The
New Zealand
Medical Journal
Journal of the New Zealand Medical Association
Vol 129 | No 1431 | 11 March 2016

Public reporting of healthcare performance data: what we know and what we should do

Overnight transfusions in New Zealand hospitals: potential risk to patients

Stroke care delivery at North Shore Hospital, Waitemata District Health Board 2014

Decision-making in an era of cancer prevention via aspirin: New Zealand needs updated guidelines and risk calculators

Valuing embryos as both commodities and singularities

The New Zealand
Medical Journal
Publication Information
published by the New Zealand Medical Association

NZMA Chairman
Dr Stephen Child

NZMJ Editor
Professor Frank Frizelle

NZMA Communications Manager
Sharon Cuzens

NZMJ Production
Jeremiah Boniface

To contribute to the *NZMJ*, first read:
www.nzma.org.nz/journal/contribute

Other enquiries to:
NZMA
PO Box 156
The Terrace
Wellington 6140
Phone: (04) 472 4741

© NZMA 2015

To subscribe to the *NZMJ*, email
julie@nzma.org.nz

Subscription to the *New Zealand Medical Journal* is free and automatic to NZMA members.

Private subscription is available to institutions, to people who are not medical practitioners, and to medical practitioners who live outside New Zealand. Subscription rates are below.

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

Read our Conditions of access for subscribers for further information
www.nzma.org.nz/journal/subscribe/conditions-of-access

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

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

Subscription rates for 2016

New Zealand subscription rates	
Individuals*	$298
Individual article	$25

Overseas subscription rates	
Individual	$415
Institutions	$557
Individual article	$25

*NZ individual subscribers must not be doctors (access is via NZMA Membership)
New Zealand rates include GST. No GST is included in international rates.
Note, subscription for part of a year is available at pro rata rates.
Please email julie@nzma.org.nz for more information.
Individual articles are available for purchase by emailing nzmj@nzma.org.nz

ISSN 1175-8716
© NZMA

Current management of acute diverticulitis: a survey of Australasian surgeons

Rebekah Jaung, Jason Robertson, David Rowbotham, Ian Bissett

Diverticular disease (DD) is a condition caused by the formation of pouch-like diverticula in the wall of the large bowel. Even though it is a relatively common condition, there is little agreement about the best way to manage DD. This survey of surgeons working in New Zealand and Australia was conducted in order to study how acute diverticulitis (AD), a common acute manifestation of DD, is routinely being managed. The results of this survey show that there is a wide range of clinical practice amongst surgeons, particularly when managing the less severe form of AD. These findings support the idea that more high quality research into this field is warranted in order to provide consistent and evidence-based care to patients with DD.

Overnight transfusions in New Zealand hospitals: potential risk to patients

Rachel Donegan, Angela Wright, Louise Bobbitt, Richard Charlewood, Hilary Blacklock

Transfusion of blood products is not without risk. Non-urgent transfusion should not take place overnight due to reduced staffing levels and patients need for rest and uninterrupted sleep. There is still evidence of patients receiving un-necessary transfusions despite efforts to reduce this.

Management of gestational trophoblastic disease: a survey of New Zealand O&G practice

Maria Kladnitski, Diane Kenwright

In very rare cases an early pregnancy tissue can undergo pre-cancerous or cancerous transformation. The definite diagnosis can only be made by examining the tissue under the microscope. The treatment may range from a simple observation to a full chemotherapy treatment .It has been proven that a prompt diagnosis and centralised management of the condition greatly improves treatment outcomes. The aim of our study was to obtain some information on the current practices in diagnosis and management of this condition, and explore the view of O&G Specialists on some form of centralisation of care.

Accuracy of frozen sections for breast cancer sentinel lymph node biopsies within a peripheral New Zealand hospital

James PL Tan, Lesley Joblin, Emily Davenport

A “frozen section” is a test performed to give a rapid (within 30 mins) result for testing if cancer has spread to lymph nodes. It is commonly used during breast cancer surgery. The rapid result has a down-side of being less accurate than traditional testing. This study confirmed that “frozen sections” performed in Hawke’s Bay meet internationally accepted standards for accuracy.

