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<table>
<thead>
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<th>Rate</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Individuals*</td>
<td>$298</td>
<td>Individual</td>
</tr>
<tr>
<td>Institutions</td>
<td>$517</td>
<td>Institutions</td>
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<tr>
<td>Individual article</td>
<td>$25</td>
<td>Individual article</td>
</tr>
</tbody>
</table>

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EDITORIAL
6
How much can we achieve with simulation?
Ian Bissett

ARTICLES
9
Can team training make surgery safer? Lessons for national implementation of a simulation-based programme
Jennifer Weller, Ian Civil, Jane Torrie, David Cumin, Alexander Garden, Arden Corter, Alan Merry

18
The effect of removing funding restrictions for atorvastatin differed across sociodemographic groups among New Zealanders hospitalised with cardiovascular disease: a national data linkage study
Suneela Mehta, Susan Wells, Rod Jackson, Jeff Harrison, Andrew Kerr

30
Pilot study of feasibility of a randomised controlled trial of asthma risk with paracetamol versus ibuprofen use in infancy
Judith Riley, Anna Hunt, Alice McDouall, Steve Waqanivaluva, Irene Braithwaite, Mark Weatherall, Thorsten Stanley, Richard Beasley, Edwin A Mitchell, Stuart R Dalziel

43
Costs of bariatric surgery in a randomised control trial (RCT) comparing Roux en Y gastric bypass vs sleeve gastrectomy in morbidly obese diabetic patients
Siva T, Delendra Wijayanayaka, Rinki Murphy, Delwyn Armstrong, Richard Cutfield, David D Kim, Michael G Clarke, Nicholas J Evennett, Martin L Humphreys, Steven J Robinson, Michael WC Booth

53
Rapid access carotid endarterectomy: winning the RACE following a natural disaster
Manar Khashram, Rachel Falconer, Afif Mahmud, Adib Khanafer, Peter Laws, Tim Beresford, Justin Roake

61
Emergency EVAR for ruptured abdominal aortic aneurysms: New Zealand experience
Sam Taylor, Ian Thomson, Jo Krysa

67
The impact of the Hand Hygiene New Zealand programme on hand hygiene practices in New Zealand’s public hospitals
Joshua T Freeman, Louise Dawson, Deborah M Jowitt, Margo White, Hayley Callard, Christine Szieczkowski, Ron Kuriyan, Sally A Roberts

77
Where to from here? The treatment of impetigo in children as resistance to fusidic acid emerges
Alison Vogel, Diana Lennon, Emma Best, Alison Leversha

CLINICAL CORRESPONDENCE
84
Erythematous gingival lesion
Pallav Patni, Mona J Patni

87
Syringomyelic Neuropathic Arthropathy of the Elbow
Neil Stewart, Kevin Karpik

LETTER
92
The awareness and uptake of free flu vaccination offered to University of Otago staff
Matloob Husain, Andrew Gray, Richard Carlos Torr

METHUSELAH
94
Acetaminophen (paracetamol) versus ibuprofen in young children with mild persistent asthma

100 YEARS AGO
95
An interesting gynaecological case
Can team training make surgery safer? Lessons for national implementation of a simulation-based programme
Jennifer Weller, Ian Civil, Jane Torrie, David Cumin, Alexander Garden, Arden Corter, Alan Merry
Operations don’t always go as intended, and patients can occasionally suffer preventable harm. Good communication between the staff looking after patients has been identified as one factor that may reduce this harm and improve outcomes for patients. We ran a team training program for all members of the surgical team using a simulated patient and operating theatre. Analysis of follow-up interviews identified very positive changes in communication practices for many participants, and those factors that will need to be addressed in our national implementation of this program in 2017.

The effect of removing funding restrictions for atorvastatin differed across sociodemographic groups among New Zealanders hospitalised with cardiovascular disease: a national data linkage study
Suneela Mehta, Susan Wells, Rod Jackson, Jeff Harrison, Andrew Kerr
Simvastatin and atorvastatin are the two most common cholesterol-lowering medications prescribed in New Zealand to people with a history of cardiovascular disease to prevent further cardiac events like heart attacks and strokes. Publicly-funded atorvastatin required prior approval until September 2010 whereas simvastatin did not. We examined if overall statin dispensing and atorvastatin dispensing among patients hospitalised for cardiovascular disease changed by age, sex, deprivation status or ethnic group during and after special authority funding restrictions for atorvastatin. Atorvastatin prior approval requirements did not affect overall statin use during and after funding restrictions (80% in both periods). After restrictions were lifted, the proportion of statin-users dispensed atorvastatin increased around two-fold or more across all sociodemographic strata but greater increases (three–four fold) were noted among patients <55 years and for Māori, Pacific and Indian peoples.

Pilot study of feasibility of a randomised controlled trial of asthma risk with paracetamol versus ibuprofen use in infancy
Judith Riley, Anna Hunt, Alice McDouall, Steve Waqanivavalagi, Irene Braithwaite, Mark Weatherall, Thorsten Stanley, Richard Beasley, Edwin A Mitchell, Stuart R Dalziel
This pilot study assessed the likelihood of recruiting infants into a study that would randomly allocate infants to use only paracetamol or ibuprofen for fevers and pain from birth until the age of one year, and to then compare the rates of asthma between the two groups when the children turned six years old.

Costs of bariatric surgery in a randomised control trial (RCT) comparing Roux en Y gastric bypass vs sleeve gastrectomy in morbidly obese diabetic patients
Siva T Gounder, Delendra Wijayanayaka, Rinki Murphy, Delwyn Armstrong, Richard Cutfield, David D Kim, Michael G Clarke, Nicholas J Evennett, Martin L Humphreys, Steven J Robinson, Michael WC Booth
This study looks at role of bariatric surgery in obese patients with diabetes. Two types of surgery (sleeve gastrectomy and gastric bypass) were compared. Cost of provision of surgery and medication usage and cost were also examined.
Rapid access carotid endarterectomy: winning the RACE following a natural disaster
Manar Khashram, Rachel Falconer, Afif Mahmud, Adib Khanafer, Peter Laws, Tim Beresford, Justin Roake

Carotid endarterectomy needs to be performed within two weeks to provide the greatest benefit in stroke prevention. In Christchurch Hospital, after several audits conducted, a rapid access pathway was established. This was challenged during the 2011 earthquakes. However, we noted that the service remained efficient and the majority of patients underwent surgery within two to four weeks. This highlights the importance of developing pathways for common and critical conditions.

Emergency EVAR for ruptured abdominal aortic aneurysms: New Zealand experience
Sam Taylor, Ian Thomson, Jo Krysa

An endovascular aortic repair (EVAR) is a minimally invasive combined radiology/surgical procedure that has been recently introduced in New Zealand and is an alternative to the open surgical repair of a ruptured abdominal aortic aneurysm (rAAA)—a life-threatening emergency. This paper reviews the current New Zealand approach to rAAAs and shows that our rates of emergency EVARs are lower than those internationally. The length of hospital stay and combined in-hospital mortality/post-operative complication rate was significantly reduced in the New Zealand emergency EVAR group compared to the New Zealand open repair group. The recent introduction of emergency EVARs in New Zealand may represent the beginning of a shift in the management of ruptured AAAs here, although it is currently unlikely to be an option available 24/7 outside the few New Zealand centres with well-established EVAR capabilities.

The impact of the Hand Hygiene New Zealand programme on hand hygiene practices in New Zealand’s public hospitals
Joshua T Freeman, Louise Dawson, Deborah M Jowitt, Margo White, Hayley Callard, Christine Sieczkowski, Ron Kuriyan, Sally A Roberts

Performing hand hygiene is one of the most effective measures to reduce healthcare-associated infections. Every time a healthcare worker delivers care, they are at risk of transiently contaminating their hands with bacteria from the skin of the patient or from the surface of medical equipment or devices, or surfaces in the patient's bed space. When the healthcare worker provides care to another patient, they can transfer the bacteria to the patient. In vulnerable patients these bacteria can cause infection. The use of alcohol-based hand rubs between patient-care activities and following contact with the patient environment reduces the risk of this occurring. Improving hand hygiene is linked to reduced rates of healthcare-associated infections and it is an essential activity that will protect our patients.

Where to from here? The treatment of impetigo in children as resistance to fusidic acid emerges
Alison Vogel, Diana Lennon, Emma Best, Alison Leversha

Impetigo (school sores) are a very common problem especially in children. Fusidic acid is the funded topical antibiotic treatment for impetigo in New Zealand but there is substantial concern about increasing use and increasing resistance to this antibiotic. Our paper reviewed the evidence about the effectiveness of alternative treatments, especially antiseptic creams and found very little high-quality evidence. A randomised controlled trial comparing treatment with fusidic acid, treatment with hydrogen peroxide antiseptic cream and simple wound care is about to commence in Auckland and will help to provide quality new evidence to guide practice.
How much can we achieve with simulation?

Ian Bissett

The importance of good teamwork in the provision of healthcare is clear and the stakes are highest in the operating room. Although errors are more likely to occur when there is poor communication, the introduction of the surgical checklist has reduced these in both the short and longer term.1 However, evidence of the benefit of other interventions is lacking.

In this issue of NZMJ, Weller et al have provided the medium term results of a pilot intervention using Multidisciplinary Operating Room Simulation (MORSim) for team training.2 The full details of the intervention have been previously described.3 In brief, the study involved a full-day training for operating room teams; consisting of two nurses, an anaesthetist, an anaesthetic technician, a surgeon and a surgical trainee. It was ambitious, utilising a high fidelity simulation operating theatre that included not only a realistic surgical model but also a complete anaesthetic monitoring setup. The simulation functioned with real-time physiological recordings and dynamic clinical and anaesthetic changes in response to management. Twenty courses were run with general surgical operating teams from two District Hospital Boards (DHB).

This particular study was based on qualitative analysis of responses from a selection of the participants six months after the simulation. Of the 120 initial MORSim participants, 48 were interviewed to identify whether any changes in attitudes and behaviours had been retained at six months. It also sought to discover barriers to the implementation of change. This particular study did not extend to assessment of the impact on clinical outcomes.

Almost all the respondents reported that they had learned something new from MORSim and 35 reported at least one positive change in practice, particularly in information sharing and communication. A quarter of those interviewed considered that patient management had improved through better processes. Most had encountered barriers to the introduction of changes to practice. Difficulty in coordinating time management, a culture of not talking together and hierarchical behaviour all figured strongly in these barriers. Resistance to the introduction of changes by the interviewees’ colleagues was also an important impediment. Of some concern was the fact that there were fewer surgeons interviewed and among these there were fewer positive responses. None of the surgeons reported using new communication strategies despite the fact that these formed a major component of the training.

The changes identified in these medium term outcomes for MORSim are encouraging. However, they do not represent a dramatic change in behaviour. The challenge now is to find ways to break down the barriers that have limited this training’s effectiveness.

This pilot study was carried out to inform the implementation of a much wider use of the MORSim model at each DHB in New Zealand and has now been funded by the ACC. This represents a unique opportunity to demonstrate whether simulation training can improve not just operating room communication and behaviour but also patient outcomes and safety on a national scale. Such an educational intervention will be resource intensive and if this is to be effective, the lessons identified here will need to be incorporated into the future training. These lessons include the importance of:

• prioritising time together
• reducing resistance to change
• engaging surgeons
• reducing hierarchical behaviour
• measuring appropriate clinical, attitudinal and communication outcomes in the pre- and post-intervention periods.

EDITORIAL
The barriers noted to spending prioritised time together were both organisational and personal. The three separate groups involved in the operating room (nurses, anaesthetists and surgeons) tend to function in isolated communication silos. Finding a time for everyone to ‘get on the same page’ before starting an operating list was only achieved by a minority of participants. The patient checklist pauses (sign in, time out and sign out) have not translated into an atmosphere of broader information sharing. Identifying practical ways to implement a beginning of day discussion including all parties is important.

Resistance to change by those who had not participated in the training was a recurrent theme in this study. This will be partly addressed when MORSim is introduced more broadly across DHBs. There will still need to be a strategy, however, to bring on board those individuals who do not see any benefit in being part of such an activity. Demonstrating the utility of this intervention in improving clinically important endpoints will go a long way towards achieving this.

In general, we surgeons see ourselves as the leaders of the operating room teams, deciding who needs surgery and putting the patients on the lists. It would be expected that surgeons would therefore have the most to gain by improving communication and teamwork in the operating room. Despite this, none of the interviewed surgeons volunteered that they had implemented the new communication tools that had been presented. Moorthy et al performed a similar simulation training that compared expert and trainee surgeons in difficult operative situations. Interestingly, this study clearly showed greater technical and operative skills in the experts but struggled to demonstrate that they had better communication skills. We, as surgeons, need to recognise that we may not be as good at communication as we think we are! If it can be demonstrated that this is a matter of patient safety, one hopes it will stimulate us to be more engaged in the whole process.

This is closely aligned to the hierarchical nature of many OR teams. The days of the powerful, decisive, dominating surgeon functioning independently are over. Modern operating requires the close cooperation of all OR members who are each expert in their own field. The recent initiative by the RACS, ‘Let's operate with respect’, was introduced in response to the revelation of widespread discrimination, bullying and sexual harassment in surgery. This has recognised that much of what has happened in the OR has not demonstrated the mutual respect that is foundational to teamwork. Addressing this can only improve the communication and culture of work in the OR.

Finally, the countrywide introduction of MORSim requires careful assessment of communication skills, attitudes and clinical outcomes. There are now validated measures of each of these that can be implemented both before and after the roll out of MORSim nationally. We have an opportunity as a country to show that we can change communication and attitudes in OR teams and that these changes translate into better clinical outcomes for patients. If this can be achieved it will provide a model that should be transferrable internationally. Weller et al are to be applauded for taking on this challenge.

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Can team training make surgery safer? Lessons for national implementation of a simulation-based programme

Jennifer Weller, Ian Civil, Jane Torrie, David Cumin, Alexander Garden, Arden Corter, Alan Merry

ABSTRACT

AIM: Unintended patient harm is a major contributor to poor outcomes for surgical patients and often reflects failures in teamwork. To address this we developed a Multidisciplinary Operating Room Simulation (MORSim) intervention to improve teamwork in the operating room (OR) and piloted it with 20 OR teams in two of the 20 District Health Boards in New Zealand prior to national implementation. In this study, we describe the experience of those exposed to the intervention, challenges to implementing changes in clinical practice and suggestions for successful implementation of the programme at a regional or national level.

METHODS: We undertook semi-structured interviews of a stratified random sample of MORSim participants 3–6 months after they attended the course. We explored their experiences of changes in clinical practice following MORSim. Interviews were recorded, transcribed and analysed using a general inductive approach to develop themes into which interview data were coded. Interviews continued to the point of thematic saturation.

RESULTS: Interviewees described adopting into practice many of the elements of the MORSim intervention and reported positive experiences of change in communication, culture and collaboration. They described sharing MORSim concepts with colleagues and using them in teaching and orientation of new staff. Reported barriers to uptake included uninterested colleagues, limited team orientation, communication hierarchies, insufficient numbers of staff exposed to MORSim and failure to prioritise time for team information sharing such as pre-case briefings.

CONCLUSION: MORSim appears to have had lasting effects on reported attitudes and behaviours in clinical practice consistent with more effective teamwork and communication. This study adds to the accumulating body of evidence on the value of simulation-based team training and offers suggestions for implementing widespread, regular team training for OR teams.

There is increasingly strong evidence that failures in teamwork and communication in healthcare contribute significantly to unintended treatment injury and poor outcomes for patients.¹⁻³ The operating room (OR) is a high acuity, complex environment in which good communication and teamwork are essential. However, staffing patterns in the OR may predispose teams to errors in communication. The composition of the OR team varies from day to day or even over the course of any one day. There may be limited time for staff to gain an understanding of one anothers’ capabilities and establish the sense of mutual respect and trust required for open communication and effective teamwork. Opportunities for OR teams to share information about the patients, plan for the day and identify concerns may be limited by the way work is organised. OR teams are typically composed of three sub-teams (surgical, anaesthesia and nursing disciplines) with consequent differences in professional backgrounds and clinical responsibilities. These differences and established hierarchies or professional boundaries may inhibit speaking up or sharing of information,⁴ or lead to variable engagement with safety interventions such as the WHO Surgical Safety Checklist.⁵
Patient safety has advanced through the study of human error and the identification of defences to prevent repeat failures in the delivery of care but this approach tends to be retrospective and reactive. It is equally important to understand why things go right and thereby build resilience into systems, where team members constantly predict future developments, adapt to changing circumstances and enhance success in the management of patients' problems. The fundamental underpinnings of such adaptable, effective teams have been described by Salas on the basis of empirical evidence from teams across multiple industries. These underpinning mechanisms are shared mental models, mutual trust and respect, and clear communication. The evidence on surgical team training improving patient outcomes is mounting, justifying the investment of time and resources.

We have previously described the Multidisciplinary Operating Room Simulation intervention (MORSim). MORSim addresses the fundamental underpinnings of effective teamwork described by Salas by bringing whole OR teams together for a day of challenging simulated clinical cases, debriefing and intense discussion. MORSim cases involve simultaneous simulation of nursing, anaesthetic and surgical activities around shared clinical scenarios, with each group dealing with realistic challenges involving their own specialty as well as requiring interaction with the whole team. The aim of MORSim is to improve information sharing in clinical practice, convince participants of the value of effective teamwork and communication through shared simulated experiences, teach specific communication strategies to develop shared mental models and build relationships between OR staff. The ultimate goal of MORSim is to reduce treatment injury and improve outcomes for patients. An important and relatively novel feature of MORSim is the integration of surgical and anaesthesia simulators to enable realistic and challenging clinical tasks to be undertaken by all participants, including open surgical procedures and haemorrhage control. This contrasts with many simulation-based educational endeavours aiming to improve teamwork in the OR, which are either lower in fidelity or lacking in multidisciplinary participation.

We ran 10 MORSim study days for staff from each of the two sites. One anaesthetist (a specialist or senior trainee), two nurses, one anaesthetic technician, one specialist surgeon and one surgical trainee attended each study day. In total there were 120 participants over 20 study days, comprising 20 specialist anaesthetists or senior anaesthetic trainees, 20 anaesthetic technicians, 40 nurses, 20 specialist surgeons and 20 surgical trainees, split evenly between the two hospitals. End-of-day evaluation of MORSim found positive participant reactions to the intervention, self-reported evidence of learning, improved scores for teamwork and communication, and demonstrated proof of concept, feasibility and value of the intervention. In-theatre observations before and after MORSim provided some evidence of improvement in observed teamwork scores.

The Accident Compensation Corporation (ACC) is a New Zealand Crown entity responsible for administering the country's universal no-fault accidental injury scheme. The scheme provides financial compensation and support to those who have suffered personal injuries, including treatment injuries from surgery. The ACC has provided funding for MORSim to be implemented across all District Health Boards in New Zealand over the next five years.

The aim of this study was to identify factors that would inform implementation and outcomes assessment of the national programme. To this end, we identified the following main questions:

- How did MORSim participants subsequently implement changes in clinical practice?
- What challenges arose while attempting to implement these changes?
- What did participants perceive to be the requirements for change?

To address these questions, we undertook a qualitative study to interview previous MORSim participants on how they incorporated the lessons from MORSim into their clinical work place, using the “Process evaluation on quality improvement interventions” framework described by Hulscher et al.
Methods

Ethics approval was obtained from the Auckland Regional Ethics Committee (NTX/12/EXP/067) and the ethics committees of the two hospitals involved in the study.

Interviews

We invited a sample of MORSim attendees to participate in a semi-structured interview three to six months after they attended the MORSim intervention. The interview guide is provided in Appendix 1. Email invitations were sent to a randomly selected sample of anaesthetists (specialists and final year trainees) and specialist surgeons from each site, and we interviewed those who responded on a first available basis. We used convenience sampling of available nurses and anaesthetic technicians at the two sites on days identified by the local theatre co-ordinators. We did not invite surgical trainees for an interview. We planned to recruit up to 48 participants or until we reached a point of thematic saturation of the data where no new ideas were being generated in the interviews that would change the identified themes or their description.

Interviews were conducted, transcribed and analysed by one researcher (AC). A second researcher (JW) read through the transcripts and analysis to crosscheck and further refine the themes. These themes were checked for validity by another researcher (JW). The analysis followed a general inductive approach as described by Thomas.14

Results

Semi-structured interviews

In total, 48 interviews were conducted with 11 of the 20 specialist anaesthetists or final year trainees (A), 10 anaesthetic technicians of the 20 (T), 20 of the 40 nurses (N) and 7 of the 20 specialist surgeons (S) who had attended MORSim. The split between sites was even for nurses and technicians. There were five anaesthetists and three surgeons from one hospital, and six anaesthetists and four surgeons from the second hospital. Interviews were on average of approximately 30 minutes duration. The following themes were identified: changes in clinical practice, including information sharing strategies; observed changes in others’ work styles; effect on patient management/outcome; sharing learning with staff members and barriers to change in clinical practice.

Changes in clinical practice and lessons learnt

Thirty-five (out of 48=73%) interviewees (A=9, T=9, N=14, S=3) reported at least one positive change in practice. Themes of positive change included improved communication and information sharing, improved confidence, greater awareness of team members and the working environment as well as development of new skills.

Nine interviewees (19%) reported no change in practice resulting from the intervention (A=2, T=1, N=4, S=2). The main reasons given were: no clinical opportunities to try out the new learning; all processes working well already or difficulties translating learning to everyday practice. The majority of participants (n=45, 94%), even some who reported no changes in practice, reported that they learned something new from MORSim, such as the importance of and strategies for communication, the importance of teamwork and planning, and that the intervention provided an opportunity to reinforce existing skills. Some interviewees said they had learned about the importance of taking a pause to plan before engaging in challenging clinical situations. Most reported learning about other team members’ roles, competencies or times of stress.

“In terms of the Checklist, I’ve changed my attitude ... saying or highlighting things that are important or that might go wrong or change ... and definitely paying more attention ... it’s an important time to discuss things.” (A2)

“I’m able to communicate more. Like, if I feel like the patient is at risk in theatre, I’ll be able to say—‘Oh, he might get a pressure area there.’” (N3)

“... just to make sure that everybody got the chance to share information they knew... a couple of the general surgeons are trying to do it here ... it feels quite useful ... get a sense of the expectations for the day ... you can pre-plan your day.” (T3)

“Globally my awareness of ... the needs, or the things I can do to help other people on the team has probably improved.” (S2)
Eleven interviewees referred specifically to using new communication strategies (A=5, T=1, N=5) while 10 reported no change from previous practice (A=2, T=2, N=2, S=4). These strategies included the use of ‘SNAPPI’, a framework for structured call out taught during MORSim (Stop, Notify the team, provide your Assessment of the situation, suggest Priorities and Plan, Invite ideas). Interviewees also reported increased information sharing such as verbalising the procedure, speaking up to address concerns about a patient, better handover and pre-case briefing and using a common language among team members. Interviewees reported learning about the importance of sharing information to achieve a shared mental model within their team. Many said they had learned to speak up more confidently, be more explicit or clearer and more directed with their communication. A few suggested that the intervention reinforced what they already knew about communication and teamwork.

“It's something that simulation has taught me ... to try and verbalise what you're thinking so that other people can pick up on the cues or pick up on what help you need.” (A4)

Observed changes in others' work styles
Most interviewees (n=31, 65%) talking to this theme had not observed any changes in others’ work practices (A=9, T=6, N=13, S=3). However, 16 interviewees (A=4, T=4, N=7, S=1) commented on positive changes including increased rapport across the team and increased communication (listening/feedback/information sharing).

