How simple mistakes and short-term bias elevate cardiovascular risk

The impact of different tumour subtypes on management and survival of New Zealand women with Stage I–III breast cancer

Is general practice identification of prior cardiovascular disease at the time of CVD risk assessment accurate and does it matter?

Achilles tenotomy as an office procedure and current practising trends among New Zealand orthopaedic surgeons

Inappropriate prescribing of antibiotics following discharge after major surgery: an area for improvement
Subscription to the *New Zealand Medical Journal* is free and automatic to NZMA members. Private subscription is available to institutions, to people who are not medical practitioners, and to medical practitioners who live outside New Zealand. Subscription rates are below.

All access to the *NZMJ* is by login and password, but IP access is available to some subscribers.

Read our Conditions of access for subscribers for further information

www.nzma.org.nz/journal/subscribe/conditions-of-access

If you are a member or a subscriber and have not yet received your login and password, or wish to receive email alerts, please email: julie@nzma.org.nz

The NZMA also publishes the *NZMJ Digest*. This online magazine is sent out to members and subscribers 10 times a year and contains selected material from the *NZMJ*, along with all obituaries, summaries of all articles, and other NZMA and health sector news and information.

### Subscription rates for 2018

<table>
<thead>
<tr>
<th>New Zealand subscription rates</th>
<th>Overseas subscription rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals*</td>
<td>Individual</td>
</tr>
<tr>
<td>$306</td>
<td>$426</td>
</tr>
<tr>
<td>Institutions</td>
<td>Institutions</td>
</tr>
<tr>
<td>$530</td>
<td>$571</td>
</tr>
<tr>
<td>Individual article</td>
<td>Individual article</td>
</tr>
<tr>
<td>$25</td>
<td>$25</td>
</tr>
</tbody>
</table>

*NZ individual subscribers must not be doctors (access is via NZMA Membership)

New Zealand rates include GST. No GST is included in international rates.

Note, subscription for part of a year is available at pro rata rates.

Please email julie@nzma.org.nz for more information.

Individual articles are available for purchase by emailing nzmj@nzma.org.nz
Trade agreement may limit actions against climate change and risk our nation’s health

Why do our patients choose CAMs?

From the frontline: Gloria
A view from Boston
Review: Early Man

The NZMA publishes the e-magazine NZMJDigest 10 times a year. It contains news and views from the profession and the NZMA, including the NZMA Chair’s editorial, along with highlights from and links to the New Zealand Medical Journal.

Click on the image above to view the latest issue.

We welcome contributions from members and readers. To contribute to the NZMJDigest, please email digest@nzma.org.nz
EDITORIAL

7
How simple mistakes and short-term bias elevate cardiovascular risk
Ralph AH Stewart

ARTICLES

10
Is general practice identification of prior cardiovascular disease at the time of CVD risk assessment accurate and does it matter?
Sue Wells, Katrina K Poppe, Vanessa Selak, Andrew Kerr, Romana Pyltpchuk, Billy Wu, Wing Cheuk Chan, Corina Grey, Suneela Mehta, Dudley G R Gentles, Rod Jackson

21
Symptoms of bowel dysfunction and their management after spinal cord injury in a New Zealand centre
Edwin P Arnold, Giovanni Losco, Sharon English, Frank Frizelle, Angelo Anthony

27
Excess cost and inpatient stay of treating deep spinal surgical site infections
James Barnacle, Dianne Wilson, Christopher Little, Christopher Hoffman, Nigel Raymond

35
Inappropriate prescribing of antibiotics following discharge after major surgery: an area for improvement
Mary De Almeida, Catherine Gerard, Joshua T Freeman, Eamon Duffy, Sally A Roberts

44
Achilles tenotomy as an office procedure and current practising trends among New Zealand orthopaedic surgeons
Lewis Agius, Angus Wickham, Joshua Knudsen, Cameron Walker

51
The impact of different tumour subtypes on management and survival of New Zealand women with Stage I–III breast cancer
Ross Lawrenson, Chunhuan Lao, Ian Campbell, Vernon Harvey, Sanjeewa Seneviratne, Mark Elwood, Diana Sarfati, Marion Kuper-Hommel

61
Incidence, demographics and surgical outcomes of cutaneous squamous cell carcinoma diagnosed in Northland, New Zealand
Brodie M Elliott, Benjamin R Douglass, Daniel McConnell, Blair Johnson, Christopher Harmston

69
Development of an otitis media strategy in the Pacific: key informant perspectives
Elizabeth A-L Holt, Judith McCool, Vili Nosa, Peter R Thorne

CLINICAL CORRESPONDENCE

77
Pharyngoconjunctival fever
Kate E Alfeld, Simon C Dalton

LETTER

81
Primum non nocere: first do no harm
Linda Bryder

METHUSELAH

84
High rates of respiratory symptoms and airway disease in mental health inpatients

100 YEARS AGO

85
Krönlein’s Operation for Orbital Tumour
Is general practice identification of prior cardiovascular disease at the time of CVD risk assessment accurate and does it matter?

Sue Wells, Katrina K Poppe, Vanessa Selak, Andrew Kerr, Romana Pylypchuk, Billy Wu, Wing Cheuk Chan, Corina Grey, Suneela Mehta, Dudley G R Gentles, Rod Jackson

It is important for patient care to identify a patient’s full clinical history so that they may be offered the most appropriate treatment known to improve health outcomes. For people with a history of prior cardiovascular disease (CVD) such as heart attack, stroke or narrowing of major blood vessels, triple therapy (a combination of blood pressure-lowering, lipid-lowering and antiplatelet/anticoagulant medications) could reduce the risk of recurrent events by at least 50% over five years. Information may get lost in multiple ways from hospital to general practice to the patient visit. We found that lack of accurate recording at the time of a first CVD risk assessment did impact on patients’ receiving evidence-based medications and was worse for people aged less than 55 years, women and those of non-European ethnicities. This study highlights the need for ‘whole of system’ clinical information to be available via robust data sharing, automation of coding and clinical reminders to better support patients and general practices at the time of clinical decision making and address inequities in health outcomes.

Symptoms of bowel dysfunction and their management after spinal cord injury in a New Zealand centre

Edwin P Arnold, Giovanni Losco, Sharon English, Frank Frizelle, Angelo Anthony

This study looked at two groups of patients that were admitted to the Burwood Spinal Unit over a 20-year period. Burwood is one of only two spinal units in New Zealand, draining a population of over two million. We were particularly interested to understand how bowel function is affected in these men and women. The findings showed that there are no good predictors of bowel outcome but most people do suffer significant long-term bother from bowel issues after a spinal injury.

Excess cost and inpatient stay of treating deep spinal surgical site infections

James Barnacle, Dianne Wilson, Christopher Little, Christopher Hoffman, Nigel Raymond

This study identified inpatients treated for deep infections following spinal surgery at a regional tertiary spinal centre between 2009 and 2016. Excess hospital cost and length of stay (LOS) were calculated from the hospital costing systems, and compared with people who had the same spinal surgery without an infection. Twenty-eight patients were identified. The average excess cost per patient was NZ$51,434 (range $1,398–$262,206.16) and LOS 37.1 days. In patients whose original surgery required metal implants there was a greater average cost ($56,258.90) and LOS (40.4 days), than the cost ($11,228.61) and LOS (9.7 days) following operations not requiring implants.

Inappropriate prescribing of antibiotics following discharge after major surgery: an area for improvement

Mary De Almeida, Catherine Gerard, Joshua T Freeman, Eamon Duffy, Sally A Roberts

This study examined the indications for antibiotic use in 378 patients discharged from Auckland City Hospital after major surgery. Overall, one-third of antibiotic use was inappropriate and in another 13%, the indication for antibiotic use was not assessable. This study demonstrates that a significant proportion of antibiotics prescribed in patients discharged following surgery are inappropriate and there is a need for enhanced antimicrobial stewardship in this area.
Achilles tenotomy as an office procedure and current practising trends among New Zealand orthopaedic surgeons
Lewis Agius, Angus Wickham, Joshua Knudsen, Cameron Walker

Achilles tenotomy as an outpatient procedure has been shown to be safe and effective. We believe it can be performed safely with results comparable to that performed in theatre. It avoids any potential risks associated with general anaesthesia and potential delays associated with theatre lists. Pain can be controlled adequately, and there is no increased risk of complications or re-tenotomy rate. Parental satisfaction to this procedure is excellent and there are significant financial savings.

The impact of different tumour subtypes on management and survival of New Zealand women with Stage I–III breast cancer
Ross Lawrenson, Chunhuan Lao, Ian Campbell, Vernon Harvey, Sanjeewa Seneviratne, Mark Elwood, Diana Sarfati, Marion Kuper-Hommel

There are 3,000 new cases of breast cancer diagnosed in New Zealand each year. Pathologists test the tumours for the presence of different hormonal markers. These markers are important in helping to guide treatment which is personalised to the woman's cancer including her particular hormonal subtype. Sixty percent of women will have Luminal A subtype, which has a very good prognosis, but women with non-Luminal A cancer will generally have a poorer prognosis and be offered more aggressive treatment. This paper describes the characteristics of women with five different subtypes, shows what treatment is usually used and informs them of their likely prognosis.

Incidence, demographics and surgical outcomes of cutaneous squamous cell carcinoma diagnosed in Northland, New Zealand
Brodie M Elliott, Benjamin R Douglass, Daniel McConnell, Blair Johnson, Christopher Harmston

We examined all the cutaneous squamous cell carcinomas diagnosed in Northland in 2015. This is a form of skin cancer which is more common and different to melanoma. Health funding has been based off studies almost 20 years old and it has been shown that the rates of non-melanoma skin cancer have been increasing since. Our study calculated that 668 per 100,000 Northlanders were treated for this disease in one year, which when accounted for age and ethnicity, extrapolates to 24,605 lesions in New Zealand per year.

Development of an otitis media strategy in the Pacific: key informant perspectives
Elizabeth A-L Holt, Judith McCool, Vili Nosa, Peter R Thorne

There are very few health services to prevent, detect, and treat childhood ear and hearing disorders in Pacific Island countries and territories, despite a high need. Key informants interviewed for this study expressed that while there is the potential to develop better services to address this need, the success of any strategy is dependent on a number of factors. Factors include improving data collection systems, focusing on the education and prevention of childhood ear disease, training a locally-mentored ear and hearing health workforce and nestling the strategy within the existing health and education infrastructure to maximise synergies across established health programmes. Long-term success of any strategy must be developed by local people for the benefit of local communities, and nested within a culturally appropriate framework.
How simple mistakes and short-term bias elevate cardiovascular risk

Ralph AH Stewart

During the last 10 years, thousands of New Zealanders have had a cardiovascular risk assessment completed in primary care using simple risk algorithms such as “PREDICT”. When completing this risk score, the most important ‘box’ is ‘prior cardiovascular disease’ (CVD). This identifies patients who usually have a much higher risk compared to people with risk factors alone, and who almost always have a clear indication for preventive medication.1

In this issue of the NZMJ, Sue Wells and colleagues report on what initially seems a mundane question; “Is general practice identification of prior cardiovascular disease at the time of CVD risk assessment accurate and does it matter?”2

The answer is staggering and the consequences substantial. Wells found that ~40% of patients who had a previous hospitalisation for a major cardiovascular event had ‘no’ indicated for prior CVD in the PREDICT risk algorithm. The mistake was most common for patients with an admission for peripheral arterial disease, whose risk for recurrent CV events is particularly high.3

This apparently simple error translated to more than double the failure to dispense appropriate evidence-based treatment during the next six months. For CVD, incorrectly compared to correctly recorded lipid-lowering therapy was not dispensed for 40% vs 15% of patients respectively, an antiplatelet or anticoagulant in 40% vs 17%, blood pressure lowering medication for 30% vs 14%, and for all three or ‘triple therapy’ in 57% vs 31% of patients.

From many randomised clinical trials we know that lowering LDL cholesterol, decreasing blood pressure, and anti-platelet therapy reduce the risk of myocardial infarction, stroke and cardiovascular death. The ‘triple therapy’ target evaluated by Wells is easy to audit, but for patients at high cardiovascular risk even ‘triple therapy’ may not be optimal therapy. During the first year after an acute coronary event, dual antiplatelet therapy with ticagrelor and aspirin lowers the risk of ischaemic events and death more than clopidogrel and aspirin,4 and both are better than aspirin alone. The reduction in risk is greater for treatment regimens which lower LDL cholesterol more.5 Blood pressure lowering medication to achieve a target systolic blood pressure of 120mmHg decreases cardiovascular events more than when the target is 140mmHg.6 The benefits of combining medications and optimising dose regimens are cumulative, so that optimal therapy compared to no therapy can reduce relative risk by more than 70%.

A healthy diet, regular physical activity and not smoking are also important. For sedentary people even modest increases in regular physical activity are associated with lower cardiovascular and all-cause mortality.7 As for preventive therapy, the benefits of favorable lifestyle risk factors accumulate over time, and have been associated with many additional years of life.8 However, in patients with CVD, encouraging a healthy lifestyle is not a substitute for preventive medication—both are important.

Despite strong evidence and clear guidelines, a third of New Zealanders are not taking a statin one year after acute myocardial infarction,9 and adherence to all recommended therapies is even less. Several factors may explain why patients and doctors often decide that persisting with secondary preventive medication is not worth the effort. These medications do not directly improve wellbeing or quality of life. Some people think taking medication makes them less healthy and...
want to reduce the number of tablets they take, even though for many an increase in treatment could lower risk further. The same medications are widely prescribed for primary prevention where the absolute benefits are often, although not always lower, and this may bias perceptions of benefit. Statistical concepts of ‘risk’ are hard to understand, and people respond differently depending on how it is framed. Most people have a short-term bias, and in the short term, benefits of medication seem small. For example, a 50-year-old man with coronary artery disease taking no medication may have a ~5% risk per year of death, myocardial infarction or stroke, and this can be decreased to ~1.5% by optimal medical therapy. Taking the medication would reduce the risk of a major cardiovascular event in the next week by less than 1 in 1,000. But risks, as well as benefits of treatment, accumulate over time. Over 20 years adhering to optimal preventive medication may increase the chance of being alive without a major heart attack or disabling stroke from less than one in three to more than 70%. It is important to remember that short-term risks of non-adherence to medication are much higher during the first three months after an acute coronary syndrome or arterial stenting.

Side effects, either real or perceived, are a common reason for patients to stop medication. Some, such as cough with angiotensin converting enzyme inhibitors, and ankle edema with calcium antagonists, are easy to ascribe to medication and an alternative or dose reduction can be considered. However, often the link between a medication and suspected side effect is less certain. Is the beta-blocker the reason for fatigue, or a statin for muscle ache? Temporarily stopping medication to see if the problem improves seems reasonable, but symptoms often improve either way. Reluctance to restart a possible offending medication is understandable, but the consequence over the longer term can be a substantial increase in CV risk.

Nocebo effects, or adverse events which result from expectations of harm, are a major contributor to treatment non-adherence. They may be driven by warnings about adverse effects from clinicians, or misleading information in the media. The high rate of muscle aches, memory impairment and other symptoms attributed to statins in clinical practice may largely reflect nocebo effects. In controlled trials, when neither patients nor their doctors know they are taking an active medication, suspected side effects are reported in up to 10% of patients, but the rate is almost the same on placebo and statin. When patients know they are taking a statin, discontinuation because of side effects increases even more.

The importance of access to healthcare and trust is demonstrated by a recent US study where monitoring blood pressure in barbershops with pharmacist support dramatically improved blood pressure control in middle aged black men. In New Zealand, primary care practitioners have the central role in achieving optimal long-term secondary prevention. Trusted advice from their GP is important if patients with cardiovascular disease are to believe that taking four or five medications every day is one of the most important things they can do to live a longer life. However, effective implementation is not as simple as it looks. The study by Wells shows how easy it is to make simple mistakes during busy consultations, and doctors and patients can both ‘forget’ important medical events. Improved systems which automatically link electronic records and lab results to decision support tools and then check and guide decisions may reduce these types of mistakes. Also important is effective communication of the long-term benefits of preventive medications, and considered evaluation of possible side effects. During a 15-minute consultation with more immediate concerns, this can be difficult.

Better implementation of treatment guidelines for secondary prevention would substantially decrease cardiovascular morbidity and mortality. Recognising that choices made by both patients and doctors are influenced by human error and bias could suggest novel approaches to achieve this goal.
Competing interests:
Nil.

Author information:
Ralph AH Stewart, Green Lane Cardiovascular Service, Auckland City Hospital, Auckland.

Corresponding author:
Professor Ralph AH Stewart, Green Lane Cardiovascular Service, Auckland City Hospital, Private Bag 92024, Auckland 1030. rstewart@adhb.govt.nz

URL:

REFERENCES:
Is general practice identification of prior cardiovascular disease at the time of CVD risk assessment accurate and does it matter?

Sue Wells, Katrina K Poppe, Vanessa Selak, Andrew Kerr, Romana Pylypchuk, Billy Wu, Wing Cheuk Chan, Corina Grey, Suneela Mehta, Dudley GR Gentles, Rod Jackson

ABSTRACT

AIMS: To determine the accuracy of general practice recording of prior cardiovascular disease (CVD) at the time of CVD risk assessment and whether recording impacts on CVD management.

METHODS: Prior CVD status entered at the time of a first CVD risk assessment from 2002–2015 was compared to prior ischaemic CVD hospitalisations from national datasets using anonymous linkage with an encrypted National Health Index identifier. Clinical factors associated with inaccurate recording of prior events were identified using multivariable logistic regression. The impact of recording accuracy was assessed by the dispensing of CVD preventive medications in the six months after first CVD risk assessment.

RESULTS: Among 454,369 people aged 35–74 years who had CVD risk assessments, 30,924 (6.8%) had previously been admitted with ischaemic CVD. Of these people, only 61% were recorded as having prior CVD during risk assessment, with better recording for coronary and stroke events than for peripheral vascular procedures. Inaccurate primary care recording was more likely for younger people (<55 years), women, Māori, Pacific, Indian and Asian ethnic groups whereas smokers and people with diabetes were more likely to have prior CVD correctly identified. Over more than a decade, the odds of inaccurate recording during risk assessment increased [OR 1.09 (95% CIs 1.08–1.10)]. If prior CVD was entered at the time of risk assessment then dispensing of blood pressure-lowering, lipid-lowering, antiplatelet/anticoagulant medications, separately or together, was higher (86%, 85%, 83% and 69%, respectively) than if not recorded (70%, 60%, 60% and 43%).

CONCLUSIONS: Overall, 39% of people with prior CVD hospitalisations were not recorded as having prior CVD when their CVD risk was first assessed in general practice. This was associated with inequities in evidence-based risk management. System-based measures are required for robust data sharing at the time of clinical decision making.

New Zealand cardiovascular disease (CVD) risk management guidelines recommend that people with prior ischaemic CVD should be managed intensively with diet, lifestyle and triple medication therapy as tolerated. Triple therapy (i.e., a combination of blood pressure-lowering, lipid-lowering and antiplatelet/anticoagulant medications) could reduce the risk of recurrent events by at least 50% over five years. National analyses indicate that maintenance of triple therapy for patients with prior CVD in New Zealand is suboptimal at around 59% and varies from 54% to 66% across district health boards (DHBs). Patients aged less than 50 years were about 20% less likely than older patients, and women were 10% less likely than men, to be maintained on triple therapy. This evidence-practice gap and variation by age...
and sex has been recognised as a potential contributor to ambulatory sensitive hospitalisations, and is being monitored as an indicator for healthcare quality.

At the point of hospital discharge from cardiology services, 80–86% of patients who have presented with an acute coronary syndrome are prescribed triple therapy, but a variety of system, information technology (IT), provider and patient factors may affect medication initiation, dispensing and maintenance.

While New Zealand primary care is highly computerised, accurate and timely identification of these high-risk patients may be hindered by a number of issues. For example, electronic data transfer at hospital discharge may be suboptimal (eg, wrong general practice [GP], wrong address or patient has no GP), discharge summaries may not be saved in GP records, CVD events may not be coded or classified in electronic health records (EHR) and triple therapy on discharge may not be reconciled with patients’ long-term medication lists. However, even if a CVD event was known and recorded in one general practice, a patient may move to another region without their EHR (especially prior to GP2GP software), thus interrupting continuity of care. Furthermore, patients may not realise that they need to continue these medications long-term, particularly after coronary procedures (eg, stenting).

Since 2002, PREDICT software, integrated into practice patient management systems, has enabled primary care practitioners to conduct CVD risk assessments of patients with and without prior CVD and to access individualised risk management advice. The software has been implemented in approximately 35–40% of New Zealand primary care practices mainly in the Auckland and Northland regions. These practices serve around 1.6 million people and represent around 35% of the New Zealand resident population.

PREDICT records structured CVD history and risk factor data from routine consultations via an online form. If available, data fields are automatically filled in with relevant clinical data from the EHR. This can be checked with the patient and missing fields completed by the practitioner. A copy of each patient’s CVD risk profile is stored both in the EHR and on a secure off-site server held by a private IT company (Enigma) on behalf of primary care providers. Over 98% of New Zealanders have a National Health Index number (NHI) allowing identification and linkage of multiple health contacts such as primary health organisation (PHO) enrolment, pharmaceutical dispensing, hospitalisations and deaths. With provider permission, patient risk factor profiles are anonymised by encrypting the NHI and then transferred to the University of Auckland. These anonymous profiles are then annually linked to national health databases via similarly encrypted NHIs.

In terms of representativeness of the PREDICT cohort to the general population, the socio-demographic distribution of the cohort is strongly influenced by New Zealand CVD guidelines recommendations for screening. National primary care performance indicators have progressively resulted in increased recruitment. By 2014, the cohort included between 79% and 88% of eligible patients.

We compared patients’ prior CVD status entered by primary care practitioners at the time of first CVD risk assessments to prior ischaemic CVD hospitalisations from national hospitalisation datasets, to determine the accuracy of recording, whether it is changing over time, and whether this recording impacts on CVD management.

## Methods

CVD risk profiles relating to patients’ first (baseline) CVD assessment from 1 August 2002 to 12 October 2015 were stratified by clinical history of CVD. Data fields for a history of prior CVD included angina, myocardial infarction (MI), percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), ischaemic stroke, transient ischaemic attack (TIA) and peripheral vascular disease (PVD). Data relating to prior CVD are mandatory fields and without completion a CVD risk assessment cannot be submitted.

The study population were all people aged 35–74 years, which is the age group New Zealand guidelines recommend should have CVD risk assessments. Ethnicity was defined using a prioritisation process based on a

---

**ARTICLE**
national protocol in the following order; Māori, Pacific, Indian, Asian, New Zealand European and Other combined ethnicities (including Middle Eastern, Latin American, African, not specified, other). Socio-economic status was assessed using the New Zealand Deprivation Index (NZDep), a measure assigned to patients according to the deprivation score of their area of residence. NZDep is based on nine variables from the national Census reflecting eight dimensions of relative deprivation of census tracts. For these analyses, NZDep was divided into quintiles from 1 (least deprived) to 5 (most deprived).

A person’s smoking status was defined as either a smoker (including recently quit in the last 12 months) or non-smoker and diabetes status was classified as none or type 1, type 2 or type unknown entered at the time of CVD risk assessment.

The Charlson comorbidity index is a weighted scoring system that assesses the degree of previously hospitalised comorbidity burden. It is based on 12 conditions that predict one-year survival and has been adapted for use with hospital discharge data using a well-validated ICD-10 coding algorithm. Comorbidities were identified from hospitalisations up to five years prior to the first CVD risk assessment.

