. The concordance of the evidence supports the principle, if not the precise detail. We have recently published an update of the evidence[3] and we plan to update the position statement.

The Return to Work Survey was completed annually up to 2014. The survey conducts interviews with approximately 4,700 employees with an accepted claim in Australia or New Zealand, to assess return to work rates over time across jurisdictions.[4]

The *current return to work rate*[5] reported in the Return to Work Survey represents the percentage of employees who say they are back at work at the time the interview takes place, 7–9 months after claim lodgement, in what is termed the *historic* cohort.[6] Seventy-seven percent of employees, on average across Australia and New Zealand, were at work at this point. The *current return to work proportion* is the percent of employees at work at the time of the interview for the entire cohort sample. This includes employees who have an accepted claim lodged within the previous 2 years. These results show 83% of Australian employees and 85% of New Zealand employees at work. While survival curves suggest that some will return to work beyond 2 years, many will not.

We again stress the importance of early strategies to aid the individual, and the importance of early activity to support return to work. Numerous studies indicate that being out of work long-term is associated with higher rates of adverse health. Our call to urgent action aims to focus attention on the importance of considering work rehabilitation at the same time as medical treatment and medical rehabilitation.

This does not mean inappropriate certification of work capacity. If an individual has a medical problem that requires time off work, this should occur. There are medical conditions where an individual is not capable of working, such as after certain fractures or while recovering from surgery. However, there are many situations in which employees are certified totally unfit for work without justification. There is also substantial variation in certification practices between different practitioners.[7]

The AFOEM policy aims to inform those involved with managing workplace injuries about the importance of early intervention. Early reporting of injuries and early management is associated with higher return to work rates.[8] Early effective case management can significantly improve return to work results.[9-11] Most people return to work without problems or intervention. However, the small but significant group that do not return deserve early assistance and attention.

Dr Purdie points out the survival curve used cannot be generalised; it is specific to Victoria and only applies to males. The data used is an example, and while it is not directly applicable to all jurisdictions, it generally reflects patterns of time to return to work. Such curves will vary by jurisdiction, age, gender, industry, scheme design, and many other factors.


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In terms of the relevance of data from the mid-1990s, the Return to Work Survey and its predecessor, the Return to Work Monitor, include return to work results dating back to 1997/98 for Australia and 2001/02 for New Zealand. Return to work rates have fluctuated over the years, but there is no material change in the return to work rates since the Monitor's inception.[12] The data thus remains relevant.

We appreciate the time and thoroughness of Dr Purdie's review of the data used in the policy work. We will adjust our policy documents accordingly. The importance of early approaches to support individuals back to work is a key message of the policy, and we again stress the importance of active case management to minimise the chance of long-term adverse health consequences.[13-15]

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# Anti-androgen contraceptive pills and higher risk of venous thromboembolism

Irene Braithwaite, Philippa Shirtcliffe, Mark Weatherall, Richard Beasley

Venous thromboembolism (VTE) is associated with the use of combined oral contraceptives (COCs). Older contraceptives, containing the second-generation progestogens levonorgestrel or norethisterone, are associated with up to a three-fold increased risk of VTE compared with otherwise similar non-users.[1]Third-generation progestogens, such as desogestrel or gestodene, are in turn associated with a two-fold higher risk of VTE compared to second-generation OCs.[2] However, the association of newer formulations, including OCs containing the anti-androgen cyproterone acetate (CPA) and the fourth-generation progestin, drosperinone (DRSP) which also has anti- androgenic activity, with VTE, may be less well known in New Zealand. In a study reported in *The New Zealand Medical Journal* in 2004, we compared the frequency of specific COC use in patients with VTE with the expected frequency derived from national prescription data, and found that the association of VTE with anti-androgen use is at least as strong as with third-generation OC use.[3]

In this study, we report a secondary analysis of case-control studies of the association of VTE with use of OCs containing CPA or DRSP.

The two case-control studies combined for this study used similar methodology and questionnaires to investigate the association between occupational seated immobility and other factors, and VTE.[4,5] The first study used data from 196 consecutive patients with VTE attending the Capital & Coast District Health Board (CCDHB) VTE clinics and 197 controls admitted to the CCDHB Coronary Care Unit (CCU) between February 2007 and February 2009.[4] The second study used data from 200 new consecutive patients attending the CCDHB VTE clinics and 200 controls attending the CCDHB fracture clinic with upper limb injuries between October 2011 and January 2013.[5]

In both studies, cases were patients to be aged between 18 and 65 years, with a confirmed diagnosis of VTE within the last 6 months. Controls were patients aged between 18 and 65, admitted to CCU in the first study, or with a traumatic upper limb injury for any reason other than VTE, in the second study.