“... when I used to work with the surgeon before, they didn't really participate in the checklist or time out—but now on their own they try to explain what they are doing or just their plan, which they didn't do before. So they do their part now which is quite good.” (N10)

“... the nurse, we developed a relationship that we can follow through from that day, which was great.” (TC2)

Effect on patient management
Twelve interviewees (25%) considered patient management had improved (A=1, T=2, N=9) through improved processes. These included: better communication (better preparation and planning which reduced operative time, prevented mistakes and smoothed processes); more patient-centred care; increased vigilance; or change in patient safety procedure. Reasons volunteered for lack of effect on patient management included the need for a critical mass of MORSim participants or attendees interpreting the training as relevant only to crisis situations.

“If we can share the information beforehand, we can make sure it's not a surprise and we can get things prepared so that things run more smoothly for the patient.” (T2)

“I'm more aware of the fact that when I'm not 100% sure of what's going on or where the surgery is heading or exactly where they're at, I'm just a bit more inclined to say 'what are we doing now, where are we up to and what's going on?'” (AC2)

Sharing learning with staff members
Thirty-one interviewees (65%) reported positively on sharing learning with other staff (A=6, T=8, N=15, S=2). These reports included incorporating key messages into clinical teaching, orientation of new staff and sharing ideas with colleagues. Interviewees also reported positively on the intervention to their colleagues and reflected on their experiences with others who had attended MORSim. There were examples of role modelling new behaviours and encouraging or empowering others to communicate. Fourteen reported not sharing learning from MORSim with others.

“... talking about the importance of ... (a pre-brief) with surgeons that I work with regularly. There's a list that I do regularly where we seem to just very frequently run into problems with equipment or positioning or things like that so I have talked about that a little bit about—that if there's some way we can improve the communications before the list so we can try and prevent all these distractions from happening.” (AC5)

“When I was training new staff I was using skills that I learned from the study and kind of talk through and encourage them to be more proactive and get more involved in the teamwork.” (N6)
Barriers to change in clinical practice

Thirty-nine interviewees (81%) reported one or more barriers to change in practice (A=11, T=7, N=15, S=6). Eight reported no barriers (A=1, T=2, N=4, S=1). Many interviewees suggested that time pressures and logistics of how the work was organised made it hard to get all team members in one place at the same time to carry out prompted pauses (eg pre-surgery briefings). Others suggested that some staff at their hospitals could not see the value in concepts of teamwork and information sharing, and there was a culture of not talking about such things or socialising together. Others expressed the view that spending time on pre-surgery briefings or time-out was not considered important or useful for patient management.

The cultural and language backgrounds of some staff were also cited as barriers to the implementation of knowledge learned from the intervention. Some interviewees argued that it was unrealistic to expect staff from some cultures to have the confidence to articulate perceived problems to more senior members of staff. In fact, status hierarchies were more generally identified as a barrier to putting knowledge into practice, regardless of ethnicity.

Limited exposure of staff to the MORSim intervention was seen as a barrier to successful implementation. Sometimes there was only one person in theatre who had participated in MORSim. Some interviewees also stated that frequent changes in team structure made it difficult to develop a culture of teamwork and communication.

“Making sure that everyone stops what they’re doing and participates rather than counting and doing what they’re doing carrying on in the background ... we all think we can multitask but obviously we can’t.” (SC1)

“In a work situation ... We don’t stop, we don’t talk about things, we don’t talk about things before or after ... The barriers to implementing what I learned are the social barriers that exist in the work environment ... we don’t socialise together.” (A1)

“The study there was good but the thing is the attitudes always come from the top of the team. So all the junior ones are wanting to change but if the boss is not doing what he should be doing it is really hard. I guess if we start training all the junior ones then hopefully this culture can carry on and things will get better.” (6N)

Discussion

This study extends our prior work by showing that at least some of the positive changes in attitude and behaviour produced by MORSim, and previously demonstrated in simulated cases over the course of the MORSim training day, are reportedly maintained over time and lead to changes in clinical practice. Neily et al, who based their intervention on the principles of crew resource management, exposed teams to day-long training involving lectures, group interactions and videos. They were able to show reductions in mortality and improvement in communication and other teamwork attributes in Veterans Administration hospitals in the US. Simulation-based team training is emerging as a popular approach to team training, however, in a recent systematic review of what works in OR teamwork training, we found only one study reporting an effect. This was in the form of participant self-report of changes in the OR based on responses of 12 interviewees of whom 50% reported changes. A subsequent report on an insurer-funded multidisciplinary simulation-based OR team training intervention also reported that interviewees intended to make changes in clinical practice after the intervention.

Our study (in a different country and context) adds to the body of literature on simulation-based team training interventions. It goes beyond reporting participant intent and identifies participant reports of actual changes in practice, as well as providing insights into factors facilitating or impeding change.

It is worth summarising some of the key themes that emerged from our study, using the “Process evaluation on quality improvement interventions” framework described by Hulscher et al.

How did the target group experience the intervention and the changes?

Interviewees described adopting into practice many of the elements of the MORSim intervention and reported...
positive experiences of change in communication, culture and collaboration. Some interviewees made attempts to spread the MORSim concepts to their colleagues. Many examples were linked to the WHO Surgical Safety Checklist.

What problems arose while implementing the changes?

Time emerged as a frequent impediment to change—participants described a task-focused approach to getting the job done without time to stop for a brief or stop to share information and with limited value placed on opportunities to socialise.

Other factors limiting uptake included a lack of a culture of teamwork and collaboration, lack of leadership and hierarchical relationships. The latter may be more prominent in some ethnic groups.

What requirements for change were identified?

Making time for team-building and scheduling times for communications required commitment from hospital management and clinical colleagues. Importantly, insufficient exposure of staff to MORSim was considered a major shortcoming. Staff education needs to include knowledge of evidence on teamwork, error and patient safety, and competence in effective teamwork and communication behaviours. MORSim appears not to have had as powerful an effect on surgeons as it did on the other OR groups. For example, compared to other groups, there were generally fewer positive responses from specialist surgeons in regards to both personal changes and observed change in the OR. This may reflect a hierarchical surgical culture where communication is viewed as a one-way process from surgeons to the rest of the surgical team, or they may overrate their own teamwork.18 This may be a key group to target for engagement in MORSim implementation.

Implications from the pilot study for the national implementation of MORSim

The process evaluation framework described by Hulscher et al.13 suggests the experience of participants in a pilot study can provide important information about the factors associated with success or failure. These interviewees have identified some crucial success and failure factors that will guide our national implementation of MORSim. The interviewees' perceptions of the MORSim course indicate that it can translate into worthwhile changes in clinical practice. Opportunities for socialising over the course of a full day of MORSim training may be a factor in breaking down hierarchies and professional boundaries and should not be forgotten. Repeated reference by interviewees to the WHO Safe Surgery Checklist identifies this as an opportunity to build on an existing structure, supporting integration of MORSim with existing Health Quality and Safety Commission quality improvement interventions in Checklist administration.19 The question of ethnic differences in perceptions of team hierarchies and speaking up suggests a need to engage with leaders from diverse groups to find the most appropriate intervention.

Resistance to the intervention by interviewees' colleagues underpins the requirement for a comprehensive, multi-level engagement strategy prior to the national implementation of MORSim. Institutional and clinical leaders need to be convinced that improving teamwork and communication is important for their patients and worth the investment in time. The engagement strategy will need to incorporate evidence that is rigorous, of obvious relevance to patient care and clearly conveyed. A critical mass of OR staff need to be exposed to the intervention at each institution. A strategy where the majority of staff are exposed to MORSim suggests training needs to occur locally, and to be feasible, needs to be run by local staff. This will require building capacity within each DHB to deliver regular MORSim team training, implying the need for a national instructor training programme, provision of resources to run simulation training and ongoing monitoring to maintain the quality of MORSim training.

Strengths and Limitations

The strengths of this study include its focus on change in practice some months after the intervention, and on the relatively high proportion of MORSim participants interviewed (48 of 120 MORSim attendees: 55%, 50%, 50%, 35% of anaesthetists, anaesthetic technicians, nurses, surgeons respectively). It is possible that interviewees
may have differed in some systematic way from other MORSim participants despite our efforts to avoid this. Furthermore, interviewees may provide answers supporting their own teamwork and communication skills, or the interviewer may have introduced bias through the framing of questions. However, the interview questions were guided by a schedule and interviewees were encouraged to give honest feedback on the programme, which would remain confidential and anonymous. We therefore hoped to reduce any response bias.

The study was limited to two large city hospitals and the extent to which our findings would predict the experiences of staff from other hospitals remains to be tested. Demonstrating improved patient outcomes was beyond the scope of this study but is an area for future research. As indicated, planned future work involves a national implementation of MORSim, funded through the ACC. This will allow evaluation of the MORSim team training over a range of hospital sizes and surgical disciplines, and has the potential to show reductions in mortality and perioperative harm at a national level.

Conclusions

MORSim had lasting effects on reported attitudes and behaviours in clinical practice. These effects are consistent with more effective teamwork and communication. This study adds to the accumulating body of evidence on the value of simulation-based team training and provides some additional recommendations on how widespread implementation of regular team training for healthcare teams could be accomplished. Time and resources are needed for building, maintaining and enabling behaviours and processes that support effective communication and sharing of information in OR teams.

Ethics approval

Ethics approval was obtained from the Auckland Regional Ethics Committee (NTX/12/EXP/067) and the ethics committees of the two hospitals involved in the study.

Competing interests:

All authors report grants from Health Workforce NZ, grants from Auckland Medical Research Foundation, grants from Joint Anaesthesia Foundation Auckland, non-financial support from Kimberly-Clark, non-financial support from Smith & Nephew, non-financial support from NZ Blood, non-financial support from Covident, non-financial support from Baxter, non-financial support from Definitive Surgical Trauma Care Course (NZ), non-financial support from OBEX and non-financial support from Zimmer during the conduct of the study. Dr Alan Merry reports relationship with the Chair of Board Health Quality and Safety Commission in New Zealand.

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REFERENCES:


Appendix 1: Post-MORSim semi-structured interview guide

Thank you for participating in the simulation-based course for whole OR teams back in <month>. We’d like to follow up with some questions about the course to help evaluate its impact and how to improve it in the future. Thank you for your time.

• When did you participate in MORSim?
• What led you to participate in MORSim?
• How did you feel about the training day before and after attending?
• What is the one thing that has stuck in your mind about the training day?
• On reflection, what were the most useful things you learnt?
• Can you describe what you found out about the skills and attributes of your team members—perhaps starting with those from other professional groups—during the training day?
• Did you learn anything new about the roles, responsibilities or maybe the stressors of the other OR team members?
• Did this knowledge affect the way the team worked together?
• What would you say was the main change in your team’s behaviour which occurred over the course of the day? Did that affect the way you worked together?

Subsequent to the training day

• Have you changed some aspect of your practice or behaviour as a result of your participation in the study? Can you provide a specific example? What have been the barriers to changing your practice?
• Have you tried to share these ideas with other staff members to change their behaviour? Can you give an example? What have been the barriers to sharing the ideas?
• Do you think there has been any impact on the way any of your patients have been managed as a result of this course? Can you describe something you’ve done differently in a particular patient encounter? Can you describe any potential impact on the outcome for a patient in your care?
• Have you noticed any changes in the way others, who have attended the course, work as a result of the course?
• One of the aims of the course was to improve information sharing between team members. What strategies did you learn during the course? Have you tried these out? Do you think the course had any effect on information sharing in your clinical work? Can you give any examples?
• Are there any aspects of the course or your experiences on that day that you were concerned about?
• Is there anything that you would suggest we did differently? Or any further training strategies you would suggest?
• Finally, is there anything else about the course, or the idea of team training for operating room teams, that you would like to add?

Thank you for your time.
The effect of removing funding restrictions for atorvastatin differed across sociodemographic groups among New Zealanders hospitalised with cardiovascular disease: a national data linkage study

Suneela Mehta, Sue Wells, Rod Jackson, Jeff Harrison, Andrew Kerr

ABSTRACT

**AIM:** Publicly-funded atorvastatin required prior approval until September 2010 whereas simvastatin did not. Our aim was to examine if overall statin dispensing and atorvastatin dispensing among patients hospitalised for cardiovascular disease (CVD) differed systematically across sociodemographic groups during and after special authority criteria.

**METHOD:** National medication dispensing data were anonymously linked to patients hospitalised across New Zealand with CVD and discharged between 1/07/2009–31/12/2009 when special authority criteria applied and 1/09/2010–28/02/2011 after restrictions ceased. Statin dispensing at least once within six months post-discharge was analysed by sociodemographic characteristics.

**RESULTS:** Overall statin use was the same (80%) among patients discharged during (n=14,094) and after (n=13,274) restrictions.

With restrictions, atorvastatin dispensing was 32–33% less frequent among statin-users <45 years and ≥75 years than 65–74 year olds and 28–55% less among Māori, Pacific and Indian peoples than all others. Minimal relative differences occurred by sex or deprivation status. After restrictions were lifted, the proportion of statin-users dispensed atorvastatin increased around two-fold or more across all sociodemographic strata with three–four fold increases for patients <55 years and for Māori, Pacific and Indian peoples.

**CONCLUSION:** After funding restrictions ceased, disparities in atorvastatin dispensing appeared to reduce across age and ethnic groups among patients with CVD-related hospitalisations, but overall statin use was unchanged.

The benefit of lipid-lowering therapies in the secondary prevention of cardiovascular disease (CVD) events is unequivocal. Randomised controlled trials and meta-analyses consistently show that statin therapy reduces the five-year incidence of cardiovascular events by approximately 20% for each 1 mmol/l reduction in LDL cholesterol. Simvastatin and atorvastatin comprise the vast majority of lipid-lowering medications prescribed in New Zealand. Atorvastatin is approximately twice as potent as simvastatin. Nevertheless, both medications achieve similar LDL cholesterol reduction at doses considered to be therapeutically equivalent, and treatment with either statin is likely to be clinically beneficial. At maximum dosage,
however, atorvastatin can be used to deliver more intensive lipid-lowering therapy\textsuperscript{5,7} with a lower risk of adverse effects such as myopathy\textsuperscript{6,9} than simvastatin. High dose statin regimens are associated with reduced mortality and better non-fatal clinical outcomes compared with standard treatment\textsuperscript{10,11} particularly when initiated early after a cardiovascular event.

Simvastatin has been fully government-subsidised without restriction in New Zealand since 2002. Atorvastatin, on the other hand, required an application to the Pharmaceutical Management Agency of New Zealand (PHARMAC) for special authority approval of full funding until 1 September 2010, when this restriction was lifted and the barrier to atorvastatin access consequently reduced. Many countries and health insurers employ a similar prior approval system to manage the entry of new and expensive pharmaceuticals. The special authority criteria for funded atorvastatin in New Zealand required patients to have an estimated CVD event risk over five years of $\geq15\%$ and a prior trial of simvastatin, with either inadequate LDL reduction following two months of therapy or simvastatin intolerance\textsuperscript{12}. Specialists or primary care practitioners could complete atorvastatin applications, either electronically or on a hard copy form that was subsequently faxed or mailed. Once the application was approved by PHARMAC, a special authority number was sent back to the health professional. For patients, atorvastatin prescriptions that included a special authority number resulted in a copayment charge that was identical to the copayment required for simvastatin. The remaining costs associated with funded atorvastatin prescriptions were subsequently reclaimed by the dispensing pharmacist from the Ministry of Health.

Policies intended to ensure appropriate population-wide medication access can have unintended consequences for particular sub-populations. Vulnerable demographic groups are often most affected by barriers to accessing healthcare\textsuperscript{13,14}. To our knowledge, there are no Australasian studies and very few international analyses that have examined whether prior approval policies such as the New Zealand special authority system lead to lower statin use in some sociodemographic groups. We sought to determine if the special authority requirements for atorvastatin in New Zealand resulted in systematic differences in the use of 1) statins overall, and 2) atorvastatin alone by sociodemographic status.

**Methods**

**Study population**

We included all patients with a CVD-related admission to publicly-funded hospitals across New Zealand who were discharged between 1 July 2009 and 31 December 2009 (while atorvastatin special authority requirements applied) and from 1 September 2010 to 28 February 2011 (after cessation of funding restrictions). (See Appendix 1 for a diagrammatic timeline of key study milestones). The period spanning the last six months of 2009 was chosen to allow included patients to complete six months of follow-up before funding restrictions ended. If an individual had multiple admissions during the periods of interest, the first admission was used. The discharge and procedural codes used to identify patients with a CVD-related hospitalisation are listed in Appendix 2 (including codes for coronary heart disease, transient ischaemic attack, stroke, peripheral vascular disease and CVD-related procedures).

All patients who died as inpatients, died within six months of hospital discharge or whose data was associated with data entry errors (such as hospital discharge dates before admission dates) were excluded.

**Data sources**

National pharmaceutical claims, sociodemographic status, hospitalisation and mortality data were anonymously linked for the study population. Data linkage was carried out using an encrypted version of the National Health Index (NHI) number which uniquely identifies patients within the New Zealand health system and is available for more than 98% of the national population\textsuperscript{15}. The NHI database records patient demographic data and is administered by the New Zealand Ministry of Health along with the national hospitalisation and mortality datasets. Medication dispensing claims data were obtained from the Pharmaceutical Information Database that is jointly administered by the New Zealand Ministry.
of Health and PHARMAC, and collects data on government-subsidised medications such as simvastatin and atorvastatin dispensed by community pharmacies nationwide. From 2009 onwards, more than 95% of dispensing episodes were reliably identified by NHI numbers (S. Ross, New Zealand Ministry of Health, personal communication 2014).

**Analyses**

Included patients were followed up for six months following hospital discharge. The main outcomes of interest were dispensing of any statin (we used the combined dispensing of either simvastatin or atorvastatin as a proxy for overall statin-use in New Zealand since these two formulations account for close to 100% of statins dispensed nationwide) or atorvastatin alone, at least once within the six-month interval. A six-month follow-up period was used because, although cardiovascular medications are usually prescribed three-monthly, obtaining prescriptions and subsequently getting these dispensed does not occur exactly every 90 days.

A priori, dispensing was analysed by age, sex, deprivation status and ethnic group. Age was stratified according to 10-year intervals. The NZDep2006 Index of Deprivation (NZDep06) was used to approximate socio-economic status. The NZDep06 score is derived for small areas and combines nine variables from the 2006 New Zealand Census that reflect eight dimensions of deprivation including household income, home ownership, educational qualifications and car access. NZDep06 scores were then used to assign individuals to quintiles of deprivation according to their area of residence; people included in quintile 1 resided in the least deprived areas while quintile 5 comprised individuals residing in the most deprived locations. Ethnic groups were defined according to the New Zealand Ministry of Health’s *Ethnicity Data Protocols for the Health and Disability Sector*. Ethnic groups of interest were: Māori (Level 2 code 21), Pacific (Level 2 codes 30–37), Indian (Level 2 code 43), and Other (Level 2 codes 10–12, 40–42, 44 and 51–99). The ‘Other’ group was predominantly comprised of New Zealand Europeans.

STATA 10.0 statistical software was used for all analyses. Binomial regression modelling was undertaken to estimate the crude and adjusted relative risks, with 95% confidence intervals, of being dispensed statins overall and of being dispensed atorvastatin among statin-users for each of the sociodemographic characteristics examined. The relative increases in the proportion of statin-users dispensed atorvastatin after funding restrictions were lifted, with 95% confidence intervals, were also calculated. This was determined by dividing the proportion of statin-users dispensed atorvastatin after cessation of funding restrictions by the proportion of statin-users dispensed atorvastatin while the prior approval policy was in place for each age, sex, deprivation and ethnicity group.

**Ethics approval**

The study process was approved by the Multi-region Ethics Committee in 2010 (MEC/10/090/EXP).

**Results**

Between 1 July 2009 and 31 December 2009, 16,328 people were discharged from public hospitals following a CVD-related admission. Of these patients, 2,234 were excluded as 42 died as hospital inpatients, 2,077 died within six months of discharge and 115 people had data entry errors. From 1 September 2010 to 28 February 2011, 15,451 CVD-related hospital discharges were recorded, with subsequent exclusion of 2,177 patients due to 41 inpatient deaths, 2,019 deaths within six months of discharge and data entry errors for 117 people.

The baseline characteristics for the remaining patients discharged during the last six months of 2009 (n=14,094) and in the six months immediately following cessation of atorvastatin funding restrictions (n=13,274) are detailed in Table 1. For each discharge period, more than half the patient group were aged between 45 to 74 years, 59% were male, 15% were of Māori, Pacific or Indian ethnicity and deprivation quintiles 4 and 5 accounted for almost 50% of patients.

In each period, 80% of patients were dispensed a statin (either simvastatin or atorvastatin), but the proportion dispensed simvastatin decreased from 68% to 54% following removal of funding restrictions while the proportion dispensed atorvastatin increased from 14% to 33%. (Note: these
proportions include patients dispensed both statins so the proportions dispensed simvastatin and atorvastatin separately do not sum to 80%.

Table 2 presents the numbers and proportions of patients dispensed a statin (ie either simvastatin or atorvastatin) and adjusted RRs of statin dispensing according to age, sex, deprivation status and ethnic group, before and after atorvastatin funding restrictions ceased. Crude RRs were not presented as they were not appreciably different to the adjusted RRs.

There were minimal changes in the absolute proportion of patients dispensed a statin across the sociodemographic variables examined after funding restrictions were lifted.

In both discharge periods, people under 45 years of age were about 35% less likely

<table>
<thead>
<tr>
<th>Baseline characteristic</th>
<th>Number (%) discharged between 01/07/09–31/12/09</th>
<th>Number (%) discharged between 01/09/10–28/02/11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45</td>
<td>679 (5%)</td>
<td>657 (5%)</td>
</tr>
<tr>
<td>45–54</td>
<td>1,562 (11%)</td>
<td>1,410 (11%)</td>
</tr>
<tr>
<td>55–64</td>
<td>2,732 (19%)</td>
<td>2,603 (20%)</td>
</tr>
<tr>
<td>65–74</td>
<td>3,669 (26%)</td>
<td>3,413 (26%)</td>
</tr>
<tr>
<td>≥75</td>
<td>5,452 (39%)</td>
<td>5,191 (39%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8,296 (59%)</td>
<td>7,795 (59%)</td>
</tr>
<tr>
<td>Female</td>
<td>5,798 (41%)</td>
<td>5,479 (41%)</td>
</tr>
<tr>
<td>Deprivation quintile (assessed using NZDep06)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintile 1—NZDep 1–2</td>
<td>1,969 (14%)</td>
<td>1,905 (14%)</td>
</tr>
<tr>
<td>Quintile 2—NZDep 3–4</td>
<td>2,300 (16%)</td>
<td>2,132 (16%)</td>
</tr>
<tr>
<td>Quintile 3—NZDep 5–6</td>
<td>2,965 (21%)</td>
<td>2,747 (21%)</td>
</tr>
<tr>
<td>Quintile 4—NZDep 7–8</td>
<td>3,574 (25%)</td>
<td>3,390 (26%)</td>
</tr>
<tr>
<td>Quintile 5—NZDep 9–10</td>
<td>3,279 (23%)</td>
<td>3,080 (23%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Māori</td>
<td>1,286 (9%)</td>
<td>1,252 (9%)</td>
</tr>
<tr>
<td>Pacific</td>
<td>630 (4%)</td>
<td>575 (4%)</td>
</tr>
<tr>
<td>Indian</td>
<td>289 (2%)</td>
<td>274 (2%)</td>
</tr>
<tr>
<td>Others</td>
<td>11,889 (84%)</td>
<td>11,173 (84%)</td>
</tr>
<tr>
<td>Type of CVD event (categories are not mutually exclusive)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>8,024 (57%)</td>
<td>7,337 (55%)</td>
</tr>
<tr>
<td>Stroke or TIA</td>
<td>4,072(29%)</td>
<td>4,015 (30%)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>1,314 (9%)</td>
<td>1,230 (9%)</td>
</tr>
<tr>
<td>Cardiovascular procedure</td>
<td>3,580 (25%)</td>
<td>3,418 (26%)</td>
</tr>
<tr>
<td>Dispensed statins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simvastatin</td>
<td>9,638 (68%)</td>
<td>7,187 (54%)</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>2,007 (14%)</td>
<td>4,324 (33%)</td>
</tr>
<tr>
<td>Either simvastatin or atorvastatin</td>
<td>11,266 (80%)</td>
<td>10,631 (80%)</td>
</tr>
<tr>
<td>Both simvastatin and atorvastatin</td>
<td>379 (3%)</td>
<td>880 (7%)</td>
</tr>
<tr>
<td>Total Number with CVD</td>
<td>14,094</td>
<td>13,274</td>
</tr>
</tbody>
</table>

*Quintile data was missing for seven people during 01/07/09–31/12/09 and 20 people between 01/09/10–28/02/11; quintile 1 is least deprived and quintile 5 is most deprived.
and people 75 years or older were about 10% less likely to be dispensed a statin as compared with 65–74 year-olds, and women were 11% less likely to be dispensed statins as compared with men.