The National Minimum Dataset was used to identify patients who had prior CVD-related public hospital admission before their baseline CVD risk assessment to determine clinical history. Over 95% of CVD hospitalisations are to the New Zealand’s state-funded public health service. The capture of history of a hospitalised event used data starting at 1 January 1988 and was truncated at 12 July 2015 to allow three months for discharge summaries to arrive at the primary care practice or for a patient to visit their GP post-discharge, especially if triggered by a need for repeat prescriptions. (Appendix 1 has the full list of the International Classification of Diseases, version 10 (ICD-10) codes used to define an ischaemic CVD-related hospitalisation). While all our definitions use ICD-10 codes, any hospital diagnoses recorded in the ICD-9 format was forward-mapped using the New Zealand Ministry of Health ICD-9 to ICD-10 forward mapping convention. Hospitalisation for haemorrhagic stroke and heart failure were not included as these diagnoses were not included as prior ischaemic CVD in the CVD risk assessment template.

The pharmaceutical collection (PHARMS) is a national database of subsidised pharmaceutical dispensing. Reliable identification of dispensing episodes by NHI number has increased over the last decade from 64% in 2004, to 92% in 2006 and over 96% from 2009 onwards. PHARMS was used to identify patients who were dispensed blood pressure-lowering, lipid-lowering and antiplatelet/anticoagulant medications at least once in the six months after the baseline CVD risk assessment from 2006 until 2015. All classes of these medications were considered. While aspirin is available in New Zealand without a prescription, the objective was to detect any differences in dispensing by concordance of recording not the absolute proportion per se.

Outcomes

The primary outcome was concordance between prior CVD hospitalisations and recording of prior CVD at the baseline CVD risk assessment. Concordance by year of first CVD risk assessment (entry into the PREDICT template) was also assessed. To gauge the impact of recording accuracy in primary care on CVD risk management, we assessed the dispensing of cardiovascular medications at least once in the six months after the first CVD risk assessment.

Statistical analysis

We initially generated a 2x2 table plotting the concordance of prior CVD recorded in PREDICT and in national hospitalisation data. Using patients with prior CVD hospitalisations as the denominator, descriptive analyses were undertaken by socio-demographic and clinical characteristics and concordance by year of first CVD risk assessment for all and by hospitalisation diagnosis (ie, MI, PCI or CABG, stroke or TIA, and peripheral vascular procedures). Multivariable logistic regression was undertaken to determine the odds ratio (with 95% confidence intervals [CI]) of the associations with discordance (ie, prior CVD hospitalisation not being recorded in PREDICT). Dispensing of CVD preventive medications in the six months after CVD risk assessment was compared in patients with concordant/discordant recording of prior CVD. This was undertaken from 2006 given the completeness of dispensing records.

ARTICLE
Statistical significance was assessed using the 2-sample test of proportions. All analyses were performed using R v3.0.2.

Ethics approval
The PREDICT study was approved by the Northern Region Ethics Committee Y in 2003 (AKY/03/12/314) with subsequent annual approval by the National Multi Region Ethics Committee since 2007 (MEC07/19/EXP).

Results
There were 454,367 people aged 35–74 years who had baseline PREDICT CVD risk assessments between August 2002 and October 2015. Of these, 30,925 had a prior CVD hospitalisation recorded in the national hospitalisation database. The concordance of being reported in both the primary care risk assessment template and the hospitalisation database was 61% (18,765/30,925). Therefore 12,160 people with a prior ischaemic CVD hospitalisation were not recorded as such at the time of their first risk assessment (Table 1, Figure 1).

There were also 9,989 patients recorded as having prior CVD in the risk assessment template who were not recorded as having a prior CVD-related admission in the national hospitalisation database. These people had one or more CVD diagnoses entered and were recorded as having angina (32%), MI (13%), PCI/CABG (19%), stroke or TIA (29%) and PVD (15%). Some of these events will have been managed only in primary care (eg, angina, TIA, claudication, or ‘silent’ MI detected later by electrocardiogram), whereas other events/procedures will have occurred/been managed overseas or in private hospitals.

Table 2 describes the characteristics of people with a prior CVD hospitalisation (30,925) at the time of first CVD risk assessment in general practice according to

---

**Table 1: Concordance of prior CVD recording in PREDICT primary care risk assessment template and in national hospitalisation database.**

<table>
<thead>
<tr>
<th>Prior CVD recorded in national hospitalisation database</th>
<th>No</th>
<th>Yes</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior CVD recorded in PREDICT risk assessment template</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>413,453</td>
<td>12,160 (39%) discordance</td>
<td>425,613</td>
</tr>
<tr>
<td>Yes</td>
<td>9,989</td>
<td>18,765 (61%) concordance</td>
<td>28,754</td>
</tr>
<tr>
<td>Totals</td>
<td>423,442</td>
<td>30,925</td>
<td>454,367</td>
</tr>
</tbody>
</table>

---

**Figure 1:** Venn diagram of patients with a prior public hospitalisation of ischaemic CVD (30,925 [12,160 + 18,765]), patients with CVD entered only on the PREDICT template in general practice (9,989) and the concordance in both general practice and hospital records (18,765).
Table 2: Baseline characteristics of those with prior hospitalisation with CVD according to PREDICT and hospital records and multivariable logistic regression of the associations with discordance (n=30,925).

<table>
<thead>
<tr>
<th>Concordance (hospital and PREDICT)</th>
<th>Discordance (hospital only)</th>
<th>Odds ratio (95% CI) of a prior CVD hospitalisation not being recorded in PREDICT (discordance)*</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n 18,765</td>
<td>12,160</td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female, % 5,852 (31)</td>
<td>5,165 (43)</td>
<td>1.67 (1.59, 1.76)</td>
<td></td>
</tr>
<tr>
<td>Age group, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35–44 years 583 (3)</td>
<td>575 (5)</td>
<td>1.36 (1.20, 1.55)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>45–54 years 3,076 (16)</td>
<td>2,430 (20)</td>
<td>1.14 (1.06, 1.22)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>55–64 years 6,576 (35)</td>
<td>4,495 (37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65–74 years 8,530 (45)</td>
<td>4,660 (38)</td>
<td>0.81 (0.76, 0.85)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ethnic group, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Māori 2,977 (16)</td>
<td>2,193 (18)</td>
<td>1.21 (1.12, 1.30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pacific 1,788 (10)</td>
<td>1,654 (14)</td>
<td>1.62 (1.49, 1.76)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Indian 1,257 (7)</td>
<td>1,018 (8)</td>
<td>1.43 (1.30, 1.58)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Asian 731 (4)</td>
<td>543 (5)</td>
<td>1.21 (1.07, 1.36)</td>
<td>0.002</td>
</tr>
<tr>
<td>European 11,793 (63)</td>
<td>6,596 (54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other** 219 (1)</td>
<td>156 (1)</td>
<td>1.22 (0.98, 1.51)</td>
<td>0.073</td>
</tr>
<tr>
<td>Deprivation Index, quintile</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (least) 2,708 (14)</td>
<td>1,730 (14)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2 2,637 (14)</td>
<td>1,598 (13)</td>
<td>0.96 (0.87, 1.04)</td>
<td>0.312</td>
</tr>
<tr>
<td>3 3,610 (19)</td>
<td>2,154 (18)</td>
<td>0.90 (0.83, 0.98)</td>
<td>0.019</td>
</tr>
<tr>
<td>4 4,049 (22)</td>
<td>2,440 (20)</td>
<td>0.89 (0.82, 0.97)</td>
<td>0.006</td>
</tr>
<tr>
<td>5 (most) 5,733 (31)</td>
<td>4,220 (35)</td>
<td>1.02 (0.94, 1.10)</td>
<td>0.665</td>
</tr>
<tr>
<td>Diabetes, % 6,833 (36)</td>
<td>4,230 (35)</td>
<td>0.99 (0.85, 0.95)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Current smoker, % 2,975 (16)</td>
<td>1,877 (15)</td>
<td>0.90 (0.84, 0.96)</td>
<td>0.001</td>
</tr>
<tr>
<td>Charlson Index</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 13,369 (71)</td>
<td>8,716 (72)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>1–2 3,856 (21)</td>
<td>2,431 (20)</td>
<td>0.95 (0.89, 1.01)</td>
<td>0.089</td>
</tr>
<tr>
<td>≥3 1,540 (8)</td>
<td>1,013 (8)</td>
<td>1.01 (0.92, 1.10)</td>
<td>0.914</td>
</tr>
<tr>
<td>Year of CVD risk assessment, per year</td>
<td>1.09 (1.08, 1.10)</td>
<td></td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Intercept for multivariable logistic regression model 0.32 (0.29, 0.36).
**Other combined ethnicities included Middle Eastern, Latin American, African, other, not specified.

primary and secondary care records and the factors associated with discordance using a multivariable logistic regression model. The adjusted odds ratios for discordance were higher for people aged less than 55 years, for women, for all ethnic groups (Māori, Pacific, Asian, Indian, Others) compared to European but lower for smokers and those with diabetes. Having one or more comorbidities was not significantly associated with discordance and there was no clear pattern with socio-economic status (NZDep quintile). However, over more than a decade of CVD risk assessments, the odds per year of inaccurate recording increased (OR 1.09 [95% CIs 1.08–1.10]).
Figure 2: Concordance for all CVD and CVD subgroups between hospitalisation records and first CVD risk assessment conducted in general practice.

Figure 2 shows the level of concordance for all CVD and CVD subgroups between the national hospitalisation records and the CVD risk assessment template (first CVD risk assessment). Due to small numbers of CVD risk assessments in 2002–2005, these years have been aggregated together. As 2015 was only a partial year, concordance has not been shown. Prior ischaemic heart disease events (MI, PCI or CABG) were most likely to be recorded at the time of CVD risk assessment, prior peripheral vascular procedures the least likely. Overall, the concordance of recording declined over time; from 72% before 2006 to 52% in 2013 and 55% in 2014.

We investigated the dispensing of CVD medications in the six months after the first CVD risk assessment. This was undertaken from 2006 as dispensing records were 92% complete after this date and therefore includes 28,995 (94%) of the CVD cohort of interest. Table 3 shows that if prior CVD was recorded in both the hospitalisation database and the CVD risk assessment template (ie, concordant) then dispensing of blood pressure lowering medications was 86%, lipid lowering 85%, antiplatelet/anticoagulant medications 83% and triple therapy 69%. However, if people with prior CVD-related hospitalisations were not recorded in the CVD risk assessment template, it was 70%, 60%, 60% and 43% respectively.

### Table 3: Dispensing—up to six months after first CVD risk assessment (from 2006).

<table>
<thead>
<tr>
<th></th>
<th>Concordant (hospital and PREDICT)</th>
<th>Discordant (hospital only)</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>17,371</td>
<td>11,624</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aspirin/anticoagulant</td>
<td>14,353 (83%)</td>
<td>6,966 (60%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lipid lowering</td>
<td>14,744 (85%)</td>
<td>6,990 (60%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BP lowering</td>
<td>14,861 (86%)</td>
<td>8,128 (70%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Triple therapy</td>
<td>12,024 (69%)</td>
<td>5,044 (43%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Discussion

We found that 39% of people with prior publicly-funded CVD hospitalisations were not recorded as such (i.e., had discordant recording) at the time of their first CVD risk assessment in general practice. This discordance worsened over time and was associated with markedly lower dispensing of evidence-based medications. People aged less than 55 years, women and those of non-European ethnicities were more likely to have discordant recording whereas smokers and people with diabetes were more likely to have their prior CVD hospitalisations accurately recorded in the primary care risk assessment.

The findings suggest a classic ‘swiss cheese’ system failure where information is lost through one or more process steps; when preparing and sending hospital discharge letters (via secure portal, fax or paper-based); transmitting discharge summaries to the right GPs at the right general practices; filing in general practice EHRs after receipt; coding events in the EHR; using codes compatible with the integrated risk assessment template; and accurately entering CVD history at the time of CVD risk assessments in primary care. The decreasing accuracy in recording over time may be due to several factors. CVD hospitalised events that might have occurred in the previous 14 years may have been more subject to patient recall bias or loss of information from the system. In addition it might have been influenced by a recommendation in a 2013 guideline update supporting virtual CVD risk assessments. While this helped primary health organisations (PHOs) meet national performance targets it meant that patients were not present at the time CVD risk assessment to check the fields and update clinical history data. Also some of these assessments may have been done by people not familiar with the patient, who relied only on medical record queries.

One enabler of more accurate identification is the facility for patients to access their EHR via portals. If practices allow patients to view their medical history, they could potentially report gaps and inaccuracies in CVD classification. Currently 47% of New Zealand practices have implemented portals and about 10% of the population over 18 years have been registered, so this will take time to develop.

Patients may also move or change GPs. Approximately half the population change addresses every five years between censuses. While many will remain with their original GP, about 10% per year will change their general practice, but this varies by age group (unpublished report W Cheuk Chan CMDHB 2017). New practices are not always forwarded the patient’s EHR. While electronic transfer is much improved with GP2GP file transfer, one of the ongoing problems is the loss of previous recalls/follow-up reminders (personal communication J Kriechbaum 2017). While we could find no published New Zealand data, Read coding of long-term conditions is also likely to vary between providers. A systematic review investigating the quality of morbidity coding in general practice in the UK found the completeness of heart disease registers was ‘poor’ compared to a combination of information (eg. hospital discharge information, hospital letters, medications and procedures stored electronically). One study reported that heart disease registers captured approximately 72% of patients with validated coronary heart disease based on related information (paper notes and computer records) while a further study noted that only 43% of patients who had left hospital following a heart attack were coded in four practices. Our findings for ischaemic heart disease are higher than this; around 80% over the past decade from at least 200 practices using PREDICT.

Information chaos in healthcare is thought to be comprised of information overload, information underload, information scatter, information conflict and erroneous information and has implications for clinical performance and patient safety. Each of the steps in the process highlighted above (at the transfer of care to, within, and between general practices) are recurrent error traps. All hospital discharge summaries in the Auckland region (where the majority of patients in this cohort resided at the time of risk assessment) are now in electronic form. At least 90% are written before discharge with a small proportion written after the patient has left the hospital. Most are electronically transmitted via a secure portal to general practices. If the discharge summary
does arrive at the right practice, it is usually in PDF format, so while it can be saved, it cannot be directly imported into the EHR and so does not immediately provide an opportunity for appropriate coding, recalls or medication review. The very high burden of documentation, coding, setting up recalls and medication reconciliation falls directly on individual providers who are working in very time constrained environments. Our findings provide some explanation for the national findings of suboptimal triple therapy for people who have had a prior ischaemic CVD hospitalisation; that patients aged less than 50 years were about 20% less likely than older patients, and women were 10% less likely than men to be maintained on triple therapy. One limitation is the accuracy of hospital admission coding which we have used to benchmark primary care recording against. While some of the hospital CVD records will be incorrect, recent analyses have found that over 90% of people with an ICD coded acute coronary syndrome hospitalisation did have coronary heart disease on review of the hospital clinical notes (A Kerr, 2017 unpublished study). Yarnall et al found that one of the major reasons for large evidence-practice gaps in primary care was an absolute lack of time. In 2009, they estimated that a primary care physician with 2,500 patients needed 22 hours a day to deliver the recommended care (preventive services, long-term conditions plus acute care). If we translate that to the Ministry of Health estimates of an average of one full-time equivalent (FTE) per 1,650 enrolled patients, it equates to New Zealand GPs working 15-hour days to meet recommended care. Furthermore, with an ageing population, rising burden of long-term conditions, and new diagnostic and treatment options being recommended, we can expect the primary care workload to increase. Some of the important potential benefits of electronic patient records are to facilitate timely access to relevant data, simplify data entry and help document processes of care, rather than add to information chaos and burden primary care providers with unnecessary documentation and coding. Clinical time is much better used being present for patients. It has been suggested that EHRs could easily aggregate and accept structured clinical data from external sources. In addition, clinicians need EHRs that can facilitate the coordination and tracking of care across different settings using standard data models, coding systems and vocabularies such as SNOMED-CT or ICD codes. One potential solution might be automated coding of hospitalisations into primary care records. Such system-based measures are required for robust data sharing and accurate detection at the time of clinical decision making.

Conclusion

Overall, 39% of people with prior CVD hospitalisations did not have this information recorded when they completed a CVD risk assessment in primary care. This inaccurate recording of prior CVD was associated with lower levels of evidence-based CVD preventive drug treatment. This study highlights the need for ‘whole of system’ clinical information to be available to better support primary care. It is timely that the Ministry of Health is investigating the implementation of a unified national electronic health record.
Appendix 1: International Classification of Diseases, version 10 Australian modification (ICD-10-AM) codes used to define an ischaemic CVD-related hospitalisation.

<table>
<thead>
<tr>
<th>Category</th>
<th>ICD-10-AM codes*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest</td>
<td>I46b</td>
</tr>
<tr>
<td>IHD</td>
<td>Angina pectoris: I20; Acute MI: I21; Subsequent MI: I22; Complications of acute MI: I23; Other IHD: I24; (except I241 – Dressler’s syndrome), Chronic IHD: I25</td>
</tr>
<tr>
<td>Ischaemic stroke</td>
<td>Cerebral infarction: I63; Stroke, not specified as haemorrhage or infarction (as these are usually ischaemic): I64 (no subcategories), Sequelae of cerebral infarction: I693, Sequelae of stroke, not specified as haemorrhage or infarction: I694</td>
</tr>
<tr>
<td>Haemorrhagic stroke</td>
<td>Subarachnoid haemorrhage: I60; Intracerebral haemorrhage: I61; Sequelae of subarachnoid haemorrhage: I690, Sequelae of intracerebral haemorrhage: I691</td>
</tr>
<tr>
<td>Other CeVD</td>
<td>TIA: G45 (except G44 – transient global amnesia), G46 Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction: I65 Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction: I66 Dissection of cerebral arteries, nonruptured: I670, Cerebral ath erosclerosis: I672, Sequelae of other and unspecified CeVD: I698</td>
</tr>
<tr>
<td>PVD procedures‡</td>
<td>The following procedures: aneurysm excisions, repairs and replacements, bypasses, endarterectomies and patch grafts, resections and re-anastomoses Involving the following arteries: carotid: 327000-3271011, 3270300, 3310000, 3350000 aorta: 3270800-3270803, 3311200, 3311500, 3311800, 3312100, 3315100, 3315400, 3315700, 3316000, 3350900, 3351200, 3351500 femoral: 3271200-3271201, 3271500-3271503, 3271800-3271801, 3273900, 3274200, 3274500, 3274800, 3275100-3275103, 3275400-3275402, 3275700-3275701, 3351501, 3352100, 3354200 mesenteric: 3273000-3273001, 3273300-3273301, 3273600, 3353001, 3353300, 3353600 other: 3276300-3276303, 3276305-3276314, 3276316-3276319, 3305000, 3305500, 3307500, 3308000, 3312400, 3312700, 3313000, 3316300, 3317800, 3318100, 3350600-3350601, 3351800, 3352400, 3352700, 3353000, 3353900, 3354800-3354803, 3355100, 3355400, 3353006-3353007, 33531200-33531201, 33531500-33531501, 9022900, 902300</td>
</tr>
</tbody>
</table>

Hospital records from 1 January 1988 to 31 December 2015.


*These are the codes used by the Vascular Informatics Using Epidemiology and the Web (VIEW) team, Department of Epidemiology and Biostatistics, University of Auckland (at March 2016) to identify people with ischaemic CVD from hospital records. Only ICD-10-AM codes were used because diagnoses and procedures were mapped by the Ministry of Health to ICD-10-AM 2nd edition (where mappings existed), as well as the original submitted ICD-9-CM-A /ICD-10-AM version.

†Includes any subcategories that come after the last number, unless specified as excluded.
Competing interests:
SW was the recipient of a Stevenson Fellowship in Health Innovation and Quality Improvement and reports grants from Roche Diagnostics Ltd and from National Heart Foundation of New Zealand outside the submitted work. CG reports grants from Health Research Council, grants from National Heart Foundation, during the conduct of the study. SM reports grants from Health Research Council.

Acknowledgements:
The authors would like to thank the primary health care organisations, affiliated general practitioners, practice nurses and patients for their contribution to this study.

The development of the PREDICT cohort is the result of a collaboration between epidemiologists and other clinical researchers at the University of Auckland, IT specialists at Enigma Solutions Ltd (a private IT company who developed and maintain the PREDICT software and webserver), Primary Health Care Organisations (and their member GPs), non-governmental organisations (New Zealand Guidelines Group, National Heart Foundation, Diabetes New Zealand, Diabetes Auckland), several district health boards, and the Ministry of Health.

Author information:
Sue Wells, Section of Epidemiology and Biostatistics, School of Population Health, University of Auckland, Auckland; Katrina Poppe, Department of Medicine, University of Auckland, Auckland; Vanessa Selak, Section of Epidemiology and Biostatistics, School of Population Health, University of Auckland, Auckland;
Andrew Kerr, Cardiology Department, Middlemore Hospital, Auckland;
Romana Polyuchuk, School of Population Health, University of Auckland, Auckland;
Billy Wu, Section of Epidemiology and Biostatistics, School of Population Health, University of Auckland, Auckland; Wing Cheuk Chan, Public Health Physician, Population Health, Counties Manukau District Health Board, Manukau;
Corina Grey, Section of Epidemiology and Biostatistics, School of Population Health, University of Auckland, Auckland; Suneela Mehta, Section of Epidemiology and Biostatistics, School of Population Health, University of Auckland, Auckland;
Dudley GR Gentles, Centre for Tobacco Control, University of Auckland, Auckland;
Rod Jackson, Section of Epidemiology and Biostatistics, School of Population Health, University of Auckland, Auckland.

Corresponding author:
Sue Wells, Section of Epidemiology and Biostatistics, School of Population Health, University of Auckland, PO Box 92019 Auckland Mail Centre, Auckland.
s.wells@auckland.ac.nz

URL:

REFERENCES:
Symptoms of bowel dysfunction and their management after spinal cord injury in a New Zealand centre

Edwin P Arnold, Giovanni Losco, Sharon English, Frank Frizelle, Angelo Anthony

ABSTRACT

AIM: To document the symptoms of bowel dysfunction, and how the bowels are managed, in a cohort of patients following a spinal cord injury. To relate these to the level of the spinal injury and to examine the relationship between bowel symptoms and bladder dysfunction.

METHOD: Participants were identified from the discharge data from the Burwood Spinal Unit, one of two national Spinal Units in New Zealand, in two two-year sets from 1–3 years post-injury and from 20–21 years post-injury. With informed consent, they completed a survey developed for symptoms and management using Survey Monkey. This was cross-related to the level of cord injury and the AIS Scale, and then to the latest urodynamic analysis.

RESULTS: A total of 54 patients were included; data was incomplete in five patients. No specific relation was found between bowel sensation, bowel continence, bowel management, nor with bladder function.

CONCLUSION: Lack of correlation of patterns of bowel function with the level and severity of the cord lesion indicates the need to continue to individualise advice on bowel care according to symptoms.

The bladder and bowel dysfunction that may follow a spinal cord injury (SCI) can have a major impact on quality of life. Bowel dysfunction results from a complex interplay between intrinsic nerve supply of the gut, its external autonomic innervation and the somatic innervation involving the sphincters. While symptoms of bladder dysfunction can be broadly defined by the level and severity of the injury, this relationship is less predictable in the case of bowel dysfunction. Symptoms vary between individuals, resulting in variable strategies for bowel management and their outcomes.

This study aimed to describe the bowel function and bowel management strategies used by a group of SCI patients with injuries at various levels and degrees of completeness according to the American Spinal Injury Association Impairment Scale (AIS).

A secondary outcome measure was to seek any correlation between bowel dysfunction and urodynamic dysfunction over the course of time.

Method

Patients selection

Participants were identified from discharge data documented at the Burwood Spinal Unit. Those injured 1–3 years earlier, and those injured over a two-year period 20 years ago, were identified. Those aged under 16, those who had non-traumatic lesions, those who had a colostomy or a Brindley sacral anterior root stimulation plus deafferentation, were excluded.