An exploratory study of the health harms and utilisation of health services of frequent legal high users under the interim regulated legal high market in central Auckland

Chris Wilkins, Jitesh Prasad, KC Wong, Thomas Graydon-Guy, Marta Rychert

We recruited 105 frequent legal high users from outside of licensed legal high stores in central Auckland in early 2014. Eighty percent used synthetic cannabinoids (SC) and 20% ‘party pills’. Fifty-four percent of SC users were classified as SC dependent. The most common problems reported from SC use were insomnia (29%), ‘vomiting/nausea’ (25%), ‘short temper/agitation’ (21%), ‘anxiety’ (21%), ‘strange thoughts’ (16%) and ‘heart palpitations’ (14%). The health services most commonly accessed by SC users were a ‘doctor/GP’ (9%), ‘counsellor’ (9%), ‘DrugHelp/MethHelp’ websites (7%), ‘Alcohol & Drug Helpline’ (4%), ‘ambulance’ (3%), ‘A&E’ (3%) and hospitalisation (3%). Frequent use of SC products was associated with health problems, including drug dependency. Further research is required to determine the health risks of these products.

Social and spatial inequalities in Rotaviral enteritis: a case for universally funded vaccination in New Zealand

Christopher Bowie, Malcolm Campbell, Paul Beere, Simon Kingham

Rotavirus is the most common cause of diarrhoea related illness among children worldwide, prior to the introduction of a funded vaccine in New Zealand the annual health sector cost due to hospital admissions were more than $7 million. This research looked at clusters of rotaviral hospital admissions in Auckland, New Zealand between 2006 and 2011 based on the home address of affected children. We found that clusters of rotavirus shifted across the city, with little relationship to socio-economic status or neighbourhood conditions. This research supports the introduction of a fully funded vaccine in New Zealand in 2014 as the rate of vaccination paid for by parents before this date was extremely low, and targeted intervention of affected communities is unlikely to reduce the overall burden of disease.

Stroke care delivery at North Shore Hospital, Waitemata District Health Board 2014

Jennifer Yeo, Lifeng Zhou, Yogini Ratnasabapathy

This paper provides a snapshot of stroke care at North Shore Hospital (NSH) over a 2 month period. It shows significant gains being made around rates of admission to the stroke unit and brain scanning. Overall, therapy intensity received by patients at NSH is similar to UK patients, however longer delays are seen from time of admission to the first assessment of therapy for NSH patients. It is encouraging to see that prescription rates for secondary prevention (blood pressure and cholesterol) medication are similar to our Australian counterparts. For stroke survivors who are discharged from hospital, delays in access to community physiotherapy and occupational therapy are seen.

Valuing embryos as both commodities and singularities

Michael Legge, Ruth Fitzgerald

We have considered the argument that to donate, sell or research on gametes and embryos is to treat them as a commodity, to be traded or exchanged. In this work the concept of gametes and embryos becoming utilities to resolve childlessness is discussed in relation to the use of human reproductive material.

Decision-making in an era of cancer prevention via aspirin: New Zealand needs updated guidelines and risk calculators

Nick Wilson, Vanessa Selak, Tony Blakely, Josh Knight, Nhung Nghiem, William Leung, Philip Clarke, Rod Jackson

Based on new systematic reviews of the evidence, a key US Task Force has drafted updated guidelines on the use of low-dose aspirin for the primary prevention of both cardiovascular disease (CVD) and cancer. This Task Force generally recommends consideration of aspirin in adults aged 50-69 years with 10-year CVD risk of at least 10%, in whom absolute health gain (from reduction of CVD and cancer) is estimated to exceed absolute health loss (increase in bleeds with aspirin). With the ongoing decline in CVD, current risk calculators for New Zealand are probably outdated. Nevertheless, we suspect that most smokers aged 50-69 years and some non-smokers in New Zealand would probably meet the new threshold for taking low-dose aspirin. New Zealand therefore needs updated guidelines and risk calculators that are ideally informed by estimates of absolute net health gain (in quality-adjusted life-years or QALYs per person) and cost-effectiveness.