Few relative differences in statin dispensing were noted across deprivation quintiles during the two periods. Compared with the ‘Other’ group, the likelihood of being dispensed statins was similar for Māori and Pacific peoples but slightly higher for Indian patients irrespective of funding restrictions.

Table 3 presents adjusted RRs with 95% CI of statins-users being dispensed atorvastatin by sociodemographic characteristics in the two periods. During restrictions, atorvastatin dispensing was around 30% less likely among statin-users aged under 45 years and 75 years or older compared to 65–74 year-olds, and 28–55% less likely among Māori, Pacific and Indian peoples compared to the Other group. After removal of the prior approval policy, statin-users under 45 years of age were 24% more likely to be dispensed atorvastatin than 65–74 year-olds with no change in the likelihood of dispensing among elderly patients. Relative differences across ethnic groups narrowed considerably, with atorvastatin dispensing 21% and 5% less likely among Māori and Pacific statin-users respectively and 14% more likely among Indian patients compared to all others. By contrast, few relative differences by deprivation status were noted while funding restrictions applied. However, statin-users in deprivation quintiles 4 and 5 were 10–15% less likely to be dispensed atorvastatin as compared with the least deprived quintile once prior approval requirements were lifted.

Table 4 shows the proportions of statin-users dispensed atorvastatin by sociodemographic characteristics during and after atorvastatin funding restrictions applied. After prior approval requirements were lifted, the proportion of statin-users dispensed atorvastatin increased about two-fold or more across all sociodemographic strata. However, the greatest relative
### Table 3: Adjusted relative risk of statin-users being dispensed atorvastatin according to sociodemographic characteristics.

<table>
<thead>
<tr>
<th>Sociodemographic characteristics</th>
<th>Adjusted RR† (95% CI)</th>
<th>Discharge period 01/07/09–31/12/09</th>
<th>Discharge period 01/09/10–28/02/11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45</td>
<td>0.67 (0.51–0.88)</td>
<td>1.24 (1.12–1.38)</td>
<td></td>
</tr>
<tr>
<td>45–54</td>
<td>0.89 (0.78–1.03)</td>
<td>1.19 (1.12–1.28)</td>
<td></td>
</tr>
<tr>
<td>55–64</td>
<td>1.07 (0.96–1.18)</td>
<td>1.11 (1.05–1.18)</td>
<td></td>
</tr>
<tr>
<td>65–74</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>≥75</td>
<td>0.68 (0.61–0.75)</td>
<td>0.66 (0.62–0.70)</td>
<td></td>
</tr>
<tr>
<td>Sex‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.96 (0.88–1.03)</td>
<td>0.93 (0.89–0.98)</td>
<td></td>
</tr>
<tr>
<td>Deprivation quintile§</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (least deprived)</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.96 (0.83–1.09)</td>
<td>0.97 (0.90–1.05)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0.99 (0.87–1.13)</td>
<td>0.94 (0.88–1.01)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0.96 (0.84–1.09)</td>
<td>0.85 (0.79–0.91)</td>
<td></td>
</tr>
<tr>
<td>5 (most deprived)</td>
<td>0.94 (0.82–1.08)</td>
<td>0.88 (0.82–0.95)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity§</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Māori</td>
<td>0.57 (0.47–0.68)</td>
<td>0.79 (0.72–0.86)</td>
<td></td>
</tr>
<tr>
<td>Pacific</td>
<td>0.45 (0.34–0.60)</td>
<td>0.95 (0.85–1.05)</td>
<td></td>
</tr>
<tr>
<td>Indian</td>
<td>0.72 (0.53–0.96)</td>
<td>1.14 (1.02–1.28)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

†Crude relative risks were not presented as they were not appreciably different to the adjusted relative risks.

‡Relative risks by age were adjusted for sex, ethnicity and deprivation.

§Relative risks by deprivation were adjusted for age, ethnicity and deprivation.

### Table 4: Proportion of statin-users dispensed atorvastatin according to sociodemographic characteristics.

<table>
<thead>
<tr>
<th>Sociodemographic characteristics</th>
<th>Discharge period 01/07/09–31/12/09</th>
<th>Discharge period 01/09/10–28/02/11</th>
<th>Relative increase in atorvastatin-users after funding restrictions ceased (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin after funding restrictions ceased (95% CI)</td>
</tr>
<tr>
<td>&lt;45</td>
<td>47 (12%)</td>
<td>192 (53%)</td>
<td>4.4 (3.2–3.8)</td>
</tr>
<tr>
<td>45–54</td>
<td>216 (17%)</td>
<td>598 (52%)</td>
<td>3.1 (2.7–3.5)</td>
</tr>
<tr>
<td>55–64</td>
<td>501 (21%)</td>
<td>1,087 (48%)</td>
<td>2.3 (2.1–2.5)</td>
</tr>
<tr>
<td>65–74</td>
<td>651 (21%)</td>
<td>1,320 (44%)</td>
<td>2.1 (2.0–2.3)</td>
</tr>
<tr>
<td>≥75</td>
<td>592 (15%)</td>
<td>1,127 (29%)</td>
<td>2.0 (1.8–2.1)</td>
</tr>
<tr>
<td>Sex</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin after funding restrictions ceased (95% CI)</td>
</tr>
<tr>
<td>Male</td>
<td>1,299 (19%)</td>
<td>2,830 (43%)</td>
<td>2.3 (2.2–2.5)</td>
</tr>
<tr>
<td>Female</td>
<td>708 (17%)</td>
<td>1,494 (37%)</td>
<td>2.1 (2.0–2.4)</td>
</tr>
<tr>
<td>Deprivation quintile</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin after funding restrictions ceased (95% CI)</td>
</tr>
<tr>
<td>1 (least deprived)</td>
<td>300 (19%)</td>
<td>689 (45%)</td>
<td>2.3 (2.1–2.6)</td>
</tr>
<tr>
<td>2</td>
<td>340 (18%)</td>
<td>733 (43%)</td>
<td>2.3 (2.1–2.6)</td>
</tr>
<tr>
<td>3</td>
<td>441 (19%)</td>
<td>912 (41%)</td>
<td>2.2 (2.0–2.4)</td>
</tr>
<tr>
<td>4</td>
<td>509 (18%)</td>
<td>1,005 (37%)</td>
<td>2.1 (1.9–2.3)</td>
</tr>
<tr>
<td>5 (most deprived)</td>
<td>416 (16%)</td>
<td>977 (39%)</td>
<td>2.5 (2.2–2.7)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin</td>
<td>Number (%) of statin-users dispensed atorvastatin after funding restrictions ceased (95% CI)</td>
</tr>
<tr>
<td>Māori</td>
<td>114 (11%)</td>
<td>359 (36%)</td>
<td>3.2 (2.6–3.8)</td>
</tr>
<tr>
<td>Pacific</td>
<td>44 (9%)</td>
<td>204 (43%)</td>
<td>4.7 (3.5–6.4)</td>
</tr>
<tr>
<td>Indian</td>
<td>38 (14%)</td>
<td>130 (53%)</td>
<td>3.7 (2.7–5.1)</td>
</tr>
<tr>
<td>Other</td>
<td>1,811 (19%)</td>
<td>3,631 (41%)</td>
<td>2.1 (2.0–2.2)</td>
</tr>
</tbody>
</table>
increases in atorvastatin dispensing occurred among patients under 55 years of age and among Māori, Pacific and Indian patients for whom atorvastatin dispensing increased three–four fold. The relative increases presented in Table 4 are unadjusted.

**Discussion**

Overall statin use among patients with a CVD-related admission to public hospitals across New Zealand did not differ during and after atorvastatin funding restrictions (80% in both periods). Irrespective of funding restrictions, patients under 45 years appeared to be the most under-treated with statins, with slight undertreatment also noted among the elderly and women. Minimal relative differences in overall statin dispensing were apparent by deprivation status or ethnic group. While restrictions applied, lower relative rates of atorvastatin dispensing were found among young and elderly patients and Māori, Pacific and Indian peoples. The proportion of statin-users dispensed atorvastatin increased about two-fold or more across all sociodemographic strata once restrictions were lifted, but the largest increases (three–four fold) occurred in patients under 55 years and in Māori, Pacific and Indian peoples. These findings suggest that the prior approval policy created a disproportionate access barrier to atorvastatin for younger patients and high-risk ethnic groups that eased when funding restrictions ceased. However, Māori continued to be comparatively undertreated and slight under-dispensing emerged among more deprived groups.

We have conducted a nation-wide study of all publicly-funded CVD admissions during the two discharge periods of interest and more than 95% of CVD hospitalisations occur in New Zealand public hospitals. The national health databases from which all data were obtained are relatively comprehensive and almost all community dispensing of subsidised medications such as atorvastatin and simvastatin was recorded in the national pharmaceutical claims data between 2009 and 2011.

Since our analyses are based on observational data, we cannot categorically link the removal of restrictive funding criteria with the increases in atorvastatin dispensing. During the study period, however, there were no changes in national CVD management guidelines or availability of statins other than removal of the atorvastatin special authority requirements. Inclusion in our study population was based on publicly-funded hospitalisations with CVD in the two periods of interest, and therefore would be affected by clinical misdiagnosis or incorrect ICD coding of the admission.

We used dispensing of either atorvastatin or simvastatin as a proxy for overall statin use. This is a minor limitation, however, as fewer than 1% of patients are prescribed other statins in New Zealand. Lipid levels at baseline and follow-up were unavailable from the national databases and we were unable to determine whether patients experienced statin side-effects which may influence dispensing rates. We also did not differentiate between new and prior-users of statins within our study population, and we did not exclude the very small proportion of non-residents who may have left New Zealand following hospital discharge.

Few international studies have examined the effect of funding restrictions on statin use among different sociodemographic groups. Martikainen et al used nationwide prescription registry data to investigate the impact of restrictive reimbursement for expensive statins such as atorvastatin and rosuvastatin on statin use in Finland between 2002 and 2007. Similar to our findings, funding restrictions were associated with greater use of simvastatin and reduced utilisation of restricted statins but little change to overall statin consumption. However, average age and sex among new users of rosuvastatin and atorvastatin changed minimally. By contrast, we noted similar relative increases in atorvastatin dispensing among males and females but greater relative increases among younger patients as compared with other age groups after funding restrictions ceased. Our findings are not directly comparable to the Finnish study, however, as we employed a different metric for restricted-statin use (ie proportion of statin-users dispensed atorvastatin) and did not consider new statin-users separately.

Another study examined the impact of a new reimbursement policy on statin utilisation among Norwegian men and women. A prior approval policy for atorvastatin that required first-line use of simvastatin,
similar to the New Zealand special authority requirements, was introduced during 2005 in Norway. In the years before and after the new funding regulations commenced, the one-year national prevalence of statin use increased among women from 6.3% to 6.8% and from 7.5% to 8.1% among men, in contrast to our findings of little change in overall statin-use by sex as a result of atorvastatin funding restrictions.21 However, the Norwegian study included all statin-users (including those without CVD) and considered dispensing of statins at least once over a year-long period. By contrast, we used a six-month interval to consider statin dispensing among patients with CVD-related admissions to New Zealand public hospitals. The slight under-dispensing of statins to women within our study population is consistent with international studies,25–27 and may be related to increased reporting by women of statin-related myopathy28,29 and non-specific complaints that may be interpreted as statin intolerance.28,29

Our finding of reduced overall statin dispensing, irrespective of funding restrictions, to younger patients with CVD is supported by some studies30–33 but not others.34,35 Factors that may contribute to lower levels of statin therapy among younger patients include greater reluctance to commence long-term pharmacotherapy among the young, and a higher proportion (compared with older age-groups) of non-atherosclerotic pathology such as spontaneous coronary dissection where lipid-lowering therapy may not be indicated.36–37 Among statin-users within our study population, however, the greatest relative increases in atorvastatin dispensing across age groups once funding restrictions ended occurred in younger patients. Removal of the requirement to trial simvastatin first is likely to partially account for this finding; fewer young people are likely to have received statin therapy pre-hospitalisation as compared to older patients. The decision to commence first-line atorvastatin over simvastatin among younger patients may arguably be related to the perceived seriousness of a CVD diagnosis in younger age-groups, and the greater likelihood of treatment in specialist units such as coronary care facilities which are often early adopters of newer medications such as atorvastatin. We did not stratify our study population according to statin-use prior to admission, but regardless, our results indicate increased atorvastatin dispensing post-discharge among younger patients once funding restrictions ceased.

Our finding of slightly reduced overall statin use among patients 75 years and older is in keeping with other studies that have noted the influence of comorbidities, drug-drug interactions and patient wishes against treatment in this age group.32,38–41 The lower relative increase in atorvastatin dispensing after funding restrictions ended among the oldest patients in our study population may reflect prescriber concerns regarding potential side effects from a more potent medication such as atorvastatin, coupled with the current lack of a broad evidence-base for the effectiveness of high-dose lipid-lowering therapy in the elderly. Another factor is the reduced likelihood of the very elderly being treated in coronary care units where, as previously mentioned, newer pharmacotherapeutic agents such as atorvastatin are more likely to be commenced.

While funding restrictions applied, Māori, Pacific and Indian peoples (who are at high risk of CVD in New Zealand) were less likely to be dispensed atorvastatin compared to the Other group. This finding is unlikely to be related to concerns regarding side effects given the three–four fold increase in atorvastatin dispensing among these ethnic groups once funding restrictions ceased. One possibility is that Māori, Pacific and Indian patients, similar to young patients, may have been less likely to be statin users prior to hospital admission and therefore would be required to commence simvastatin while the atorvastatin prior approval policy applied. Variation in prescribing patterns across ethnic groups, which may be influenced by health-provider perceptions of patient language barriers and health literacy, may also have exacerbated the barrier created by funding restrictions.14,42,43 Once funding restrictions were lifted, however, the likelihood of being dispensed atorvastatin was similar among Pacific peoples and higher among Indian patients compared to the ‘Other’ group, but 20% less among Māori statin-users. These results are in keeping with US and UK studies that have
reported higher statin use among White and Asian groups compared to non-White/non-Asian patients.\textsuperscript{44,45} The reasons for the differences in the dispensing rates across the three high-risk ethnic groups, and particularly the lower likelihood of dispensing among Māori, warrant further investigation in light of the disproportionate burden of CVD mortality\textsuperscript{46,47} and higher case fatality\textsuperscript{48} among Māori and Pacific peoples.

Atorvastatin prior approval requirements did not result in relative underutilisation of statins overall or atorvastatin alone among patients in our study with lower socio-economic status compared to the least deprived individuals. This implies that the multiple primary health care contacts (with attendant co-payments) that would have been required to fulfil requirements for funded atorvastatin did not present significant financial barriers for deprived patients in our study population. However, slight under-dispensing of atorvastatin was noted among statin-users residing in quintiles 4 and 5 once funding restrictions were lifted. Our results are in contrast to a Danish study that reported reduced socioeconomic differences in statin use among men when a pharmaceutical prior-approval policy for Danish patients with ischaemic heart disease was replaced in 1999 with automatic reimbursement.\textsuperscript{49} However, no clear social gradient was found among Danish women with either system of prescription reimbursement. The emergence of small disparities in atorvastatin dispensing across deprivation groups in our study population once special authority criteria were removed is concerning, and the reasons for this require exploration.

In future analyses, we intend to explore lipid measures, hospitalisation rates and mortality associated with patterns of statin dispensing before and after atorvastatin funding restrictions. We also plan to examine rural and urban differences in atorvastatin dispensing following cessation of restrictions in New Zealand.

Pharmaceutical funding restrictions are a necessary cost containment measure given limited health resources, and are usually instituted after analysis of medication cost and clinical efficacy and effectiveness compared to therapeutic alternatives. Nevertheless, pharmaceutical funding bodies such as the Pharmaceutical Management Agency of New Zealand (PHARMAC) should carefully consider whether additional measures are warranted to minimise differential access across demographic sub-groups for medications subject to funding restrictions.

Firstly, provision of a user-friendly application process is essential to reduce administrative obstacles for eligible patients. Currently, special authority applications in New Zealand can be completed electronically, but some health professionals find the process unreliable and difficult to navigate, and default to using hard copy forms that must be faxed or mailed. The Pharmaceutical Management Agency of New Zealand could raise this issue with the New Zealand Ministry of Health who provide health information technology services nationally. Secondly, PHARMAC could consider whether extending routine monitoring of access to medications subject to funding restrictions is justified and administratively feasible.

In conclusion, overall statin-use was unchanged among patients with a CVD-related admission to New Zealand public hospitals following removal of funding restrictions for atorvastatin. However, special authority requirements seemed to create a disproportionate access barrier to atorvastatin for younger people and high-risk ethnic groups but disparities in atorvastatin dispensing appeared to reduce across age and ethnic groups once funding restrictions were lifted.
REFERENCES:


Pilot study of feasibility of a randomised controlled trial of asthma risk with paracetamol versus ibuprofen use in infancy

Judith Riley, Anna Hunt, Alice McDouall, Steve Waqanivavalagi, Irene Braithwaite, Mark Weatherall, Thorsten Stanley, Richard Beasley, Edwin A Mitchell, Stuart R Dalziel

ABSTRACT

AIM: To undertake a randomised controlled trial (RCT) of paracetamol versus ibuprofen use during infancy to determine if paracetamol is associated with an increased risk of developing asthma, the preferred method of recruitment needs to be determined. We assessed three different recruitment domains to determine the likely enrolment rates of newborn infants into a three-year or six-year RCT of paracetamol versus ibuprofen and the development of asthma symptoms. The proposed RCT would require 1,806 participants.

METHODS: A questionnaire was administered to a convenience sample of Auckland and Wellington based parents/guardians within three different recruitment domains: antenatal classes, postnatal wards and six-week well-child visits at primary healthcare centres.

RESULTS: Over a twelve-week period 19/586 (3.2%), 196/861 (22.8%), and 0/110 (0%) questionnaires were completed by parents/guardians of newborn infants in antenatal, postnatal and primary healthcare domains. In the postnatal recruitment domain, the likelihood of newborn infants being enrolled in the proposed RCT was rated ‘very likely’, ‘likely’ and ‘neutral’ by 15 (8%, CI 4–12%), 65 (33%, CI 26–40%) and 64 (33%, CI 25–39%) of respondents for a RCT of three years duration; and by 5 (3%, CI 1–5%), 37 (19%, CI 14–25%) and 59 (30%, CI 24–36%) of respondents respectively for a RCT of six years duration.

CONCLUSIONS: Postnatal wards are expected to be the most successful recruitment domain for the proposed RCT, likely a reflection of the face-to-face direct recruitment by researchers. It appears feasible to recruit into the proposed RCT using three large New Zealand tertiary hospitals.

Paracetamol (acetaminophen) use may be a risk factor both for the development of asthma and an increase in the severity of established asthma. Epidemiological associations between asthma and paracetamol exposure have been described in the intrauterine environment, infancy, later childhood and adult life. These associations may be confounded by indications such as respiratory tract infections, which are associated with an increased risk of asthma and a common reason for parents/guardians to use paracetamol in children. Paracetamol reduces circulating and airway glutathione levels, thereby potentiating increased oxidant-induced inflammation, either directly or by enhancing TH2 cell polarisation, hence leading to asthma.

Randomised controlled trials (RCTs) to investigate the association between paracetamol use and asthma are required in order to prove or disprove causality. There is one published RCT and one completed RCT published since the completion of this pilot study, comparing the effect of paracetamol versus ibuprofen use for fever and asthma outcomes in children with asthma. The former found that children with asthma
had a decreased risk of out-patient asthma treatment when given ibuprofen compared to paracetamol, over a four-week period.\textsuperscript{21} In contrast, the latter study, a 48-week trial in which asthmatic children, aged from one to five years, were randomised to receive either paracetamol or ibuprofen administered per parental/guardian decision, for fever and analgesia, found no difference in asthma exacerbation rates, asthma control days or albuterol use between the paracetamol and ibuprofen groups.\textsuperscript{22} There are no RCTs assessing long-term risk of asthma in children who are naïve to paracetamol or ibuprofen in early infancy.

In order to complete a RCT assessing the long-term risk of asthma in children who are naïve to paracetamol in early infancy, a number of key feasibility questions need to be answered; firstly, the suitability and acceptability of possible comparators and secondly, if recruitment into a RCT is achievable. Previously, we approached parents/guardians of infants admitted into hospital with bronchiolitis to determine the acceptability of placebo, ibuprofen or ‘restricted’ paracetamol (in accordance with World Health Organization recommendations\textsuperscript{23}) as comparators. This feasibility study established the non-acceptability of placebo and a clear preference for ibuprofen to be the comparator in future RCTs.\textsuperscript{24} Consequently we plan to undertake a RCT of paracetamol versus ibuprofen to be used (as required) exclusively from birth for fever and/or analgesia in order to determine if paracetamol use is associated with increased risk of asthma and atopic outcomes in childhood. In order to demonstrate a 25% reduction in risk of wheezing at age three years in those exposed to ibuprofen, 1,806 infants would need to be enrolled. The aim of this pilot study is to identify the most suitable recruitment domain for the proposed RCT from among antenatal classes, postnatal hospital wards or primary health care providers of the ‘six-week well-child visit’.

**Methods**

This pilot study was conducted in two New Zealand urban areas: Wellington and Auckland. Eligible participants were parents/guardians of yet-to-be-born or newborn infants, who attended antenatal classes, or were parents/guardians on a postnatal ward or parents/guardians of infants who attended a six-week well-child visit during the period 10 November 2014 to 28 February 2015 inclusive. Ethical approval was obtained from the New Zealand Southern Health and Disability Ethics Committee (HDEC 14/STH/83).

Following written informed consent, parents/guardians completed a two-part questionnaire: Part one collected demographic information of one parent and the infant; including family history of asthma, eczema and atopy. Part two investigated the likelihood of parents/guardians enrolling their infant into a proposed RCT (See Online Supplement).

**Procedures**

Antenatal domain: Study information was sent electronically to identified antenatal class coordinators in each centre where at least one class was scheduled to occur during the study period. In Wellington, permission was sought for study investigators to attend classes to promote the study and to recruit participants. Study investigators attended eight classes and spoke briefly to the whole class, answered any questions and then approached potential participants individually during break-time or after the class. Those who expressed interest, accepted a participant information sheet (PIS) and provided their contact details were followed up within three weeks. In Auckland, printed PISs and an introduction letter were provided to class coordinators who then handed these out to potential parents/guardians in 17 classes, mainly during discussions of postnatal infant care. Potential parents/guardians were invited to contact study investigators by phone or email for further information regarding participation.