An information sheet was sent to each potential participant, followed by a phone call from the spinal research nurse, to answer any questions and to encourage participation. Each were then asked to provide informed consent. The most recent urodynamic reports were checked from Unit records. The study design was a non-randomised non-controlled cross-sectional analysis.

Participants were grouped according to level of injury into cervical and upper thoracic (T1–5), lower thoracic (T6–11) and
conus/cauda (T12 and below). Complete lesions were AIS A, while AIS B-D were grouped together because of small numbers.

Survey
A symptoms questionnaire was developed in consultation with colorectal surgeons, spinal rehabilitation physicians, nurses and urologists; it was pre-tested on five patients. It included questions on bowel sensation, constipation, incontinence and the details of its management including the need for a carer to assist. SurveyMonkey was used to collect the data which was then entered into a spreadsheet for further analysis. Data from the latest urodynamic tests were also entered.

Analysis
Because of the small numbers of participants and the large number of variables, statistical analysis was not possible.

Approvals
The study and questionnaire was approved by the cultural advisor at Burwood Hospital.

Ethics approval was provided the University of Otago Human Ethics Committee (Reference HD15/038).

Results
There were 127 potential participants, 19 had died and 52 were either non-contactable or declined. Patients with non-traumatic lesions were excluded. Finally, 52 were included. Data was incomplete in five.

Table 1 outlines the levels of injury and AIS of patients included in the study.

Because of small numbers, AIS categories were grouped together and all patients were analysed according to the level of injury.

Table 2 reports the bowel symptoms, according to level of injury, and faecal continence rates.

‘Autonomic’ symptoms included bloating, nausea, abdominal pain, goose bumps, sweating and headaches when the bowel needed to be emptied. Autonomic dysreflexia was noted in 14/52 (27%) and all these were cervical or thoracic levels. All were T7 or above, with only one at T10.

Those who had faecal incontinence were not further stratified according to frequency of these accidents.

Table 3 outlines bowel management according to level of injury, the use of...
Table 3: Bowel management.

<table>
<thead>
<tr>
<th>Bowel management</th>
<th>Cervical/upper thoracic (%)</th>
<th>Lower thoracic (%)</th>
<th>Conus/cauda (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>7 (27)</td>
<td>1 (8)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Manual evacuation without suppositories</td>
<td>8 (31)</td>
<td>4 (33)</td>
<td>10 (72)</td>
</tr>
<tr>
<td>Manual evacuation with suppositories</td>
<td>10 (38)</td>
<td>5 (42)</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Enema</td>
<td>1 (4)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Missing</td>
<td>0 (0)</td>
<td>2 (17)</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Carer assistance for bowels</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Required</td>
<td>12 (46)</td>
<td>4 (33)</td>
<td>4 (29)</td>
</tr>
<tr>
<td>Not required</td>
<td>13 (50)</td>
<td>6 (50)</td>
<td>9 (64)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (4)</td>
<td>2 (17)</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frequency of bowel cares</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>9 (34)</td>
<td>3 (33)</td>
<td>8 (61)</td>
</tr>
<tr>
<td>Alternate days</td>
<td>14 (54)</td>
<td>6 (67)</td>
<td>3 (23)</td>
</tr>
<tr>
<td>Less often</td>
<td>2 (8)</td>
<td>0 (0)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (4)</td>
<td>0 (0)</td>
<td>1 (8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time taken on bowel care</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30 mins</td>
<td>12 (46)</td>
<td>3 (33)</td>
<td>8 (73)</td>
</tr>
<tr>
<td>30–60 mins</td>
<td>12 (46)</td>
<td>6 (67)</td>
<td>3 (27)</td>
</tr>
<tr>
<td>&gt;60 mins</td>
<td>2 (8)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bother from bowels</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>4 (15)</td>
<td>0 (0)</td>
<td>4 (29)</td>
</tr>
<tr>
<td>A little</td>
<td>10 (38)</td>
<td>5 (42)</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Moderate</td>
<td>8 (31)</td>
<td>4 (33)</td>
<td>5 (36)</td>
</tr>
<tr>
<td>Severe</td>
<td>1 (4)</td>
<td>1 (8)</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Missing</td>
<td>3 (12)</td>
<td>2 (17)</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change in bowel function with time, since end of first year post-injury</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No change</td>
<td>14 (53)</td>
<td>6 (50)</td>
<td>7 (50)</td>
</tr>
<tr>
<td>Takes longer</td>
<td>8 (31)</td>
<td>2 (17)</td>
<td>5 (36)</td>
</tr>
<tr>
<td>More accidents</td>
<td>2 (8)</td>
<td>0 (0)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>More bloating</td>
<td>0 (0)</td>
<td>2 (17)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Missing</td>
<td>2 (8)</td>
<td>2 (17)</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>
manual evacuation, suppositories and enemas. Carer assistance with bowels, frequency of this, time taken for bowel cares and bother from bowels is included in this table. Change in bowel function, since the end of the first-year post injury, is provided.

Table 4 compares bowel control with urodynamics findings.

<table>
<thead>
<tr>
<th>Bowel control</th>
<th>Compliance normal (%)</th>
<th>Compliance reduced (%)</th>
<th>Detrusor overactivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continent</td>
<td>5 (28)</td>
<td>6 (46)</td>
<td>7 (33)</td>
</tr>
<tr>
<td>Incontinent</td>
<td>13 (72)</td>
<td>6 (46)</td>
<td>12 (57)</td>
</tr>
<tr>
<td>Missing</td>
<td>0 (0)</td>
<td>1 (8)</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>

**Discussion**

We have described the bowel function and bowel management strategies used by a group of SCI patients with injuries at various levels and degrees of completeness according to the AIS. What is most noticeable is the variable nature of symptoms to level of spinal injury and the high number suffering from faecal incontinence. Our study did not show any correlation between bowel dysfunction and bladder dysfunction. This was the conclusion reached by others too, where none of the urodynamic parameters including cystometric capacity, presence of detrusor overactivity, poor bladder compliance, nor detrusor-sphincter-dys-synergia, correlated with any of the bowel symptom scores.1

According to Liu et al, factors which impact on the severity of the Neurogenic Bowel Dysfunction Score included high level of cord injury, its completeness on the AIS score and length of time since injury (>10 years).2

Specific symptoms such as constipation are more difficult to evaluate since there is reduced physical activity and some use laxatives too without always stating this. In our study, about 75% of patients with a SCI use manual evacuation methods to empty the bowels and half of these used suppositories in addition. Hence symptoms such as length of time for bowel cares, use of laxatives, manual evacuation or suppositories, may be more helpful that the Bristol Stool Scores in these patients. Suppositories were more commonly used in high lesions than in those with conus/cauda lesions. Where suppositories are effective, this suggests the possibility of reflex stimulation, which might be somatic or autonomic, involving colorectal and recto-anal reflexes.3

Emmanuel et al found that constipation was more prominent in patients with a lesion above T5 compared to 55% in patients with lesions below T5, 20 years after injury.4 These authors also showed that constipation correlated with a slower gut transit time, which was pan-colonic. The delay was greater in high spinal lesions, where loss of sympathetic inhibition resulted in greater mucosal blood flow than in those with lower lesions. Another group observed that upper gastrointestinal transit was prolonged in subjects with SCI suffering from bowel problems, not only in subjects with cervical or high thoracic lesions but also in subjects with conus/cauda equina lesions.5 This group speculated that the prolonged transit was secondary to colonic dysfunction and constipation.

In a study from a US VA medical centre, megacolon (bowel diameter > 6cm on plain x-ray), was reported in 94/128 (73%) and was shown to increase with time from SCI.6 Evidence is conflicting however, and other researchers have shown no increase in megacolon.7 In our study with increasing time since injury, 15/52 (29%) indicated it look longer to empty the bowels. This is in agreement with an earlier study, which found in addition that faecal incontinence did not change with time.8 Little change was noted with time in another cross-sectional study but the authors drew attention to the need for longitudinal studies.9

Nausea, distension, bloating and vague discomfort are presumably related to the autonomic innervation. About 50% of all patients had some of these symptoms. For
those with conus and cauda lesions, the sensation might be mediated by somatic sensation. To these can be added symptoms of autonomic dysreflexia like headache, sweating and reflex hypertension. In our study, autonomic dysreflexia was noted in 27% and all these were cervical or thoracic levels; all except one were T7 or above.

Bowel symptoms and their management caused moderate or severe bother for 21/52 (40%) and seemed to affect those with conus/cauda level lesions as much as the cervical ones. However, more of the cervical lesion patients had carer assistance and this reduced the level of bother.

Lynch et al demonstrated that ano-rectal manometry did not show a consistent relation to bowel dysfunction after SCI.\(^8\) The lack of a predictable bowel dysfunction after SCI probably relates to the complex innervation of the bowel with extensive intrinsic autonomic innervation and interaction with the somatic system in the rectum, anus and sphincters. The presence of intrinsic and extrinsic autonomic nerve supply to the bowel and their interactions are complex.

There are multiple clinical examples of surgical bowel denervation that do not lead to reproducible bowel dysfunction. For example:

**Parasympathetic denervation:** Truncal vagotomy formerly used in the treatment of peptic ulcers causes parasympathetic denervation of the bowel from the stomach to the splenic flexure. After an initial period of flaccidity, peristalsis returned, indeed often with increased activity associated with diarrhoea, as might be predicted as the parasympathetic system is motor to the gut. Disordered small bowel motility with absence of cyclical activity was seen in some.\(^{10}\)

**Sympathetic denervation:** Damage to the lumbar sympathetic nerves can occur during surgery in the formerly used operation of surgery for hypertension, in a pre-sacral neuroectomy formerly done for dysmenorrhoea, as part of a retroperitoneal lymph node dissection for testis tumours, in aortic aneurysm repair and with colectomy including extended lymph node dissection. However, there was no definable effect on subsequent bowel function after these procedures.\(^{11,12}\)

**Somatic sacral denervation:** Where the conus or the cauda equina are damaged, the somatic nerve supply to the pelvic floor and sphincters of bladder and anus is interrupted, resulting in abolition of reflex activity and flaccidity. The pelvic floor weakness can lead to stress urinary and bowel incontinence. Such incontinence can develop after surgical deafferentation to achieve continence by abolishing reflex detrusor contractions as part of the Brindley sacral anterior root stimulation procedure.

Reflexes between the anal margin, anal sphincter and bowel contraction are important in both defecation and bowel control. These reflexes involve both somatic and autonomic nervous systems. Further there is evidence that the urethral sphincter is subject to similar reflex actions as the anal sphincter. Chronic constipation with a distended rectum can activate the recto-anal inhibitory reflex causing bowel incontinence.

This is a small study, with a relatively low return rate of the electronic questionnaire and as such may be subject to bias, for example those who replied may be patients who are more likely to be having trouble with their bowels. Both groups, being those injured 1–3 years earlier, and those injured over a two-year period twenty years ago, were analysed as a single cohort. This was not the original intention of the study but due to small numbers, no meaningful interpretations were able to be drawn from the two groups which otherwise appeared to show very similar patterns. A larger study with more complete follow-up is recommended.

This study does give valuable insight into the variable bowel habit experienced by the SCI patients and draws attention to the fact that symptoms are not as predictable as previously thought. Hence, bespoke bowel management plans are often required irrespective of the level of the spinal lesion.
Competing interests:
Nil.

Acknowledgements:
The authors wish to acknowledge the assistance of: Dr Raj Singhal, Clinical Director, Burwood Spinal Unit; Professor Chris Frampton for statistical advice; Marian Lippiatt, Registered Nurse, Burwood Spinal Unit; Lucy Eames, Research Assistant, the patients for their participation and the Burwood Academy of Independent Living for oversight of the project. Funding was received from the Burwood Spinal Unit Education and Research Trust and the Urological Research Foundation.

Author information:
Edwin P Arnold, Clinical Professor of Urology, Department of Surgery, University of Otago, Christchurch; Giovanni Losco, Consultant Urologist, Department of Urology, Canterbury District Health Board, Christchurch; Sharon English, Consultant Urologist, Department of Urology, Canterbury District Health Board, Christchurch; Frank Frizelle, Professor and Head of Department, Department of Surgery, University of Otago, Christchurch; Angelo Anthony, Rehabilitation Physician, Burwood Spinal Unit, Canterbury District Health Board, Christchurch.

Corresponding author:
Mr Giovanni Losco, Department of Urology, Canterbury District Health Board, Christchurch Hospital, Private Bag 4710, Christchurch 8140.
giovanni@urology.co.nz

URL:

REFERENCES:
Excess cost and inpatient stay of treating deep spinal surgical site infections

James Barnacle, Dianne Wilson, Christopher Little, Christopher Hoffman, Nigel Raymond

ABSTRACT

AIM: To determine the excess cost and hospitalisation associated with surgical site infections (SSI) following spinal operations in a New Zealand setting.

METHODS: We identified inpatients treated for deep SSI following primary or revision spinal surgery at a regional tertiary spinal centre between 2009 and 2016. Excess cost and excess length of stay (LOS) were calculated via a clinical costing system using procedure-matched controls.

RESULTS: Twenty-eight patients were identified. Twenty-five had metalware following spinal fusion surgery, while three had non-instrumented decompression and/or discectomy. Five were diagnosed during their index hospitalisation and 23 (82%) were re-admitted. The average excess SSI cost was NZ$14,344 (range $1,398–$262,206.16) and LOS 37.1 days (range 7–275 days). Infections following metalware procedures had a greater excess cost (average $56,258.90 vs. $11,228.61) and LOS (average 40.4 days vs. 9.7 days) than procedures without metalware.

CONCLUSION: The costs associated with spinal SSI are significant and comparable to a previous New Zealand study of hip and knee prosthesis SSI. More awareness of the high costs involved should encourage research and implementation of infection prevention strategies.

Healthcare-associated infections (HAI) are a major source of morbidity, mortality and expense. Surgical site infections (SSI) make up approximately 22% of HAIs in the US and 17% in Europe. SSIs increase hospital inpatient length of stay (LOS) by a median of two weeks, increase the chance of readmission and re-operation by five times, and double mortality.

Surgical site infections can be divided into superficial and deep incisional/organ space (henceforth referred to as ‘deep’) as per the Centre for Disease Control and Prevention (CDC). Superficial infections usually respond well to antibiotics and wound care. Deep infections involve deep soft tissue or organs/spaces opened or manipulated during the operation and must occur within 30 days of the procedure or within one year if an implant is in situ. Deep infections cause the most severe morbidity and are usually managed with surgical debridement, by sending intra-operative tissue samples for microbiology, and intravenous (IV) followed by oral antibiotics targeted at likely or confirmed pathogens.

Surgical site infections are a significant risk of spinal surgery. A recent literature review looking at 425,180 primary spinal procedures calculated a pooled average SSI rate of 1.9%. Approximately half of these appear to be deep infections. Lieber et al reviewed the National Surgical Quality Improvement Program Database (NSQID) in the US between 2006 and 2012 and identified 1,110 post-operative wound infections out of 60,179 spinal operations giving an incidence of 1.84% of which 0.98% were superficial and 0.87% were deep. Mortality from spinal SSIs was 1.06% in a large retrospective study. Staphylococcus aureus is responsible for approximately 49% of infections and of those, 38% are methicillin-resistant Staphylococcus aureus (MRSA). This is based predominantly on studies from the US.
Risk factors independently associated with SSI after spinal operations include female sex, high body mass index, wound class, American Society of Anesthesiologists (ASA) category, operative duration, insulin-dependent diabetes and prolonged pre-operative steroids. Other papers have emphasised comorbidities, including neurological, cardiac and pulmonary disorders, and cancer.

Spinal instrumentation refers to the use of metalware to stabilise the spine. It is associated with biofilm formation and persistent infection despite antibiotics and is thought to increase the rate of SSI by 28%. This often warrants additional surgery and more prolonged antibiotics. Metalware removal is controversial and the optimal timing is debated since removal before bony fusion can lead to progressive pain and deformity. Many centres choose to retain the metalware in the case of infections (such as the centre in this study). Patel et al calculated a SSI rate of 3.8% after instrumental procedures based on 28,628 patients, double the estimated overall incidence following spinal procedures. The same review revealed a re-operation rate of 89.2% in instrumented SSIs.

There is evidence for measures to reduce SSIs and data on the cost of spinal SSIs will draw more attention to research and the implementation of preventative strategies. The aim of this study was to identify the excess inpatient costs and hospitalisation associated with post-operative spinal infections in a New Zealand setting.

Methods

Patients
The study was conducted at Wellington Regional Hospital (WRH), a tertiary regional referral centre for spinal surgery. In the Wellington region, all inpatients with spinal SSIs are referred and managed at WRH, with spinal surgery only performed at WRH or two other Wellington hospitals. Patients were retrospectively identified using the infectious disease (ID) department inpatient consultation database, which was interrogated for deep SSIs following spinal operations between August 2009 and May 2016 (6 years and 10 months), during which period the ID team was routinely involved in the care of all patients with suspected or confirmed SSI following spinal surgery. Deep SSIs were defined using the CDC criteria. Onset of infection was defined as the date of hospital readmission for infection or the date infection was diagnosed when it occurred during the same inpatient stay as the initial spinal surgery. Cases of deep non-instrumented SSI were included with onset of infection after 30 days, beyond the usual CDC time-frame, when treated as a convincing post-operative infection.

Clinical management
Patients were managed under the care of a spinal orthopaedic surgeon with inpatient and outpatient input from an ID physician. Microbiological samples were obtained by aspirate or multiple intraoperative cultures before antibiotic administration when practical. Debridement and metalware retention was undertaken in most cases. Intravenous antibiotics were used until the acute wound infection and drainage stabilised, for most patients 2–6 weeks. Patients were not detained in hospital for IV antibiotics only, as there was a well-established programme for home IV antibiotics. Oral antibiotic switch was made as soon as clinically indicated, guided by microbiological results and using biofilm-active agents as appropriate.

Data extraction and cost estimation
Demographic and clinical data were extracted from hospital electronic patient administration and clinical records, including: patient demographics, procedure date, type of procedure, diagnosis, LOS (including any infection related readmissions), organisms cultured, timing of SSI and surgical and antibiotic management. Cost data for each patient event were extracted from the Capital and Coast District Health Board (CCDHB) clinical costing system (Power Performance Manager, Power Health Solutions). Outpatient IV antibiotic and infusor costs were drawn from the ID pharmacy database and added to the inpatient costs.

For those patients in whom infection was first diagnosed following discharge home from a primary operation and uneventful initial hospital stay, excess costs and LOS were calculated as the costs of the subsequent hospital readmissions related to
infection. The follow-up observation period for readmissions was for an average of four years (range 1–8 years).

In those diagnosed with infection during the initial admission, excess costs and LOS were calculated by subtracting the mean cost and LOS for uncomplicated controls without infection from the total cost for their inpatient stay. Control data were extracted from a control group including all patients who, during financial year 2014/2015, had the same ICD-10 Procedure Code as the cases, but without infection or other complication.

The median excess LOS and cost for SSIs following operations with and without metalware were compared statistically with a Mann-Whitney U test using SPSS 25. Since the data are not normally distributed, we used median values.

Data on the total number of spinal surgical procedures from 2009–2016 from the three Wellington hospitals performing elective spinal surgery was used to calculate an estimated overall spinal SSI rate.

Literature review

A literature review of PubMed was performed searching for ‘spine’ AND ‘surgery’ AND ‘infection’ AND ‘cost’ to identify other papers that have looked at the inpatient costs associated with deep spinal SSIs. Papers were included if they estimated the hospital costs of deep SSIs after spinal operations. The references of suitable papers were checked for other papers meeting the criteria in an iterative process.

Results

Patients, SSIs and surgical management

Between 2009 and 2016, 28 patients with deep spinal SSIs required an ID consult. Their demographics, surgery and infection onset are shown in Table 1. The primary spinal surgery had been performed in the Wellington Region for 26/28 (93%) patients. Twenty-five patients had undergone operations involving posterior spinal fusions with implantation of spinal metalware. Three patients had undergone spinal discectomy and/or decompression without metalware. Diagnosis of infection was a median of 20.5 days (range 7 to 250 days) following the surgery. Two non-instrumented cases had an onset of infection more than 30 days (31, 74 days) post-operatively. Five infections were diagnosed during the initial admission and 23 resulted in readmission. Twenty-five patients (89%) went on to have surgical intervention to manage the infection, with a median of one operation (range 0–37) in addition to their primary operation. Metalware was retained in 24/25 patients who underwent instrumentation.

The estimated overall deep SSI infection rate for the three hospitals performing spinal surgery in Wellington was 0.76%.

Microbiology of SSIs

One or more definite or probable pathogens were isolated from intra-operative spinal samples from 25/28 (89%) patients. These included coagulase-negative

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patients (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: median years (range)</td>
<td>69 (17–82)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
</tr>
<tr>
<td>Female</td>
<td>13</td>
</tr>
<tr>
<td>Original operation</td>
<td></td>
</tr>
<tr>
<td>Posterior spinal fusion (instrumented)</td>
<td>25</td>
</tr>
<tr>
<td>Decompression/discectomy (un-instrumented)</td>
<td>3</td>
</tr>
<tr>
<td>Place of original operation</td>
<td></td>
</tr>
<tr>
<td>Wellington (public)</td>
<td>15</td>
</tr>
<tr>
<td>Wellington (private)</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
</tr>
<tr>
<td>Median number of days to infection presentation post-operatively (range)</td>
<td>20.5 (7–250)</td>
</tr>
<tr>
<td>Median number of repeat surgical procedures (range)</td>
<td>1 (0–37)</td>
</tr>
</tbody>
</table>

Table 1: Patient demographics, surgery and infection onset.
Staphylococcus spp. (9 patients), methicillin-susceptible Staphylococcus aureus (5), methicillin-resistant Staphylococcus aureus (2), Enterococcus sp. (5), Propionibacterium acnes (2), Proteus mirabilis (2) and one patient each with Klebsiella pneumoniae, Corynebacterium sp., Enterobacter sp. and Pseudomonas aeruginosa.

Controls for patients in whom infection was diagnosed during the initial hospitalisation

For five of the 28 patients, infection was diagnosed during their initial admission. These five patients had undergone one of two categories of surgery, which corresponded (surgery without complication) to ICD-10 Procedure codes 4864500 (posterior spinal fusion, with deformity, three or more levels) and 4865700 (Posterior spinal fusion with laminectomy, two or more levels). There were 16 controls for Procedure 4864500 with an average cost of NZ$40,877.87 and LOS 5.25 days. There were four controls for Procedure 4865700 with an average cost of $42,566.27 and LOS 7.25 days. For each of these five patients, the excess cost and LOS for the initial hospital stay was the difference between the actual total and the corresponding uncomplicated control.

Excess costs and length of stay for patients with spinal surgical site infections

For the 28 patients with spinal SSIs, the excess LOS and excess cost are shown in Table 2. The mean and median excess LOS were 37.1 and 17.4 days respectively. The mean and median excess cost per SSI were NZ$51,356 and $30,964 respectively. Patients with metalware cost an average of $56,172 per SSI with an excess LOS of 40.4 days. Those without metalware cost an average of $11,229 per SSI with an excess LOS of 9.7 days. The excess cost following SSI was significantly more in patients with metalware ($p=0.007). While the results suggest an increased excess LOS following SSIs with metalware, the sample size was probably too small to determine a statistical significance ($p=0.09$).

The contributions to the overall excess cost of spinal SSIs are shown in Table 3. Ward costs (29.4%), doctors (24.3%) and operating theatres (18.5%) were the largest contributors.