The data collected included age, sex, information about the index event and risk factors for VTE. Thrombophilia screens were only inconsistently available in some cases, were not available for the controls, and were not included as a risk factor. Logistic regression estimated the association between oral contraceptive use and VTE adjusted for age, BMI, family history of VTE, personal history of VTE, history of recent surgery, and history of recent travel. SAS version 9.3 was used.

There were 189 cases and 145 controls who were women. The univariate and multivariate analyses confirmed the known associations of VTE with obesity, personal and family history of VTE, and surgery. No OC was used in 141/189 (75%) cases and 135/145 (93%) controls. Anti-androgen OC use (CPA or DRSP) was present in 12 (6%) cases and 1 (0.7%) controls; and other OC use in 36 (19%) cases and 9 (6.2%) controls. The multivariate odds ratio (OR) for association between VTE and anti-androgen OC use compared to none was 20.0 (95% CI 2.4 to 165), P=0.006; and for other OC use compared to none 5.5 (95% CI 2.3 to 13.2), P<0.001.

This secondary analysis found a strong association with anti-androgen COC use or other OC use and VTE in New Zealand women. Limitations of the study are that this was a *post hoc* analysis, the estimates


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have very wide confidence intervals related to the small sample size, and that the control groups (CCU patients and those with upper limb fractures) may have a biased use of the OC due to age or other factors.

The association with VTE identified here is consistent with a large study reported from UK primary care datasets,[6] which included data about COCs containing desogestrel, gestodene, CPA and DRSP. The reported associations in that study were that the newer COCs were associated with a risk of VTE between 3.6- to 4.3-fold compared with non-use and by around two-fold compared with COCs containing second generation progestogens.[6,7] This is also consistent with the report of a Cochrane systematic review and meta-analysis.[8]

Media commentary around VTE risk and OCs can have a strong focus on individual experiences and outcomes, resulting in highly emotional debates, concern and confusion for women.[9,10] For example, it may not be reported that pregnancy and the post-partum period have a stronger association with VTE than that reported for any COC.[9] No currently available COC, or any likely to be developed in the future, will be 100% effective at preventing conception, be completely risk free, tolerated by all users, and associated with non-contraceptive benefits that justify and facilitate their long-term use.[9] However, prescribers should be aware of the differential risk, and in particular that the anti-androgen agents CPA and DRSP, together with third generation COCs, have a greater VTE risk than the second generation COCs. As in all health-care practice, apply this evidence to the practicalities of advice and prescription of contraception based on individual risk-benefit assessments and informed patient choice and decisions.

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# New Zealand Guidelines for Adult Echocardiography 2015: The Cardiac Society of Australia and New Zealand

Paul G Bridgman, Belinda Buckley, Mark Davis, Belinda Green, Alexander Sasse, David Tang, Niels van Pelt, Steve White

The Cardiac Society in New Zealand seeks to promote best cardiac practice and excellence in patient care. Guidelines covering a range of cardiac practices are therefore provided to the New Zealand cardiology community. This New Zealand echocardiography guideline was ratified on 5 June 2015. It should be read in conjunction with the Australian document Guidelines for Training and Performance in Adult Echocardiography ratified by the Cardiac Society of Australia and New Zealand board on the 30th of November 2012, available at http://www.csanz.edu.au/wp-content/uploads/2014/12/Adult_Echo.pdf.

## Echocardiography

Echocardiography is an indispensable tool in modern cardiology. The echocardiographic findings directly impact key management decisions in the large majority of cardiology patients. All New Zealand District Health Boards should provide access to echocardiography for their patients.

## Cardiac Sonographers

Image acquisition in echocardiography is highly operator dependent. The skills and training of the sonographer are critical in echocardiography quality. Organisations that register cardiac sonographers in New Zealand are the Medical Radiation Technologists Board and the Clinical Physiologist Registration Board. Currently there are two major post graduate echocardiography qualification pathways in Australia and New Zealand. These are the Queensland University of Technology (QUT) qualification and the Diploma of Medical Ultrasound (DMU) qualification. All trainee sonographers in New Zealand should be working towards one of these or an equivalent recognised post graduate qualification.

All sonographers should be supported in their clinical practice by a physician with a special interest in echocardiography. In instances where this physician is not a cardiologist they should have equivalent training in echocardiography to a cardiologist. All studies performed by sonographers should be archived to a digital archive. The supervision physician should have ready access to this archive to facilitate case discussion and review. Note that the ideal arrangement would have the physician and the sonographer in the same hospital but there may be instances in New Zealand where that cannot always occur. In those instances there should be a formal agreement between sites and a robust digital link providing support for the isolated sonographer.