Postnatal domain: Study investigators approached in-patient postnatal families in Wellington Regional Hospital (Wellington) and Middlemore Hospital (Auckland) during the hours of 9am to 4pm Monday to Friday over seven and eight weeks respectively. In Auckland, recruitment also occurred over two weekends. Potential parents/guardians were individually approached and offered study information; those deemed unsuitable...
by clinical staff were not. Numbers deemed unsuitable or who declined either the initial offer of information, or to participate, were recorded.

Six-week visit domain: Two Wellington-based primary health care providers gave out a letter containing study information to families who had a six-week well-child visit scheduled during the study period. Potential parents/guardians were invited to contact study investigators by phone or email for further information regarding participation.

Sample size and study power
As this was a pilot study to inform recruitment strategies for the proposed RCT, a formal sample size and power calculation was not undertaken prior to the study. We attempted to approach at least 100 possible parents/guardians in each domain as this was considered to give a sufficient comparison. We aimed to recruit 50 people from each of the three domains in both centres, giving a total of 300 completed questionnaires.

Statistical analysis
Primary outcome was the proportion of infants where parents/guardians indicated they would be ‘very likely’ or ‘likely’ to enroll their infant in the proposed RCT from each of the three domains studied. 95% confidence intervals were calculated using McCallum Layton Confidence Interval Calculator for Proportions.25 Secondary outcomes were the proportion of these infants, where parents/guardians indicated they likely enroll the infant into the proposed RCT: i) whose mother has current asthma; and ii) with any first degree family member (mother, father or sibling) with current asthma. Parental/guardian concerns about convenience, study length and their child’s health were estimated from the answers given in the questionnaire.

Post hoc analysis was undertaken to determine the number of infant births required, and likely feasibility, to recruit the appropriate sample size (n=1,806) for the proposed RCT from the postnatal wards, over a two and three year recruitment window, for the following three potential recruitment scenarios: ‘Best’, recruiting all who indicated they were ‘very likely’ and ‘likely’ to participate in the proposed RCT; ‘Intermediate’, recruiting all who indicated they were ‘very likely’ and 50% who indicated they were ‘likely’ to participate in the proposed RCT; and ‘Worst’, only recruiting those who indicated they were ‘very likely’ to participate in the proposed RCT. The proposed RCT was determined feasible if the number of infant births required per year was less than the total births reported for Wellington, Middlemore and Auckland City Hospitals for 2013 (the anticipated sites for the proposed RCT). Enhanced recruitment for each scenario was further explored for the following strategies; 1) 25% of those who indicated they were ‘neutral’ participating in the proposed RCT, 2) recruitment occurring in the weekends and 3) recruitment occurring in the Satellite Birthing Units associated with the three hospitals.

Results
The flow of parents/guardians through the study is shown in Figure 1. Overall, 1,557 possible parents/guardians were identified over the study duration. 584 parents/guardians were approached via intermediaries (coordinators of antenatal classes and of six-week checks) to complete the study questionnaire. 456 parents/guardians were approached in person by the researchers. Questionnaires were only completed by parents/guardians who had been approached face-to-face by researchers. In the antenatal domain, of the eligible 586 parents/guardians, 112 were approached face-to-face, of whom 19 (17%) completed the study questionnaire. In the postnatal wards, of the 861 parents/guardians, 344 were approached face-to-face, of whom 196 (57%) completed the study questionnaire. None of the parents/guardians (0/110) who received a letter at the time of their infants’ six-week well-child check responded and none were seen face-to-face by the research team.
Table 1: Characteristics of study participants who completed the questionnaire.†

<table>
<thead>
<tr>
<th></th>
<th>Wellington antenatal n=19</th>
<th>Wellington postnatal n=102</th>
<th>Auckland postnatal n=94</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent‡ mean age (SD), years</td>
<td>33±3</td>
<td>33±6</td>
<td>30±7</td>
</tr>
<tr>
<td>Median number of siblings of infant (range)</td>
<td>0 (0–1)</td>
<td>0 (0–8)</td>
<td>1(0–6)</td>
</tr>
<tr>
<td>Parent‡ gender female</td>
<td>13 (68)</td>
<td>66 (65)</td>
<td>34 (36)</td>
</tr>
<tr>
<td>Parent‡ ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>European</td>
<td>16 (84)</td>
<td>73 (72)</td>
<td>21 (22)</td>
</tr>
<tr>
<td>Māori</td>
<td>2 (12)</td>
<td>8 (8)</td>
<td>11 (12)</td>
</tr>
<tr>
<td>Pacific</td>
<td>1 (5)</td>
<td>3 (3)</td>
<td>35 (37)</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0)</td>
<td>15 (15)</td>
<td>22 (23)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td>3 (3)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>History of asthma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother of infant</td>
<td>3 (16)</td>
<td>25 (25)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Father of infant</td>
<td>8 (42)</td>
<td>19 (19)</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Any sibling of infant</td>
<td>0 (0)</td>
<td>10 (10)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>History of eczema</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother of infant</td>
<td>6 (32)</td>
<td>34 (33)</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Father of infant</td>
<td>5 (26)</td>
<td>15 (15)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Any sibling of infant</td>
<td>0 (0)</td>
<td>2 (2)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>History of hayfever</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother of infant</td>
<td>5 (26)</td>
<td>33 (32)</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Father of infant</td>
<td>8 (42)</td>
<td>37 (36)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Any sibling of infant</td>
<td>0 (0)</td>
<td>4 (4)</td>
<td>3 (3)</td>
</tr>
</tbody>
</table>

†Data are n (%) unless indicated.
‡‘Parent’ refers to the parent/guardian who answered the questionnaire.
Table 2: Total number of live births required in all participating sites according to possible recruitment strategies and likelihood of enrolment into the proposed three-year RCT.

<table>
<thead>
<tr>
<th>Recruitment strategy</th>
<th>Best recruitment†</th>
<th>Intermediate recruitment‡</th>
<th>Worst recruitment§</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base case</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>19,437</td>
<td>32,736</td>
<td>103,664</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if two years of recruitment</td>
<td>9,719</td>
<td>16,368</td>
<td>51,832</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if three years of recruitment</td>
<td>6,479</td>
<td>10,912</td>
<td>34,555</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - 25% of neutrals enroll</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>16,198</td>
<td>24,488</td>
<td>50,160</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if two years of recruitment</td>
<td>8,099</td>
<td>12,244</td>
<td>25,080</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if three years of recruitment</td>
<td>5,399</td>
<td>8,163</td>
<td>16,720</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - recruitment in weekends</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>14,473</td>
<td>24,375</td>
<td>77,187</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if two years of recruitment</td>
<td>7,236</td>
<td>12,187</td>
<td>38,594</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if three years of recruitment</td>
<td>4,824</td>
<td>8,125</td>
<td>25,729</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - recruitment from satellite hospitals</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>17,322</td>
<td>29,174</td>
<td>92,385</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if two years of recruitment</td>
<td>8,661</td>
<td>14,587</td>
<td>46,192</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if three years of recruitment</td>
<td>5,774</td>
<td>9,725</td>
<td>30,795</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - all three strategies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>11,055</td>
<td>16,714</td>
<td>34,236</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if two years of recruitment</td>
<td>5,528</td>
<td>8,357</td>
<td>17,118</td>
</tr>
<tr>
<td>- Annual number of births in participating hospitals if three years of recruitment</td>
<td>3,685</td>
<td>5,571</td>
<td>11,412</td>
</tr>
</tbody>
</table>

In 2013 there were 16,555 births in Wellington, Middlemore and Auckland City Hospitals (Data from Capital Coast, Counties Manukau and Auckland District Health Boards annual reports). The proposed paracetamol-ibuprofen randomised controlled trial is deemed feasible if the required number of births per year for the various recruitment scenarios is less than, or equal to, 16,555 (indicated in black). The proposed paracetamol-ibuprofen randomised controlled trial is deemed not feasible if the required number of births per year for the various recruitment scenarios is greater than 16,555 (indicated in bold black italic).

†Best recruitment: where all the “very likely” responders and all the “likely” responders enrol their infants.
‡Intermediate recruitment: where all the “very likely” responders and 50% of the “likely” responders enrol their infants.
§Worst recruitment: where only the “very likely” responders enrol their infants.
¶Recruitment of additional participants occurs at same rate as base rate.
<table>
<thead>
<tr>
<th>Recruitment strategy</th>
<th>Best recruitment</th>
<th>Intermediate recruitment</th>
<th>Worst recruitment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base case</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>37,023</td>
<td>66,169</td>
<td>310,993</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if two years of recruitment</td>
<td>18,512</td>
<td>33,084</td>
<td>155,497</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if three years of recruitment</td>
<td>12,341</td>
<td>22,056</td>
<td>103,664</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - 25% of neutrals enroll</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>27,400</td>
<td>40,653</td>
<td>78,732</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if two years of recruitment</td>
<td>13,700</td>
<td>20,326</td>
<td>39,366</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if three years of recruitment</td>
<td>9,133</td>
<td>13,551</td>
<td>26,244</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - recruitment in weekends</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>27,567</td>
<td>49,269</td>
<td>231,562</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if two years of recruitment</td>
<td>13,783</td>
<td>24,634</td>
<td>115,781</td>
</tr>
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<td>-Annual number of births in participating hospitals if three years of recruitment</td>
<td>9,189</td>
<td>16,423</td>
<td>77,187</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - recruitment from satellite hospitals</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>32,995</td>
<td>58,969</td>
<td>277,155</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if two years of recruitment</td>
<td>16,497</td>
<td>29,485</td>
<td>138,577</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if three years of recruitment</td>
<td>10,998</td>
<td>19,656</td>
<td>92,385</td>
</tr>
<tr>
<td><strong>Enhanced recruitment - all three strategies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births required in participating hospitals</td>
<td>18,702</td>
<td>27,747</td>
<td>53,738</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if two years of recruitment</td>
<td>9,351</td>
<td>13,874</td>
<td>26,869</td>
</tr>
<tr>
<td>-Annual number of births in participating hospitals if three years of recruitment</td>
<td>6,234</td>
<td>9,249</td>
<td>17,913</td>
</tr>
</tbody>
</table>

In 2013 there were 16,555 births in Wellington, Middlemore and Auckland City Hospitals (Data from Capital Coast, Counties Manukau and Auckland District Health Boards annual reports). The proposed paracetamol-ibuprofen randomised controlled trial is deemed feasible if the required number of births per year for the various recruitment scenarios is less than, or equal to, 16,555 (indicated in black). The proposed paracetamol-ibuprofen randomised controlled trial is deemed not feasible if the required number of births per year for the various recruitment scenarios is greater than 16,555 (indicated in bold black italic).

†Best recruitment: where all the “very likely” responders and all the “likely” responders enrol their infants.
‡Intermediate recruitment: where all the “very likely” responders and 50% of the “likely” responders enrol their infants.
§Worst recruitment: where only the “very likely” responders enrol their infants.
¶Recruitment of additional participants occurs at same rate as base rate.
Parent/guardian characteristics are shown in Table 1. Of the 215 parents/guardians who completed the questionnaire, 113 (53%) were female, with the cohort having a mean age of 32 years (SD six years) and having a median of 0 other children (range 0–8). European parents/guardians were more common in Wellington, while Pacific Island peoples were more common in Auckland. A history of personal/partner or sibling atopic disease was more common in parents/guardians recruited from Wellington.

Given the relative success of enrolment into the study by face-to-face recruitment with researchers while on the postnatal wards, we only report recruitment into the proposed RCT in this domain. Participation in a proposed RCT of three years duration was rated ‘very likely’, ‘likely’ and ‘neutral’ by 15 (8%, CI 4–12%), 65 (33%, CI 26–40%) and 64 (33%, CI 25–39%) of postnatal parents/guardians respectively. Participation in a proposed RCT of six years duration was rated ‘very likely’, ‘likely’ and ‘neutral’ by 5 (3%, CI 1–5%), 37 (19%, CI 14–25%) and 59 (30%, CI 24–36%) of postnatal parents/guardians respectively.

The proposed three-year RCT is deemed feasible for ‘Best’ and ‘Intermediate’ recruitment scenarios over a two- or three-year recruitment period from the postnatal wards of the three proposed recruitment domains (Table 2). Furthermore, the proposed three-year RCT is deemed feasible for ‘Worst’ recruitment scenario over a three-year recruitment period from the postnatal wards of the three proposed recruitment sites with enhanced recruitment strategies.

The proposed six-year RCT is deemed feasible only for the ‘Best’ recruitment scenario over a three-year period from the postnatal wards and may become feasible over two years with addition of enhanced recruitment strategies (Table 3). The proposed six-year RCT is deemed infeasible with the worst recruitment scenario regardless of any enhanced recruitment strategies.

### Potential barriers to participation

Parental/guardian concerns regarding convenience, study length and their child’s health on possible participation are shown in Table 3. Overall, the 52 parents/guardians who rated possible participation as ‘unlikely’ or ‘very unlikely’ had greater levels of being ‘concerned’ or ‘very concerned’ in terms of convenience study participation.

**Table 4: Potential barriers to participation in a randomised controlled trial of three years duration.**

<table>
<thead>
<tr>
<th>Convenience</th>
<th>Participation N (%) ‘ Likely’ and ‘Very likely’ (n=80)</th>
<th>Participation N (%) ‘Neutral’ (n=64)</th>
<th>Participation N (%) ‘Unlikely’ and ‘Very unlikely’ (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Very inconvenient’/ ‘Inconvenient’</td>
<td>8 (10)</td>
<td>13 (20)</td>
<td>26 (50)</td>
</tr>
<tr>
<td>‘Neutral’</td>
<td>26 (33)</td>
<td>35 (55)</td>
<td>17 (33)</td>
</tr>
<tr>
<td>‘No trouble’</td>
<td>46 (58)</td>
<td>16 (25)</td>
<td>9 (17)</td>
</tr>
<tr>
<td>Study length</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Very concerned’/ ‘Concerned’</td>
<td>11 (14)</td>
<td>27 (42)</td>
<td>28 (54)</td>
</tr>
<tr>
<td>‘Neutral’</td>
<td>28 (35)</td>
<td>20 (31)</td>
<td>11 (21)</td>
</tr>
<tr>
<td>‘No trouble’</td>
<td>41 (52)</td>
<td>17 (27)</td>
<td>13 (25)</td>
</tr>
<tr>
<td>Your child’s health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Very concerned’/ ‘Concerned’</td>
<td>26 (33)</td>
<td>32 (50)</td>
<td>40 (77)</td>
</tr>
<tr>
<td>‘Neutral’</td>
<td>27 (34)</td>
<td>25 (39)</td>
<td>8 (15)</td>
</tr>
<tr>
<td>‘Not concerned’</td>
<td>27 (34)</td>
<td>7 (11)</td>
<td>4 (8)</td>
</tr>
</tbody>
</table>
length, and the effect on their child’s health of participation in the study compared with the other parents/guardians (p<0.01 for all three comparisons). Of the 80 parents/guardians who rated possible participation as ‘likely’ or ‘very likely’, 26 (33%) were ‘concerned’ or ‘very concerned’ about the effect on their child’s health of participation in the proposed RCT. Narrative responses identified 17 (9%) parents/guardians wanting the choice of medication, 10 (5%) unwilling to use ibuprofen for a child under three years of age, seven (4%) likely to travel overseas within three years and six (4%) who stated a need for more information about both medications.

Secondary outcomes
Twenty-four (12%) postnatal parents/guardians had at least one first-degree relative with current asthma. Of these families, 17 (71%) and 14 (58%) responded ‘likely’ or ‘very likely’ to participate in the proposed RCT of three years and six years duration respectively. Current maternal asthma was reported in 14 (7%) parents/guardians. Of these, 11 (79%) and eight (57%) responded ‘likely’ or ‘very likely’ to participate in the proposed RCT of three years and six years duration respectively.

Discussion
This pilot study showed that the most successful recruitment domain for the proposed paracetamol-ibuprofen RCT is likely to be the postnatal wards. As the study progressed it became obvious that this recruitment strategy was superior to recruitment from antenatal classes or six-week checks, answering the primary objective of the study. Eighty (23%) of the 344 parents/guardians who were approached face-to-face in the postnatal wards indicated that they were ‘very likely’ or ‘likely’ to enroll their newborn infants into the proposed RCT of three years duration.

The comparatively high number of questionnaires answered in the postnatal wards is most likely due to accessibility of investigators, face-to-face recruiting and the ability to allow parents/guardians to answer questions and make decisions regarding participation over time. In contrast, antenatal recruiting was often limited to a single-class period for multiple parents-to-be, and the six-week well-child visit was dependent on new parents/guardians acting on written information given to them. For the proposed RCT, concentrating recruitment resources at a few postnatal locations appears to be the most efficient recruitment strategy. The postnatal domain also allows access to a population sample with broader demographics compared to antenatal classes, which tend to attract first-time parents and those in higher socio-economic groups.

Previously researchers in New Zealand have enrolled infants from both the antenatal and postnatal environments in large numbers for either long-term observational studies or short-term interventional studies in selected at-risk or pathological populations. To our knowledge, recruitment of large numbers of newborn infants from the general population into a long-term interventional study in New Zealand has not occurred. Given that the arrival of a newborn infant is a time of increased stress, it is very possible that recruitment into a long-term interventional study would not be successful. Thus this current study provides important information regarding the feasibility of undertaking the proposed RCT. Furthermore, the findings are generalisable to others who may be planning large long-term interventional studies in New Zealand infants from birth.

Accurate prediction of the real enrolment rate into RCTs is problematic. When assessing the feasibility of the proposed RCT we calculated recruitment from the 80 of the 861 potential parents/guardians identified on the postnatal wards, who indicated that they would ‘very likely’ or ‘likely’ enroll their newborn infants into the proposed RCT. These results are not generalisable to the antenatal or six-week check groups and given the low response rates from these two groups, they were excluded from possible recruitment calculations. Postnatal recruitment rates could be enhanced by strategies to encourage the ‘neutral’ group (33% of those who completed the questionnaire) to consider enrolling their infants, recruiting from satellite postnatal locations, recruiting outside of regular working hours and providing study information to all parents/guardians in the postnatal ward.

Recruitment of infants with a higher risk of developing asthma, such as those with...
a first degree relative with asthma, would increase the power of the proposed RCT. In our current study the potential recruitment rate in this sub-population (12% of population) was higher than the remainder of the sample. However, the percentage of newborn infants meeting this category would make limiting recruitment to this cohort impractical. By enrolling infants into the proposed RCT from a general population, the subsequent results would be broadly generalisable, but reassuringly still provide important information on the sub-population of those with a first-degree relative with asthma.

There are a number of limitations to this study. Firstly, all antenatal classes attended by study investigators were aimed at first-time parents/guardians. Study information was not provided to parents/guardians expecting a second or subsequent child and thus we were unable to explore antenatal recruitment in this population. Secondly, the study sample was a convenience sample and thus at risk of selection bias. However, as recruitment into the proposed RCT is likely to occur predominantly in the same working hours this is unlikely to have a significant effect. Thirdly, the current study is a pilot study and recruitment rates into the proposed RCT may not reflect parents/guardians responses to a questionnaire.

**Conclusion**

Recruitment into a large (n=1,806) long-term RCT of paracetamol versus ibuprofen is likely to be successful from postnatal wards but not from antenatal clinics and six-week well-child visits. By recruiting from postnatal wards in three large hospitals, the proposed RCT is likely to be feasible at high and intermediate recruitment rates, and at low rates with enhancement of recruitment strategies.

**Competing interests:**

Ms McDouall reports grants from Capital Coast District Health Board during the conduct of the study.

**Acknowledgements:**

We would like to thank the parents/guardians who participated in this pilot study, the staff at the maternity units at Capital and Coast District Health Board and Auckland District Health Board, the Lead Maternity Carers who invited us into their antenatal classes and the general practices that worked with us during this pilot study.

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**Corresponding author:**

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irene.braithwaite@mrinz.ac.nz

**URL:**

REFERENCES:


Appendix I: Pilot study questionnaire: infant paracetamol trial

DATE: __________ PARTICIPANT NUMBER: PIP/__________ PARTICIPANT INITIALS:__________

Recruited from: _____________________________________________

You have received a draft information sheet about a trial where your child would be
randomised (allocated by chance), to either paracetamol exclusively for their fevers, aches
and illnesses, OR to ibuprofen exclusively, at least until they reach the age of three. The
trial may be extended until your child reaches the age of six. You and your child would be
followed up three monthly by phone, and have a clinic visit at three years of age and then
(if extended), six years of age. The main outcome of the study would be to see if there is any
difference in wheezing and allergies of the children in the paracetamol group compared to
the ibuprofen group at the end of the study.

We would like to assess the likely enrolment rates into this study by asking you some
questions about how likely you would be to enrol in a study like this, and to see whether this
might change if your infant were to be enrolled until the ages of five or seven.

Demographics:

Parent / Guardian:
Date of Birth: __________ Gender: __________
Ethnicity: ____________ ____________ ____________

Child (if at ante-natal class, gender should be N/A)
Date of birth (or due date): __________ Gender: __________
Ethnicity: ____________ ____________ ____________
How many older siblings? ____________
1. **Family history of asthma / eczema / hayfever? (Family history to be obtained relative to child, not parent / guardian). Circle response(s).**
   - Mother: asthma / eczema / hayfever / unknown/none
     Age of asthma onset: _____________ Resolution: Yes / No
   - Father: asthma / eczema / hayfever / unknown/none
     Age of asthma onset: _____________ Resolution: Yes / No
   - Sibling 1: asthma / eczema / hayfever / unknown/none
     Age now: ______________ Age of asthma onset: ______________
   - Sibling 2: asthma / eczema / hayfever / unknown/none
     Age now: ______________ Age of asthma onset: ______________
   - Sibling 3: asthma / eczema / hayfever / unknown/none
     Age now: ______________ Age of asthma onset: ______________
   - Other siblings? Detail re asthma history: ____________________________________________
     __________________________________________
     __________________________________________

2. **How likely is it that you would enrol your child into a study as described in the information sheet provided to you for a period of THREE years?**

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very likely</td>
<td>Likely</td>
<td>Neutral</td>
<td>Unlikely</td>
<td>Very unlikely</td>
</tr>
</tbody>
</table>

   If ‘unlikely’ or ‘very unlikely’, what would be your main reason(s) for NOT participating?
   __________________________________________
   __________________________________________
   __________________________________________

3. **Please rate how you feel about the following aspects of the study as described in the information sheet provided to you:**

   - **Convenience of participating in a study like this**
     | 1 | 2 | 3 | 4 |
     |---|---|---|---|
     | Very inconvenient | Inconvenient | Neutral | No trouble |
     - **Study length**
     | 1 | 2 | 3 | 4 |
     |---|---|---|---|
     | Very concerned | Concerned | Neutral | Not concerned |
     - **Your child's health**
     | 1 | 2 | 3 | 4 |
     |---|---|---|---|
     | Very concerned | Concerned | Neutral | Not concerned |
4. How likely is it that you would enrol your child into a study as described in the information sheet provided to you for a period of SIX years?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very likely</td>
<td>Likely</td>
<td>Neutral</td>
<td>Unlikely</td>
<td>Very unlikely</td>
</tr>
</tbody>
</table>

If ‘unlikely’ or ‘very unlikely’, what would be your main reason(s) for NOT participating?
________________________________________________________________________________________________
________________________________________________________________________________________________
________________________________________________________________________________________________

Thank you for taking the time to complete this questionnaire.
Costs of bariatric surgery in a randomised control trial (RCT) comparing Roux en Y gastric bypass vs sleeve gastrectomy in morbidly obese diabetic patients

Siva T Gounder, Delendra Wijayanayaka, Rinki Murphy, Delwyn Armstrong, Richard Cutfield, David D Kim, Michael G Clarke, Nicholas J Evennett, Martin L Humphreys, Steven J Robinson, Michael WC Booth

ABSTRACT

AIM: To provide a longitudinal analysis of the direct healthcare costs of providing laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) surgery service in the context of a randomised control trial (RCT) of obese patients with type 2 diabetes in Waitemata District Health Board, Auckland, New Zealand.