Literature review

The literature review identified seven papers, all from the USA, that estimated the costs associated with spinal SSIs. The excess cost estimates ranged between US$12,619 and US$100,666 per SSI (see Table 4). The costs are not adjusted for inflation.

| Table 2: Excess cost and inpatient length of stay (LOS) for patients with spinal infections. |
|----------------------------------|------------------|------------------|
|                                  | Instrumented      | Un-instrumented  | All patients |
|----------------------------------|------------------|------------------|
| Number                           | 25               | 3                | 28           |
| Excess LOS days                  |                  |                  |
| Average                          | 40.4             | 9.7              | 37.1         |
| Median                           | 18               | 11               | 17.4         |
| (Range)                          | (7–275)          | (4–14)           | (7–275)      |
| Excess cost NZ$                   |                  |                  |
| Average                          | $56,172          | $11,229          | $51,356      |
| Median                           | $38,602          | $14,569          | $30,964      |
| (Range)                          | ($7,623–$262,206)| ($1,398–$17,718)| ($1,398–262,206)|
Table 4: Comparison of existing studies estimating the excess cost of deep surgical site infections following spinal surgery.

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedures</th>
<th>Number of patients with SSI</th>
<th>Inpatient costs included</th>
<th>Other costs included</th>
<th>Excess cost per SSI</th>
<th>Mean excess LOS per SSI (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kuhns, 2015, USA</td>
<td>Subaxial dorsal cervical fusion</td>
<td>22</td>
<td>Yes</td>
<td>Outpatient appointments, therapy and medication costs for up to two years. Estimated economic costs based on work days missed.</td>
<td>US$12,619</td>
<td>Not provided</td>
</tr>
<tr>
<td>Theologis, 2014, USA</td>
<td>Pedicle subtraction osteotomy (PSO) and vertebral column resection (VCR)</td>
<td>7*</td>
<td>Yes, excluding surgeon fees</td>
<td>NA</td>
<td>US$34,388</td>
<td>Not provided</td>
</tr>
<tr>
<td>Godil, 2013, USA</td>
<td>Posterior spinal fusion</td>
<td>5*</td>
<td>Yes</td>
<td>NA</td>
<td>US$33,705</td>
<td>Not provided</td>
</tr>
<tr>
<td>Emohare, 2014, USA</td>
<td>Fusion, discectomy, lateral lumbar decompression</td>
<td>7</td>
<td>Yes</td>
<td>NA</td>
<td>US$88,019</td>
<td>Not provided</td>
</tr>
<tr>
<td>McGirt, 2011, USA</td>
<td>Minimally invasive and open posterior and transforaminal lumbar interbody fusion (P/TLIF)</td>
<td>292</td>
<td>Yes</td>
<td>Any medical encounter within eight weeks of index hospitalisation documenting presence of SSI</td>
<td>US$15,817</td>
<td>Not provided</td>
</tr>
<tr>
<td>Parker, 2011, USA</td>
<td>Open transforaminal lumbar interbody fusion (TLIF)</td>
<td>6</td>
<td>Yes</td>
<td>NA</td>
<td>US$29,110</td>
<td>12</td>
</tr>
<tr>
<td>Calderone, 1996, USA</td>
<td>Posterolateral lumbar fusion</td>
<td>11</td>
<td>Yes</td>
<td>Outpatient follow-up for six weeks</td>
<td>US$100,666</td>
<td>58.6</td>
</tr>
<tr>
<td>Barnacle, 2016, NZ</td>
<td>Posterior spinal fusion, decompression/ laminectomy</td>
<td>28</td>
<td>Yes</td>
<td>Outpatient antibiotic infuser costs</td>
<td>NZ$51,356</td>
<td>37.1</td>
</tr>
</tbody>
</table>

* includes two superficial infections.

* excess costs for patients in control group included only.
Discussion

The present study showed that while deep spinal SSIs are uncommon, there are substantial inpatient costs and excess LOS associated with them. The observed deep SSI rate for all spinal infections was 0.76%, which is close to the NSQID rate of 0.89% for deep SSIs. The mean excess cost of NZ$51,356 broadly agrees with other papers in the literature, but comparisons are difficult due to differences in cost capturing methods and procedures. However, costing data from the US may not be generalisable to New Zealand or elsewhere. This is the first paper we are aware of which documents the cost of spinal SSIs outside of the US.

We confined the current study to the costs of inpatient management, home IV antibiotics and LOS as these had robust data available. This methodology was similar to previous studies but also looked at infusor costs. Kuhns estimated economic costs and Calderone and McGirt calculated some outpatient costs in their studies. The discrepancy in excess costs between the studies compared in the literature review may be in part due to the definitions of SSI used. Three of the studies do not state a definition, and three use non-standard definitions. Kuhns used the CDC definition, as in this study.

Comparison between SSI costs in spine, hip and knee operations is possible. A recent paper looking at hip and knee arthroplasty SSIs in New Zealand with similar methodology and also using the CDC definition for SSI found a mean excess cost of NZ$40,121. We observed the excess LOS to be an average of 37.1 days (median 17.4 days), which was comparable to the average 42 days’ excess after knee and hip arthroplasty infections. Two USA studies of lumbar SSIs reported excess LOS after spinal SSIs; Parker and Calderone reported an average excess of 12 and 58.6 days respectively.

The costs reported here may be an underestimate. Personal financial and disability costs are not included. Outpatient healthcare costs, such as ID and orthopaedic clinic visits, in this cohort were probably small in comparison to inpatient costs. With biofilm metalware infections, late clinical relapse can occasionally occur years later and warrant further surgical management, beyond a typical follow-up period.

The use of metalware has allowed increasingly complex surgery over several spinal levels. Unfortunately, clinical management of spinal SSIs with metalware is more difficult than SSIs without metalware, particularly where metalware cannot readily be removed. Our finding that SSIs in patients with metalware result in significantly higher excess costs compared with those without is consistent with this.

This study was based in a single region, where the number of spinal SSIs and denominator procedures could be ascertained reliably due to a limited number of spinal surgeons, cooperation between institutions and a single tertiary centre managing all hospitalised deep infections. It is unlikely that any local patients had their infection managed outside the region and excluding the two patients from outside the region only had a modest effect on the overall results.

In our patient cohort, there was a relatively high proportion 25/28 (89%) of patients with a confirmed microbiological diagnosis. A variety of pathogens were observed, including S. aureus, skin organisms, enterococci and aerobic Gram-negative bacilli. This emphasised the importance of obtaining a microbiological diagnosis, particularly when choosing the oral antibiotic agents in the treatment regimen. Greater use of empiric antibiotics would have been anticipated to result in a greater cost and LOS, due to a greater cost of empiric therapy and a potentially greater clinical failure rate.

While a study limitation is the relatively small number of patients (28), this is one of the largest published series of spinal SSIs, and the first outside the US. For non-instrumented cases, the small number and inclusion of clinical infections beyond the 30-day onset in the CDC definition limited comparisons with instrumented cases. Inclusion of outpatient costs was limited to the available reliable costing for IV antibiotic infusors. Existing literature uses average costs, which can be less repre-
sentative where there is a non-normal distribution, a reason for our having also reported median values and used them in our statistical analysis. The potential for missed cases is a limitation in all such studies, less likely here due to the well-defined region.

In conclusion, there is a substantial excess cost and LOS associated with deep spinal surgical site infections. More awareness of the high costs involved should encourage the implementation of infection prevention strategies and research to reduce the impact of these disabling surgical infections.

Competing interests:
NR is a longstanding employee of Capital & Coast DHB where the study was conducted (Wellington Hospital). He also is a part-time contractor to Wakefield Hospital (Acurity Health) for Infection Control, who provided data on surgical procedures for the study. There was no internal or external funding for the study.

Acknowledgements:
We thank Lisa Woods, School of Mathematics and Statistics, Victoria University, for assistance with statistical analysis.

Author information:
James Barnacle, Principal Medical Officer, Internal Medicine, Daeyang Luke Hospital, Malawi; Dianne Wilson, Manager, Business Intelligence and Analytics Unit, Grace Neill Block, Wellington Hospital, Wellington; Christopher Little, Infectious Diseases Pharmacist, Pharmacy Department, Wellington Hospital, Wellington; Christopher Hoffman, Consultant Orthopaedic Surgeon, Orthopaedic Service, Wellington Hospital, Wellington; Nigel Raymond, Infectious Diseases Physician, Infection Service, Wellington Hospital, Wellington.

Corresponding author:
Nigel Raymond, Infectious Diseases Physician, Infection Service, Level 6, Grace Neill Block, Wellington Hospital, Wellington 6021.
nigel.raymond@ccdhb.org.nz

URL:

REFERENCES:


12. IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, N.Y., USA).


Inappropriate prescribing of antibiotics following discharge after major surgery: an area for improvement

Mary De Almeida, Catherine Gerard, Joshua T Freeman, Eamon Duffy, Sally A Roberts

ABSTRACT

AIM: This study aims to determine the indications for antibiotic use in patients discharged following major surgery at Auckland City Hospital (ACH); to determine if the indications were appropriate and to identify opportunities where antimicrobial stewardship interventions would be beneficial.

METHODS: This was a retrospective study of adult patients who were dispensed an antibiotic within the first two days of discharge after major surgery at ACH between 1 January 2013 and 31 December 2013. The indication for antibiotic use was determined and subsequently classified as either ‘appropriate’, ‘not assessable’ or ‘inappropriate’.

RESULTS: Among the 378 patients analysed, an indication for antibiotic use was not documented in 52 patients (13.8%). Antibiotics were prescribed for an established infection in 172 patients (45.5%), as empiric therapy in 100 patients (26.4%), and as prolonged surgical antimicrobial prophylaxis in 41 patients (10.8%). Overall, nearly half of the antibiotic courses dispensed (48.7%) were either ‘inappropriate’ or the indication was ‘not assessable’.

CONCLUSIONS: This study demonstrates that a significant proportion of antibiotics prescribed in patients discharged following surgery are inappropriate and there is need for enhanced antimicrobial stewardship in this area.

Antimicrobial resistance (AMR) is a growing global issue which threatens the effective treatment and prevention of infections worldwide. New Zealand has seen a dramatic rise in AMR over the recent years. Inappropriate and excessive use of antimicrobials is an important driver of antimicrobial resistance, and is also associated with avoidable adverse drug reactions and increased healthcare costs. Worldwide, antimicrobial stewardship programmes aim to optimise antimicrobial use in order to lessen the impact of inappropriate use on patients and health systems.

In 2012, the Health Quality & Safety Commission (HQSC) of New Zealand introduced the “Atlas of Healthcare Variation” (the Atlas) which highlights regional variation in healthcare provision, use of specific health services and health outcomes in New Zealand. The Atlas aims to promote discussion about differences in practice and identify areas for improvement in healthcare. One domain of the Atlas examined the incidence of infection and the rate of antibiotic use following major surgery. A key finding of the Atlas was that on average, 34% of patients discharged following major surgery at New Zealand public hospitals in 2013 were dispensed an antibiotic within 30 days of discharge. A significant proportion of the dispensing occurred on the day of discharge or the following day (Figure 1). Consistent with this
national rate, 32.4% of patients discharged following major surgery at Auckland District Health Board (ADHB) were dispensed an antibiotic within 30 days of discharge. This contrasts with the average 2.6% of patients being recorded as having an infection after major surgery.4

The available data on antibiotic use following major surgery raises several important questions: what are the indications for antibiotic use after surgery—is it for infection or prophylaxis and why is the rate of antibiotic prescribing after surgery high?

The primary objectives of this study were to determine the indications for antibiotic use in patients discharged following major surgery at Auckland City Hospital (ACH); to determine if the indication was appropriate and to identify opportunities where antimicrobial stewardship interventions would be beneficial.

Method

A retrospective audit was conducted of adult patients ≥18 years discharged from ACH, after major surgery between 1 January 2013 and 31 December 2013. ACH is an adult tertiary care-teaching hospital, providing a wide range of surgical services, including general surgery, cardiothoracic surgery, neurosurgery, orthopaedics, trauma, urology, vascular and otorhinolaryngology (ORL).

Data source

Data for the Atlas was drawn from the Ministry of Health’s national hospital inpatient data (National Minimum Dataset (NMDS)) and the Pharmaceutical Collection.4 The Pharmaceutical Collection contains reimbursement claims information from community pharmacists for subsidised dispensing of medicines including antibiotics.

Infections captured by the NMDS using coded data and included in the Atlas were infections following a procedure. These include infections coded as: post-procedural infection or sepsis, intra-abdominal abscess, stitch abscess, subphrenic abscess and wound abscess.4 Surgeries were only included if they required a length of stay of at least two days (‘major surgery’).4 This excluded minor or short stay surgeries such as elective hernia or carpel tunnel operations. In addition, people with a primary diagnosis of infection or sepsis were excluded.4 People with any code of immunocompromise, any code of cancer and the major diagnostic category 14 (pregnancy, childbirth or puerperium) were also excluded.4

Data for ADHB was provided by the Ministry of Health Analytical Service using the Atlas defined cohort of those patients dispensed an antibiotic within 30 days of discharge following major surgery. For inclusion in this study, patients were
required to have had one or more antibiotics dispensed within the first two days of discharge following a major surgery at ACH (in order to capture prescriptions issued by the secondary care team and not primary care). Any patients with antibiotic prescriptions written by primary care providers or non-ADHB prescribers within those first two days were excluded. Furthermore, cases where there was uncertainty as to whether the prescription was written by a hospital clinician or a primary care provider were also excluded.

Additional clinical data were collected for each patient through review of medical records (MR) and discharge summaries. Data collected included: the specialty service on discharge; antibiotic dispensed; indication for antibiotic use; and any relevant microbiology results within one week of discharge to support a diagnosis of infection (including specimen type and organism).

Definitions and classifications

The indication for antibiotic use was categorised into one of six categories based on information available in the medical records: (1) infection present on admission (POA); (2) healthcare-associated infection (HAI); (3) surgical antimicrobial prophylaxis (SAP); (4) empiric therapy or clinical decision to use antibiotics in the absence of a definite diagnosis of infection; (5) no documented indication; and (6) other reason.

Indication category

1. Infection POA. Infection clearly documented in the MR as present on admission to hospital.

2. Healthcare-associated infection. The indication for antibiotic prescription was attributed to a HAI in one of two cases: (i) a clinical diagnosis of an infection was documented in the medical records by the clinical team; or (ii) an infection diagnosis was not documented, but there were documentation of clinical findings (with or without laboratory results) indicative of the presence of an infection and meeting the Centers for Disease Control and Prevention (CDC) criteria for a HAI. For each HAI, an assessment was made as to whether findings met the standardised surveillance definitions for specific types of infections as used by the CDC.

3. Prolonged SAP was defined as the use of any antimicrobial agent commenced peri-operatively and continued post-operatively in the absence of an infection. This included cases where prophylactic antibiotics were continued longer than that recommended by the current hospital SAP guidelines or exceeded 24 hours after the completion of surgery.

4. Empiric therapy was defined as the use of an antimicrobial, in the absence of a definite diagnosis or evidence of infection to support this decision. This included cases that were treated for suspected infection but did not meet the definition for a HAI or an infection POA.

5. No documented reason in the MR

6. Other reasons. Prescribed for conditions unrelated to the surgical procedure such as Helicobacter pylori eradication therapy, secondary prophylaxis for CSF leak or recurrent urinary tract infections.

Justification for antibiotic use

For each patient, antibiotic use was further classified as ‘appropriate’, ‘not assessable’ or ‘inappropriate’ using the Australian National Antimicrobial Prescribing Survey guideline to assist with assessment of appropriateness. Antibiotic use for an established infection (ie, infection POA or HAI) was considered appropriate. Any antibiotic use for treatment of a HAI, regardless of whether or not the CDC surveillance definition was met, was considered to be appropriate.

Antibiotic use as prolonged SAP or without a documented indication was considered ‘inappropriate’. Empiric therapy or antibiotic use for other reasons was also categorised as ‘appropriate’, ‘not assessable’ or ‘inappropriate’. ‘Appropriate’ if it was in accordance with local antibiotic guidelines or if there was a clearly defined clinical indication such as documentation in the medical record of signs and symptoms of local infection or recurrent urinary tract infection prophylaxis. ‘Not assessable’ if there was limited clinical and laboratory evidence to
support infection. ‘Inappropriate’ if there was no clinical or laboratory evidence to support infection, or if antibiotic use was not consistent with local antibiotic guidelines.

One person [MDA] reviewed all the medical records. Where there was uncertainty about indication and appropriateness the case was discussed with a senior colleague [SR].

Results

In 2013, the Atlas identified 2,241 adult patients in ADHB who were dispensed an antibiotic within 30 days of discharge after major surgery. Of these, 898 were dispensed an antibiotic within two days of discharge. A random sample of 423 of the 898 patients (47.1%) were reviewed. Of the 423 patients, 45 were excluded from analysis for the following reasons: 29 because antibiotics were prescribed by a primary care provider, a non-ADHB prescriber or the prescriber was unknown; six due to missing clinical information (surgery performed at external hospital); and an additional 10 patients as they were identified as having undergone a minimally-invasive procedure (eg, percutaneous coronary intervention, CT-guided biopsy, punch biopsy, lower limb angioplasty) rather than surgery. This left a total of 378 patients.

Indication for antibiotic use

The indications for antibiotic use in the 378 patients, as stratified by surgical specialty, are shown in Table 1. Four patients had more than one indication for antibiotic use, giving a total of 382 indications. Antibiotics were prescribed for an infection present on admission (POA) in 91 patients (24%), for a HAI in 81 patients (21.4%), as empiric therapy in 100 patients (26.5%) and as prolonged SAP in 41 patients (10.8%). An indication was not documented in 52 patients (13.8%) and 17 patients (4.5%) had other reasons for being prescribed an antibiotic (Table 2). For nine of the 91 patients with infection present on admission, the infection was unrelated to the site of surgery.

Table 1: Indications for antibiotic use stratified by specialty.

<table>
<thead>
<tr>
<th>Specialty</th>
<th>No. of patients</th>
<th>Infection POA (%)</th>
<th>HAI (%)</th>
<th>Empirical therapy (%)</th>
<th>Prolonged SAP (%)</th>
<th>No documented indication (%)</th>
<th>Other reason (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiothoracic</td>
<td>47a</td>
<td>3 (6.4)</td>
<td>21 (44.7)</td>
<td>11 (23.4)</td>
<td>2 (4.3)</td>
<td>8 (17)</td>
<td>3 (6.4)</td>
</tr>
<tr>
<td>General surgery</td>
<td>56b</td>
<td>16 (28.6)</td>
<td>11 (19.6)</td>
<td>11 (19.6)</td>
<td>8 (14.3)</td>
<td>8 (14.3)</td>
<td>3 (5.4)</td>
</tr>
<tr>
<td>Vascular</td>
<td>48</td>
<td>21 (43.8)</td>
<td>8 (16.7)</td>
<td>11 (22.9)</td>
<td>4 (8.3)</td>
<td>3 (6.3)</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Urology</td>
<td>43</td>
<td>15 (34.9)</td>
<td>6 (14.0)</td>
<td>4 (9.3)</td>
<td>8 (18.6)</td>
<td>9 (20.9)</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>20</td>
<td>3 (15)</td>
<td>4 (20)</td>
<td>4 (20)</td>
<td>3 (15)</td>
<td>4 (20)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>14c</td>
<td>0</td>
<td>5 (35.7)</td>
<td>4 (28.6)</td>
<td>1 (7.1)</td>
<td>2 (14.2)</td>
<td>3 (21.4)</td>
</tr>
<tr>
<td>Orthopaedics</td>
<td>94d</td>
<td>15 (16)</td>
<td>21 (22.3)</td>
<td>45 (47.9)</td>
<td>1 (1.1)</td>
<td>10 (10.6)</td>
<td>3 (3.2)</td>
</tr>
<tr>
<td>ORL</td>
<td>28</td>
<td>6 (21.4)</td>
<td>0</td>
<td>3 (10.7)</td>
<td>12 (42.9)</td>
<td>7 (25)</td>
<td>0</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>16</td>
<td>8 (50)</td>
<td>0</td>
<td>7 (43.8)</td>
<td>0</td>
<td>1 (6.3)</td>
<td>0</td>
</tr>
<tr>
<td>Oral health</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (100)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Renal or liver transplant</td>
<td>4</td>
<td>0</td>
<td>3 (75)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (25)</td>
</tr>
<tr>
<td>Other medical specialty</td>
<td>7</td>
<td>4 (57.1)</td>
<td>2 (28.6)</td>
<td>0</td>
<td>1 (14.3)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total (confidence intervals calculated at 95%)</td>
<td>378</td>
<td>91 (24%, 19.8–28.4)</td>
<td>81 (21.4%, 17.3–25.6)</td>
<td>100 (26.5%, 22.0–30.9)</td>
<td>41 (10.8%, 7.7–14.0)</td>
<td>52 (13.8%, 10.3–17.2)</td>
<td>17 (4.5%, 2.4–6.6)</td>
</tr>
</tbody>
</table>

*a, b, c, d includes a patient with two different indications for antibiotic use.

* includes gastroenterology, general medicine, neurology, renal and older persons health.
Healthcare-associated infections (n=81)

Among the 81 patients prescribed an antibiotic for a HAI, 59 (72.8%) met CDC surveillance definitions for a specific type of HAI. Overall, the most common HAIs were pneumonia (18 patients, 22.2%) and surgical site infections (18 patients, 22.2%). Other HAIs included urinary tract infections; both catheter-associated and non-catheter-associated (16 patients (19.8%) and 10 patients (12.3%), respectively). Forty of the 81 (49.4%) patients with a HAI had supporting microbiology.

Empiric therapy (n=100)

For patients given empiric therapy, only 8% were deemed appropriate.

Of note, 37 of 39 patients (95%) with compound fractures, penetrating injuries or open traumatic wounds received empiric treatment that was inconsistent with local guidelines. Patients with these injuries generally received intravenous antibiotics during their hospitalisation and on discharge were prescribed courses of oral antibiotic therapy ranging from 2–14 days (median 7, interquartile range 5–7). In all but two of these patients, the total duration of empiric therapy was prolonged, and thus was considered inappropriate.

Six patients were treated empirically for penetrating eye injuries (considered appropriate). Other indications for empiric therapy included suspected infection (30 patients), post-operative fever (eight patients) and wound discharge (12 patients). The use of antibiotics in these patients was considered ‘not assessable’ due to inadequate information in the medical records.

An additional five patients received empirical therapy despite no clinical evidence of infection and unhelpful microbiological results (eg, for asymptomatic bacteriuria). These were regarded as ‘inappropriate’.

Prolonged surgical antimicrobial prophylaxis (n=41)

The use of prolonged SAP in 41 patients was considered ‘inappropriate’. Use of prolonged SAP was most notable among the ORL, general surgery and urology services. The 12 ORL patients who received prolonged SAP had undergone a range of head and neck surgeries. Among the eight general surgical patients who received prolonged SAP, five had undergone breast surgery of which three had a documented plan to continue oral antibiotics until surgical drains were removed. One of two patients who underwent hernia surgery also had a documented plan to continue antibiotics until surgical drains were removed. The eight urology patients also underwent a range of procedures including urethroplasty and insertion of artificial urinary sphincter.

Other reasons (n=17)

For most patients the indication was ‘appropriate’ except in one case; a patient given prophylaxis for presence of an indwelling urinary catheter.

Antibiotic prescribed on discharge following major surgery

Amoxicillin clavulanate was by far the most commonly prescribed antibiotic (171 patients) followed by flucloxacillin (40 patients), cefaclor (34 patients), ciprofloxacin (28 patients) and doxycycline (26 patients).
Overall appropriateness of antibiotic use

Overall, nearly half of the antibiotic courses dispensed (48.7%) were ‘inappropriate’ or ‘not assessable’ (Table 3).