## Echocardiologist training

The current CSANZ/RACP guidelines for training in echocardiography detail two levels of training. Practitioners with level one training are considered competent in transthoracic echocardiography. Practitioners with level two training are considered competent in advanced echocardiography techniques such as transoesophageal and stress echocardiography and in providing echocardiography training to advanced trainees in cardiology. These


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levels are relevant to the New Zealand settings. In New Zealand practitioners with level one training who are practicing outside the scope of that training should be in a collegial relationship with a level two practitioner. In some instances this practitioner may not be working on the same site. When this is the case there should be a formal agreement between sites and a robust digital link to facilitate case review and discussion.

# Echocardiography service development

Echocardiograms should be reported by a physician with expertise in echocardiography. As per CSANZ guidelines, level one training is appropriate for transthoracic reporting and level two training for transoesophageal and stress study reporting. In instances where a sonographer's preliminary report is released without consultant review that report should clearly state the consultant who will be ultimately responsible for sign-off. It should also clearly state that it is a provisional report.

There are currently five tertiary cardiology centres in New Zealand providing intervention and cardiac surgery. Well defined pathways exist for the transfer of patients from the regional centres to these tertiary centres. It is expected that parallel relationships will continue to be developed between the echocardiography services such that all regional echocardiography centres are supported by their tertiary centre.

# Echocardiogram studies

The CSANZ guidelines list the elements of a satisfactory complete transthoracic echocardiogram. Three dimensional and strain imaging may be added to this.

All echocardiogram images should be archived to a digital medium.

## Limited echocardiogram

This is a study performed in the same manner as a standard transthoracic echocardiogram. It is undertaken by a trained or training sonographer working in a supported specialised echocardiography environment. The images are archived digitally and a formal report is issued. However in a limited echocardiogram not all of the standard images are required. The study is typically targeted for left ventricular function in instances such as oncology follow up but there are situations where other targeting is appropriate. It is expected that tertiary centres would offer limited echocardiograms as part of their suite of investigations.

## Point of Care Cardiac Ultrasound (POCCUS)

This is a point of care examination of the cardiovascular system using ultrasound that is alternatively named focused ultrasound. It is performed by a physician in an environment where they are directly caring for the patient. The scan is used as an adjunct to their physical examination. Images may not be archived and a formal report is not issued. In New Zealand POCCUS is most commonly performed in emergency departments, intensive care units and in operating theatres. Responsibility for the scan and clinical management rests with the individuals and service providing the scan. Services providing POCCUS should ensure that those undertaking the scans are adequately trained and are working within an appropriate scope of practice. Review of POCCUS needs to be incorporated into routine QA processes. This should include correlation of POCCUS findings with any subsequent diagnostic imaging, operative findings and clinical outcomes. Services should ensure POCCUS will add value and not simply time and costs, for example through duplication with cardiology provided scans or increased referrals related to false positive POCCUS.

**Competing interests:** Nil

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# Prophylactic antibiotics after acute stroke for reducing pneumonia in patients with dysphagia?

Post-stroke pneumonia occurs in 10% of patients after an acute stroke, and is associated with a trebled increase in mortality. Dysphagia occurs in approximately half of stroke patients and is an important risk factor for the development of pneumonia.

Prophylactic antibiotics might decrease the risk of pneumonia in these patients. This multicentre randomised trial involved 1,224 stroke patients with dysphagia. The researchers report that antibiotic prophylaxis did not reduce post-stroke pneumonia or mortality. There was some evidence that urinary tract infections were seen less frequently in the antibiotic treatment group. There were no serious adverse effects noted.

The conclusion reached was that antibiotic prophylaxis cannot be recommended for prevention of post-stroke pneumonia in patients with dysphagia after stroke managed in stroke units.

**Lancet 2015:386:1835-44**

# Treatment strategies for coronary in-stent restenosis

What is the most safe and effective interventional treatment for coronary in-stent restenosis? This problem is addressed in this study. The researchers note that there are seven recognised possible interventional treatments. These include the use of plain balloons, bare metal stents, brachytherapy, rotational atherectomy, and cutting balloons, drug-coated balloons and drug eluting stents.

They have performed a network meta-analysis of 24 trials (4,880 patients) which included these seven interventions. Their conclusion is that drug-coated balloons and drug eluting stents are associated with superior clinical and angiographic outcomes, with similar comparative efficacy.

**BMJ 2015:351:h5392**

# Paediatric outcome after maternal cancer diagnosed during pregnancy

Among women in whom cancer is diagnosed during pregnancy, factors such as maternal illness, diagnostic tests, cancer treatment, and increased levels of maternal stress can negatively influence foetal development. Whether this does happen is examined in this case-control study from Belgium.

Data from 129 children whose mothers had cancer diagnosed during pregnancy was compared with a control matched number group whose mothers did not have cancer. Ninety-six of the 129 children were exposed to chemotherapy.