METHODS: The Waitemata District Health Board costing system was used to calculate costs in New Zealand Dollars (NZD) associated with all pre- and post-operative hospital clinic visits, peri-operative care, hospitalisations and medication costs up to one year after bariatric surgery. Healthcare costs of medications, laboratory investigations and hospital clinic visits for one year prior to enrolment into the RCT were also calculated.

RESULTS: One hundred and fourteen patients were randomised to undergo laparoscopic sleeve gastrectomy (LSG, n=58) or laparoscopic Roux en Y gastric bypass (LRYGB, n=56). Total costs one year pre-enrolment was $203,926 for all patients (mean $1,789 per patient). Total cost of surgery was $1,208,005 (mean $9,131 per LSG patient and mean $12,456 per LRYGB patient). Total cost one year post-operatively was $542,656 (mean $4,760 per patient). The total medication cost reduced from $118,993.72 (mean $1,044 per patient) to $31,304.93 (mean $274.60 per patient), p<0.005. The largest cost reduction was seen with annual diabetic medications reducing from $110,115.78 (mean $965.93 per patient) to $7,237.85 (mean $63.48 per patient), p<0.005.

CONCLUSIONS: Among patients with type 2 diabetes and morbid obesity undergoing LSG and LRYGB, health service costs were greater in the year after surgery than in the year before, although prescription costs were lower post-operatively. There was no significant difference in reduction in prescription cost by surgical procedure at 12 months. However, the LRYGB surgery was more expensive than LSG, primarily because of the longer operative time required.

The obesity has been classified as a disease by WHO. According to 2012 data, 40% of adolescents in New Zealand were either overweight or obese and this rate was third highest among OECD (Organisation for Economic Cooperation and Development) countries. Obesity increases the risk of metabolic comorbidities such as diabetes mellitus, obstructive sleep apnoea, hypertension, hyperlipidaemia, gout and malignancy, with anticipated negative impact on quality of life and life expectancy.

Lifestyle interventions for obesity have been shown to be unsustainable in the longer term and therefore have limited role in long term management of hyperglycaemia in type 2 diabetes. Pharmacologic therapy for obesity is similarly limited by...
long-term efficacy and has issues with cost and availability particularly in the New Zealand setting. On the other hand, bariatric surgery has been shown to result in substantial weight loss that is maintained long term, and to provide up to 95% resolution of type 2 diabetes in morbidly obese patients. There are also significant improvements in other diseases such as hypertension, obstructive sleep apnoea and hyperlipidemia. Studies have also shown improved survival and quality of life after bariatric surgery.

There are also significant improvements in other diseases such as hypertension, obstructive sleep apnoea and hyperlipidemia. Studies have also shown improved survival and quality of life after bariatric surgery.

Medication costs of patients before and after surgery have been shown to decrease for most obesity related diseases. Some patients come off medication completely. There is however an additional cost associated with recommended vitamins and other supplements to be taken long term.

Bariatric surgery has been shown to be relatively safe with less than 5% major complications and less than 0.5% mortality rate. This makes it comparable to the risk profile of a cholecystectomy when performed by experienced surgeons. Various surgery types are available and are catered to patient suitability and local expertise. Laparoscopic adjustable gastric banding is reducing in frequency because of high failure rates, increased long-term complications and inferior weight-loss compared to stapling procedures such as LSG and LRYGB. LSG is increasingly being performed worldwide. LRYGB is sometimes referred to as the gold standard bariatric operation and has been performed for the past few decades with consistent results.

The comparative costs of these surgery types LSG and LRYGB have not been studied in New Zealand.

Method

This study looks at the costs of providing bariatric surgery at North Shore Hospital, Waitemata District Health Board, Auckland. This is in the context of a randomised controlled trial comparing LSG and LRYGB for the treatment of type 2 diabetes and obesity. Enrolment into the study concluded in October 2014 with 114 patients. Costs were calculated by the Waitemata District Health Board costing system and drug costs were estimated from Monthly Index of Medical Specialties (MIMS).

The costs incurred were collected and divided into the year prior to enrolment to the bariatric surgery program and one year after surgery. Every patient encounter with the Health Board was calculated using the in-house costing system which follows national costing standards. Costs were divided into bariatric surgery costs and all other department costs. This included outpatient (Figure 1) as well as inpatient costs (Figure 2). The bariatric surgery costs included every encounter with the bariatric service including consultant, dietitian, nurse specialist visits and all investigations ordered. Diabetes physician costs were included in “Other” costs.

Post-operative costs included all visits to the hospital and any subsequent related inpatient stays. This included bariatric surgery unit costs as well as any other clinical care in hospital. Treatment costs for complications were included. Post-operative clinical follow-up was standardised to one week, six weeks, three monthly to 12 months, 18 months, two years then annually until five years. Patients saw diabetes physicians annually. A standard protocol for metabolic medication adjustment was used after bariatric surgery to optimise management of metabolic comorbidities.

Non-attendance at clinic has no cost assigned although there is an undoubted lost opportunity cost together with an overhead of clerical, nursing and medical time. However, these costs are distributed across all actual bariatric surgery attendances. As the non-attendance rate for bariatric surgery is similar to that of all general surgical outpatient attendances, the non-attendance cost distribution is fair.

Medications used in the year post-surgery were recorded from prospective data collection and viewing prescriptions through the clinical information portal Concord. Costs of each medication were obtained from MIMS to calculate the total medication cost per year for each patient.
Results

There were 114 patients including 59 females. The mean BMI was 43kg/m2 and mean age was 46 years. Fifty-eight patients underwent laparoscopic sleeve gastrectomy (LSG) and 56 laparoscopic Roux en Y Gastric Bypass (LRYGB) (Table 1).

The total cost of bariatric surgery admission for all patients was $1,208,005. The pre-operative and post-operative bariatric surgery costs were $142,445 and $353,986 respectively (Figures 1–3).

The mean operation costs for LSG and LRYGB were $9,131 and $12,456 respectively. The costs were increased with

| Table 1: Patient characteristics. |

<table>
<thead>
<tr>
<th>Baseline characteristics of patients</th>
<th>LRYGB (n=56)</th>
<th>LSG (n=58)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – yr</td>
<td>46.6±6.7</td>
<td>45.5±6.4</td>
<td>0.39</td>
</tr>
<tr>
<td>Female sex – no. (%)</td>
<td>33 (59)</td>
<td>26 (45)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity – no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>42 (75)</td>
<td>44 (76)</td>
<td></td>
</tr>
<tr>
<td>Maori</td>
<td>9 (16)</td>
<td>10 (17)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (9)</td>
<td>4 (7)</td>
<td></td>
</tr>
<tr>
<td>Duration of diabetes – no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;5 years</td>
<td>23</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>5–10 years</td>
<td>14</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>19</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Use of insulin – no. (%)</td>
<td>17 (30)</td>
<td>16 (28)</td>
<td>0.92</td>
</tr>
<tr>
<td>Body weight – kg</td>
<td>123.4±6.7</td>
<td>126.5±6.4</td>
<td></td>
</tr>
<tr>
<td>Body mass index (kg/m2) – no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35–44.9</td>
<td>42 (75)</td>
<td>42 (72)</td>
<td></td>
</tr>
<tr>
<td>45–54.9</td>
<td>12 (21)</td>
<td>14 (24)</td>
<td></td>
</tr>
<tr>
<td>55–65</td>
<td>2 (4)</td>
<td>2 (3)</td>
<td></td>
</tr>
<tr>
<td>Waist circumference - cm</td>
<td>133.7±24.5</td>
<td>132.7±19.6</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1: Outpatient costing basis.

<table>
<thead>
<tr>
<th>Cost group</th>
<th>Mean unit cost in sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist first consult</td>
<td>Gen Surg consultant per First Specialist Assessment: $220</td>
</tr>
<tr>
<td>Specialist follow-up consult</td>
<td>Gen Surg consultant per follow-up: $134</td>
</tr>
<tr>
<td>Clinical nurse specialist visit</td>
<td>Cost per visit: $121</td>
</tr>
<tr>
<td>Dietitian clinic visit</td>
<td>Cost per visit: $48</td>
</tr>
</tbody>
</table>
Figure 2: Perioperative costing basis.

<table>
<thead>
<tr>
<th>Cost group</th>
<th>Cost allocation basis</th>
<th>Unit cost in sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon</td>
<td>Total surgeon cost split between theatre, inpatient days and outpatient events, then allocated between theatre events based on minutes in theatre</td>
<td>Surgeon per minute: $10.25</td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>Total anaesthetist cost first split between theatre and pre-admit clinic events, then allocated between theatre events based on minutes in theatre</td>
<td>Anaesthetist per minute: $11.10</td>
</tr>
<tr>
<td>Theatre</td>
<td>Includes nursing, anaesthetic technicians, implant and theatre consumable costs, then allocated between theatre events based on minutes in theatre</td>
<td>Theatre per minute: $19.79</td>
</tr>
<tr>
<td>Ward doctor</td>
<td>Total general surgery doctor cost first split between theatre, inpatient days and outpatient events, then allocated to inpatient bed days evenly</td>
<td>Per bed day doctor cost: $166</td>
</tr>
<tr>
<td>Ward</td>
<td>Cost of nursing, ward consumables and admin costs shared between patients based on number of inpatient bed days</td>
<td>Ward bed day cost: $378</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Pharmacist costs spread based on inpatient bed days plus individual medication costs</td>
<td>Pharmacy bed day cost: $37.78</td>
</tr>
<tr>
<td>Other</td>
<td>Radiology, laboratory, surgical pathology, diabetes specialist follow-up allied health and other</td>
<td></td>
</tr>
</tbody>
</table>

Figure 3: Total costs incurred by the bariatric patients in the study.

Total costs for all bariatric patients
12 months pre-enrolment to 12 mths post-surgery
(n=114)
RYGB in keeping with increased theatre time required to perform this procedure compared to LSG (230 minutes vs 147 minutes). There was no significant difference in length of stay (Figure 4).

Nineteen patients had adverse events ranging from one leak, two stenosis, one upper gastrointestinal bleed, one marginal ulcer and one wound infection. There was no mortality. Mean cost for patients with complications at one year was $19,568 compared to $12,602 for those without (Figure 4).

Medication usage reduced as obesity-related diseases decreased; compared to 90% of patients being on diabetic medication prior to surgery, only 13% were still taking medication at one year. The per annum cost of diabetic medications for these patients dropped from $110,115 to $7,237 at one year. Decreases were also seen with other medications (Figures 6–8).

At 12 months, mean percentage weight-loss was significantly greater following LRYGB compared with LSG (-32.2±7.7% and -27.0±7.5%). Changes in BMI and weight were also greater after LRYGB. The percentage excess weight loss was superior following LRYGB vs LSG at 84% vs 70% respectively (p<0.01).

Comparing LSG vs LRYGB, 91% vs 89% of patients required pharmacological therapy...
for their diabetes at baseline and 16% vs 10% (not significant) required pharmacological therapy at 12 months.

**Discussion**

The economic burden of obesity is increasing worldwide. It has direct costs to healthcare caused by treating obesity related disease as well as indirect costs such as loss of work productivity due to sick leave, disability benefits and loss of years of productive lives due to obesity-related premature mortality.\(^ {19,20}\) The OECD Update 2014 has listed New Zealand as having the third-highest obesity rates in the world among member states.\(^ {21}\) A study by Lal et al\(^ {22}\) showed that New Zealand healthcare costs attributable to obesity...
were estimated to be NZ$686m or 4.5% of New Zealand’s total healthcare expenditure in 2006. The combined costs of healthcare and lost productivity using Human Capital approach were $911 million dollars in 2006. In addition to increased healthcare costs compared to normal weight patients, obese patients have reduced life expectancy as well. In this study, we looked at the direct healthcare costs involved in providing bariatric surgery in a public hospital. The patients were participants of a randomised control trial and had a defined schedule of follow-up in clinics with robust data collection. The mean cost of bariatric surgery in our hospital is $12,602. The pre-operative costs coming up to $1,249 per patient and post-operative cost at one year being $3,105 per patient. This is less expensive compared to other countries such as the US where the cost of surgery alone is approximately USD$25,000. Czernichow et al has demonstrated that the initial cost and immediate post-op costs of bariatric surgery patients tend to increase compared to a non-surgical cohort. However, it is surmised that cost savings will occur in the longer term.

Cremiux et al showed that that it takes up to four years for the long-term healthcare cost savings to be realized. Cost-effectiveness of bariatric surgery is well established. Keating et al showed surgical therapy patients gained a mean 9.4 additional years in diabetes remission, 1.6 additional life-years (undiscounted) and 1.2 discounted QALYs. The Swedish Obesity Study has demonstrated improved life expectancy and reduced cancer incidence in obese patients undergoing bariatric surgery.

In this study we found a decrease in medication usage for obesity related diseases. This was observed immediately after surgery. Diabetes medication usage showing a dramatic decrease from $110,115 to $7,237 at one year and reduction of patients on diabetic medication from 90% to 13% at one year. The long-term remission rates of diabetes as well as prevention of diabetes are the main objectives of the RCT. It will be important to monitor the long-term durability of these procedures as well as costs incurred. The primary endpoint of this RCT is glycaemic control at five years. It is our intention to monitor the ongoing costs in the interim of these patients. There is increasing pressure to provide more bariatric surgery in the public hospital sector in New Zealand. It is important that we continue to monitor the costs and benefits of such programs.

There are limitations of this study. There was no medical arm in this RCT, therefore we did not have a randomised control group of patients to compare with. This was considered in the early design phase of the trial but it was felt that recruitment would

**Figure 8:** Mean annual medication cost per patient.
be difficult. To date all studies demonstrates medically treated obesity to be inferior to bariatric surgery.

However, operative costs are significant. Diligent clinical follow-up adds to these costs but benefits are already being seen in medication reductions, diabetes remission and improved quality of life (unpublished data).

Clinical workup and follow-up encounters are similar to our non-trial bariatric patients (apart from appointments with diabetes physicians), therefore although these patients are within the context of a randomised controlled trial, cost estimates are comparable to our routine non-trial follow-up patients.

Procedure costs are higher for LRYGB than LSG and may be a factor in determining which operation may be preferable given the skill mix of the surgical team, the hospital budget and numbers performed.

However, longer term follow-up assesses the durability of these procedures and will aid surgeons and hospitals in performing appropriate and cost-effective surgery.

**Conclusion**

Bariatric surgery provides a definitive treatment option for obesity and related illnesses. The cost of providing this service is comparatively less expensive in New Zealand compared to other countries. This study confirms the initial beneficial effects observed with remission of diabetes and reduced medication usage. At 12 months LRYGB costs more than LSG mainly due to longer operating time and associated costs. However, greater weight loss is seen with LRYGB; despite this, glycaemic control is similar. Long-term follow-up and further reporting of ongoing costs and outcomes will be required to assess the durability and cost-effectiveness of these procedures.

**Competing interests:**
Nil.

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Rapid access carotid endarterectomy: winning the RACE following a natural disaster

Manar Khashram, Rachel Falconer, Afif Mahmud, Adib Khanafar, Peter Laws, Tim Beresford, Justin Roake

ABSTRACT

AIMS: Rapid access carotid endarterectomy (RACE) is the gold standard for stroke prevention in symptomatic patients with 50–99% internal carotid artery stenosis. Diagnosis and referral of eligible patients may be delayed by disruption to local health services. The aim of this study was to evaluate whether service provision was maintained at an appropriate standard (<2 weeks) following a natural disaster.

METHODS: Consecutive symptomatic patients who underwent carotid endarterectomy (CEA) at a tertiary hospital between January 2006 and December 2014 were identified. The timeline from initial presentation to carotid imaging, vascular review and surgery was mapped. The post-earthquake period was defined between 22nd of February 2011 until July 2012.

RESULTS: Of the 404 patients that underwent CEA during the above period, 62 patients presented during the post-earthquake period and these patients comprised the primary study group. The median time between presentation and CEA was nine days. In all, 47 patients had CEA within two weeks from the index event. The number of CEA procedures doubled since 2009.

CONCLUSIONS: Despite many challenges following a major natural disaster, delivery of RACE has been maintained at an acceptable standard. Some delays persist and these remain areas for improvement in future.

Carotid endarterectomy (CEA) is a well-established and effective procedure for secondary stroke prevention in patients with symptomatic (>50–99%) internal carotid artery (ICA) stenosis. Meta-analysis of randomised controlled trials demonstrated that early carotid endarterectomy provided the greatest risk reduction. The Carotid Endarterectomy Trialists Collaboration (CETC) summarised the data from these studies and showed that this benefit rapidly diminished with increasing delay to CEA, such that at 12 weeks, CEA conferred no additional benefit over medical therapy alone in patients with lower grade stenosis (50–69%). The degree of risk reduction was also less in patients with higher grade stenosis (>70%) after 12 weeks. In response to these findings, Naylor proposed that rapid access carotid endarterectomy (RACE) should be introduced with the target of performing CEA in symptomatic patients within two weeks from the index event. This has subsequently been ratified into international guidelines.

In 2008 Christchurch Hospital instituted a RACE pathway following a clinical audit, to facilitate prompt referral of symptomatic patients eligible for CEA to the Vascular Department. Results from an audit of this pathway showed that this significantly reduced the time from presentation to CEA by 51 days. All patients with a transient ischaemic attack or stroke, regardless of their ABCD2 score, were recommended to have urgent carotid imaging with a carotid ultrasound (US) and those with >50% stenosis were referred for a vascular surgery opinion.

However, delivery of this service has been challenging, particularly in the context of the 2011 earthquakes, which caused considerable disruption to the local health services and the city’s infrastructure. The earthquake registered 6.3 on the Richter scale, centred 10km south east of the city and was the most...
destructive earthquake in New Zealand in the last 80 years. There were 185 deaths and a state of emergency was declared for two months. Many buildings sustained significant damage, necessitating the relocation of multiple GP practices as well as several inpatient medical wards and the stroke unit from Christchurch Hospital to other temporary sites. Moreover, an estimated 8,900 people left the city, leading to staff shortages across all hospital departments.

The aims of this study were to assess whether the delivery of RACE to patients with symptomatic ICA stenosis was being delivered during the logistical difficulties which arose in the aftermath of the earthquakes and to compare this period to when the RACE program was first initiated in 2008.

Methods

All symptomatic patients who underwent CEA in Christchurch Hospital between January 2006 and December 2014 were retrospectively identified from the Vascular Department database. The patient list was corroborated with the total number of CEAs recorded for each year from the Australasian Vascular Audit (AVA), surgeons operating logbooks and from a search of the hospital coding system using the International Classification of Diseases Code 33500 [carotid endarterectomy]. Patient demographics, carotid imaging, operation notes and discharge letters were accessed via the hospital's online patient clinical information portal. The index event was defined when the patient first developed ischaemic symptoms. A timeline from symptom to surgery were mapped. Secondary information on co-morbidities, the specialties involved in the diagnostic process and post-operative complications was also documented. Prior to any procedure the diagnosis of TIA/stroke was confirmed by a neurologist or physician with an interest in TIA/stroke management. All extracted data was reviewed by a second author (MK). The post-earthquake period was defined between 22nd of February 2011 until July 2012, as this was the phase that the health services were mostly affected by the natural disaster. Since this was a retrospective clinical audit and low risk of harm, ethical review was not required.

Table 1: Patient demographics, presenting symptoms and co-morbidities of the post earthquake period (n=62).

<table>
<thead>
<tr>
<th>Patients</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; 65</td>
<td>16 (25.8)</td>
</tr>
<tr>
<td>65–74</td>
<td>14 (22.6)</td>
</tr>
<tr>
<td>≥ 75</td>
<td>32 (51.6)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>37 (59.7)</td>
</tr>
<tr>
<td><strong>Origin</strong></td>
<td></td>
</tr>
<tr>
<td>Christchurch</td>
<td>48 (77.4)</td>
</tr>
<tr>
<td>Rural</td>
<td>14 (22.6)</td>
</tr>
<tr>
<td><strong>Type of event</strong></td>
<td></td>
</tr>
<tr>
<td>TIA</td>
<td>53 (85.5)</td>
</tr>
<tr>
<td>Stroke</td>
<td>9 (14.5)</td>
</tr>
<tr>
<td><strong>Presenting symptoms/signs</strong></td>
<td></td>
</tr>
<tr>
<td>Unilateral limb weakness</td>
<td>32 (51.6)</td>
</tr>
<tr>
<td>Unilateral sensory dysfunction</td>
<td>10 (16.1)</td>
</tr>
<tr>
<td>Dysphasia</td>
<td>20 (32.3)</td>
</tr>
<tr>
<td>Dysarthria</td>
<td>7 (11.3)</td>
</tr>
<tr>
<td>Visual deficits</td>
<td>16 (25.8)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (6.5)</td>
</tr>
<tr>
<td><strong>Co-morbidities</strong></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>37 (59.7)</td>
</tr>
<tr>
<td>IHD</td>
<td>15 (24.2)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>14 (22.6)</td>
</tr>
<tr>
<td>Hyperlipidaemia</td>
<td>21 (33.9)</td>
</tr>
<tr>
<td>Previous stroke/TIA</td>
<td>22 (35.5)</td>
</tr>
<tr>
<td><strong>Smoking status</strong></td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>10 (16.1)</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>38 (61.3)</td>
</tr>
<tr>
<td>Never smoked</td>
<td>14 (22.6)</td>
</tr>
</tbody>
</table>

Statistical analysis

Continuous variables were presented as median (range) and categorical variables were presented as counts and as percentages. Non-parametric Mann-Whitney test was used to test differences between the post-earthquake period and the index year (2008) of the RACE program. P-value was set at <0.05 and statistical analysis was performed using SAS version 9.3.
Results

There were 404 patients with symptomatic carotid stenosis that underwent CEA during January 2006 and December 2014. Of these, 62 patients underwent CEA in the post-earthquake period. The median (range) age was 75 (44–89) years and 37 (60%) males. These patient group demographics, presenting symptoms and co-morbidities are presented in Table 1. Referrals to the vascular department were from six specialties following diagnosis of TIA or stroke and of these, general medicine was the most common referral source (48%).

The median (range) duration from onset of symptoms to surgery was 9 (3–133) days. The median times from symptoms to presentation, to carotid imaging and to vascular review were 0, 3.5 and 6 days respectively. There were 47 patients (76%) who had surgery within two weeks from the index event, with a further seven patients (11%) undergoing CEA within four weeks. Only eight patients (13%) had surgery after one month. The median time from vascular review to surgery was two days. The median times from presentation to carotid imaging, to vascular review and to surgery by referring specialty are presented in Figure 1. Compared to 2008, the average wait to CEA decreased by 23 days (P<0.001) and during 2014–2015, the proportion of patients undergoing CEA within 2 weeks and >4 weeks was 70% and 4%, respectively.

Figure 1: Time from presentation to imaging, to review and to surgery in 2008 and 2011–2012 (diamond shape = mean values and lines on box plots = maximum and minimum values).
Table 2: Cumulative times from presentation to USS, vascular review and CEA between initiating the RACE program (n=26) and the post-earthquake period (n=62).

<table>
<thead>
<tr>
<th>Event</th>
<th>Median (Q1, Q3)</th>
<th>Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2008</td>
<td>2011–2012</td>
<td></td>
</tr>
<tr>
<td>Presentation—USS</td>
<td>6 (3, 22)</td>
<td>3.5 (1, 7)</td>
<td>14.7 (18.3)</td>
</tr>
<tr>
<td>Presentation—review</td>
<td>13 (5, 46)</td>
<td>6 (3, 12)</td>
<td>31.0 (36.3)</td>
</tr>
<tr>
<td>Review—CEA</td>
<td>13.5 (5, 28)</td>
<td>2 (1, 6)</td>
<td>20.5 (21.8)</td>
</tr>
<tr>
<td>Presentation—CEA</td>
<td>32 (17, 78)</td>
<td>9 (6, 14)</td>
<td>51.5 (48.1)</td>
</tr>
</tbody>
</table>

(Q1: 25%, Q3:75%, SD: standard deviation).