Discussion

The Atlas demonstrated that a third of patients were dispensed an antibiotic within 30 days of discharge from hospital following major surgery. Among the random sample of patients dispensed an antibiotic within two days of discharge, clear evidence to support the use of the antibiotic was only present for half of the patients. For one-third the use was inappropriate, and for the remainder, (13%), the reason for use was not assessable and may have been inappropriate. Reducing the unnecessary prescribing of antibiotics will reduce the adverse effects seen in patients such as an increased risk of antibiotic resistance, Clostridium difficile infection and other side effects that may lead to readmission.

This study demonstrates that improvement in the use of antibiotics following surgery is needed. Nearly all prescriptions given empirically were given for inappropriate (42%) or not assessable (50%) reasons. Of equal concern was that about 14% had no clear documented indication for antibiotic use and 11% had surgical antimicrobial prophylaxis given beyond recommended timeframes.

All patients treated for a HAI in this study were considered to have been treated appropriately. However, only ~73% of these patients met the CDC surveillance definition for a specific type of HAI and it possible that we have overestimated the number of true HAIs regarded to have been treated appropriately.

Empiric therapy for suspected, or where there is a high risk of infection, was the most common indication for antibiotic use in this study, accounting for a quarter of prescriptions. Nearly a half (42%) of empiric therapy was considered inappropriate (Table 3). Use of empiric antibiotics was particularly notable among the orthopaedic service and involved patients with traumatic injuries such as open fractures or wounds, lacerations and penetrating injuries, in whom pre-emptive antibiotics were continued for extended durations. Careful evaluation and classification of wounds could direct appropriate antibiotic therapy and reduce overuse of antibiotics. For open fractures, the importance of early administration of antibiotics is well accepted. The Gustilo-Anderson classification system is the most commonly used classification system for grading open fractures and has been used in guidelines to direct the choice and duration of antibiotic therapy. Although the optimal duration of pre-emptive antibiotics for open fractures is yet to be defined, our hospital guidelines are consistent with international guidelines (eg, EAST Practice Management Guidelines and British Orthopaedic Association/British Association of Plastic Reconstructive and Aesthetic Surgeons Guideline), which recommend a maximum of 72 hours for the most severe fractures. In a recent retrospective, case-control study, even shorter courses of antibiotics (one day) were not inferior to longer courses in preventing infections in open fractures.

Table 3: Appropriateness of antibiotic therapy by indication.

<table>
<thead>
<tr>
<th>Number of indications (%)</th>
<th>Appropriate</th>
<th>Not assessable</th>
<th>Inappropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection POA</td>
<td>91 (23.8)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HAI</td>
<td>81 (21.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Empiric therapy</td>
<td>100 (26.2)</td>
<td>8</td>
<td>50 (42)</td>
</tr>
<tr>
<td>Prolonged SAP</td>
<td>41 (10.7)</td>
<td>-</td>
<td>41 (52)</td>
</tr>
<tr>
<td>No documented indication</td>
<td>52 (13.6)</td>
<td>-</td>
<td>52 (52)</td>
</tr>
<tr>
<td>Other reason</td>
<td>17 (4.5)</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>382</strong></td>
<td><strong>196 (51.3%)</strong></td>
<td><strong>50 (13.1%)</strong></td>
</tr>
</tbody>
</table>
This study also found a considerable number of patients were prescribed antibiotics in response to discharge or drainage from surgical wounds. In some cases, the antibiotic was inappropriately prescribed for a wound with serous discharge suggesting that the knowledge about the characteristics of a surgical site infection by ward staff could be improved. In other cases, the nature of the wound discharge was not adequately described (ie, purulent versus serous) to allow an assessment of the appropriateness of antibiotic therapy. Antibiotic therapy is only required for wounds that are clinically infected.12

Approximately 10% of patients in this study were prescribed courses of SAP that were prolonged and not adherent with current guidelines. In some cases, prophylactic antibiotics were continued while surgical drainage tubes were in place, although there is no evidence to support this practice.13 International guidelines recommend that the duration of prophylaxis for all procedures (except cardiac surgery) should be less than 24 hours.13 While appropriate SAP is undoubtedly effective in reducing the risk of surgical site infection, prolonged use of prophylaxis provides no additional benefit, is associated with increased costs and could potentiate antimicrobial resistance.13 At a national level, the HQSC’s Surgical Site Infection Improvement programme has successfully introduced ‘Surgical Antimicrobial Prophylaxis Intervention Guidelines’ in order to optimise SAP in hip and knee arthroplasties, and cardiac surgery.14,15

This study has several limitations. Firstly, it is a retrospective, single-centre study and was limited by the quality of documentation in the patient records. Often, the reason behind the decision to prescribe antibiotics was not documented, or apparent, following a review of the medical records. Hence, it is possible that we may have overestimated the prescriptions that were considered ‘inappropriate’. Secondly, the data for the Atlas and for this audit was extracted from the NMDS using coded data following patient discharge (ICD-10 codes). Patients with a primary diagnosis of infection or sepsis were excluded. However, 24% of patients in our study had an infection present on admission and required antimicrobial treatment for this infection, which was continued after discharge. Our findings highlight the limitations of relying on coded data as has been found in previous studies.16 Thirdly, the findings from ADHB may not be generalisable to other hospitals in New Zealand because the complexity and types of surgeries performed and antibiotic practices of surgeons at different centres may differ. We think that this is less likely because high rates of prescribing were seen across all district health boards in New Zealand.

Antimicrobial stewardship programmes aim to optimise antimicrobial use in order to improve patient outcomes while limiting unintended consequences such as the emergence of resistance, drug toxicity and adverse events, and healthcare costs.3 Surgical patients are a complex group of patients where antimicrobials may be prescribed for a number of reasons. This study has demonstrated a need for enhanced antimicrobial stewardship in this area and the results of this study will assist the ADHB Antimicrobial Stewardship team to target specific areas such as documentation of antibiotic therapy, adherence to SAP guidelines and use of antibiotic following complex trauma. A Quality Improvement strategy would be useful in improving antibiotic use among surgical units. Such QI strategy could include various interventions (eg, education focusing on diagnosis, investigation and treatment of post-operative infections; promotion of institutional guidelines (eg, SAP guidelines); prospective audit and feedback, including the measurement and feedback of process measures (eg, adherence to guidelines) and outcomes measures (eg, local antibiotic consumption)).

**Conclusion**

In conclusion, this study demonstrates that one-third of antibiotics prescribed following major surgery were inappropriate, and the supporting evidence for use in another 13% was poorly documented. Given the growing problem of antibiotic resistance globally, it is important now more than ever, to take actions to reduce the use of inappropriate and unnecessary antibiotics.
Competing interests:
Nil.

Author information:
Mary De Almeida, Clinical Microbiologist, Department of Microbiology, Auckland City Hospital, Auckland; Catherine Gerard, Evaluation Manager, New Zealand Health Quality & Safety Commission, Wellington; Joshua T Freeman, Clinical Microbiologist, Department of Microbiology, Auckland City Hospital, Auckland; Eamon Duffy, Antimicrobial Stewardship Pharmacist, Adult Infectious Diseases Service, Auckland City Hospital, Auckland; Sally A Roberts, Clinical Microbiologist, Department of Microbiology, Auckland City Hospital, Auckland.

Corresponding author:
Mary De Almeida, Department of Microbiology, ADHB, Auckland.
mdealmeida@adhb.govt.nz

URL:

REFERENCES:


5. Center for Disease Control and Prevention. CDC/NHSN surveillance definitions for specific types of infection.


Achilles tenotomy as an office procedure and current practising trends among New Zealand orthopaedic surgeons

Lewis Agius, Angus Wickham, Joshua Knudsen, Cameron Walker

ABSTRACT

BACKGROUND: Percutaneous Achilles tenotomy (PAT) is performed during the final phase of casting with Ponseti method. Several settings have been proposed as venues for this procedure, however it is increasingly being performed in theatre under a general anaesthetic (GA). General anaesthesia, however, is expensive and not without risks. The purpose of the present study was to compare results of outpatient releases to theatre releases, and assess current practising trends among orthopaedic surgeons.

METHODS: Retrospective comparison of patients with idiopathic clubfoot managed by Ponseti method who had Achilles tenotomy performed in outpatient clinic and in theatre. Surveys were sent to all POSNZ members to determine current practising trends in New Zealand. Parental satisfaction surveys were performed. Comparative cost analysis was performed using hospital billing information.

RESULTS: The current study includes 64 idiopathic congenital clubfeet (19 bilateral cases). PAT was performed on 26 clubfeet under local anaesthetic in an outpatient setting, and 33 clubfeet under GA in a theatre setting. There was no significant difference for post-operative complications, or recurrence (p=0.67). Those in theatre group were exposed to a greater number of general anaesthetics before the age of four. Among practising New Zealand paediatric orthopaedic surgeons, 77.78% perform this in theatre under general anaesthesia, while only 22.22% perform PAT in outpatient clinic. The main barriers included concerns regarding pain control, concerns regarding incomplete release, concerns regarding distress to family and concerns regarding sterility. Parental satisfaction surveys found pain management to be excellent. Financial data was analysed and indicative costs were $6,061 NZD per procedure in theatre, compared to $378 NZD per procedure in clinic.

CONCLUSION: PAT performed in a clinic setting is both safe and efficacious with results comparative to that performed in theatre. There was no difference in post-operative complications or recurrence. Parental satisfaction to this procedure is excellent. There are significant financial advantages. Based on this data, our institution now performs all releases in an outpatient setting.
choice in New Zealand and around the world.\textsuperscript{4,5} Percutaneous Achilles tenotomy (PAT) is performed during the final phase of casting to correct residual equinus contracture. This is required in approximately 80–90% of patients with clubfoot.\textsuperscript{6,7} Several settings have been proposed as venues for this procedure, however there is an increasing trend to performing this in theatre under general anaesthetic (GA). Ponseti originally chose to perform this as an outpatient procedure under local anaesthesia, yielding a success rate of close to 90%.\textsuperscript{8,9} Some surgeons, however, have preference to perform this in theatre,\textsuperscript{10,11} while others believe it can be performed safely in the outpatient setting.\textsuperscript{12} General anaesthesia is expensive and not without potential risks. To date there have been no studies comparing PAT performed as an outpatient procedure to those performed in theatre that have looked at parental concerns to the procedure and evaluated cost effectiveness.

We implemented a retrospective study using prospectively gathered data to evaluate the safety and efficacy of PAT performed as an outpatient procedure compared to those performed in theatre. We assess parental satisfaction to this procedure, and analyse current practising trends among New Zealand orthopaedic surgeons in regard to Ponseti management.

Patients and methods

The study was approved by our Institutional Research Office. All infants referred to our department at Hastings Hospital for clubfoot between January 2013 to December 2015 were included in the study. Patients with a diagnosis other than non-idiopathic clubfoot were excluded from the study. All patients recruited into the study were treated according to Ponseti protocol. A single surgeon performed all outpatient releases percutaneously in a clinic setting. A comparison group of patients were recruited who had their PAT performed in theatre under a general anaesthetic by a different surgeon whose preference was to perform releases in a theatre setting. This was a group of patients who had consecutive PAT performed by this surgeon prior to the study. Both groups had identical Ponseti management. Demographic data was collected to ensure no differences between the two groups existed. Clinical and outcome data was collected prospectively at each clinic for both groups. All patients had a minimum follow-up of two years following PAT. PAT was indicated when the mid-foot deformity had been corrected (MFS = 0) and the hind-foot deformity remained in an equinus position (unable to dorsiflex past 10 degrees). The outpatient procedure was performed during the final stage of serial casting in a routine clubfoot outpatient clinic. Pain prevention protocol included application of Emla Cream 5% 1.0g/10cm area (Prilocaine/Lignocaine combination) placed topically on the surgical site one hour prior to procedure (Table 1).

Table 1: Pain prevention protocol for outpatient Achilles tenotomy.

<table>
<thead>
<tr>
<th>One hour before procedure</th>
<th>Application of Emla Cream 5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mins before procedure</td>
<td>Feeding the baby</td>
</tr>
<tr>
<td>Immediately after procedure</td>
<td>Subcutaneous injection 2mls 1% Lignocaine</td>
</tr>
</tbody>
</table>

In November 2015, a survey was emailed to members of the Paediatric Orthopaedic Society of New Zealand (POSNZ). Registrars and surgeons who did not manage patients with clubfoot were excluded. The survey was designed to evaluate current practising trends among New Zealand orthopaedic surgeons who manage and treat clubfoot. Within the email was a link to perform the survey online using the online survey website, surveymonkey.com. By emailing all members of POSNZ, this was thought to reflect an accurate cross-section of the majority of surgeons managing this deformity in New Zealand.

Patient-parental satisfaction surveys were sent to all cases performed in outpatient clinic. The survey enquired about precautions taken to manage pain, convenience of having release performed in the clinic setting, and overall quality of the care received. For those that did not respond, the Māori Health Liaison team was recruited to help meet and make contact with the family.

Cost analysis was performed using clinic and hospital billing information, and a cost of care per procedure was deter-
mined. Average cost per procedure based on national data is often an overestimate, therefore a more detailed analysis was performed. Cost of PAT performed in theatre was calculated from data for all releases performed between September 2005 to November 2015.

**Statistical analysis**

Statistical analysis was performed to compare demographic characteristics and outcome data. A Student t-test was used for continuous variables. A two-tailed Fisher exact test was used for categorical variables. For patients who had recurrence, a separate cox regression analysis was performed to see if one group was more likely to recur than the other. This analysis was performed to correct for the fact that the study is “right censored” (ie, has stopped before all patients that would recur have had time to). Ninety-five percent confidence intervals were used. A p value of ≤0.05 was defined as significant. All analyses were done using the R statistical package. The cox regression was performed using the “survival” library.

**Results**

The current study includes 59 clubfeet (40 babies, 19 bilateral cases) with a diagnosis of idiopathic congenital clubfoot. All were regularly seen in routine clubfoot outpatient clinics. PAT was performed on 26 clubfeet (19 patients) under local anaesthetic in an outpatient setting, and 33 clubfeet (21 patients) under GA in a theatre setting.

The Achilles tenotomy rate in our study was 92%. The ratio of males to females was 2:1. Ratio of Māori/Polynesian to New Zealand European referred with clubfoot was 5.6:1. The average Catterall-Pirani score for the outpatient group and theatre group was 5.26 and 5.32 respectively. Demographic comparisons were made and no significant differences were found between the two groups with regard to gender (p=0.83), ethnicity, Deprivation Index or severity (p=0.84) (Table 2).

Tenotomy was performed at an average post-natal age of 10.5 weeks in the clinic group and 12.1 weeks in the theatre group. For age at release there was no evidence of a difference between the two groups (p=0.25). No patients had complications of infection, bleeding or neurological deficit. Those in the theatre group were exposed to a greater number of general anaesthetics before the age of four, but this did not reach statistical difference (p=0.023) (Table 3).

Recurrence was defined as either early or late and requiring minor or major

---

**Table 2: Demographic comparisons.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Outpatient release</th>
<th>Theatre release</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of feet</td>
<td>26</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>19</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>No. of bilateral cases</td>
<td>7</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
<td>15</td>
<td>0.83</td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Māori/Polynesian</td>
<td>17</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>1</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Average Pirani Score per foot</td>
<td>5.3</td>
<td>5.3</td>
<td>0.84</td>
</tr>
<tr>
<td>Average NZDep2013</td>
<td>8.4</td>
<td>8.7</td>
<td></td>
</tr>
<tr>
<td>Positive family history (%)</td>
<td>53%</td>
<td>67%</td>
<td></td>
</tr>
</tbody>
</table>
Early recurrence was defined as recurrence of deformity identified before six months of age. Minor recurrence was that requiring an extra-articular soft tissue procedure such as repeat PAT, open Achilles tendon lengthening or Tibialis Anterior transfer procedure. Three patients had early recurrence in the clinic group compared to one patient in the theatre group. One in the outpatient group was thought to have an incomplete release requiring repeat tenotomy (Table 4). Major recurrences were defined as those that required an intra-articular surgical approach. There was no significant difference for the probability of recurrence between the two groups (p=0.67). There was no difference in re-tendonomy rate (p=0.58). Odds ratios (OR) with respect to recurrence were calculated to see if there was an association between the setting of the release, and outcome of either major or minor recurrence. There was no statistical difference for minor revision or major revision (p=0.742, p=0.741 respectively).

Among practising New Zealand orthopaedic members of POSNZ, 30/39 responses were received (response rate 77%). The average number of years in practice was 17.2. All respondents preferred Ponseti method as their choice for initial management of clubfoot. One respondent chose surgical and Ponseti as preferred initial management. The majority (14/18) chose to perform this in theatre under general anaesthesia, while only four surgeons regularly perform PAT as an outpatient procedure. Of those that perform the procedure in theatre, only five said they would consider changing their practice to performing PAT as an outpatient procedure. The main concerns voiced included facility or staffing issues, concerns regarding inadequate pain control, concerns regarding incomplete release, concerns regarding distress to family and concerns regarding sterility. Only a small proportion (4/18) of practising New Zealand orthopaedic surgeons preferred to perform PAT as an outpatient procedure.
outpatient procedure. The reasons given for electing to perform PAT as an outpatient procedure included avoiding potential risks associated with general anaesthesia, logistical issues, difficulty with access to theatre and potential cost savings.

A response rate of 6/19 (32%) was achieved for the parental satisfaction survey. Māori Health Liaison services were recruited to help make contact with the families. Of the replies, all reported that the clinic environment was excellent in regards to convenience of setting. Five reported precautions taken to manage pain were ‘excellent’, while the remaining reported that this was ‘very good’. Overall, the quality of care provided in clinic was reported as ‘excellent’, and there were no concerns regarding inadequate pain control.

Theatre and financial data was analysed for all PAT performed in the operating theatre between 2005 and 2015. Indicative costs were $6,061 NZD per procedure based on 2015 data at our district health board (DHB). Costs over this 10-year period increased from $4,801 NZD in 2005 to $6,061 NZD per procedure in 2015. Cost for PAT performed in clinic was determined by our finance department. Indicative cost per percutaneous procedure in outpatient clinic was $378 NZD at our DHB in 2015.

Discussion

Achilles tenotomy is an important step in Ponseti management. Performing Achilles tenotomy in the outpatient clinic can be performed safely and effectively. Performing Achilles tenotomy in theatre under general anaesthesia also has its merits, thus why many surgeons prefer this setting. Potential advantages include better ability to reduce pain, ability to perform the procedure in a more controlled manner, and the relative sterility of the operating room. No studies to date have shown that the controlled nature of the operating theatre allows the surgeon to perform a more accurate and complete release, resulting in lower re-tenotomy rate, and our study was no exception.

There has been concern in the literature regarding use of volatile anaesthetic gases and the potential adverse effects on neurocognitive development. A number of studies have shown volatiles can induce neuronal cell apoptosis due to N-methyl-D-aspartate antagonists. These hypotheses are based on animal models.\textsuperscript{15,16} Wilder et al found a statistically significant increase in the risk for developing a learning disability in those who had received general anaesthesia either two or three times before the age of four.\textsuperscript{17} Other studies have found no increased risk with general anaesthesia in this age group.\textsuperscript{11} In our study those who had PAT performed in clinic had less overall exposure to general anaesthetics before the age of four.

For those who had releases performed in clinic there were no complications such as casting issues, infection or bleeding identified. One patient, however, was thought to have an incomplete release requiring repeat tenotomy. We recognise that post-operative surgical complications following this procedure are rare and unlikely to be statistically affected whether procedure is performed in clinic or theatre. After implementing the change to performing our releases in a clinic setting, other advantages

<table>
<thead>
<tr>
<th>Case</th>
<th>Ethnicity</th>
<th>Age at tenotomy (weeks)</th>
<th>Documented compliance</th>
<th>Age at repeat tenotomy (weeks)</th>
<th>Incomplete release</th>
<th>Ethnicity</th>
<th>Age at tenotomy (weeks)</th>
<th>Documented compliance</th>
<th>Age at repeat tenotomy (weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Māori</td>
<td>20</td>
<td>Poor</td>
<td>167</td>
<td>No</td>
<td>Māori</td>
<td>12 (bilat)</td>
<td>Poor</td>
<td>43 (bilat)</td>
</tr>
<tr>
<td>2</td>
<td>Māori</td>
<td>15 (bilat)</td>
<td>Good</td>
<td>41 (bilat)</td>
<td>No</td>
<td>Māori</td>
<td>8</td>
<td>Poor</td>
<td>87</td>
</tr>
<tr>
<td>3</td>
<td>Māori</td>
<td>9</td>
<td>Poor</td>
<td>12</td>
<td>Yes</td>
<td>NZ European</td>
<td>14 (bilat)</td>
<td>Not documented</td>
<td>48 (bilat)</td>
</tr>
<tr>
<td>4</td>
<td>Māori</td>
<td>11</td>
<td>Poor</td>
<td>119</td>
<td>No</td>
<td>Māori</td>
<td>12</td>
<td>Poor</td>
<td>82</td>
</tr>
<tr>
<td>5</td>
<td>Māori</td>
<td>11</td>
<td>Poor</td>
<td>28</td>
<td>No</td>
<td>Māori</td>
<td>12</td>
<td>Poor</td>
<td>70</td>
</tr>
<tr>
<td>6</td>
<td>Māori</td>
<td>12</td>
<td>Good</td>
<td>82</td>
<td>No</td>
<td>Māori</td>
<td>7</td>
<td>Poor</td>
<td>96</td>
</tr>
<tr>
<td>7</td>
<td>Māori</td>
<td>8</td>
<td>Poor</td>
<td>96</td>
<td>No</td>
<td>Māori</td>
<td>7</td>
<td>Poor</td>
<td>38</td>
</tr>
</tbody>
</table>

Table 4: Repeat tenotomy.
were identified. We found it allowed infants to have their release despite being unwell with concurrent viral-like illnesses that would have otherwise resulted in cancellation of the procedure. Parents were only away from their baby for a short period relative to performing releases in theatre, and the infant did not have to be nil by mouth, which parents also appreciated.

For those patients included in both the clinic and theatre group the rate of recurrence seen was higher than that reported in the overseas literature, but similar to other New Zealand studies. These findings support other New Zealand studies that propose clubfoot managed in New Zealand may be more severe and impervious to treatment than clubfoot seen elsewhere. It is uncertain if poor compliance leads to an increased risk of recurrence, or if it is due to recurrence of a stiff foot resulting in difficulty with boot and bar wear and therefore presumed poor compliance. This is a major issue and has been reported in many existing studies but remains unsolved.

A study evaluating practising trends in North America was performed in 2003, and was then revisited in 2010. The majority of Achilles tenotomies were performed percutaneously (92.8%). The tenotomy was performed under local anaesthesia in 39.4% of patients, while 45.4% were performed under general anaesthesia in the operating theatre. Reasons for preferences on the setting of release were not evaluated. In our study, the majority of surgeons prefer to perform PAT in the operating theatre, and would not consider changing their practice to performing PAT in an outpatient setting. The greatest concerns to the surgeon include facility and/or staffing issues, concerns regarding incomplete release and concerns regarding infection risk.

Parental concerns were specifically evaluated in this study. The response rate was very low despite involvement of Māori Health Liaison services. This reflects why follow-up with these patients is so difficult and why outcomes are poor and recurrence is high. Despite this, the data received was very reassuring in regard to the convenience of having PAT performed in clinic. Effectiveness of analgesia was deemed excellent by parents including bilateral cases. There were no parental concerns with regard to this procedure performed in an outpatient setting.

Procedure costing within a DHB environment is not precise and should be taken as indicative. Notwithstanding the approximation in costing of this procedure in both theatre and clinic settings the cost differential between the two settings is clear, theatre is at least 10 times greater than clinic for the same procedure. Our study suggests that performing PAT in clinic would decrease the cost per foot significantly.