The conclusions reached were that prenatal exposure to maternal cancer with or without treatment did not impair the cognitive, cardiac, or general development of children in early childhood. Prematurity was correlated with a worse cognitive outcome, but this effect was independent of cancer treatment.

**N Eng J Med 2015:373:1824-34**

**URL:**
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1430-19-february-2016/6824

# Editorial: February 1916


J M, fl 1915. Dressing station, Gallipoli - Photograph taken by J M. Price, William Archer, 1866-1948: Collection of post card negatives. Ref: 1/2-000579-F.
Alexander Turnbull Library, Wellington, New Zealand. http://natlib.govt.nz/records/22767885

Since our last issue the most important event of the war, so far as New Zealand is concerned, has been the evacuation of Gallipoli. This event directly affects the medical profession out here. Owing to the abnormal numbers rendered hors de combat through wounds and sickness in Gallipoli, the number of medical officers at the front proved altogether insufficient, and a demand was made upon the profession in the Dominion for immediate help. This demand was nobly responded to, and a number of doctors left New Zealand to help their brethren at the front. As a consequence, since the evacuation and the resultant diminution in wounds and disease, there are now more than enough medical men to fill all the needs of the troops. Instructions have lately been received from the Home authorities that no more doctors are to be sent to the front for the present; therefore medical men on the waiting list will understand why their services are not required as urgently as was originally expected, and why it is in every way probable the services of no more doctors will be required for the New Zealand Army for some months to come.

Lt.-Colonel Elliott, the editor of this journal, left Wellington in January last, in charge of the hospital ship "Maheno." His appointment has given universal satisfaction and we feel sure he will as ever do conscientious and excellent service. Lt.-Colonel Begg, who left with the main body and was in charge of the Field Ambulance, has been honoured with the C.M.G. and has been promoted A.D.M.S. to the New Zealand Division, with the rank of colonel whilst so employed.

We would commend to our readers an excellent article by Colonel Begg in the *British Medical Journal* for December 4, 1915. It gives a wonderfully vivid description of work with a Field Ambulance on Anzac beach.

Lt.-Colonel Parkes, who went in charge of No. 2 Stationary Hospital, has also been honoured with the C.M.G. for services rendered in connection with the Pont de Koubbeh Hospital in Cairo. He has also been appointed an A.D.M.S.

The medical profession of New Zealand has not been lagging in this great war, and has proved incontestably its devotion to King and Empire.

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# Charge

On 6 October 2015, the Tribunal considered two charges laid by a Professional Conduct Committee against Dr N (the Doctor).

The first charge alleged the Doctor was guilty of professional misconduct as he used Practitioner Supply Order (PSO) forms for a purpose other than that set out in the Pharmacy Schedule and/or to obtain large quantities of subsidised medicines to take overseas.

The second charge alleged the Doctor was guilty of practising without a practising certificate in that he wrote prescriptions and/or submitted PSOs and/or treated patients when he did not hold a current practising certificate.

## Finding

The charges were admitted by the Doctor. The Tribunal found the first charge was not established and the second charge established.

When considering the first charge the Tribunal considered that the Doctor's PSO claims were made, at the very least, to a significant extent, with a view to stockpiling medical supplies to be used by him in his work abroad. The Tribunal was satisfied that the Doctor breached the tenns of the schedule and his obligations in making the PSO claims referred to in the charge. However, it concluded that the Doctor did not set out intentionally to defraud the Agency by making a false claim but rather he did not carefully read the details of the PSO Claims Schedule in order to determine what he was or was not entitled to claim by way of a PSO and he was not acting for his own financial gain in any way. The Tribunal concluded a reasonable member of the public fully informed of the details would not conclude that the reputation or standing of the medical profession was lowered by the Doctor's actions and determined that the first charge was not established to the necessary standard.

The second charge was established and the Tribunal concluded the Doctor practised extensively between May 2010 and February 2014 while not holding a practising certificate.

## Penalty

The Doctor was censured and the Tribunal ordered that for a period of three years the following conditions on his practice be imposed:

- The Doctor is to arrange and undertake quarterly supervisory meeting with a supervisor approved by the Medical Council. The supervisor is to write a short report after each meeting to the Medical Council confirming that the meeting had taken place, the subjects covered and any areas of concern that had been identified.
- The Doctor is not to sign any PSO fonns without consulting his supervisor so as to ensure that any such applications are compliant in all respects with the Pharmacy Schedule.

The Doctor was also ordered to pay a contribution of $6,197.16 towards the costs of the investigation, prosecution and hearing ofthe charges.

There was an order for permanent non-publication of the name and identifying details of the Doctor.

The Tribunal further ordered publication of the decision in *The New Zealand Medical Journal* and the HPDT website.

The full decision can be found on www.hpdt.org.nz: Reference Med l 5/322P.

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www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1430-19-february-2016/6826