There was significant improvement in each part of the patients’ journey during the post-earthquake phase compared to the first year when RACE was initiated at the hospital in 2008 (Figure 2). The comparative cumulative times, confidence intervals and significant levels are shown in Table 2.

Between 2006 and 2014 the overall annual numbers of CEA performed for symptomatic carotid disease has also increased. There was a notable doubling in the number of procedures performed since the development of the RACE programme, which has been consistently maintained since 2009 (Figure 3).
Discussion

Urgent management of strokes and TIA remain a public health concern, requiring a multidisciplinary team and a robust system to ensure adequate delivery of health care. When challenged with a major natural disaster such as an earthquake, the default would be to rationalise established treatment pathways. In this study, we observed since the RACE pathway had already been established, delivering procedures in an effective manner continued in our centre.

In this clinical audit we have documented that the majority of patients with symptomatic ICA stenosis eligible for surgery underwent CEA within two weeks, despite the devastating effects of a major natural disaster. A recent study from a vascular unit of similar size in the UK showed that 78% patients had surgery within 14 days from presentation and 90% within 14 days from vascular referral. The 30-day combined stroke and death rate for patients undergoing CEA within 14 days was comparable at 2.4%.10 The consensus from other studies supports the conclusion that early CEA, even within 48 hours from the acute event, can be performed safely for prevention of recurrent strokes in appropriate selected symptomatic patients.11–13 In addition, more than half of the patients in this audit were male and aged 75 years or older, which is the subgroup that derives the greatest benefit, in terms of risk reduction, from early CEA.1 Therefore, particularly in this population, the benefit greatly outweighs the morbidity and mortality associated with early operative intervention.2

In comparison to 2008, there has been a significant reduction in delays at each stage in the pathway from presentation to surgery, all of which will have facilitated the provision of CEA within the two-week target. The majority of referrals during this audit period were from General Medicine. Maintenance of timely imaging and referral to the Vascular service is commendable given that this department experienced significant disruption following the earthquake, with three of the inpatient wards temporarily transferred to another local hospital and clinicians cross-covering between the two sites. However, the greatest delay remains between presentation and carotid imaging. In particular, there continues to be a notable discrepancy between patients imaged as inpatients and those as outpatients. For example, almost all patients presenting to ophthalmology had carotid ultrasound as an outpatient, resulting in 38% patients referred following US more than two weeks after the index event. Although the Vascular department in Christchurch has a dedicated carotid US service, which automatically refers patients with a significant scan result to the vascular registrar on-call for review, patients imaged elsewhere may still have to wait for the
referring clinician to review the US result prior to referral. This creates an inherent delay when compared to inpatient imaging. However, most patients presenting to GPs as outpatients did have carotid imaging and have been referred within two weeks.

In New Zealand, the practice of carotid surgery has changed during the past five years towards medical management of asymptomatic carotid artery stenosis and urgent CEA for symptomatic patients. National data from the Australasian Vascular Audit (AVA) indicate that there was 281 CEA procedures performed between April 2015 and April 2016 of which 217 (77.2%) patients were symptomatic. The proportion of symptomatic patients undergoing CEA within 2, 2–4 and >4 weeks was 62.7, 23.0 and 14.3% respectively.

Locally, the pattern of referrals also changed, which may also contribute to the reduction in time from presentation to surgery. In 2008, up to half of all patients initially presented to their GP, with 62% of imaging requested as an outpatient. In the recent audit, only 10% of referrals for vascular review were from GPs, with the majority of patients undergoing inpatient imaging. The reason for this may be multi-factorial, including lack of access to primary care providers in the immediate aftermath of the earthquakes. The balance of inpatient versus outpatient management for patients with TIA or minor stroke remains uncertain. Studies show that inpatients are more likely to have timely investigation and treatment.14,15 However, outpatient management remains a viable option for low risk patients, or for higher risk patients within the context of a specialist service, such as dedicated “TIA clinic”. This should be considered in Christchurch to further reduce the time from imaging to vascular review, particularly for patients initially seen in the Emergency Department or Ophthalmology.

Overall, the number of CEA performed has increased over the past six years and has doubled since 2008. The reasons for this are not clearly elucidated in this study but are likely to be an increased awareness of the importance of urgent TIA/minor stroke management and prompt referrals. Greater public awareness of the symptoms of TIA/stroke should lead to earlier presentation of patients suitable for CEA. A telephone survey of 1,000 New Zealanders in 2007 found that 65% could name the signs or symptoms of stroke correctly and 81% would call the emergency service if they suspected someone was developing a stroke.16 However, time from onset to presentation does vary depending on the presenting symptoms, with patients who experience unilateral weakness or speech disturbance likely to seek medical attention earlier.17 Although ongoing public education is needed to minimise pre-hospital delay, education of healthcare providers is also important in ensuring prompt imaging and early specialty referral. It is therefore of paramount importance to ensure an effective and efficient pathway to risk-stratify patients in order to provide appropriate preventative treatment to those at greatest risk.

This study has limitations that should be mentioned. The retrospective nature of the data collection has its weaknesses. In addition the relatively small number of patients included in the post-earthquake phase precluded meaningful multivariate analysis to determine what factors influenced the delay in each part of the journey. However, the main message from this study was that RACE could be performed in unusual circumstances such as a natural disaster when a formal programme has been established. This further highlights the importance of establishing health care pathways for managing common and critical conditions such as strokes and TIAs to improve patient care.

**Conclusion**

The provision of RACE has been maintained at an acceptable standard, despite the widespread disruption to the local health services following the 2011 earthquakes. In addition, the number of CEA performed has incrementally increased year on year. The time from presentation to CEA has been significantly reduced since the introduction of a referral pathway in 2008. However, further improvement is needed to address the delays in the imaging and referral of outpatients to ensure that all patients with symptomatic carotid disease receive optimal treatment.
Competing interests:
Nil.

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Emergency EVAR for ruptured abdominal aortic aneurysms: New Zealand experience
Sam Taylor, Ian Thomson, Jo Krysa

ABSTRACT

AIM: A ruptured abdominal aortic aneurysm (rAAA) remains a significant threat to life, with a 30–50% in-hospital mortality rate. The recent introduction of emergency endovascular aneurysm repair (rEVAR) in New Zealand presents an alternative to open repair for rAAAs. The aim of this paper is to review the current experience in New Zealand in the repair of rAAAs.

METHODS: Data from the Australasian Vascular Audit (AVA) was reviewed, with data pertaining to rAAAs collected for the five-year period from January 2010 to December 2014.

RESULTS: Two hundred and eighty-five rAAAs were reported over the five-year period, with an overall mortality rate of 34.0%. There was no significant difference in in-hospital mortality rates alone after rEVAR vs open repair (rOR) (OR 0.39, 95% CI 0.14–1.06, P=0.065). Significant reductions in length of hospital stay (9.7±10.2 days vs 16.8±12.9 days, P=0.0125) and the combined in-hospital mortality/post-operative complication rate (35.7% vs 63.6%, OR 0.3, 95% CI 0.1–0.7, P=0.005) were observed after rEVAR vs rOR.

CONCLUSION: A primary rEVAR approach is appropriate in selected patients and may represent a paradigm shift in the management of ruptured AAAs in New Zealand.

In spite of significant advances in the fields of surgery, anaesthetics and intensive care over the last few decades, a rAAA remains a serious threat to life, with a 30%–50% in-hospital mortality rate. The combination of pre-existing co-morbidities, hemodynamic instability, significant physiological stress resulting from a major open repair (rOR) and frequently encountered peri-operative complications all present major challenges in the management of these high-risk patients.

The success of elective EVARs over the last two decades in reducing peri-operative mortality and morbidity for patients with intact AAAs has garnered interest in rEVARs, with their inherent minimally invasive nature providing a physiological advantage over rORs. This has seen an increase in rEVAR rates internationally, with a review of nine countries reporting an average annual rate increase from 5.3% (95% CI 4.0%–6.9%) to 15.1% (95% CI 13.3%–17.0%) between 2005 and 2009. More recent data suggests current annual rEVAR rates of 35% to 70% within individual EVAR capable centres in Sweden and the US. The ability to perform rEVARs under local anaesthetic (6LA) provides an alternative option for patients at high risk for general anaesthetic (GA), who previously would have had no choice but to undergo a major rOR under GA.

Despite a combination of established benefits in morbidity and mortality outcomes following elective EVARs for intact AAAs, and the theoretical physiological advantages of rEVARs over rORs, there is an increasing debate regarding whether a true survival benefit truly exists with rEVARs compared to rORs. Initial results from a series of observational studies suggest a significant reduction in short-term mortality after rEVAR compared to rOR, in contrast to two recent randomised controlled trials that demonstrated no significant differences in this outcome. Advocates of the rEVAR approach argue that a non-inferiority in short-term mortality after rEVAR compared to rOR, in combination with a reduction in
other outcomes such as a shorter stay in ICU, and a shorter overall stay in hospital favour the endovascular approach. However, there is emerging evidence that these benefits may be offset by higher re-intervention rates in the rEVAR group.

Regardless of whether or not a true benefit exists following rEVARs compared to rORs, the recent introduction of rEVARs may represent a paradigm shift in the treatment of ruptured AAAs in New Zealand. Here we review the New Zealand experience in the setting of rEVARs.

**Method**

A search of the AVA was undertaken for all ruptured AAAs in New Zealand from 1 January 2010 to 31 December 2014. Emergency and semi-urgent surgery types were included. Operative site terms included were ‘Aorta (AAA rupture no bypass)’, ‘Aortic tube-endoluminal’, ‘Aortic tube-open’, ‘Aorto fem bypass(aneurysm)’, ‘Aorto iliac-open(aneurysm)’ and ‘Aorto/iliac-endoluminal’. All supra-renal and solitary unilateral or bilateral iliac aneurysms were excluded.

**Statistical analysis**

Baseline and post-operative outcomes were compared between the rEVAR and rOR groups using unpaired t-tests and Fisher’s exact test as appropriate. A two-tailed P-value <0.05 was taken to indicate statistical significance. Data analysis was performed using GraphPad (Graphpad Software, Inc., La Jolla, CA, US).

**Results**

**Overview**

There were 285 reported rAAAs in New Zealand between January 2010 and December 2014, all of which were graded as emergency surgery. Of these, 78.9% were male and the overall mean age was 74.68.79 years. The mean duration of stay in hospital among survivors was 15.912.8 days, based on the 188 patients who were discharged alive. Mean AAA diameter on presentation was 7.41.7 cm and the overall mortality rate was 34.0%.

The majority of patients (43%) had an ASA score of 4, with a mortality rate of 38%. Five patients (1.8%) had an ASA score of 1, all of whom underwent an open repair and survived, while 37 (13%) had an ASA score of 5, with a mortality rate of 48.6%.

In regards to recorded co-morbidities, 106 (42%) had a background of ischemic heart disease, 22 (7.7%) diabetes and 202 (70.9%) hypertension. A serum creatinine level >150mMol/L was present in 38 (14.8%) of patients on admission.

**rEVAR vs rOR demographics**

Of the 285 rAAAs, 257 (90.2%) underwent a rOR and the remaining 28 (9.8%) had a rEVAR. There was no increasing trend in the rate of rEVAR on a year-to-year basis (Figure 1).

**Figure 1:** Yearly number of rEVAR and rOR in New Zealand.
There were no significant differences between the rEVAR and rOR groups with respect to mean age (76.57.6 years vs 74.48.9 years), male gender (OR 1.2, 95% CI 0.5–3.4), mean AAA diameter (7.01.7cm vs 7.511.7cm) or proportion of individual ASA scores within each group (P>0.15 for each ASA score).

There was also no significant difference in the prevalence of co-morbidities between the two groups, both overall and by type of co-morbidity; Ischemic heart disease (OR 1.4 95% CI 0.7–3.1), Diabetes (OR 2.1 95% CI 0.7–6.7), Hypertension (OR 1.0 95% CI 0.4–2.4), serum creatinine >150 mMol/L (OR 0.5 95% CI 0.1–2.1).

rEVAR vs rOR in-hospital mortality rate
There were five (17.9%) rEVAR and 92 (35.7%) rOR in-hospital deaths. Although the difference between the in-hospital mortality rates was suggestive of a benefit towards rEVARs, this was not significant (OR 0.39 95% CI 0.14–1.06, P=0.065).

rEVAR vs rOR duration of hospital stay
There was a significantly shorter duration of stay in hospital for the survivors within the rEVAR group compared to those who underwent a rOR (9.710.2 days vs 16.812.9 days, P=0.0125).

rEVAR vs rOR complication rate
In-hospital post-operative complications were recorded as wound, cardiac, respiratory, renal, gastrointestinal or central nervous-system related. Among the survivors in each of the rEVAR and rOR groups, there were five (21.7%) and 73 (43.9%) patients respectively who had one or more post-operative complications. The difference was not statistically significant (P=0.069).

When combining mortality and reported post-operative complications together, there was a significant reduction in this composite rate within the rEVAR group compared to those undergoing a rOR (35.7% vs 63.6%, OR 0.3, 95% CI 0.1–0.7, P=0.005).

Of the 28 patients who underwent an emergency EVAR, one (3.6%) was converted to an open repair due to a persistent type 1 endoleak.

There was no data available on late complications or re-interventions.

Survivors vs non-survivors
Overall 97 patients died in hospital, while 188 were discharged alive. Survivors were significantly younger (73.29.1 vs 77.27.5, P=0.0002) and had a significantly lower proportion with an ASA of four or five than non-survivors (49.7% vs 67.0%, OR 0.5 95% CI 0.3–0.8, P=0.009). The proportion of rOR patients with a >3L blood loss intra-operatively was also significantly lower in the survivors group (18.1% vs 50.0%, OR 0.2 95% CI 0.1–0.4, P=0.0001).

There was no significant difference between the survivor and non-survivor groups with respect to AAA size (7.51.6 vs 7.41.8), male gender (OR 1.4 95% CI 0.8–2.5), rate of rEVAR (OR 2.2 95% CI 0.8–6.0) or presence of specific co-morbidities; Ischemic heart disease (OR 0.8 95% CI 0.5–1.3); Diabetes (OR 0.8 95% CI 0.4–2.0); Hypertension (OR 0.8 95% CI 0.5–1.4); Creatinine >150mMol/L (OR 0.8 95% CI 0.4–1.5).

Local anaesthetic rates in emergency EVARs
Emergency EVAR under local anaesthesia took place in six (21.4%) of the endovascular cases while the remaining 22 (78.6%) had general anaesthesia. None of the local group required a conversion to general anaesthesia intra-operatively. There were two deaths (33.3%) in the local anaesthetic group and three (13.6%) in the general anaesthetic group.

Due to the small number of cases, no meaningful comparisons could be made between the general anaesthetic and the local anaesthetic groups.

Discussion
New Zealand is a relative newcomer to the field of rEVARs. Factors such as level of endovascular experience, available resources and volume of cases may explain the lower rates of rEVARs compared to international data. However, the recent introduction of rEVARs may represent a paradigm shift in the treatment of rAAAs in New Zealand.

Our overall in-hospital mortality rate of 34.0% was comparable to the mean peri-operative mortality averaged across nine countries with EVAR capable centres between 2005–2009 (31.6%, 95% CI 30.6–32.8%)3.
while our treatment modality specific in-hospital mortality rates compared well with two recent meta-analyses,\textsuperscript{6,11} which included over 40 observational studies and two to three RCTs comparing rEVARs to rORs (Figure 2).

Although the trend of in-hospital mortality after rEVAR vs rOR in New Zealand was suggestive of a benefit towards rEVAR, there was no significant difference between these two groups (OR 0.39 95% CI 0.14–1.06, P=0.065).

To date there have been three RCTs comparing short-term mortality after rEVARs to rORs, one of which was a pilot study.\textsuperscript{8,9,11} Of the remaining two trials, one carried out a direct comparison between the two groups, with randomisation after computerised topography angiogram (CTA). As a result, they excluded those who were unstable for imaging and those who were anatomically unsuitable for a rEVAR. There was no difference between the two groups in short-term mortality rates.\textsuperscript{8} The largest and more recent IMPROVE study conducted a real world trial where randomisation occurred prior to CTA imaging. Patients with clinically ruptured AAAs were randomised into either an endovascular-first strategy or open repair first strategy. In the endovascular group there was a crossover rate of 44% to open repair, either because of anatomical unsuitability or rapid clinical deterioration. They reported a trend towards a reduction in short-term mortality rates in the endovascular-first group 35.4% vs 37.4%, OR 0.92, P=0.62).\textsuperscript{9} Although this was not significant, it may suggest non-inferiority compared to the primary open repair group.

The results of the two RCTs contrast those of a large body of observational studies which have consistently reported a significant reduction in short-term mortality rates in the endovascular group. A recent meta-analysis of 29 observational studies noted a pooled odds ratio for death after EVAR vs open repair of 0.44 (95% CI 0.37–0.53), suggesting a benefit in the endovascular group.\textsuperscript{10} In the same study, the pooled odds ratio among the three RCTs was 0.9 (95% CI 0.65–1.24), which shows no benefit. They noted a major limitation of the observational studies was a high risk of patient selection bias, in that patients with a higher-risk profile tended to undergo a rOR while the more stable patients proceeded for CTA imaging to assess suitability for rEVAR. This is in agreement with our limited experience in three rEVARs at our centre which took place after the cut-off date of the AVA data collection where all three patients were both hemodynamically stable and anatomically suitable on CTA for a rEVAR.

We also noted no significant differences between the rEVAR and rOR groups in the New Zealand cohort when looking at short-term post-operative complication rates alone. This is in contrast to the findings of Antoniou et al in their meta-analysis, who observed a significant reduction in respiratory (OR 0.59, P<.01) and acute renal failure complications (OR 0.65, P<.01) within the rEVAR group,\textsuperscript{6} as well as of a more recent
A retrospective review of 514 rEVARs and 651 rORs who reported a significant reduction in several post-operative morbidity types following rEVAR vs rOR; cardiac complications (29% vs 38%, P=.001); respiratory complications (28% vs 46%, P<.0001); renal insufficiency (24% vs 38%, P<.0001); lower extremity ischaemia (2.7% vs 8.1%, P<.0001) and bowel ischaemia (3.9% vs 10%, P<.0001). When we combined our post-operative complication and in-hospital mortality rates, we observed a significant reduction within the rEVAR group (35.7% vs 63.6%, OR 0.3, 95% CI 0.1–0.7, P=0.005). This may be a combination of the reduced physiological impact of rEVAR compared to rOR, and of the lower risk profile patients being selected for rEVARs. The largest RCT to date did not report on post-operative complications.

There was a significant reduction in length of hospital stay in our rEVAR group. This outcome is in agreement with Ali et al in their large retrospective observational study (six days [interquartile range 4–12] vs 13 days, P<0.001). The IMPROVE trial also noted a reduction in length of hospital stay in their rEVAR cohort but this was not significant (9.89.0 days vs 12.210.2 days) (Figure 3).

A small proportion (21.4%) of emergency EVARs in New Zealand were performed under LA. This has a theoretical benefit in preserving the tamponade effect of the abdominal wall muscles, which is lost on induction of GA. None of the LA group were converted to GA. There were two deaths (33.3%) in the LA group and three (13.6%) in the GA group, however this difference was not significant. International experience suggests that local anaesthetic use is proportionally low despite its theoretical benefits. Patient agitation or hemodynamic instability may account for this.

We did not analyse the cost-effectiveness of emergency EVARs in New Zealand. In the IMPROVE trial, the mean total 30-day cost in the endovascular-first strategy was similar to the open repair-first strategy (£13,433+/–£10,354 vs £14,619+/–£12,353). Shorter duration of stay in intensive care, shorter length of hospital stay and potentially reduced complication rates are significant drivers in lowering costs in patients undergoing an emergency EVAR. A small amount of data on long-term outcomes following rEVARs, in combination with long-term follow up of elective EVARs in intact AAAs data suggests that late re-interventions may offset these benefits in the rEVAR group.

A potential limitation of this study is the reliance on the AVA database which is dependant on the surgeon updating the patient information. However, the capture rate of AVA in New Zealand with regards to both ruptured and non-ruptured AAAs has been recently reported as greater than 80% in a validation study. Other limitations include the small number of reported cases and the lack of follow-up data beyond discharge.

In conclusion, an endovascular-first strategy has been previously shown to be non-inferior to a primary open repair with regards to short-term mortality rates and has the benefit of a shorter stay in hospital. The results of this review indicate an association between rEVARs in New Zealand and significant reductions in length of hospital stay and combined in-hospital mortality/post-operative morbidity rates. Its recent introduction here may represent the beginning of a shift in the management of ruptured AAAs in New Zealand although it is currently unlikely to be an option available 24/7 outside the few New Zealand centres with well-established EVAR capabilities.

**Figure 3:** Comparison of New Zealand and international mean duration of hospital stay following rEVAR and rOR.
Competing interests: Nil.

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The impact of the Hand Hygiene New Zealand programme on hand hygiene practices in New Zealand’s public hospitals

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ABSTRACT

AIM: To detail the progress made by Hand Hygiene New Zealand (HHNZ) since 2011 and also describe the challenges experienced along the way and the factors required for delivery of a successful hand hygiene programme at a national level.

METHOD: HHNZ is a multimodal culture-change programme based on the WHO ‘5 moments for hand hygiene’ approach. The key components of the programme include clinical leadership, auditing of hand hygiene compliance with thrice yearly reporting of improvement in hand hygiene practice, biannual reporting of the outcome marker, healthcare-associated Staphylococcus aureus bacteraemia (HA-SAB), effective communication with key stakeholders and the use of the front-line ownership (FLO) principles for quality improvement.

RESULTS: The nationally aggregated hand hygiene compliance has increased from 62% in June 2012 to 81% in March 2016. There has been improvement across all ‘moments’, all healthcare worker groups and a range of different clinical specialties. The rate of HA-SAB has remained stable.

CONCLUSION: The HHNZ programme has led to significant improvements in hand hygiene practice in DHBs throughout New Zealand. The principles of FLO are now widely used to drive hand hygiene improvement in New Zealand DHBs.

Background

Healthcare associated infections (HAIs) are a significant problem worldwide, with up to 10% of patients admitted to modern hospitals acquiring one or more HAIs during their hospital stay.1,2 HAIs result in longer hospital stays; cause pain and distress; lead to increased mortality and can have long term physical, social and financial repercussions for both patients and families.3,4

While in New Zealand hospitals, serious infections caused by methicillin-resistant Staphylococcus aureus (MRSA) are relatively uncommon by international standards; HAI with MRSA and other multiple antibiotic resistant organisms (MROs—such as extended-spectrum beta lactamase-producing Enterobacteriaceae) continue to increase.5,6

As MROs become more common as a cause of HAI, treatment will become more difficult, making prevention even more important.

Direct contact between patients and healthcare workers (HCWs) is an important mechanism for transmitting MROs between patients and contaminating indwelling medical devices and surgical wounds.7 Despite this knowledge, a systematic review published in 2010 found that the overall median compliance of HCW with best hand hygiene practice was just 40%.8

Multimodal programmes to improve hand hygiene practice among healthcare workers can result in sustained improvements in hand hygiene practice and reductions in infections with MRSA and other nosocomial pathogens.9-12
Hand Hygiene New Zealand (HHNZ) is a multimodal programme developed with the aim of improving hand hygiene practice within the 20 district health boards (DHBs) in New Zealand.