**Conclusion**

As implied in the current study, Achilles tenotomy as an outpatient procedure has been shown to be safe and effective. We believe it can be performed safely with results comparable to that performed in theatre. It avoids any potential risks associated with general anaesthesia and potential delays associated with theatre lists. Pain can be controlled adequately, and there is no increased risk of complications or re-tenotomy rate. Parental satisfaction to this procedure is excellent and there are significant financial savings.
Competing interests:
Nil.

Acknowledgements:
The authors would like to acknowledge Tuakana August and Dianne Wepa from Māori Health Liaison Services for their support.

Author information:
Lewis Agius, Department of Orthopaedic Surgery, Hastings Hospital, Hastings;
Angus Wickham, Department of Orthopaedic Surgery, Hastings Hospital, Hastings;
Cameron Walker, University of Auckland, Auckland;
Joshua Knudsen, Department of Orthopaedic Surgery, Hastings Hospital, Hastings.

Corresponding author:
Dr Lewis Agius, Department of Orthopaedic Surgery, Hastings Hospital, Hastings.
lewisagius@gmail.com

URL:

REFERENCES:


The impact of different tumour subtypes on management and survival of New Zealand women with Stage I–III breast cancer

Ross Lawrenson, Chunhuan Lao, Ian Campbell, Vernon Harvey, Sanjeewa Seneviratne, Mark Elwood, Diana Sarfati, Marion Kuper-Hommel

ABSTRACT

AIMS: This study aims to describe the prevalence and characteristics of the different ER/PR/HER2 subtypes in New Zealand women with breast cancer, and to explore their treatment and outcomes.

METHODS: This study included women diagnosed with Stage I–III breast cancer between January 2006 and May 2013, recorded in the combined Waikato and Auckland Breast Cancer Registers, and with complete data on their ER, PR and HER2 status. Five ER/PR/HER2 phenotypes were classified. Kaplan-Meier method and Cox proportional hazards model were used to examine the survival differences among these subtypes.

RESULTS: Of the 6,875 eligible women, 4,274 (62.2%) were classified as Luminal A, 836 (12.2%) as Luminal B HER2-, 605 (8.8%) as Luminal B HER2+, 401 (5.8%) as HER2+ non-Luminal and 759 (11.0%) as Triple Negative. Māori and Pacific women were less likely to have Triple Negative disease, while Pacific women were more likely to be HER2+ non-Luminal. The five-year breast cancer-specific survival was worst for HER2+ non-Luminal (80.1%) and Triple Negative (81.9%), followed by Luminal B HER2- (89.3%) and Luminal B HER2+ (91.6%), and was the best for Luminal A (96.8%). The adjusted breast cancer-specific mortality hazard ratio for Triple Negative and HER2+ non-Luminal compared to Luminal A was 4.91 (95% CI: 3.86–6.26) and 3.94 (95% CI: 2.94–5.30), respectively.

CONCLUSIONS: The pattern of phenotype in women with Stage I-III breast cancer is similar to the overseas cohorts. Most New Zealand women with Luminal A breast cancer have a very good prognosis, but the less common subtypes have relatively poor outcomes.

Breast cancer outcomes have been shown to be strongly linked not only to patient characteristics, and the extent of disease at diagnosis but also to the presence or absence of hormonal biomarkers. In the 1970s the discovery of an estrogen receptor (ER) led to the finding that only those tumours that were ER positive were sensitive to hormonal treatment. This led to the routine measurement of ER status and targeting of treatment, and subsequently, the introduction of the measurement of a progesterone receptor (PR). ER and PR receptor status have implications for prognosis—women with breast cancers that are both ER and PR positive (+) have a better prognosis. ER status in particular, and to a lesser extent PR status currently have a major influence on the choice of systemic treatment.

In New Zealand, ER and PR status have been routinely measured for the last 25 years. The measurement of human epidermal growth factor receptor 2 (HER2) status became increasingly common from the first part of this century and has been routine since 2006. This is in line with many other countries. In 2006, 12 months of adjuvant therapy was licensed by the FDA for the treatment of Stage I–III HER2 positive breast cancer. PHARMAC approved funding...
a nine-week course of trastuzumab for Stage I–III breast cancer from July 2007, and a 12-month course from July 2010. Other biomarkers such as Ki67, or BRCA gene mutation status, are not routinely measured at this time but may become more relevant in the future. It has become common practice to categorise cancer into conceptual molecular classes that have different prognostic features, and predict response to specific therapies. This has led to a more personalised approach to treatment based on a patient’s molecular phenotype. While a number of studies have been published on the prevalence of individual biomarkers in different ethnic groups in New Zealand, there has been little opportunity to look at different molecular categories and how they influence treatment or patient outcomes.

The aim of this study was to describe the prevalence and characteristics of the different breast cancer tumour types as indicated by these biomarkers in women with Stage I–III breast cancer. We then looked at the treatment of these women including the use of endocrine therapy, chemotherapy and trastuzumab for breast cancers that were HER2+. Finally we wanted to examine the outcomes in these different groups of breast cancers.

Methods

The studied population have been identified from the combined Waikato and Auckland Breast Cancer Registers. It has clinical details of 12,372 women diagnosed with invasive breast cancer between June 2000 and May 2013. Only women who were diagnosed with Stage I–III breast cancer between January 2006 and May 2013 and had complete data on their ER, PR and HER2 status were included in this study, as HER2 status testing has been routine since 2006.

The register’s data includes: 1) patient characteristics: age and ethnicity; 2) tumour information: diagnosis date, cancer stage and biomarkers, and 3) information on treatment: surgery, chemotherapy, trastuzumab, endocrine therapy and radiation therapy. Information on comorbidities has been obtained by reviewing linked data from the National Minimum dataset (NMDS) and characterising patients using the C3 comorbidity index: 1) less or equal to zero, 2) greater than zero but less or equal to one, and 3) greater than one.

In this study, HER2+ was defined as FISH amplified or IHC 3+ according to the 2013 American Society of Clinical Oncology (ASCO) guideline. Recommended in the 2001 St. Gallen Consensus, ER+ or PR+ was assessed as IHC positive (1+). Based on whether the three biomarkers ER, PR and HER2 were either positive or negative, there were eight possible groups defined by ER, PR and HER2 status. We reduced these groups to five categories based on the St. Gallen Consensus recommendation and clinical advice and practice in our region. The most common finding in women with breast cancer is a cancer that is both ER and PR positive but HER2 negative. These breast cancers were categorised as Luminal A. Luminal B HER2- includes women whose breast cancer is ER+, but PR- and HER2- This group is important as women with breast cancers that are PR negative have a poorer prognosis. There is also a small group (1%) of women with breast cancer that is ER- but PR+. We have included these cases in Luminal B HER2-. A further category is women with breast cancers that are HER2+. These women are usually offered adjuvant chemotherapy plus trastuzumab. These women can be divided into those who would benefit from endocrine therapy (ie, breast cancers that are ER+ or ER- but PR+ (Luminal B HER2+) and a second group of breast cancers that are ER-, PR-, but HER2+ (HER2+ non-Luminal)). Finally there is a group that are Triple Negative (ER-, PR-, and HER2-).

Patient outcomes include breast cancer-specific survival and all-cause survival. These mortality data were derived from the New Zealand National Mortality Collection and linked by the National Health Index (NHI) number to the register data. The NHI number is a unique identifier for people who use health and disability services in New Zealand. For all-cause survival analyses, patients without mortality information were considered to be censored on the last updated date for Mortality Collection which was 31 December 2014. For cancer-specific analyses, deaths from other causes were censored on the date of death. Kaplan-Meier method was used to examine the breast cancer-specific survival in the five subtypes. We used Cox proportional hazards model to estimate the hazard ratio of breast cancer-specific mortality and
Results

Of the 12,372 invasive breast cancer cases, 574 were metastatic at diagnosis and 11,798 were Stage I–III at diagnosis. Of the Stage I–III breast cancer cases, 4,475 cases were diagnosed in 2000–2005 and 7,320 were diagnosed in 2006–2013. Of those 7,320 cases diagnosed in 2006–2013, 448 (6.1%) without complete ER, PR or HER2 results were excluded from this study. Those 6,875 women who had complete information on their ER, PR and HER2 status were included.

Of the included cancer cases, 4,274 (62.2%) cases were classified as Luminal A, 836 (12.2%) as Luminal B HER2−, 605 (8.8%) as Luminal B HER2+, 401 (5.8%) as HER2+ non-Luminal and 759 (11.0%) as Triple Negative (Table 1). The mean age varied by subgroup from 58.5 years in Luminal A, 61.1 years in Luminal B HER2−, 54.1 years in Luminal B HER2+, 53.5 years in HER2+ non-Luminal and 57.2 years in Triple Negative. Women with breast cancers that were HER2+ or Triple Negative breast cancer were younger than those classified as Luminal A or Luminal B HER2−. Māori and Pacific women were more likely to have HER2+ breast cancer but less likely to have Triple Negative disease than non-Māori/non-Pacific women. There were stark differences in stage and grade of cancer at diagnosis between the different subtypes: 32.4% of women in HER2+ non-Luminal had Stage III cancer compared to 12.5% in Luminal A; 80.8% of women with Triple Negative cancer had Grade 3 disease while only 12.0% in Luminal A had Grade 3 cancer (Table 2).
Table 2: Tumour characteristics and treatment by cancer subtype.

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>Luminal A</th>
<th>Luminal B HER2-</th>
<th>Luminal B HER2+</th>
<th>HER2+ non-Luminal</th>
<th>Triple Negative</th>
<th>P-value for Chi-square test</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour size (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–10</td>
<td>720</td>
<td>133</td>
<td>70</td>
<td>71</td>
<td>84</td>
<td>11.2%</td>
<td>1,078</td>
</tr>
<tr>
<td>10–20</td>
<td>1,661</td>
<td>251</td>
<td>187</td>
<td>93</td>
<td>220</td>
<td>29.3%</td>
<td>2,412</td>
</tr>
<tr>
<td>20–30</td>
<td>931</td>
<td>208</td>
<td>158</td>
<td>82</td>
<td>217</td>
<td>28.9%</td>
<td>1,596</td>
</tr>
<tr>
<td>30–50</td>
<td>603</td>
<td>154</td>
<td>115</td>
<td>86</td>
<td>178</td>
<td>23.7%</td>
<td>1,136</td>
</tr>
<tr>
<td>50+</td>
<td>286</td>
<td>62</td>
<td>60</td>
<td>55</td>
<td>53</td>
<td>7.0%</td>
<td>516</td>
</tr>
<tr>
<td>Unknown</td>
<td>73</td>
<td>28</td>
<td>15</td>
<td>14</td>
<td>7</td>
<td>137</td>
<td></td>
</tr>
<tr>
<td>Stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>2,223</td>
<td>358</td>
<td>214</td>
<td>121</td>
<td>268</td>
<td>35.3%</td>
<td>3,184</td>
</tr>
<tr>
<td>II</td>
<td>1,515</td>
<td>346</td>
<td>245</td>
<td>150</td>
<td>358</td>
<td>47.2%</td>
<td>2,614</td>
</tr>
<tr>
<td>III</td>
<td>536</td>
<td>132</td>
<td>146</td>
<td>130</td>
<td>133</td>
<td>17.5%</td>
<td>1,077</td>
</tr>
<tr>
<td>Grade</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1,545</td>
<td>190</td>
<td>30</td>
<td>5</td>
<td>17</td>
<td>2.3%</td>
<td>1,787</td>
</tr>
<tr>
<td>2</td>
<td>2,164</td>
<td>374</td>
<td>282</td>
<td>74</td>
<td>126</td>
<td>16.9%</td>
<td>3,020</td>
</tr>
<tr>
<td>3</td>
<td>504</td>
<td>250</td>
<td>282</td>
<td>309</td>
<td>603</td>
<td>80.8%</td>
<td>1,948</td>
</tr>
<tr>
<td>Unknown</td>
<td>61</td>
<td>22</td>
<td>11</td>
<td>13</td>
<td>13</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>Lymph nodes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No positive lymph nodes</td>
<td>2,601</td>
<td>479</td>
<td>296</td>
<td>175</td>
<td>462</td>
<td>62.4%</td>
<td>4,013</td>
</tr>
<tr>
<td>Positive lymph nodes</td>
<td>1,479</td>
<td>312</td>
<td>288</td>
<td>211</td>
<td>278</td>
<td>37.6%</td>
<td>2,568</td>
</tr>
<tr>
<td>Unknown</td>
<td>194</td>
<td>45</td>
<td>21</td>
<td>15</td>
<td>19</td>
<td>294</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast conserving surgery</td>
<td>2,520</td>
<td>424</td>
<td>267</td>
<td>132</td>
<td>361</td>
<td>47.6%</td>
<td>3,704</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>1,650</td>
<td>384</td>
<td>324</td>
<td>259</td>
<td>390</td>
<td>51.4%</td>
<td>3,007</td>
</tr>
<tr>
<td>No primary surgery</td>
<td>104</td>
<td>28</td>
<td>14</td>
<td>10</td>
<td>8</td>
<td>1.1%</td>
<td>164</td>
</tr>
<tr>
<td>Endocrine therapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No endocrine therapy</td>
<td>1210</td>
<td>213</td>
<td>75</td>
<td>381</td>
<td>723</td>
<td>95.3%</td>
<td>2,602</td>
</tr>
<tr>
<td>Endocrine therapy</td>
<td>3,064</td>
<td>623</td>
<td>530</td>
<td>20</td>
<td>36</td>
<td>4.7%</td>
<td>4,273</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No chemotherapy</td>
<td>3,302</td>
<td>575</td>
<td>173</td>
<td>92</td>
<td>252</td>
<td>33.2%</td>
<td>4,394</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>972</td>
<td>261</td>
<td>432</td>
<td>309</td>
<td>507</td>
<td>66.8%</td>
<td>2,481</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No trastuzumab</td>
<td>4,264</td>
<td>832</td>
<td>204</td>
<td>106</td>
<td>750</td>
<td>98.8%</td>
<td>6,156</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>10</td>
<td>4</td>
<td>401</td>
<td>295</td>
<td>719</td>
<td>10.5%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4,274</td>
<td>836</td>
<td>605</td>
<td>401</td>
<td>759</td>
<td>6,875</td>
<td></td>
</tr>
</tbody>
</table>
Table 3: Five-year breast cancer-specific survival and all-cause survival by subtype.

<table>
<thead>
<tr>
<th>Subtype</th>
<th>Breast cancer-specific survival</th>
<th>All-cause survival</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5-year survival (95% CI)</td>
<td>5-year survival (95% CI)</td>
</tr>
<tr>
<td>Luminal A</td>
<td>96.8% (96.2%–97.4%)</td>
<td>91.9% (90.9%–92.8%)</td>
</tr>
<tr>
<td>Luminal B HER2-</td>
<td>89.3% (86.9%–91.8%)</td>
<td>81.6% (78.6%–84.7%)</td>
</tr>
<tr>
<td>Luminal B HER2+</td>
<td>91.6% (89.0%–94.2%)</td>
<td>87.5% (84.4%–90.6%)</td>
</tr>
<tr>
<td>HER2+ non-Luminal</td>
<td>80.1% (75.6%–84.6%)</td>
<td>78.1% (73.5%–82.7%)</td>
</tr>
<tr>
<td>Triple Negative</td>
<td>81.9% (78.9%–84.9%)</td>
<td>76.7% (73.4%–79.9%)</td>
</tr>
</tbody>
</table>

CI: confidence interval

Figure 1: Breast cancer-specific survival by subtype using the Kaplan Meier method.
As expected, the treatment varied depending on the subtype identified. In total, 97.6% of women were treated with surgery, and women with Luminal A were more likely to be treated with breast conserving surgery. In contrast, 64.6% of women with ER-, PR- and HER2+ breast cancer (HER2+ non-Luminal) were treated with a mastectomy. Of Luminal A women, 71.7% received endocrine therapy compared to 87.6% of the women with Luminal B HER2+ cancer. Chemotherapy was more likely to be prescribed for breast cancers with the worst prognosis, ie, cancers that were HER2+ or Triple Negative. Of the cancers that were HER2+, those who were ER- and PR- (HER2+ non-Luminal) were more likely to receive trastuzumab than those who were ER/PR positive (Luminal B HER2+).

Overall Luminal A women had a very good prognosis while women with cancers that were HER2+, ER- or were Triple Negative had a relatively poor prognosis (Figure 1). The five-year breast cancer-specific survival (Table 3) was worst for HER2+ non-Luminal (80.1%) and Triple Negative (81.9%), followed by Luminal B HER2- (89.3%) and Luminal B HER2+ (91.6%), and was the best for Luminal A (96.8%, Log-rank test p-value <0.001).

After adjustment for age, ethnicity, stage, comorbidity and year of diagnosis, women with Triple Negative breast cancer had the worst prognosis (Table 4): hazard ratio of 4.91 (95% CI: 3.86–6.26, p-value<0.001) for breast cancer-specific mortality and 2.74 (95% CI: 2.29–3.28, p-value<0.001) for all-cause mortality compared to Luminal A. The second worst prognosis was HER2+ non-Luminal with a hazard ratio of 3.94 (95% CI:2.94–5.30, p-value<0.001) for breast cancer-specific mortality and 2.46 (95% CI:1.92–3.15, p-value<0.001) for all-cause mortality compared to Luminal A. Breast cancer-specific mortality hazard ratios were 3.19 (95% CI: 2.65–3.85, p-value<0.001) for ER-, 3.29 (95% CI:2.72–3.98, p-value<0.001) for PR-, 1.58 (95% CI:1.28–1.96, p-value<0.001) for HER2+ and 1.18 (95% CI:0.89–1.55, p-value=0.248) for lymph node positive, respectively.

Table 4: Hazard ratios in breast cancer-specific mortality and all-cause mortality after adjustment for age, ethnicity, stage, comorbidity and year of diagnosis.

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>Breast cancer-specific mortality</th>
<th>All-cause mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hazard ratio</td>
<td>95% CI</td>
</tr>
<tr>
<td><strong>Subtype</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Luminal A</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Luminal B HER2-</td>
<td>2.64</td>
<td>1.98–3.51</td>
</tr>
<tr>
<td>Luminal B HER2+</td>
<td>2.04</td>
<td>1.47–2.82</td>
</tr>
<tr>
<td>HER2+ non-Luminal</td>
<td>3.94</td>
<td>2.94–5.30</td>
</tr>
<tr>
<td>Triple Negative</td>
<td>4.91</td>
<td>3.86–6.26</td>
</tr>
<tr>
<td><strong>ER status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ER+</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>ER-</td>
<td>3.19</td>
<td>2.65–3.85</td>
</tr>
<tr>
<td><strong>PR status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PR+</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>PR-</td>
<td>3.29</td>
<td>2.72–3.98</td>
</tr>
<tr>
<td><strong>HER2 status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HER2-</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>HER2+</td>
<td>1.58</td>
<td>1.28–1.96</td>
</tr>
<tr>
<td><strong>Lymph nodes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No positive lymph nodes</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Positive lymph nodes</td>
<td>1.18</td>
<td>0.89–1.55</td>
</tr>
</tbody>
</table>
Discussion

The proportion of women in each subgroup was similar to that found in other large studies with 62% women having Luminal A tumours and 11% having Triple Negative type tumours.\(^2,25\) The differences in characteristics by subtype in our study are also consistent with other international cohorts.\(^2,26\) As age increased, the proportion of women with Luminal A breast cancer increased. HER2+ non-Luminal and Triple Negative breast cancers were more likely to be Grade 3 (80%), and Luminal A cancers were the least likely to be Grade 3 (12%). HER2+ cancers were more likely to have positive lymph nodes and worse cancer stage than other subtype cancers.\(^2,26\)

The findings from two large cancer centres in New Zealand show that treatment for Stage I–III breast cancer is tailored to the subtype with variation in the use of endocrine therapy, chemotherapy and trastuzumab. Women with rarer subtypes such as HER2+ and Triple Negative were more likely to receive chemotherapy and when identified either endocrine therapy or trastuzumab. On the other hand, women with Luminal A disease who have a good prognosis were less likely to receive chemotherapy. Surgical treatment also varied by subtype. Women with Luminal A cancer were more likely to be treated with breast conserving surgery. However, women with phenotypes with poor prognosis were less likely to receive breast conserving surgery. No doubt this is affected by the prognosis of the subtype, but other factors such as the size of the tumour, lymph node involvement, stage and grade also affect surgical treatment.\(^27\)

As well as noting the different characteristics and treatment of women at the time of diagnosis in the five subgroups there were also differences in outcomes. The survival curves show that in the majority of women, ie, those in Luminal A, the five-year survival was 97%, while for those with ER and PR negative, HER2+ disease only 80% survive five years. Having a cancer that was either ER or PR negative was also an important prognostic indicator, with a hazard ratio for ER negative of 3.19 and for PR negative of 3.29. Women with HER2+ or Triple Negative disease and are more likely to be younger and have Grade 3 disease. On the other hand, women with Luminal A disease are likely to be older and do better.

This is consistent with the literature.\(^2,28\) We also know that in New Zealand outcomes for Māori and Pacific women are poor.\(^1,29–31\) While they may be slightly more likely to have HER2 positive disease, they are less likely to have the subtype with the worst prognosis, ie, Triple Negative disease. It has been shown that for Māori the differences in biology only make a small contribution to the differences in outcomes.\(^1\)

The strength of this study is that it comprises a relatively large population-based database with comprehensive data on patient characteristics, patient treatment as well as outcomes. One weakness is that we did not take into account other important biomarkers such as Ki67. We also have not included grade of disease in our classification. Some classification systems would classify ER+, PR+ and HER2- breast cancers as luminal B rather than luminal A if they are high grade or have a high Ki67,\(^32–34\) but these were all classified into Luminal A in our study. Doing the classification this way would slightly bias luminal A cases towards worse outcomes in our study. Our classification may differ from a classification based on gene expression profiling. On the other hand, our grouping of cancers into five subtypes is also a strength of this study as breast cancer treatment decisions are generally based on the presence or absence of these three biomarkers. Gene expression profiling is not routinely available in clinical practice and only infrequently used to assist treatment decisions in New Zealand at present.

Conclusions

The pattern of phenotype in women with Stage I–III breast cancer is similar to the international cohorts. Most New Zealand women with Luminal A breast cancer have a very good prognosis, but the less common subtypes have relatively poor outcomes. We have demonstrated differences in tumour grade, stage, patient age and ethnicity according to breast cancer subtype in a New Zealand population. The treatment of women with Stage I–III breast cancer varies by molecular phenotype. Treatment is becoming personalised to their individual molecular phenotype. Despite this there was a major variation in the prognosis of women with Stage I–III breast cancer with differing molecular phenotype.
Competing interests:
RL, SS, IC, ME, CL and DS report grants from Health Research Council of New Zealand during the conduct of the study.

Acknowledgements:
We would like to acknowledge the financial support from the Health Research Council of New Zealand, the Auckland and Waikato Breast Cancer Registers for providing the detailed data, and the New Zealand Breast Cancer Foundation and the Waikato Bay of Plenty Division of the Cancer Society for funding the Registers.
This study was supported by the Health Research Council of New Zealand for the project ‘Improving outcomes for women with breast cancer in NZ’ (grant number: 14/484).
The funding source did not have any role in the design of the study; in the analysis and interpretation of the data; or in the preparation of the manuscript.

Author information:
Ross Lawrenson, Professor of Population Health, Waikato Medical Research Centre, The University of Waikato, Hamilton; Chunhuan Lao, Research Fellow, Waikato Medical Research Centre, The University of Waikato, Hamilton; Ian Campbell, Associate Professor of Surgery, School of Medicine, The University of Auckland, Auckland; Vernon Harvey, Medical Oncologist, Auckland City Hospital, Auckland; Sanjeeewa Seneviratne, Senior Lecturer, Department of Surgery, Faculty of Medicine, University of Colombo, Sri Lanka; Mark Elwood, Professor of Cancer Epidemiology, School of Population Health, The University of Auckland, Auckland; Diana Sarfati, Professor of Epidemiology, Department of Public Health, The University of Otago, Wellington; Marion Kuper-Hommel, Medical Oncologist, Waikato District Health Board, Hamilton.