Context
In 2007 the Ministry of Health’s Quality Improvement Committee (QIC) initiated a number of National Quality Improvement Projects (NQIPs). The Infection Prevention and Control projects included the delivery of a national hand hygiene improvement programme based on the World Health Organization ‘5 moments for hand hygiene’ approach. This was implemented and delivered by the Auckland District Health Board (ADHB). ADHB, in conjunction with Waikato and Tairawhiti District Health Boards (DHBs), piloted the national rollout of HHNZ.

In 2010 the Minister of Health established the Health Quality & Safety Commission (the “Commission”) which inherited the NQIP IPC programmes including HHNZ. In 2011 ADHB was awarded the lead agency role to reinvigorate HHNZ on behalf of the Commission. This provided the opportunity to build on achievements made in the first few years of the programme.

A cornerstone of the HHNZ programme from the outset was a nationally standardized process for auditing and monitoring hand hygiene performance according to WHO’s ‘5 moments for hand hygiene’ (WHO-5). That is: moment 1, before patient contact; moment 2, before a procedure; moment 3, after a procedure or body fluid exposure risk; moment 4, after patient contact and moment 5, after contact with patient surroundings. HHNZ aligned with the modified WHO-5 as adopted and adapted by the Hand Hygiene Australia (HHA) initiative.

This report details the progress made by HHNZ since 2011, along with challenges experienced along the way and the factors required for delivery of a successful hand hygiene programme at a national level.
online test with a score of 100%, pass the workshop test with a score of >90% and demonstrate the ability to audit appropriately on the wards. All gold auditors and gold auditor trainers are required to complete an online auditing skills validation test on an annual basis and are also required to collect a minimum of 100 moments each year. Inter-auditor and intra-auditor reliability are assessed during training.

The aim was to support a transparent auditing process; the nurse manager of each unit was informed when hand hygiene auditing was to take place and they, in turn, inform their staff. Advice was sought from the Office of the Health and Disability Commissioner to ensure that the auditing process took into account the Code of Rights. They recommended that a common sense approach be applied; identifying themselves to patients, talking with patients about the process if asked and moving on if the patient raised any concerns.

Each participating DHB audits and submits data to HHNZ three times per year through a trained and certified auditor. The number of moments required is determined by the number of beds in the DHB; the more beds the more observations required.\(^{15}\) There were a number of options for choosing auditing wards.\(^{15}\) Wards were categorised into two groups: high risk wards containing patients who may be at higher risk of developing a HAI and standard risk wards. High risk wards typically included intensive care, haematology/oncology, transplant, renal dialysis units and wards with immunocompromised patients. The options suggested were as follows:

- **Option A** – high risk wards with rotation of standard risk wards.
- **Option B** – high risk wards in addition to all standard risk wards.
- **Option C** – intensive care units with auditing of all other wards in the hospital.

It was up to the DHB Hand Hygiene Steering Group and the Hand Hygiene coordinator to determine which option to take. Regardless of which option was taken by each DHB, all auditing was performed by trained gold auditors. HHNZ auditors were encouraged to audit using an electronic application developed by HHA that can be downloaded to a smart phone. This helped improve data quality and made the auditing process easier and quicker. This data can subsequently be accessed by the National and DHB coordinators for reporting purposes.

**Communications and promotional activities**

A communications plan was developed in 2011 and new communication channels developed. These included the development of the HHNZ website (handhygiene.org.nz) which provides a central hub for sharing promotional materials, auditing results, journal articles, videos, newsletters and guidelines.

Regular electronic newsletters were sent out on a bimonthly basis targeted at hand hygiene coordinators, auditors, IPC specialists, quality managers and others involved in implementing the programme. These provided a platform for sharing ideas, showcasing achievements and profiling innovative approaches taken to improve hand hygiene practice.

A range of promotional activities were conducted to generate interest in the programme. This included the Hand Hygiene Video Competition, in which healthcare teams were invited to film and submit a video that highlighted the importance of hand hygiene and demonstrate the WHO-5 moments. (The prize of $1,000 was given to a charity of the winning team’s choice.) This initiative received an enthusiastic response, with 11 video entries from DHBs around the country.

Considerable efforts were put into helping DHBs promote World Hand Hygiene Day, held on 5th May every year. Hand Hygiene promotional material was made available and information sent out to Hand Hygiene Coordinators with a number of suggestions on how the day could be promoted within their DHB. (ADHB marked the day in 2013 with a large ‘Flash Mob’ in the hospital’s atrium).

**Quality and Safety Markers**

In 2013 HHNZ and the Commission in the setting of the ‘Open for better care’ campaign developed a set of Quality and Safety Markers (QSMs) to help drive improvement, with an annual national performance target being set each year.
That same year, hand hygiene performance rates were no longer reported anonymously. This meant DHBs could see how their results compared with other DHBs around the country, as well as how different categories of healthcare workers compared to others. These results were made publicly available on the HHNZ website.

Quality improvement methodology

While this is a national programme, there is wide variation in the clinical settings in which hand hygiene is being promoted and monitored. Intensive Care, for instance, has a different set of pressures and priorities than a general ward. In recognition of this, the programme worked to promote the principles of Front-Line Ownership (FLO) within the overall multimodal framework. The primary principle of FLO is to empower healthcare workers to develop their own local approaches to improving hand hygiene practices according to their unique local circumstances. Although the various components of the multimodal programme are not optional, exactly how those components are realised in the local context is left as much as possible to front line staff.

This approach has been promoted in various ways, in workshops, through e-newsletters and on the website. The Commission hosted two workshops with guest speaker Dr Michael Gardam, an international expert in using FLO as a quality improvement tool for infection control.

Building resilience and sustainability

In 2014 the Commission, at the directive of the DHB chief executives, led a move from national to regional delivery of the Commission’s IPC programmes. To facilitate this transition, the Commission (with representatives from the HHNZ team) hosted multidisciplinary IPC meetings around the country for each of the four regions; Northern, Midland, Central and South Island.

The first round of meetings included discussion about what is required at a regional level to further improve and sustain hand hygiene. Each region was presented with its hand hygiene performance data and how this compared to national hand hygiene averages. These interactive sessions gave attendees an opportunity for reflective learning with colleagues working in infection prevention and control in DHBs in their region. The second round of meetings, also interactive, supported sharing of ideas but had a strong focus on creating sustainable network structures to support DHBs with HHNZ work at a local and regional level.

Results

The HHNZ programme has led to significant improvements in hand hygiene practice in DHBs throughout New Zealand. The results of the November 2015 to March 2016 auditing period showed a nationally aggregated compliance rate of 81% (63,483 observations).

All 20 DHBs now participate in the programme and regularly submit hand hygiene data. Compliance against the WHO-5 moments has increased annually throughout the duration of HHNZ, as evidenced in the March 2016 National Audit Report (Figures 1 and 2).

Figure 1: Trends in national aggregate and average hand hygiene performance: October 2012 to March 2016.
In 2013, the QSM target for hand hygiene compliance was set at 70% which was met in June that year. The QSM target of 75% for 2014 was achieved in October that year and the QSM target of 80% for 2015 was achieved in June 2015. In this latter auditing period, 19 DHBs achieved 75% or more compliance and of those 19 DHBs, 12 achieved 80% or more. The results show considerable improvements in compliance with all the 5 moments (Figure 3). This is particularly apparent for moments 3 and 4 (the ‘after’ moments) which in the November 2015 to March 2016 auditing period were 88.8% (7,909 observations) and 86.2% (19,464 observations), respectively. Consistent improvements have also been made in relation to moments 1 and 2 (the ‘before’ moments) although compliance here was 76.1% (19,192 observations) and 80.5% (5,925 observations) in the November 2015 to March 2016 period which is not as
high as for moments 3 and 4. Significant improvements in hand hygiene practice are evident across all healthcare worker categories and across a range of different clinical services (Figures 4 and 5).

The outcome measure—the rate of healthcare-associated S. aureus bacteraemia (HA-SAB)—has remained stable at approximately 0.13 events/1,000 inpatient days.

Discussion

The HHNZ programme has led to significant improvements in hand hygiene practice in DHB hospitals throughout New Zealand. At the end of 2009, the first year of the NQIPs, the nationally aggregated measured compliance with hand hygiene was 47% (25,148 observations over 12 months from 12 participating DHB). In the November 2015 to March 2016 audit period, the nationally aggregated measured compliance rate was 81% (63,483 observations over five months from 20 DHB). All DHBs now actively participate in the programme and national QSM targets have been met in the three years since they were introduced in 2013. Improvements have been made among all healthcare worker categories and against all of the WHO-5 moments. Nursing staff have achieved a measured compliance rate of 84.4% but however, medical staff perform less well at 74.2%. The highest rates are seen in the ‘after’ moments; moments 3 and 4. Overall, the results suggest that a culture of good hand hygiene practice is becoming embedded within DHBs.

There has been no improvement so far in the outcome marker, however, there may be a number of reasons for this. Firstly, the definition used to determine the rate of HA-SAB includes all events regardless of whether the event was hospital-onset or community onset. It is unlikely that hospital hand hygiene practices have any impact on community-onset HA-SAB. Secondly, healthcare-associated bacteraemia most likely reflects the worst outcome for an episode of healthcare-associated infection. The incidence of other healthcare-associated infections such as peripheral intravascular access device-related phlebitis, catheter-associated urinary tract infections and non-surgical site skin infections may have been impacted upon by improvement in hand hygiene practices. However, defining such events and then ensuring consistency with reporting is considerably more difficult than capturing episodes of bacteraemia. Thirdly, measuring laboratory data such as rates of patients newly identified as being colonised or infected with a multiple antimicrobial resistant organisms (MDRO) such as
MRSA or extended spectrum beta lactamase producing strains of *Klebsiella pneumonia* is also fraught with difficulty as the distribution of these MDRO varies significantly across the country and in the absence of entry and exit screening it is difficult to assign the place of acquisition. Finally, the HHNZ programme was first rolled out in 2008 in a limited, non-sustainable way and not all DHBs actively participated in the programme. The reinvigoration of the programme in 2011 led to increasing participation by all 20 DHBs and the development of a more sustainable programme with a strong focus on locally owned quality improvement strategies. By 2012 the national aggregated hand hygiene compliance rate for June was 62%: diminishing returns in disease reduction may occur when hand hygiene compliance rates improve to 50 to 70%. It is possible that most of the impact on HA-SAB rates coincided with the earlier work and preceded HA-SAB data collection. Reduction in the HA-SAB rate was reported with the ADHB programme, following an increase in compliance with hand hygiene from 35% to 60% over a 36-month period. Regardless, our findings are comparable to those of HHA which has reported reductions in MRSA bacteraemia but not hospital-onset *S. aureus* bacteraemia rates. It seems likely that the development of the QSMs and corresponding targets were a key contributor to this success. The results for each DHB are no longer anonymized, which allows DHBs to benchmark their performance against other DHBs and to publicly demonstrate their improvement in measured hand hygiene performance over time. It has also helped motivate senior management to give greater priority to their local programmes and to provide them with greater support and resourcing. There has been criticism associated with the public reporting of the DHB hand hygiene performance. Critics have suggested that the current approach of DHB choosing which wards to audit and report allows for an element of ‘gaming’. However, more recently a number of DHB have taken to reporting the results of auditing across their entire DHB or have shifted from auditing high performing areas to more challenging areas within the DHB such as emergency departments. While the DHB hand hygiene performance may have reduced following these changes, HHNZ favours this approach and is working to acknowledge these changes in the quarterly report.

While public reporting has resulted in at least one DHB being singled out for negative media attention, this was used as an opportunity by local proponents of the programme to generate greater support from staff and senior management. Ultimately this helped to drive considerable improvement in that DHB.
The principles of FLO are now widely used to drive hand hygiene improvement in New Zealand DHBs. Many healthcare workers involved in the implementation of the programme in their DHB have reported that using the principles of FLO has been an effective way to engage teams and overcome the specific barriers that may be present in local settings.

Surveys among those involved in the programme have also pointed to the value of effective communications, which has helped ensure that people working in different DHBs around the country feel part of a unified and collaborative national programme.

While many achievements have been made, it remains to be seen how improvements will be sustained after 2015 when the nationally-led improvement programme will be transitioned to regional patient safety and IPC networks. It is expected that the series of multi-disciplinary meetings hosted by the Commission’s IPC team will have laid the groundwork for the sustainability of these regional networks. Despite some HHNZ champions and coordinators expressing concerns early on about the withdrawal of support and assistance at a national level, the results from a recent HHNZ survey suggest that these networks are already providing support at a regional level to sustain the programme (unpublished data, HHNZ). We believe that even once regional networks become more established ongoing leadership at a national level will still be beneficial.

Challenges and Limitations

Rolling out a national programme such as HHNZ has not been without challenges. Healthcare workers within some DHBs resisted the idea of a national monitoring programme being imposed on them. Initially there was also some resistance and/or lack of interest in the programme among senior management. This has improved substantially over the last three years however; a development probably linked to the establishment of QSMs and the national results being made public, as well as the use of FLO.

In many DHBS the hand hygiene coordinator role has been given to an IPC staff member to manage over and above their usual workload, which in some cases has limited the ability of co-ordinators to coordinate local programmes effectively. This issue has been repeatedly raised in surveys conducted by the programme, and has also been highlighted in the New Zealand Nurses Organisation’s journal, *Kai Tiaki.*

The results of an attitudinal survey conducted in 2014 indicated that while an overwhelming majority of healthcare workers believed hand hygiene is important to patient safety, just over half believed that practicing the ‘5 moments’ had become the social norm at their place of work. The most commonly identified barriers to improvements were “bad habits” and being “too busy” (unpublished data, HHNZ).

It appears therefore that higher standards of hand hygiene practices are becoming embedded as standard practice in DHBs but there is still concern about whether these practices will be sustained.

There are some limitations to the manner in which the auditing was undertaken. It is carried out by direct observation of staff working in a clinical area. The distribution of moments observed is uneven and with the most number of moments observed occurring for moments 1 and 4, before and after touching a patient. This is not surprising as these moments are the most common HCW and patient interactions. Also it is likely that multiple moments may have been observed during the same HCW and patient interaction and multiple observations on the same HCW. In reality the short observation periods used by the auditors and the pace of work in a busy ward may have compensated for both these issues.

Key to success

We have identified seven key factors that have contributed to the success of the HHNZ programme.

1. Strong international evidence and leadership shown by the WHO ‘Clean care is safer care’ programme.
2. Collaboration with the Hand Hygiene Australia team, including the sharing of expertise, ideas and resources.
3. A strong commitment to the programme by the Commission, which increased the credibility of HHNZ as a national quality improvement programme.
4. The establishment of a standardised auditing and reporting process that allowed DHBs to monitor their own progress over time.

5. An effective communication strategy. This generated interest in programme and kept those involved up-to-date with its aims and achievements.

6. The introduction of QSMs, which increased accountability among senior leadership teams and therefore encouraged engagement with the programme.

7. Increased quality improvement capability within the IPC sector with the emphasis on local ownership.

Conclusion
Core components of the HHNZ programme have been education of frontline staff, universal placement of alcohol based hand rub at the point of care and nationally standardised performance monitoring along with public reporting. Good communications with the sector have been central to establishing the programme. Within this broad national framework, HHNZ has encouraged frontline staff to innovate and devise specific approaches to improving practice according to local needs. Over the last three years, this has resulted in substantial improvements in hand hygiene practice. Sustaining these improvements, however, will require ongoing national reporting along with effective regional networks comprised of both clinical and managerial staff.

The success of the approach used by HHNZ over the last three years suggests that it may provide a useful model for national quality improvement programmes in other areas of clinical practice.

Competing interests:
Auckland DHB was funded by the Health Quality and Safety Commission to deliver the HHNZ programme. Dr Freeman reports that he was Clinical Lead of the HHNZ programme between 2011 and 2015.

Acknowledgements:
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Where to from here? The treatment of impetigo in children as resistance to fusidic acid emerges

Alison Vogel, Diana Lennon, Emma Best, Alison Leversha

ABSTRACT

Admissions for skin and soft-tissue infections have been increasing steadily in children and in the general population. Concerns have been raised recently about the increasing widespread use of topical fusidic acid and concurrent increase of fusidic acid-resistant Staphylococcus aureus. Fusidic acid resistance and methicillin resistant Staphylococcus aureus (MRSA) are both more prevalent in youngest age group (<5 year-olds) and particularly in the North island. In New Zealand, fusidic acid is recommended for treatment of minor impetigo and is the only fully-funded topical antibiotic. The evidence base for alternative treatment strategies for mild impetigo is limited. Most children with impetigo in the current skin and sore throat schools programmes received care with wound management with only a few requiring escalation. An upcoming randomised controlled trial comparing topical hydrogen peroxide cream, topical fusidic acid and wound management only (clean and cover) will help provide evidence about the effectiveness of alternative treatments in the New Zealand setting.

Background

Hospitalisations due to Staphylococcus aureus (S. aureus) infections have been steadily increasing in New Zealand; a trend also recognised internationally. In New Zealand, admissions are predominantly due to community-onset, methicillin susceptible S. aureus (MSSA) skin and soft tissue infections (SSTI) with admission rates for staphylococcal SSTIs in New Zealand increasing approximately 5% per year from 2000 to 2011. SSTI admission rates are highest for preschool children, the elderly, Māori and Pacific populations, among those living in the most deprived deciles and in Northern and Central regions. It is estimated that for each hospital admission, up to 14 children may visit their general practice with an SSTI.

Impetigo has often been regarded as a minor skin complaint. However, the high burden and the possibility of more serious sequelae (serious skin sepsis leading to hospitalisation or post-streptococcal glomerulonephritis) is acknowledged. In addition, current guidance includes recommendations that children should not attend school or day-care until 24 hours after antibiotic treatment has been commenced. With recurrent and household re-infections, such measures can potentially result in significant time off school with consequent educational impact for children and impact on work for parents.

Current treatment advice for minor skin infections outlines a small number of indications for topical antibiotics including children with localised impetigo (no more than three areas of the body affected or <5cm; <5% of body surface area) with topical fusidic acid being the first choice. In addition it is the Pharmac-subsidised topical antimicrobial. The second-line topical antibiotic, mupirocin, which has additional methicillin resistant S. aureus (MRSA) activity, is reserved for small localised areas of infection resistant to fusidic acid with funding restricted to proven MRSA infection. For other infective skin conditions such as boils and carbuncles, treatment is incision and drainage without antibiotics and oral antibiotics are reserved for more extensive areas of infection, cellulitis or skin infection with systemic symptoms. However, increased resistance amongst S. aureus to fusidic acid is a concerning development and has
coincided with rising prescription rates for fusidic acid.16,17 Rates of prescribing are highest for preschool children followed by those age 75+ and 5–14 years.17 Dispensing rates are highest for Pacific and Māori, and in the Northern regions.17 Rates of mupirocin dispensing have fallen significantly, coincident with removal of the Pharmac subsidy.16 Concern about the increasing resistance to fusidic acid has led to calls to consider limiting access via prescriber and funding restrictions.13,17,18

Fusidic acid resistance is important for three reasons. It may lead to ineffective treatment in SSTI. Fusidic acid resistance may be associated with other antimicrobial resistance and an increasing prevalence of MRSA. The gene conferring fusidic acid resistance (FusC) and the gene conferring methicillin resistance (MecA) are located on the same mobile genetic element. A specific fusidic acid-resistant community associated methicillin-resistant clone (AK3) has recently emerged to rapidly become the current dominant MRSA clone causing illness in New Zealand.17 Thirdly, fusidic acid is also available in oral and intravenous formulations with a limited role as part of combination adjunctive treatment for invasive infections, especially of bone and joints (including those caused by MRSA) and efficacy in these situations might be impacted.18,19

Microbiology and resistance patterns

Impetigo has traditionally been considered due to Streptococcus pyogenes although the role of co-infection with S. aureus may be important. Most studies do not include phage typing which if done suggests S. aureus may only be a secondary invader and not require specific treatment.21 S. aureus is thought to be the more common causative impetigo pathogen in temperate climates while S. pyogenes may be more common in warmer, humid regions.22 There are no published New Zealand data describing the prevalence of S. aureus and S. pyogenes in impetigo in the community.

National data for S. aureus antimicrobial resistance patterns and molecular epidemiology from community laboratory isolates for children with skin and soft tissue infections is available from a national survey of laboratory isolates performed in 2014 by ESR. (Table 1: reproduced with permission Helen Heffernan ESR). Almost half the isolates from pre-schoolers were fusidic acid resistant, and 20% of those from school age children. Fusidic acid resistance and methicillin resistant Staphylococcus aureus (MRSA) are both more prevalent in the youngest age group (<5 year olds) and particularly in the North Island.

The call to reduce fusidic acid use requires urgent reconsideration of the best strategies

<table>
<thead>
<tr>
<th>Antimicrobial</th>
<th>MSSA</th>
<th>MRSA</th>
<th>All S. aureus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusidic acid</td>
<td>36.8</td>
<td>16.7</td>
<td>93.7</td>
</tr>
<tr>
<td>Mupirocin</td>
<td>10.2</td>
<td>10.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>14.7</td>
<td>2.5</td>
<td>6.3</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Co-trimoxazole</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

MSSA: methicillin-sensitive S. aureus
MRSA: methicillin-resistant S. aureus
Source: Heffernan et al 2015, ESR

Table 1: Antimicrobial resistance for community acquired S. aureus skin and soft tissue infections in children by age: New Zealand 2014.
for impetigo treatment relevant to current New Zealand pathogenesis and resistance patterns. Although inappropriate use of topical fusidic acid may also occur in other age groups, the large burden of SSTI, high use of fusidic acid and very high rates of resistance in young children means the problem needs to be addressed at this level.

**Treatment strategies for impetigo**

The basis of current recommendations for childhood impetigo treatment in New Zealand is a Cochrane review of treatment for impetigo, with local guidelines influenced by considerations of availability and funding. The Cochrane review is a meta-analysis of evidence from randomised controlled trials identified to July 2010. For this article we applied the search strategy from the Cochrane review to search for further relevant literature indexed in Medline or Embase from 2010 to March 2016, and reviewed abstracts to determine relevance.

**Topical antibiotics**

In New Zealand, fusidic acid and mupirocin are the two available topical antibiotics. Retapamulin is a newer alternative topical antibiotic available overseas. Mupirocin, fusidic acid or retapamulin are more effective compared with placebo cream in RCTs, although some of this evidence includes studies aged up to 30 years old.

There is no difference in cure rates between fusidic acid and mupirocin or between retapamulin and fusidic acid.

Prior to the year 2000, mupirocin was available as a pharmacy dispensed agent with no restrictions and was also subsidised on prescription. Community dispensing rates of mupirocin in the late 1990s were high and associated with higher rates of mupirocin resistance in S. aureus which has dropped following removal of Pharmac subsidy and restricted prescribing indications. Mupirocin remains useful for decontamination for MRSA and this, along with prior resistance in the face of high community use, means it is inappropriate to use in routine treatment of impetigo in the community. Resistance to retapamulin has also been reported (seen in almost 10% of S. aureus in a Texan study), again indicating that use of topical antibiotics is likely to lead to resistance in skin pathogen flora.

**Hygiene intervention: “Clean, Cut, Cover”**

The simplest treatment strategy is using ‘Clean, Cut (finger nails), Cover’ advice without topical or oral agents. Nurse-led school clinics have been implemented since 2012 in 61 Counties Manukau schools as part of initiatives to address high rates of rheumatic fever and serious skin infection. In 2013 6,774 skin infections were treated and over 10,000 in the first nine months of 2014. Analysis of a sample shows that only 4% of those assessed with skin infections were prescribed antimicrobials, mostly topical fusidic acid or oral cephalexin.

Therefore the vast majority were treated with the ‘Clean, Cut, Cover’ advice. The Cochrane review demonstrated studies with placebo cream found cure rates ranging from 8–42% at 7–10 days.

**Antiseptic creams**

Antiseptic topical agents that have been used to treat impetigo include hydrogen peroxide, povidine iodine and chlorhexidine solution. There is an identified research gap in the evidence about the effectiveness of antiseptic agents. Evidence is summarised in the table below (Table 2).

---

**Table 2: Evidence for use of antiseptic creams.**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Evidence Type</th>
<th>Author, year</th>
<th>Site</th>
<th>Age</th>
<th>Comparison</th>
<th>Number</th>
<th>Outcomes measured</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen peroxide</td>
<td>RCT</td>
<td>Christensen 1994</td>
<td>UK, Sweden, Germany total 47 sites</td>
<td>2–74 yrs</td>
<td>Hydrogen peroxide vs fusidic acid, 2–3x daily to maximum 21 days</td>
<td>256</td>
<td>Healing; composite severity score, assessed 3, 7, 14, 21 days</td>
<td>HP 72% healed vs 82% fusidic acid NS</td>
<td>Composite report of three trials. Poor quality-in-adequate blinding.</td>
</tr>
<tr>
<td>Povidine iodine cream</td>
<td>No trials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorhexidine cream</td>
<td>No trials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HP: hydrogen peroxide
Importantly, reported resistance is much lower for topical antiseptics and mechanisms of resistance more complex for the organism. Antiseptics are also not related to antibiotics used for systemic treatment of infection therefore even if it does occur, development of resistance is less concerning. Reported resistance, adverse effects and current funding/availability are shown in Table 3.

Oral or intramuscular antibiotic treatment for impetigo
For moderate to severe impetigo, recommendations are for the use of oral antibiotics. The preferred options are flucloxacillin or cephalexin in children where palatability of flucloxacillin elixir is an issue. Erythromycin is indicated in penicillin allergy and co-trimoxazole for MRSA.

A recent rigorously performed randomised controlled trial in the Northern Territory of Australia raises pertinent questions for the management of impetigo in New Zealand. This non-inferiority trial enrolled 508 indigenous children aged three months to 13 years; 72% of whom had severe impetigo (as defined as two or more purulent or crusted sores, or five or more sores in total). Treatment with intramuscular benzathine penicillin was compared with the use of twice daily co-trimoxazole (4mg/kg plus 20mg/kg) for three days or once daily co-trimoxazole (8mg/kg plus 40mg/kg) for five days. Benzathine penicillin has been widely used in tropical settings to treat extensive impetigo although oral penicillin is not effective. Cotrimoxazole was used due to high community prevalence of MRSA being reported and isolated from impetigo lesions. The primary outcome was treatment success at day seven as measured by blinded assessment of photographs of the most severe lesion(s). Treatment was successful at 85% in each arm at seven days. S. aureus was identified from 81% of children, S. pyogenes from 90% and both from 74% pre-treatment. Ninety-percent of adverse events occurred in the benzathine penicillin group. The only independent predictor of treatment success was clearance of S. pyogenes. Clearance of S. aureus was not an independent predictor. Important differences about health access mean that in remote communities where close supervision is difficult the use of long acting IM agents was justified, in contrast to New Zealand where close follow-up of high risk groups is usually possible via school-based clinics or primary care. The use of shorter courses of oral antibiotic treatment however is effective in severe lesions.

Table 3: Alternative antiseptic topical treatments in New Zealand.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Resistance</th>
<th>Adverse events</th>
<th>Funding in New Zealand</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen peroxide</td>
<td>Not reported</td>
<td>Short term burning Mild SE 11% HP vs 7% fusidic acid</td>
<td>Funded General sale</td>
<td>$8.56 per 15g</td>
</tr>
<tr>
<td>Povidine iodine cream</td>
<td>Some</td>
<td>Sensitivity (rare) Interference with thyroid function tests Avoid if breastfeeding</td>
<td>Funded General sale</td>
<td>$3.27 25g</td>
</tr>
<tr>
<td>Chlorhexidine cream</td>
<td>Some reports</td>
<td>Contact dermatitis, rare severe hypersensitivity (Medsafe warning)</td>
<td>General sale Cost??</td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion**

The dual concerns of increasing rates of skin infection and increasing antibiotic resistance to fusidic acid require careful deliberation. Despite the prevalence of this problem there is insufficient evidence to guide informed treatment of childhood impetigo in the New Zealand context. The current large scale (population served 5–12 year-olds- n=30,000) community interventions to manage skin infections in school age children such as those occurring in Auckland offer an excellent opportunity to advance knowledge. These include studies to determine the relative frequency of S. aureus and S. pyogenes and of mixed
infections and ongoing surveillance of resistance patterns among isolates from skin infections. Shorter courses of oral antibiotics may be effective and could be subject to study. More pressing, there is a need for well conducted trials of alternative treatments particularly the use of antiseptic creams. An upcoming funded randomised controlled trial (ACTRN 1261600356460p)37 of mild to moderate impetigo in school children comparing topical hydrogen peroxide cream, topical fusidic acid and local therapies only (clean and cover) should provide evidence about the effectiveness of alternative treatments. The school-based health services operating in low decile schools across the Auckland region provide an ideal opportunity for this to be examined.

Competing interests:
Nil.

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A 46-year old woman was seen for a chronic maxillary erythematous gingival lesion above central incisors that had been present for several years. She had history of trauma due to fall eight years back. She had undergone multiple antibiotic, antifungal and topical steroid regimens. She had also undergone surgical excision of the same but the lesion recurred. She was otherwise well. On examination, there was a 12mm x 11mm erythematous area on maxillary gingival mucosa (Figure 1).

Vitality tests with electrical pulp tester (Digitest™ II Pulp Vitality Tester, Parkell inc, NY, USA) showed that both maxillary central incisors were. An intra-oral peri-apical radiograph using radio-vi-siography revealed large peri-apical radiolucency around roots of both maxillary central incisors (Figure 2).

A clinical diagnosis of necrosis of pulp leading to chronic peri-apical periodontitis was made. The dental infection had perforated from maxillary cortical plate into the gingiva leading to erythematous lesion. The patient’s gingival lesion improved after root canal treatment of both maxillary central incisors. The lesion healed completely after one month of dental treatment. The peri-apical lesion healed significantly after one year.

Figure 1: Erythematous area on maxillary gingival mucosa.
Discussion

Mucosal lesions are associated with various systemic diseases and can present as oral manifestations of squamous cell carcinoma, lichen planus, pemphigus vulgaris, erythema multiform, epithelioid hemangioendothelioma, plasma cell gingivitis, spindle cell carcinoma, foreign body gingivitis, discoid lupus erythematosus, oral psoriasis and dermatomyositis. They can be either mucosal alterations like erythroplakia, candidiasis, stomatitisis migrans, vitamin deficiency, and hematologic disorders or vascular lesions like Kaposi's sarcoma, and reactive lesions like peripheral giant cell granuloma. The treating physician and surgeons should primarily consider dental pulp necrosis as a differential diagnosis of such mucosal lesions if the patient does not have a history of any systemic disease. Proper history and investigations can make diagnosis of such lesions less complicated.

Figure 2: Radiograph revealing large peri-apical radiolucency around roots of both maxillary central incisors.
Competing interests: Nil.

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Syringomyelic Neuropathic Arthropathy of the Elbow
Neil Stewart, Kevin Karpik

ABSTRACT
Neuropathic Arthropathy or Charcot joint is a progressive, destructive arthritis that is associated with an underlying neurological disorder. We present a case of a 30 year-old male who, three years prior, had ruptured his right distal biceps tendon with subsequent development of a deep infection. At representation, the patient’s clinical picture was consistent with the re-emergence of a deep elbow infection. Laboratory testing found no evidence of infection. Magnetic Resonance Imaging (MRI) of the patient’s spine revealed a syringomyelia and a NA was diagnosed. The purpose of this report is to raise awareness of a unique presentation of a rare clinical condition in the early stages of the disease.

Neuropathic Arthropathy (NA) is a rare disorder which typically affects the joints of the lower limb. Among patients with NA, the elbow joint is thought to be affected in only 3% of cases. NA of the elbow as a presenting symptom of syringomyelia is extremely rare. We describe a unique case of NA of the right elbow preceded by a septic arthritis of the same joint. The purpose of this case report is to raise awareness of an uncommon pathology in its early stages where outcomes may be influenced by early diagnosis and management.

Case Report
A 30 year-old, right-hand dominant, non-diabetic male presented to the emergency department with a three week history of insidious onset pain, reduced range of motion, crepitus and circumferential swelling of his right elbow.

Three years prior he had ruptured his right distal biceps tendon at its musculotendinous junction while lifting heavy furniture. His tendon had been surgically repaired. He re-presented seven weeks later with swelling and erythema over the anterior aspect of his elbow, pain on elbow movement and subjective fevers. A deep infection of his biceps tendon had developed. This infection was managed with three washout and debridement procedures. Intra-operative tissue samples isolated Staphylococcus Aureus. He received six weeks of intravenous antibiotics via a peripherally inserted central catheter. Clinical follow-up at two, three and six months had noted normal inflammatory markers, radiographs and resolution of symptoms.

On representation, his right elbow was circumferentially 12cm larger than his non-affected side. Range of motion was limited to -20° extension and 120° of flexion. The limb was neuro-vascularly intact. C-Reactive Protein was 38mg/L (Reference Range [RR] 0–5), Eosinophil Sedimentation Rate was 41mm in one hour (RR 1–10) and Neutrophil count was 7.3 xE9/L (RR 1.9–7.5). Radiographs revealed a large joint effusion, calcification within the joint capsule, loose bodies, increased density within the distal humerus, proximal radius and ulnar, joint deformity and destruction (Figure 1 and Figure 2).

The patient was subsequently taken to theatre for washout and debridement of the right elbow for a suspected septic arthritis. No purulent material was seen, instead large amounts of straw-coloured synovial fluid, full thickness cartilage loss of the radial head and trochlear, complete loss of the capitulum and multiple loose bodies were identified.

Intra-operative aspirates found no crystals or organisms. Biopsies of the synovium and distal humerus failed to identify any organisms with Gram stain or extended cultures. Polymerase Chain Reaction did not identify Mycobacterium Tuberculosis DNA; and Quantiferon-TB gold testing was negative. DNA Sequence Analysis did not amplify any bacterial DNA.
Figure 1: Anteroposterior plain radiograph of the right elbow. Joint effusion, calcification within the joint capsule, loose bodies and increased density within the distal humerus, proximal radius and ulnar are evident.

Figure 2: Lateral plain radiograph of the right elbow. Joint effusion, calcification within the joint capsule, loose bodies and increased density within the distal humerus, proximal radius and ulnar are evident.
A possible diagnosis of a NA was raised. The patient underwent MRI investigation of his brain and spinal cord which identified a Chiari I Malformation and Syrinx extending from C1 to T7 (Figure 3). A NA had been confirmed.

Discussion

NA is a progressive, degenerative arthritis associated with an underlying neurological disorder. Charcot first reported this form of destructive arthropathy in 1868, which accompanied neurosyphilitic infection.

Table 1: Central and peripheral causes of Neuropathic Arthropathy.

<table>
<thead>
<tr>
<th>Central</th>
<th>Peripheral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tabes dorsalis\textsuperscript{1,10,15}</td>
<td>Diabetes Mellitus\textsuperscript{1,10,15}</td>
</tr>
<tr>
<td>Leprosy\textsuperscript{1,10,11}</td>
<td>Alcoholism\textsuperscript{1,10,11}</td>
</tr>
<tr>
<td>Syringomyelia\textsuperscript{1,3,10}</td>
<td>Amyloid neuropathy\textsuperscript{1,10,11}</td>
</tr>
<tr>
<td>Multiple Sclerosis\textsuperscript{1,10}</td>
<td>Infection\textsuperscript{1}</td>
</tr>
<tr>
<td>Charcot Marie-Tooth\textsuperscript{1,10,12}</td>
<td>Familial sensory neuropathies\textsuperscript{1}</td>
</tr>
<tr>
<td>Neurofibromatosis\textsuperscript{11}</td>
<td>Pernicious anaemia\textsuperscript{1,10}</td>
</tr>
<tr>
<td>Herpetic encephalitis\textsuperscript{11}</td>
<td>Intra-articular or systemic corticosteroid use\textsuperscript{1,10,11}</td>
</tr>
<tr>
<td>Systemic Scleroderma\textsuperscript{12}</td>
<td>Congenital insensitivity to pain\textsuperscript{12}</td>
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<td>Poliomyelitis\textsuperscript{1}</td>
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and demyelination of the dorsal columns of the spinal cord (Tabes Dorsalis). Since first reported, multiple other causes of NA have been described (Table 1). These causes can be divided into either central or peripheral neurological insults, dependent on the distribution of nervous system involvement. In contemporary times, NA is most commonly associated with Diabetes Mellitus and its peripheral neuropathic sequelae. Weight-bearing joints such as the foot, ankle, knee and hip are typical. Involvement of the upper limb is uncommon but when this does occur, typically involves the shoulder joint. NA of the elbow joint is exceedingly rare. The pathogenesis of NA remains controversial, with several proposed theories. The Neurotraumatic theory suggests that repetitive trauma sustained by an insensate joint results in joint destruction. The Neurovascular theory describes active bone resorption by osteoclasts secondary to sympathetic dysfunction and a neutrally mediated persistent hyperaemia. A further theory proposes that joint changes result from damage to central nervous system ‘trophic centres’ which control bone and joint nutrition. The classical clinical presentation of NA involves joint swelling, erythema, reduced range of motion, crepitus, joint instability and the absence of pain. However, presentations involving various degrees of joint pain have now been reported. The radiological and pathological features of NA have been summarised into the ‘6-Ds’: dense bones (subchondral sclerosis), destruction of articular cartilage, disorganisation (joint deformity), debris (loose bodies), distention (fluid) and dislocation. In this case report, syringomyelia was identified as the underlying cause of the patients elbow NA. Syringomyelia is a progressive degenerative disorder of the spinal cord characterised by longitudinal cavitation (syrinx) containing a fluid which involves the cervical or cervicothoracic regions. Patients with a syrinx typically present with a dissociated segmental anaesthesia over the neck, shoulder and arm in a cape or hemicape pattern. The perturbation of sensory symptoms are the result of the interruption of the decussating fibres of the lateral spinothalamic tract that mediates pain and thermal sense while sparing fibres that mediate deep touch sensation. As the syrinx expands it may damage the anterior horn cells, causing a lower motor neuron lesion at the same level or damage to the descending cortical motor tracts, leading to an upper motor neuron lesion below the level of the syrinx. The object of treatment is to manage the underlying disease and reduce the rate of joint deformity. Thus, it is important to diagnose and treat NA as early as possible. Several management strategies have been proposed. Typically, physical therapy is recommended to ensure range of motion and function are maintained. Functional bracing may also be utilised, particularly if the joint destruction has resulted in instability. Nonsteroidal anti-inflammatory drugs can be used for the control of synovial inflammation. Aspiration of large effusions may prevent ligamentous laxity. Generally, surgical management is not recommended and has been associated with high rates of complications and unpredictable outcomes. Total elbow replacement is contraindicated due to the lack of protective pain sensation and reflexes, the presence of osteopenic bone and weakness of the surrounding ligamentous and muscular tissues. This causes abnormally high stress on implanted components, with associated loosening and periprosthetic fractures resulting in high failure rates. One report of successful arthrodesis is reported in the literature.
COMPETING INTERESTS:
Nil.

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The awareness and uptake of free flu vaccination offered to University of Otago staff

Matloob Husain, Andrew Gray, Richard Carlos Torr

Influenza virus, in addition to impacting human health, also has a significant impact on workplace productivity due to absenteeism. Like many other employers, the University of Otago, one of the largest employers in New Zealand has offered the free flu vaccination to staff every year since 2005. To assess the effectiveness of this programme, we conducted an anonymous survey of staff on the University payroll in October 2015.

A total of 1,809 responses were received. The majority (77.1%) of respondents were aged 36 and above, 17.2% were aged 26–35 and only 5.8% were aged 25 or below. The majority (90.7%) of respondents knew that they need to get flu vaccination every year to reduce the risk of getting flu. Interestingly, age group was not associated with this knowledge (overall $P=0.09$). Most of the respondents (32.2%) learned this fact from the media (TV, newspaper, magazine). A close second, 31.3% cited other sources which included communication through workplace, general practitioner (GP), hospital or friends and personal knowledge as healthcare professionals, educators or students, whereas 16.8%, 11.8% and 8.0% of them learned this from their doctor, a colleague or a family member respectively. Further, 93.2% respondents knew that the University of Otago provides free flu vaccination to staff every year. This knowledge displayed a linear trend with respect to age group ($P=0.001$).

In 2015 67.3% respondents got the flu vaccination through this programme. Protecting themselves from flu and believing that vaccine reduces the risk of getting flu were the most common reasons for them to get vaccinated. Further, no associated cost and preventing spread of flu to others were also common reasons. Out of 540 (32.7%) respondents who responded in the negative to having been vaccinated through this programme in 2015, 19.1% believed that vaccination is ineffective against flu, 17.4% said that they never get the flu, while 12.6% were concerned about the side-effects of vaccination. However, 51.9% (279) of them specified other reasons which included getting vaccinated through their GP or other workplace (100), preferring a “healthy lifestyle” over vaccination (94) and missing the vaccination drive due to various reasons (76).

Overall, 85.6% of total respondents (72.3% ‘Yes’ and 13.3% ‘Maybe’) intended to get vaccinated in 2016. The age group was associated with this and the oldest age group (56+) had the highest intention ($P=0.009$). Out of 289 respondents who responded to the question specifying information they would need before deciding to get vaccinated in 2016, 42.6% wanted to know the efficacy and formulation of flu vaccine and any side-effects associated with it. However, 34.6% of them did not need any information and were against getting vaccinated. For 17.7%, it would have depended upon convenience like location and availability during the vaccination drive.

The majority (61.6%) of 671 respondents who responded to the question specifying any improvements needed to this programme did not think that any improvements were needed. However, 16.7% respondents wanted more vaccination clinics and on different days of the week, and 13.6% commented that programme needed more and frequent publicity. Few (5.4%) of them also wanted the programme to be extended to staff’s families, casual staff and students.
Overall, among respondents, flu vaccination knowledge and awareness were associated with vaccine uptake in 2015 and intention to get it in 2016. From a generalised path model, the respondents who knew that annual vaccination is needed were more likely to know that it was free ($P=0.004$), and more likely to have gotten it in 2015 ($P<0.001$) and intended to get it in 2016 ($P<0.001$). Furthermore, the awareness that the vaccine is free was positively associated with an intention to get it in 2016 ($P=0.038$).

One limitation of this study is that the data might only reflect the opinions of people who responded to the survey. During the survey period, the University employed 6,025 staff. In 2015 there were approximately 2,250 flu vaccine doses consumed, which was slightly higher from 2014 (approx. 2,000 doses). This indicates that overall vaccine uptake among University staff is still low. Based on survey responses, we believe that the lack of a timely and targeted aggressive promotional campaign could be one of the reasons for this.

**Competing interests:** Nil.

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Acetaminophen (paracetamol) versus ibuprofen in young children with mild persistent asthma

Studies have suggested an association between frequent acetaminophen use and asthma-related complications among children, leading some physicians to recommend that acetaminophen be avoided in children with asthma. This report concerns a trial designed to elucidate this issue.

The trialists enrolled 300 children (age range, 12 to 59 months) with mild persistent asthma and assigned them to receive either acetaminophen or ibuprofen when needed for the alleviation of fever or pain over the course of 48 weeks. The children in each group received a median of 5.5 doses. The number of asthma exacerbations did not differ significantly between the two groups over the one-year study period.

The conclusion reached was that among young children with mild persistent asthma, as-needed use of acetaminophen was not shown to be associated with a higher incidence of asthma exacerbations or worse asthma control than was as-needed use of ibuprofen.


Whole grains and health

Is there an association between consumption of whole grains and the risk of cardiovascular disease, total cancer, and all cause and cause specific mortality?

This Norwegian meta-analysis reviews data from 45 cohort studies. The authors report that higher intake of whole grains was associated with a reduced risk of coronary heart disease, cardiovascular disease, total cancer, all cause mortality, and mortality from respiratory disease, diabetes, infectious diseases, and all non-cardiovascular, non-cancer causes of death. These risk reductions were noted in those eating 7 to 7.5 servings per day. Three servings (90 g) is equivalent to two slices of bread and one bowl of cereal or one and a half pieces of pitta bread made from whole grains.

An editorial commentator speculates that such a high intake of whole grain might be difficult to achieve; she suggests that the largest health benefit might be achieved simply by shifting people from low or no intake of whole grains to an intake of just one serving.

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Neuropsychiatric safety and efficacy of varenicline, bupropion and nicotine patch in smokers with and without psychiatric disorders

Substantial concerns have been raised about the neuropsychiatric safety of the smoking cessation medications varenicline and bupropion. In this study the researchers compared the relative neuropsychiatric safety risk and efficacy of varenicline and bupropion with nicotine patch and placebo in smokers with and without psychiatric disorders.

Over 8,000 participants, half with psychiatric disorders and half with no history of such disorders were involved. Overall there were more reports of neuropsychiatric adverse events in the psychiatric cohort compared with the non-psychiatric cohort (238/4074 vs 84/3984), but there was no difference in incidence of neuropsychiatric adverse events among the four treatment groups (varenicline 4.0%, bupropion 4.5%, nicotine patch 3.9% and placebo 3.7%).

The researchers conclude that their study did not show a significant increase in neuropsychiatric adverse events attributable to varenicline or bupropion relative to nicotine patch or placebo. Varenicline was more effective than placebo, nicotine patch and bupropion in helping smokers achieve abstinence, whereas bupropion and nicotine patch were more effective than placebo.

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The following case to my mind appears rare, and with peculiar interesting features. I therefore consider it worth while to report.

The patient, aged 43, and married many years, but without any history of pregnancy, complained of severe headaches as her most predominant symptom. This, she says, she has had upon awaking every morning, almost without exception, for over 20 years, but especially worse at her monthly periods. Her other less marked symptoms were dysmenorrhoea, menorrhagia and sacral pain. Another condition present was a peculiar and exceptionally marked irritability of temper at her periods. She was so bad at these times that her husband always feared their return, as then and only then she became jealous and suspicious without any apparent cause. Her nurse described her as like a raving lunatic at these periods, but during her intermenstrual times she seemed quite a different person, being amiable, and without any signs of mental aberration.

Upon palpation, I felt a small sensitive swelling in the left iliac region, which I regarded as probably ovarian.

Bimanually, per vaginam, a large, fairly soft, evenly rounded and movable mass was felt in the posterior fornix. This was not exceptionally tender, and neither appeared more to one side than the other. On the left side, just within reach of the internal examining finger, a small harder swelling was felt.

I recommended operation as soon as conveniently possible, and operated upon her in a private hospital three days later.

Through a mid line incision the abdominal cavity was opened, and I was confronted with a few slight adhesions between the parietal peritoneum and the small intestine. When these were broken down, a small, almost perfectly rounded tumour, about the size of a pigeon's egg and yellowish in colour, appeared in the wound. It was semi-fluid in character, almost free in the abdominal cavity except for its pedicle and a strong band of adhesion between it and the sigmoid flexure. This band was divided, and deep down appeared a small cystic ovary situated well away from the tumour. The pedicle of the tumour was then followed to the fundus of the uterus, to which it was densely adherent, requiring to be snipped away with scissors. It was then, and not till then, I realised that the so-called pedicle was the fallopian tube twice doubled upon itself, with part of its ampulla attached to the fundus uteri, and then returning outwards to be attached at its now tumour-made extremity.

Diagrammatic drawing showing right side laid open, with the apparent complete closure of tube at cyst wall and the papillomatous growth within the cyst.

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