Corresponding author:
Prof Ross Lawrenson, University of Waikato, Level 3 Hockin Building, Waikato Hospital, Hamilton 3240.
ross.lawrenson@waikatodhb.health.nz

URL:

REFERENCES:
2. Parise CA, Caggiano V. Breast cancer survival defined by the er/pr/her2 subtypes and a surrogate classification according to tumor grade and immunohistochemical biomarkers. Journal of Cancer Epidemiology 2014 ;Vol 2014:469251.
8. Anderson WF, Pfeiffer RM, Wohlfrath J, Ejlertsen B, Jensen MB, Kroman N. Associations of pari-


Incidence, demographics and surgical outcomes of cutaneous squamous cell carcinoma diagnosed in Northland, New Zealand

Brodie M Elliott, Benjamin R Douglass, Daniel McConnell, Blair Johnson, Christopher Harmston

ABSTRACT

AIM: Non-melanoma skin cancer (NMSC) is the most commonly diagnosed and most costly cancer in Australasia. Cutaneous squamous cell carcinoma (cSCC) accounts for approximately 25% of NMSC. Despite this, reporting of cSCC is not mandatory in Australasia. This creates difficulties in planning, resourcing and improving outcomes in cSCC. Previous studies in New Zealand have lacked data on ethnicity. The aim of this study was to define the incidence and demographics of cSCC diagnosed in Northland, New Zealand, including data on ethnicity.

METHODS: A 12-month retrospective study was carried out of all primary cSCC histologically diagnosed in Northland for one year. The cohort was identified by searching the Northland District Health Board pathology database. Data on outcomes and ethnicity were obtained from the hospital results system. Primary outcome of interest was the incidence of cSCC in Northland. Secondary outcomes of interest were lesion characteristics and positive margin rate.

RESULTS: 1,040 cSCC were identified in 890 patients. Mean age of patients was 75. Crude incidence of primary cSCC was 668/100,000 patient years. Age standardised incidence was 305/100,000 patient years. An estimate of New Zealand incidence adjusted for age and ethnicity is 580/100,000 patient years. Overall positive margin rate in excised lesions was 9.5%.

CONCLUSION: This study has defined the rate of cSCC in a large, well defined New Zealand population, and estimated age and ethnicity adjusted incidence in New Zealand. It has demonstrated the highest incidence of cSCC in the world outside Australia. Overall positive margin rate of excised lesions was acceptable.

Non-melanoma skin cancer (NMSC) is the most commonly diagnosed malignancy in Australasia, accounting for around 75% of cancers, with Australia having the highest incidence in the world. It consumes significant healthcare resources with an estimated annual cost of $703 million dollars in Australia, and $51 million dollars in New Zealand. This is 9% of total cancer costs, making NMSC the costliest of all cancers.1-3 It is commonly treated in primary care by general practitioners, as well as secondary care by dermatologists, general and plastic surgeons.

Cutaneous squamous cell carcinoma (cSCC) accounts for approximately 25% of NMSC. Unlike basal cell carcinoma, cSCC frequently metastasises and can be fatal.4,5 It is however, potentially preventable with relatively simple measures, and is easily treated by excision if detected early.6-7 Despite this, there is good evidence that the incidence of cSCC continues to increase worldwide.8-15

Mandatory reporting for cSCC and other NMSC in New Zealand was discontinued in 1958 due to resource constraints. Therefore, statistics on incidence and outcomes are not
easily available. Previous studies in New Zealand populations have demonstrated some of the highest absolute and age-adjusted incidence rates of cSCC in the world outside Australia, with the most recent published rate of 118/100,000 patient years in 2007. The markedly different cSCC rates between Māori and non-Māori mean accurate extrapolation of data to the entire country from local studies where ethnicity is not known is difficult, due to differing ethnic population make-up across the country. All prior studies haven’t accounted for ethnicity in this regard. Finally, data addressing surgical outcomes including positive margin rate in cSCC is also inconsistent. Planning, resourcing and improving outcomes in patients with cSCC in New Zealand is therefore difficult using currently available data.

Aim

The aim of this study was to define the incidence, characteristics and surgical outcome of cSCC diagnosed and treated in Northland, including data on ethnicity. This will allow age- and ethnicity-adjusted estimates of New Zealand population incidence.

Methods

Northland is a well-defined region in Northern New Zealand with a population of approximately 151,000 in 2015 (Data obtained from Statistics New Zealand). It is serviced by a single district health board through four hospitals which share the same data management system and pathology service. This includes all primary, secondary and private care pathology. Northland has double the national proportion of Māori, at approximately 30%, and a significantly older population with a higher representation in the over 50 age brackets.

Cohort selection

A 12-month retrospective study was carried out of all primary cSCC diagnosed in Northland for one year commencing 1 January, 2015.

The primary cohort consisted of consecutive diagnoses of primary cSCC diagnosed on punch biopsy or excision. Patients with a final diagnosis of squamous cell carcinoma in situ, even if a previous punch biopsy suggested cSCC, were excluded. Extended resections involving cartilage (excluding ear), bone or periosteum were included in incidence and lesion analysis but not included in margin analysis.

The primary cohort was identified by searching the Northland District Health Board pathology database and a database of outsourced pathological specimens using key terms. Together these databases contain all histological specimens processed in Northland, both public and private from primary and secondary care. The 15,719 pathology reports obtained from this search were manually screened to identify all cSCC. These patients were entered into a Microsoft Excel spread sheet. Demographic data was obtained from the district health board data warehouse, lesion characteristics were extracted from the pathology report and further information on secondary care excisions was obtained from the hospital results reporting system CONCERTO.

Histological specimens were stained with haematoxylin and eosin stain, fixed, and deep and lateral margins inked. Specimens were serially sliced in 2–3mm sections. Positive margins were defined as when tumour was present at the excised margin.

Biopsy was defined as histology obtained by punch biopsy or partial lesion excision before definitive excision. Lesions excised with positive or close margins without further intervention were classified as excisions.

Primary outcome of interest

The primary outcome of interest of the study was the crude and age-adjusted incidence of primary cutaneous squamous cell carcinoma in Northland, New Zealand. Secondary endpoints included positive margin rate at surgical excision.

Incidence analysis

Direct age standardised incidence was compiled using the World Health Organization (WHO) standard population. Estimates of population incidence corrected for age and ethnicity in New Zealand were calculated using direct standardisation of population age and ethnicity data from Statistics New Zealand during the same year. Socioeconomic deprivation was calculated through applying a patient’s domicile address to the New Zealand Index of Deprivation (NZDep), which is an area-based
measure of deprivation based on census information. Quintile 1 represents people living in the least deprived 20% of areas; quintile 5 represents people living in the most deprived 20% of areas.

Statistical analysis

Data was analysed using Microsoft Excel and IBM SPSS. Descriptive statistics were used to describe basic demographics. Mann-Whitney U test was used to compare nonparametric data, and chi-square test to ascertain differences between categorical data. A p-value of <0.05 was considered significant.

The data used in this study was collected as part of a service evaluation of patients with suspicious skin lesions referred to Northland District Health Board. Data collection was discussed with the Health and Disability Ethics Committee and an “out of scope letter” obtained on 29 March 2016.

Results

Basic demographics and incidence

1,040 cSCC were identified in 890 unique patients. 819 lesions were surgically excised; 100 lesions contained cSCC on punch biopsy and further excision revealed no further tumour cells and 121 lesions were identified from punch biopsy, but had no recorded further excision. The latter group was included in incidence and demographic calculations, but because no formal excision had been completed they weren't included in surgical outcome or margin analysis.

The mean age of patients was 75 (SD 10.4). 54.9% of patients were aged over 75. There was slight gender preponderance with 60% of lesions diagnosed in males and 40% in females, giving a M/F ratio of 1.52:1 (See Table 1). Very few patients identified as Māori (1.0%).

Table 1: Demographics and tumour characteristics.

<table>
<thead>
<tr>
<th>Patient demographics of 890 unique patients</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years (range)</td>
<td>75 (33–100)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>537 (60)</td>
</tr>
<tr>
<td>Female</td>
<td>353 (40)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>881 (99)</td>
</tr>
<tr>
<td>Māori</td>
<td>9 (1)</td>
</tr>
<tr>
<td>Socioeconomic deprivation, n (%)</td>
<td></td>
</tr>
<tr>
<td>Quintile 1</td>
<td>19 (2)</td>
</tr>
<tr>
<td>Quintile 2</td>
<td>115 (13)</td>
</tr>
<tr>
<td>Quintile 3</td>
<td>192 (22)</td>
</tr>
<tr>
<td>Quintile 4</td>
<td>253 (29)</td>
</tr>
<tr>
<td>Quintile 5</td>
<td>311 (35)</td>
</tr>
<tr>
<td>Multiple lesions</td>
<td></td>
</tr>
<tr>
<td>Multiple SCCs Excised, n (%)</td>
<td>107 (12)</td>
</tr>
<tr>
<td>Mean cSCC per patient, n (range)</td>
<td>1.17 (1–6)</td>
</tr>
</tbody>
</table>

Tumour characteristics of the 819 formally excised cSCC

<table>
<thead>
<tr>
<th>Tumour size, mm, range</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean tumour diameter</td>
<td>7.8 (0.65–50)</td>
</tr>
<tr>
<td>Mean tumour thickness</td>
<td>2.77 (0.2–20)</td>
</tr>
<tr>
<td>Tumour factors, n (%)</td>
<td></td>
</tr>
<tr>
<td>Perineural invasion</td>
<td>11 (1)</td>
</tr>
<tr>
<td>Lymphovascular invasion</td>
<td>6 (1)</td>
</tr>
<tr>
<td>Metastatic disease</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Anatomical region, n (%)</td>
<td></td>
</tr>
<tr>
<td>Head and neck</td>
<td>384 (47)</td>
</tr>
<tr>
<td>Trunk</td>
<td>73 (9)</td>
</tr>
<tr>
<td>Upper limb</td>
<td>181 (22)</td>
</tr>
<tr>
<td>Lower limb</td>
<td>178 (22)</td>
</tr>
<tr>
<td>Not stated</td>
<td>3 (0)</td>
</tr>
</tbody>
</table>
Table 2: Age distribution and incidence of cSCC.

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–4</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5–9</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10–14</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>15–19</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>20–24</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>25–29</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>30–34</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>35–39</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>40–44</td>
<td>4</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>45–49</td>
<td>11</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>50–54</td>
<td>16</td>
<td>11</td>
<td>27</td>
</tr>
<tr>
<td>55–59</td>
<td>21</td>
<td>13</td>
<td>34</td>
</tr>
<tr>
<td>60–64</td>
<td>51</td>
<td>27</td>
<td>78</td>
</tr>
<tr>
<td>65–69</td>
<td>87</td>
<td>49</td>
<td>136</td>
</tr>
<tr>
<td>70–74</td>
<td>100</td>
<td>76</td>
<td>176</td>
</tr>
<tr>
<td>75–79</td>
<td>135</td>
<td>75</td>
<td>210</td>
</tr>
<tr>
<td>80–84</td>
<td>100</td>
<td>66</td>
<td>166</td>
</tr>
<tr>
<td>85 and over</td>
<td>92</td>
<td>104</td>
<td>196</td>
</tr>
</tbody>
</table>

Crude incidence (per 100,000) 817.3 527.4 668
NZ age standardised incidence (per 100,000) 544
WHO age standardised incidence (per 100,000) 305
NZ age + ethnicity standardised (per 100,000) 580
Expected lesions annually in NZ 2015 24,605
Based on a Northland population of 151,000 (2013 New Zealand census) the crude incidence of primary cSCC in this study was 668/100,000 patient-years. The age standardised incidence was 305/100,000 patient-years. Given Northland is a region that has a higher proportion of Māori, we standardised for age and ethnicity and extrapolated this to provide an estimate of national incidence, which was 580/100,000 patient-years. Age standardised rates increased with age, and were higher in males in all age groups (See Figure 1). Based on the New Zealand population, this equates to 24,605 new cSCC diagnosed in New Zealand each year (See Table 2).

Patients in the two least deprived quintiles were proportionally under-represented, forming 2 and 13% respectively of the study population. The three most deprived quintiles were markedly overrepresented; forming 85% of this population compared to the expected 60% of the national population. This follows the trend for the total Northland Regional Population where 82% of people belong to these most deprived quintiles.

Anatomical location and lesion characteristics
Almost half of the lesions were found above the level of the clavicle (47.1%) with the lower limb being the next most common location (24.6%) followed by the upper limb (18.7%) and trunk (8.3%). Anatomical location of the lesion was not stated in 0.3% of cases (Table 1).

There was a marked variation in pathologic reporting of lesions. Tumour size and thickness were recorded on the pathology reports of 581 (70.9%) of excised specimens. Mean size of excised lesions was 7.79mm, with a mean tumour thickness of 2.77mm. Eleven (1.13%) patients diagnosed had perineural invasion and six (0.73%) had evidence of lymphovascular invasion.

Details of surgical excision and outcome
Of the 819 surgically excised lesions, 433 (52.9%) were excised in primary care, 313 (38.2%) in secondary care and 73 (8.9%) by a private specialist. Twenty-two percent of lesions excised in secondary care were excised by a general practitioner with a specialist interest in skin cancer (GPwSI). Lesions in excised in primary care were more likely to have a smaller tumour diameter; 5.0mm vs 6.1mm (P<0.0001), smaller radial margin of excision; 2.2mm vs 3.0mm (P<0.0001) and less likely to be excised from the head and neck; 38.2% vs 57.1% (P<0.0001). There were no significant differences in histologic tumour thickness nor deep margins.

In the 232 lesions excised in hospital, 107 (46.1%) had an elliptical excision, 15% underwent a skin flap, 20% a full thickness skin graft and 11% a partial thickness skin graft. Twenty-five percent of patients had an excision in a formal theatre environment and 67% in a minor procedures room.

The overall positive margin rate of formally excised lesions was 9.5%. Superficial margins were positive in 3.1%, deep margins positive in 4.4% and both margins were positive in 2.1% of lesions.

Discussion
This study has assessed the rate of cutaneous squamous cell carcinoma in a large, well-defined New Zealand population, and provided estimations of age- and ethnicity-adjusted incidence in New Zealand. It has demonstrated the highest incidence of cSCC in the world outside Australia. Overall positive margin rate in excised lesions was acceptable.

A recent systematic review of the incidence of non-melanoma skin cancer has demonstrated wide geographical variance in incidence, with the lowest rates seen in Croatia and the highest rates seen in Australia.\(^1\) It is unfortunate that no New Zealand studies were included in the review. Three previous studies have, however, examined incidence of cSCC in New Zealand. O’Dea in a report to the Cancer Society in 2009 estimated both incidence and total number of New Zealand cSCC diagnosis by applying findings from a 1998 Bay of Plenty to a 2007 population profile.\(^3\) His findings, although not adjusted for ethnicity, were similar to those that we present, with crude rate of 628/100,000, age-adjusted rate of 377/100,000 and national annual estimation of 23,100 lesions.\(^3\) These estimations are significantly higher than both those seen in a study published a year later by Brougham et al examining pathology reports of over 13,000 patients during a 10-year period, as
well as those demonstrated in the Hamilton area in 1982 by Freeman and Fairbrother.\textsuperscript{8,16} Both these studies estimated below 8,000 new cSCC in New Zealand per year. The latter study used methodology that likely missed diagnosis of cSCC and is now over 30 years old. The reasons for these differences seen in the former study are unclear, but it is likely that several factors are involved. Firstly, historical data tends to underestimate current incidence.\textsuperscript{3} Secondly, as ethnicity was not considered in the study it is likely that the true adjusted rate was underestimated due to the extremely low rate of NMSC in people of Pacific and Māori descent. Finally, it is possible that the methodology did not effectively capture all diagnosed cSCC.

The crude and absolute rates that we present are approaching the rates seen in population studies in Australia, with comparable rates in Caucasian males.\textsuperscript{18} As ultraviolet radiation is the commonest environmental cause of cSCC, with areas of similar latitude and high population rate of European descent, this would be expected.\textsuperscript{19} The demographics we present are also in keeping with those seen around the world, with an incidence increasing with age, a male predominance in all age groups and a high proportion of lesions seen on the head and neck.\textsuperscript{19–20} The majority of patients are Caucasian, with an extremely low rate in other ethnic groups.

Although retrospective in nature, this study identified a large number of pathology reports using broad search terms. Every diagnosis entered had histological confirmation of cSCC. It is likely therefore that the absolute number of cases identified represents a “minimum” number for the population. It is possible that cases in which a patient travelled out of region for treatment were missed, but it is likely that this number is small. It is also possible that there is a variation in the incidence of cSCC across the country due to regional differences in levels of UV radiation and that this affects our estimations of population incidence. However, this is difficult to control due to lack of regional radiation data as UV index is only consistently measured at five stations across the country with the most northern station located in Leigh.

It is however, the first large study in New Zealand to utilise data on ethnicity. We believe therefore that the data presented allow the most accurate assessment to date of the incidence of cSCC and total lesion count in New Zealand. It is expected that this data will therefore help guide future planning and resource allocation on both a local and national level.

The overall incomplete excision rate at 9.5% was comparable to that in the worldwide literature. There is however, a wide variation in outcomes with a recent review demonstrating positive margin rates of between 6.3% and 17.6%.\textsuperscript{21–25} The rate published here is however, significantly lower than that seen in the most recent New Zealand study of 1,100 malignant skin cancer excisions from Bay of Plenty, where the incomplete excision rate in GPs was 23% and specialist surgeons 20%.\textsuperscript{26} This discrepancy is most likely due to inclusion of cSCC in situ.

In short, this study has demonstrated a high age and ethnicity adjusted incidence of cSCC in a large New Zealand population with an acceptable positive margin rate.
Supplementary Figure 1: Socioeconomic deprivation of patients undergoing excision of cSCC.

**New Zealand Index of Deprivation Quintiles**

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q5</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCC Population Northland</td>
<td>Total Northland Population</td>
<td>National Average</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Competing interests:
Nil.

## Author information:
Brodie M Elliott, Department of General Surgery, Whangarei Hospital, Northland; Benjamin R Douglass, Department of General Surgery, Whangarei Hospital, Northland; Daniel McConnell, Department of General Surgery, Whangarei Hospital, Northland; Blair Johnson, Clinical Analyst, Whangarei Hospital, Northland; Christopher Harmston, Department of General Surgery, Whangarei Hospital, Northland; Consultant General and Colorectal Surgeon, Whangarei Hospital, Northland; Honorary Lecturer, Department of Surgery, University of Auckland.

## Corresponding author:
Dr Brodie Elliott, General Surgical Department, Whangarei Hospital, Private Bag 9742, Whangarei 0148.
brodie.elliott@northlanddhb.org.nz

## URL:

## REFERENCES:


Development of an otitis media strategy in the Pacific: key informant perspectives

Elizabeth A-L Holt, Judith McCool, Vili Nosa, Peter R Thorne

ABSTRACT

AIM: Ear and hearing health services are scarce within Pacific Island countries. Where available, they remain under-resourced, despite there being a high estimated prevalence of otitis media and otitis media-related hearing loss. This study examines the potential for improving ear and hearing health strategies by examining key factors, opportunities and challenges, working with Fiji as a case study.

METHOD: A series of semi-structured interviews were conducted with professionals who had experience in otitis media programme implementation and/or professionals with working experience within the Pacific region and the Fiji health system. Interviews were audio-recorded, transcribed verbatim and analysed using thematic analysis methods.

RESULTS: The three main themes, Identification, Integration, Sustain, highlight the importance of a Pacific-based, locally-driven strategy that builds on existing infrastructure. Three operational themes, Advocacy, Funding and Long-Term Vision, were pivotal to the viability of the main themes.

CONCLUSION: Despite significant challenges, there is potential to develop sustainable otitis media identification, treatment and prevention strategies in Fiji. The sustainability of such a strategy is contingent on a number of key factors, which includes a long-term commitment by stakeholders, be culturally appropriate and responsive to local need, develop close linkages across health, social and educational sectors, and ensure it is embedded within a broader public health framework.
and capabilities within the health workforce is a regional priority, with various measures being a key agenda item at the recent Pacific Health Ministers meeting. One crucial way in which PICTs can stem this shortage of human resources to build health workforce capacity and capabilities is to provide comprehensive workforce support and ensure the professional recognition of worker skills. Within the domain of ear and hearing health, The Strengthening Specialist Clinical Services in the Pacific programme (which has recently been replaced by the Pacific Regional Clinical Services and Workforce Improvement Programme) has recognised the importance of developing specialist services in Ear, Nose and Throat and Audiology in PICTs in order to strengthen the prevention, early recognition and treatment services for OM.

Although PICTs have limited country-based strategies to identify and manage OM, they remain largely reliant on NGOs or other organisations to provide ear and hearing health services. This approach often precludes the involvement of Ministry of Health systems and tend to be uncoordinated and inadequately resourced. The challenge therefore is to ensure that OM, as a preventable and treatable condition that adversely affects child health and development, is recognised. Compounding the lack of services and infrastructure is a dearth of information on what elements constitute an effective strategy and where best to focus initial efforts in a resource-limited setting to reduce the impact of this condition. Meaningful engagement and consultation with Pacific Island communities is critical to understand the key elements of an effective strategy. By focusing on Fiji, a populous Pacific Island country, this paper ascertains the key elements of an effective ear and hearing health strategy in order to build towards a framework that is relevant and responsive to the needs of PICTs. The aim of this study was to assess key informants’ views on the relative priority, process and potential benefits and challenges of establishing a dedicated OM and hearing health strategy or service within the Pacific region.

Method

A series of semi-structured interviews were conducted with key informants based in the Pacific region. A qualitative approach is a useful method to examine a relatively under-researched area that is affected by individual, social and cultural interactions. The use of qualitative interviews is a valid methodology as there is limited knowledge of what constitutes an effective OM programme within a Pacific setting and it gives value to the subjective, lived experiences of the research participants as a source of knowledge.

Key informants were identified via various informal and formal networks as holding expertise in OM, Pacific clinical service development, or Pacific health development. Participants were recruited through a thorough online search of journals, websites and conference proceedings, as well as established networks at The University of Auckland.

Invitations to participate in the study were extended to 17 eligible individuals. Inclusion criteria were potential stakeholders in Fiji and the Pacific and health or medical professionals with regional or non-regional specific experience of public health programme implementation. As many of the key informants were located across different parts of the Pacific region, interviews were conducted either face to face or via Skype (synchronous) or online (asynchronous). Interviews were conducted using a semi-structured format whereby a series of open-ended questions were presented and discussed. This method allowed participants’ views to be accurately captured, generating in-depth responses and viewpoints and resulting in the collection of information-rich data.

Twelve interviews were conducted due to availability of interviewees to participate. Interview type included face-to-face (n=6) and synchronous (n=3) and asynchronous (n=3) online interviews. Participants included senior Fijian health clinicians (n=4), Fiji-based senior managers (n=2), a senior Fiji health systems specialist, New...
Zealand-based senior clinicians with Pacific region experience ($n=2$) and three senior managers working in Pacific-based non-governmental organisations. To ensure the questions were appropriate to the participants’ area of expertise, opening questions gained information on their professional background. Once professional expertise was established, participants were asked to consider the potential value of a dedicated OM intervention or strategy and comment on the details regarding strategy development.

Interviews were audio-recorded and then transcribed verbatim before an inductive analysis was conducted using an open coding process. Thematic analysis as described by Braun and Clarke\textsuperscript{25} was utilised to identify key descriptive themes within each interview and subsequently merged with themes from all interviews to generate a coherent explanation of the dominant perspectives on this issue. Coding was conducted by the authors to strengthen the validity and reliability of the coding process.

Results

A strategy targeting OM, a common child health condition in PICTs, was seen as an excellent starting point in order to prevent a myriad of adverse medical consequences and limit the long-term impact that hearing loss can have on social inclusion and economic prosperity.

Figure 1 shows all of the main themes, sub-themes and integral themes suggested as being critical for programme viability.

Participants expressed the view that improved initiatives would be welcome by the Fijian community ($n=3$) and four informants recognised that there was a need for more comprehensive interventions in the area of ear and hearing health services. Health and medical service provision can thus be enhanced in two key ways; Forge partnerships with players outside of the public health system such as with community groups and non-governmental organisations, and link private and public enterprise to ensure sustainability in
funding and resources. A hearing-screening strategy could only be viable if it were to be embedded within a broader programme that supports the treatment and rehabilitation of that individual. Advocacy and awareness raising, and dispelling common myths around ear conditions and hearing loss need to be done along the entire community chain, from the grassroots and community level to the political level.

The majority of the informants (n=8) emphasised it was critical to collate reliable and accurate ear and hearing health data in order to determine the extent of the problem and to track programme efficacy. However, challenges were noted, these included: inconsistent use of standardised definitions across the health system records, ear and hearing data not being captured within the national health database, and laboratory testing not being available. This makes accurate diagnosis and appropriate treatment regimens difficult to implement. Technical support and ongoing research was seen as a crucial part to ensure programme sustainability.

Scarcity of funding and resources is a major challenge for any potential OM strategy, with many health programmes in Fiji depending on external donors for support. While a funding model that involves external organisations has proved critical for providing sustainable, Pacific-based services, this can have serious consequences for long-term sustainability for a strategy if support is withdrawn and then re-directed to fund other priorities. Many informants emphasised that the provision of reliable funding must allow for a long-term vision of service and workforce development.

Any strategy could benefit from health worker development from primary to tertiary care. Depending on local need, this may also include expanding clinical scope of practice and the development of specialist clinical skills. Building a base of community workers who are well trained to provide a triaging service of health education and basic procedures was identified by many participants as a potentially cost-effective model of service delivery. This will allow early identification of ear disease, health promotion, and improve access to services for rural communities. Awareness-raising should not only be done within the community, but also among health practitioners and MoH policy-makers on the importance of ear and hearing health. While the nursing profession was seen as a critical component of any potential service, workers across the healthcare continuum should be able to provide key services, including health education, the initiation of medical management and teaching simple management for parents such as ear wicking and instilling eardrops. Ear nurses could offer huge benefits on the proviso that the numbers of trained specialists must be appropriate for country need as to not divert nurses away from the general pool of resources. Adequate recognition of such skills, through appropriate remuneration, ongoing training and appropriate clinical support was deemed to be important if Fiji were to retain such skilled professionals in-country.

A locally-driven strategy supported by country and regional stakeholders will enhance the sustainability of an OM intervention. Such a model can be seen with the Strengthening Specialised Clinical Services in the Pacific programme and the development of the first Ear, Nose and Throat (ENT) and Audiology Strategy for the Pacific Region. An aspirational document, the Strategy was presented and adopted by all Pacific Heads of Health in Suva, Fiji, in April 2016 and provides a cohesive Pacific-led vision for strengthening ENT and Audiology in the Pacific. Through its Mission Statement, the Strategy identifies the importance of prevention and treatment of ENT and Audiological conditions:

“To prevent, identify and treat ear, nose and throat and hearing conditions in Pacific communities to maximise individual development, learning and contribution to society.”

The area of OM and prevention of hearing loss is identified both within the Strategy and by key informants within this work as an important initial focus for Pacific Island nations. Furthermore, it identified the importance of developing public health strategies based around prevention and increasing public awareness.
Discussion

Based on the views of informants in this study, who come from a range of disciplines, a dedicated OM strategy in Fiji is both feasible and preferable in order to address the suspected high burden of OM. This study reflects the collective opinion that if an OM strategy were to be developed, it is vital that it is embedded within a public health framework: population based, cost-effective, prevention oriented and involving early detection and clinical support. Such a framework is also advocated by the World Health Organization (WHO). With 50% of global hearing loss potentially preventable, the WHO promotes a public health approach with a particular emphasis on implementing cost-effective primary prevention strategies, such as improvements in hygiene, nutrition, breastfeeding awareness and better management of upper respiratory tract infections. Secondary prevention such as early detection, and tertiary strategies such as hearing aids, cochlear implants and hearing rehabilitation can also be developed. As the cost of such services is often prohibitive in many low-to middle-income countries, this places a greater emphasis on the importance of more affordable primary prevention strategies to be implemented. This level of development requires greater multiple-level contribution, including commitment from medical and educational professionals, government officials, civil society and members of the community.

The key informants emphasised that rather than functioning as a separate entity, an ear and hearing health strategy should be developed to be embedded within the existing health and education infrastructure to maximise synergies across the health system and established health programmes. While selective, disease-specific programmes can allow a rapid scaling-up of service delivery, working across various sectors has shown to be critical to prevent the undermining of established health programmes and maintain health worker retention, people who may be attracted to work in more well-resourced sectors. Key informants emphasised it must also ensure that this level of intervention is appropriate so as not to over-burden the already resource-limited health system and not to cause a re-direction of technical and human resources away from already established health programmes. Regional literature indicates that professional growth and support, service development and professional recognition can enhance professional satisfaction and with the potential to stem turnover of staff and limit the high emigration of health sector workers.

This study has shown that accurate ear and hearing health data, such as knowing the prevalence of hearing loss across the population, and OM within the paediatric population, is critical for determining both the burden of the issue as well as tracking strategy effectiveness. In Fiji, the reporting and collation of accurate disease data was reported to be challenged by difficulties in obtaining accurate diagnoses, limited information being recorded by health facilities and weak service infrastructure. While reliable, country-based data on OM and hearing loss in children are critical to an evidence-based approach to policy and planning, limited or localised data should not be considered a deterrent to strategy development if it is considered valuable by the community.

Gaining an understanding of attitudes towards ear and hearing health from community members such as parents, teachers for example, is important to the design and delivery of appropriate, relevant services. Similarly, canvassing community views of hearing health, perceptions of hearing loss and paediatric ear disease, barriers to accessing health services and level of health literacy within different communities will assist the development of a responsive and culturally-appropriate programme.

The Ear, Nose and Throat (ENT) and Audiology Strategy for the Pacific Region provides the platform to guide broader strategic development in ear and hearing health programmes for the Pacific Region. It provides much-needed high-level strategic direction in order to support policy development for individual Pacific Island nations. Alongside improving political priorities, the study identified the importance of dedicated resourcing for the long-term viability of an ear and hearing health strategy, including the value of locally-trained and mentored health workforce. Due to resource constraints within the Fiji Ministry of Health external sources will be necessary contribute to the establishment of
a bespoke, local programme. As the impact of hearing loss gains greater awareness at a global level, this has significant potential to mobilise greater international investment, such as the development of cheaper and more accessible hearing technologies.15

Several challenges to the generalisability of this work need acknowledging. First, although some interviews were conducted in person in Fiji, others were conducted via email and Skype. As Pacific health research is founded on active participation and meaningful engagement, it is important to understand people in-context.35 With in-person dialogue a preferred method of communication in the Pacific, online interviewing therefore may not be the ideal method to facilitate open dialogue between interviewer and participant. Despite strong representation of participants with in-country knowledge, the majority of the key informants were medical professionals or were NGO based. Having more participants with experience in the education sector or within grass-roots organisations may have provided further richness and perspectives to the data.

Decision makers face a perennial problem of how to achieve a reasonable balance in priorities in the face of competing demands and limited resources.15 The consideration of a strategy or initiative to address the estimated high burden of OM and hearing loss in Pacific Island populations is no exception. By taking lessons from Pacific experts, this study highlights the powerful opportunities and key lessons that can be used to harness energy towards the development of a sustainable and culturally appropriate intervention led by Pacific communities. With 90% of disabling hearing loss being experienced by communities in low- to middle-income countries,36 a targeted initiative may be seen as an intervention of health equity. Critically, any strategy designed and implemented for this purpose in Pacific Island nations should be developed in respect to the chronic technical, financial and human resource limitations. The findings of this study can be employed within initial processes of programme planning in order to build momentum towards improving ear and hearing health for children of the Pacific region.

Competing interests:
Ms Holt reports grants from The University of Auckland during the conduct of the study.

Acknowledgements:
We thank the participants for generously sharing their time and their experiences. We are grateful to Dr Berlin Kafoa, Pacific Community, for providing his support to this study. The work formed part of a thesis for a Master of Public Health. EH received a University of Auckland Master’s Scholarship.

Author information:
Elizabeth Holt, Section of Audiology, Faculty of Medical and Health Science, University of Auckland, Auckland; Eisdell Moore Centre for Balance and Hearing Research; Judith McCool, Epidemiology and Biostatistics, Faculty of Medical and Health Science, University of Auckland, Auckland; Vili Nosa, Section of Pacific Health, Faculty of Medical and Health Science, University of Auckland, Auckland; Peter Thorne, Section of Audiology, Faculty of Medical and Health Science, University of Auckland, Auckland; Eisdell Moore Centre for Balance and Hearing Research.

Corresponding author:
Elizabeth Holt, Section of Audiology, School of Population Health, University of Auckland, Auckland.
e.holt@auckland.ac.nz

URL:
REFERENCES:


30. Oman K. Should I migrate or should I remain?: professional satisfaction and career decisions of doctors who have undertaken specialist training in Fiji. James Cook University; 2007.


A 32-year-old health worker presented to the emergency department with a three-day history of headache, left eye pain, fevers and rigors. There was no eye swelling or change in vision and no associated rash. Her past medical history included only asthma and a previous tonsillectomy.

On examination she was tachycardic (heart rate 116bpm), hypotensive (blood pressure 88/50mmHg) and febrile (40°C). The external upper and lower eyelids appeared erythematous bilaterally. The upper lids were everted and diffuse follicular conjunctivitis was seen in both eyes (Figure 1A). The bulbar conjunctivae were injected bilaterally but not chemotic. The anterior chambers were quiet and both corneas were clear without fluorescein uptake. There was overt painless cervical lymphadenopathy in the anterior and posterior triangles of the neck. She was photophobic without evidence of neck stiffness and the remainder of the neurological examination was normal. Examination of the cardiovascular, respiratory and gastrointestinal systems was otherwise unremarkable.

Empiric antibiotics for the possibility of meningitis were administered in conjunction with intravenous fluids. Initial investigations revealed a normal haemoglobin and white cell count with a mild thrombocytopenia (platelets 134x10^9/L). The urea and electrolytes were normal, however the CRP was elevated (115mg/L). Blood cultures were negative. Her CSF had a white cell count of 2x10^6/L, normal protein and glucose, negative gram stain and no subsequent growth from bacterial culture. There was serological evidence of prior exposure to EBV but not to CMV or toxoplasma.

CT imaging of the head and neck demonstrated low-grade pan-sinusitis of the paranasal sinuses, marked thickening of the soft palate and uvula, and extensive cervical adenopathy extending from the skull base to the thoracic inlet involving both anterior and posterior chains bilaterally (Figure 2). There was minimal periorbital oedema.

On Day 2 she briefly developed a blanching macular exanthem on her abdominal and thighs (Figure 1B), which spontaneously resolved.

Respiratory multiplex PCR (Fast Track Diagnostics Respiratory Pathogens 21) of a nasopharyngeal swab was positive for adenovirus. This was also detected on specific adenovirus PCR from a swab of the...
**Figure 1B:** A blanching macular exanthema developed on day 2.

**Figure 2:** A transverse CT section of the neck demonstrates enlarged lymph nodes (arrows).
left eye. Subsequent typing completed by the Institute of Environmental Science and Research (ESR) New Zealand using PCR and sequencing techniques revealed this to be adenovirus type 4.¹

Over the next several days she continued to improve clinically and was discharged with GP follow-up to ensure resolution of lymphadenopathy. She was stood down from work until her symptoms had completely resolved.

Discussion

Pharyngoconjunctival fever is a constellation of febrile pharyngitis, benign follicular conjunctivitis and cervical adenitis. Given its highly infectious nature and many well-described outbreaks, the recognition of its clinical features has important public health implications.

Worldwide, adenovirus is becoming increasingly prevalent and is sometimes associated with severe morbidity and mortality, particularly in those aged under 18 years.² Adenovirus can be responsible for infections arising in the respiratory tract (most commonly), gastrointestinal system, urinary tract and eyes. The clinical features of pharyngeal infection (high fever, exudative tonsillitis, leucocytosis and elevated CRP) may mimic severe bacterial infections such as those caused by Group A Streptococci.³ Occasionally adenovirus can cause pharyngoconjunctival fever, which occurs mainly in children. Pharyngoconjunctival fever can be caused by multiple subtypes of adenovirus, but adenovirus types 3 and 7 are the most common.⁴

This clinical syndrome is most frequently described in outbreaks within schools, school camps and swimming pools; an outbreak in a swimming pool in Spain in 2008 was attributed to adenovirus type 4.⁵

Pharyngoconjunctival fever outbreaks are more often reported in Australia, the US and China, particularly in the summer months.⁶ We are not aware of any literature describing an outbreak of pharyngoconjunctival fever in New Zealand. However, in line with global epidemiological trends adenovirus is also becoming more common in New Zealand with 1,802 cases reported in 2015 compared to only 842 cases in 2014.⁷ The predominant serotype isolated in 2015 was type 7 (61%), followed by type 3 (10%) and of those whose clinical details are available, the majority presented with respiratory symptoms, with 50 patients admitted to hospital (including nine requiring ICU) and two deaths.⁷

Adenovirus is highly contagious and can be transmitted via droplet, faecal-oral and contact routes. It is able to survive long periods on environmental surfaces, which increases transmission risk. Medical practices and hospitals, in particular eye outpatient clinics, should be considered as potential sources of transmission. Currently there are no approved antiviral agents for the treatment of adenovirus infections, and in this patient group treatment is supportive. However, in those with severe disease, particularly in the setting of immunocompromise, cidofovir (a nucleoside DNA polymerase inhibitor which has activity against adenovirus) may be tried.⁸ Of note, this is an unapproved medication available under Section 29 of the Medicines Act 1981.

Due to the morbidity associated with respiratory adenovirus infections in military recruits, successful live oral vaccines for adenovirus types 4 and 7 were developed and began being administered in 1971. The vaccine is currently only available to the US military after large outbreaks caused hospitalisations and fatalities.⁹

Given the potential associated morbidity and mortality, it is important to identify cases of adenoviral infection early and emphasise diligent infection prevention and control practices to reduce the transmission of this virus and the potential for an outbreak.
CLINICAL CORRESPONDENCE

Competing interests:
Nil.

Acknowledgements:
The photographs and images were used with kind permission of the patient described in this case report.

Author information:
Kate E Alfeld, Medical Registrar, Department of General Medicine, Christchurch Hospital, Christchurch; Simon C Dalton, Infectious Diseases Physician, Infectious Disease Department, Christchurch Hospital, Christchurch.

Corresponding author:
Dr Kate Alfeld, Christchurch Public Hospital, Private Bag 4710, Christchurch.
kalfeld4@hotmail.com

URL:

REFERENCES:


Primum non nocere: first do no harm

Linda Bryder

In 2010 following the publication of my book, *A History of the "Unfortunate Experiment" at National Women's Hospital*, there was an extended correspondence in the *New Zealand Medical Journal* which was drawn to a close by the editor who declared, “Any further letters published in the NZMJ on this topic must provide new insights into the issue, not just re-stating what an author previously said (or did not say)...”

Important new information has now appeared. On 27 February 2018 the *British Medical Journal* published a systematic review and meta-analysis of the clinical course of untreated cervical intraepithelial neoplasia grade 2 (CIN2) under active surveillance. The study covering 3,160 women concluded, “Active surveillance of CIN2 rather than immediate intervention is justified, especially among younger women.”

In other words, after conducting a meta-analysis and systematic review over the period 1973 to 2016, these authors support what Associate Professor Herbert Green suggested to the National Women’s Hospital Medical Committee in 1966, ie, that young women diagnosed with carcinoma in situ by cytology should be given a punch biopsy and carefully monitored rather than immediately offered radical treatment.

Green’s critics might say the new study only refers to CIN2, not CIN3 or ‘carcinoma in situ’, the focus of Green’s management. But the BMJ study points to inter-observer variability between CIN2 and CIN3 and “misclassifications of lesions” at the present time, and this would have been even more pronounced in the 1960s and 1970s with less advanced technology. A 2007 publication by the International Agency for Research on Cancer referred to the “extremely poor inter- and intra-observer reproducibility in the differentiation of carcinoma in situ from dysplasia” in those earlier decades.

Reflecting these continuing uncertainties, the WHO decided in 2014 to reclassify the dysplasias from three (CIN1- CIN3) to two groups (low grade and high grade) with the high grade group including both CIN2 and CIN3 (CIS).

Thus the findings of the researchers in the BMJ study have direct relevance to the high grade cervical dysplasias. They found that, “Despite the observed heterogeneity and even bias resulting from possible misclassification of lesions, the rates of regression were still high in young women even at the most conservative estimates.” They conclude: “The results of our analysis show higher rates of regression and lower rates of progression of histologically confirmed CIN2 lesions than previously reported, particularly in women aged less than 30. Conservative management with active surveillance, instead of immediate local excision, is therefore justified in selected women, especially if further pregnancies are considered and compliance with surveillance is likely to be high (primum non nocere). With increasing maternal age and increasing awareness that local treatment for CIN is associated with increased preterm birth and mid-trimester loss, treating only those with disease that has a true progressive potential is of utmost importance. In cases of disease that persists beyond two years, treatment is likely to be warranted.”

When Green took his proposal for conservative treatment to National Women’s Hospital Medical Committee in 1966 he specified, “If at any stage concern was felt for the safety of a patient, a cone biopsy would be performed.” As he later explained, “Clearly patients treated in this manner must be assessed and followed carefully, and if clinical, cytological or colposcopic evidence requires it, be subjected to more radical diagnosis and treatment.” The authors of the 2018 study, suggesting treatment if the disease persists beyond two years, would agree.
Professor Charlotte Paul critiqued Green’s protocol in the New Zealand Medical Journal in 1990, responding to Dr Graeme Overton’s statement that there was no group of ‘untreated’ patients at National Women’s Hospital. Paul admitted that “most of these women did eventually receive treatment”, but her concern was the absence of ‘initial’ treatment, which she and co-researchers claimed then, and in subsequent publications, caused harm. Yet, as noted, the BMJ report suggests as good practice that, “In cases of disease that persists beyond two years, treatment is likely to be warranted.” The meta-analysis also acknowledges the influence of human papillomavirus. The study comments, “The risk of progression was particularly low in women negative for high risk human papillomavirus (HrHPV) or HPV16/18.” The 2007 IARC study referred to above also made this point, stating, “In general, cervical abnormalities persist longer and progress more quickly in women who have carcinogenic HPV infections than in women who have noncarcinogenic infections or no HPV.” HPV was first identified in the 1980s and was not something that Green and colleagues could have taken into account, but the failure of the subsequent long-term follow-up studies of patients from National Women’s Hospital6 to acknowledge this possible influence is a matter for concern. The BMJ paper markedly contradicts the frequent claim that Green was a maverick and questions Judge Silvia Cartwright’s assessment that he was attempting to prove a ‘personal belief’. The new systematic review identified no fewer than 250 studies around the world between 1973 and 2016 that addressed the same questions, reporting studies in which women with histologically proved CIN2 were not treated at diagnosis, but were monitored for three or more months (follow-ups varied from 3 to 60 months). Here is convincing evidence that many health professionals around the world have long grappled with the issue that Green raised—primum non nocere.

### Competing interests:
Nil.

### Author information:
Linda Bryder, History, School of Humanities, University of Auckland, Auckland.

### Corresponding author:
Dr Linda Bryder, History, School of Humanities, University of Auckland, Auckland.

l.bryder@auckland.ac.nz

### URL:

### REFERENCES:


6. Paul C, Holloway L. No new evidence on the Cervical Cancer Study. NZMJ. 1990; 103:581–3; McCredie MRE,

High rates of respiratory symptoms and airway disease in mental health inpatients

People with severe mental illness (SMI) have a lower life expectancy due in part to a higher prevalence of cardiac and metabolic disease. Less is known of the prevalence of respiratory disease in this group.

This report is of a study designed to throw some light on this issue. Eighty-two inpatients with SMI had a structured interview and a questionnaire designed to detect respiratory disease and sleep disordered breathing. The patients recorded high rates of respiratory symptoms—wheezing 38%, dyspnoea 44% and productive cough 37%. The mean age of the subjects was 38 years and 51% were males. Fifty-two percent were tobacco smokers whereas the smoking prevalence in Australia generally is 19–21%.

The authors conclude that people with SMI have high rates of respiratory symptoms and a high incidence of chronic obstructive pulmonary disease on spirometry. Half of these had not been previously diagnosed. This study was undertaken in a tertiary centre in Queensland but it could be surmised that the findings might well apply to SMI patients everywhere.

*Internal Medicine Journal* 2018; 48:433–438

Siponimod versus placebo in secondary progressive multiple sclerosis

No treatment has consistently shown efficacy in slowing disability progression in patients with secondary progressive multiple sclerosis (SPMS). This report is of a randomised trial gauging the effect siponimod, a selective sphingosine phosphate receptor modulator, has on the progression of multiple sclerosis compared with a placebo.

Siponimod reduced the three-month risk of confirmed disability progression by 21%. The incidence of serious adverse effects was similar in both groups.

The researchers concluded that siponimod treatment reduced the risk of disability progression with a safety profile similar to other sphingosine modulators and is likely to be a useful treatment for SPMS.

*Lancet* 2018; 391:1263–73

Change in overweight from childhood to early adulthood and risk of type 2 diabetes

Childhood overweight is associated with an increased risk of type 2 diabetes in adulthood. In this study the researchers investigated whether remission of overweight before early adulthood reduces the risk.

The study involved over 60,000 Danish men whose weights and heights had been measured at 7 and 13 years of age and in early adulthood (17–26 years of age). Overweight at each of these three ages was found to be positively associated with the development of type 2 diabetes. However, men who had had a remission of overweight before the age of 13 years had a risk of having type 2 diabetes that was similar to men who had never been overweight.

It was concluded that childhood overweight at seven years of age was associated with increased risks of adult type 2 diabetes only if it continued until puberty or later ages.

I operated, a few years ago in Wellington, on Miss A. for the condition shown in the accompanying photograph No. 1. There was very marked proptosis of the right eyeball, which was also pressed downwards well below the level of the other eye. The mydriasis shown was artificially produced for purposes of ophthalmoscopic examination. Vision nil. Optic atrophy.

A rounded swelling was very apparent between the globe and the superior orbital margin.

I decided to operate by Krönlein’s method for purposes of exploration and to save the eye if possible. This was happily effected with the very satisfactory result to the lady’s appearance as shown in photograph No. 2, taken at no very long date subsequently.

The tumour, which was the size of a walnut, turned out to be a cyst filled with an oily collection of cholesterin crystals, doubtless dermoid in origin.

The operation consisted in cutting down to the bone along the outer margin of the orbit,
following its curve, for nearly half an inch each side of the external canthus; separating the periosteum and stripping it from the external orbital wall as far as possible; chiselling through the orbital margin above and below at each extremity of the wound and continuing backwards through the wall of the orbit in converging lines until they met in front of the inferior orbital fissure. The triangle of bone thus separated was then, with its external coverings, everted, giving ample access to the orbital cavity, from which, with a curved pair of medium-sized scissors and the fingers, the cyst was gradually separated from its attachments and completely removed. The loosened bone was finally pressed back into position and the wound stitched and dressed. Healing was complete in a few days and eventually the scar became hardly visible.

**Figure II.**