Public reporting of health care performance data: what we know and what we should do

R Hamblin, C Shuker, I Stolarek, J Wilson, AF Merry

ABSTRACT

Journalists have recently filed complaints with the Ombudsman calling for the release of the patient mortality and complications rates of named individual surgeons. This is a fraught and complex issue: are the intrinsic benefits of such increased transparency potentially outweighed by evidence of negative practical effects? The potential negative effects of such public reporting include unfair criticism of experienced clinicians working with our sickest patients, potentially misleading information for the public, and the risk of inferring statistically unfounded interpretations due to insufficient data.

However, different forms of public reporting have been associated with improved outcomes internationally, and there is a drive toward greater transparency both for consumers and for clinicians to aid quality improvement. In this summary of the Health Quality & Safety Commission's position paper on the public reporting of health care performance data, we discuss the evidence and make recommendations for the future of transparency in New Zealand health care. These recommendations include that such reporting ought to be at the level of the team, unit, or institution, and that measures should be determined in consultation with consumers, clinicians, providers and professional bodies.

Journalists have recently filed complaints with the Ombudsman after Southern, Canterbury, Capital & Coast, Waikato, and Auckland district health boards (DHBs) responded variably to their requests under the Official Information Act that the patient mortality rates and other complications rates of named surgeons be released—DHBs either refused, or released data at DHB level. The Ombudsman will soon rule on this matter.

This is a fraught and complex issue. New Zealand is upon the difficult road to increased transparency in health care as many countries and jurisdictions before us, such as the UK, Australia and many major US states. Media and the public want to be reassured that our health system is working well, and that doctors have nothing to hide. On the other hand, many clinicians are concerned about important statistical considerations—that the release of raw, insufficient or inadequately risk-adjusted data may mislead the public, or that the potentially higher mortality rates associated with experienced surgeons who care for our sickest patients may lead to unjustified media criticism of skilled and valued doctors.

How can these tensions be reconciled?

The Health Quality & Safety Commission (the Commission) supports transparency—'shining the light'—and the appropriate reporting of data to assure and improve the quality and safety of health care. Feedback to the Commission confirms general support in New Zealand for this position, which is widely held in most comparable countries.

However, the balance of the positive and negative practical effects of transparency on quality of health care is not clear in the context of the publication of outcomes data, such as rates of surgical mortality and other complications. In particular, it seems there is an important distinction between reporting information on the performance of individual practitioners and reporting

information on the performance of units, organisations or teams.

The Commission has reviewed the international evidence for such public reporting, and its practical effects. The Commission has also consulted widely in the health sector, solicited responses to a draft version of a position paper for the Ombudsman and alongside the Ministry of Health held a workshop with consumers to inform the evidence base with local practice and local viewpoints.

In this summary of the Commission's position paper, we discuss the evidence and make recommendations for the future of such public reporting in New Zealand health care. The full position paper, evidence review and more extensive list of references is available at http://www.hqsc.govt.nz/publications-and-resources/publication/2463/.

The views of New Zealand patients and consumers

The views of patients and consumers are important in determining which outcome measures be reported and how.[1-4] In New Zealand's publicly funded hospitals, consumers are not usually able to choose individual practitioners, or even teams or hospitals. Consumer workshop participants stated this was all the more reason for complete transparency to drive improvement across the sector.[5] However, consumers seem to want simple things: trust and confidence in the system; to know that professionals are competent and meet or are above the acceptable standard and that this competence is publicly demonstrated; that the system is reliable and organisations have the right culture of openness and transparency; and that there are visible processes to improve quality.[5]

Information publicly reported should meet consumers' needs.[4,6] Modest differences in mortality rates are often difficult to relate to—in most operations the rates are low, and difficult to interpret.[6] Other serious complications, such as infections (notably in the context of joint replacement surgery) are also—and arguably more—important. Strokes may be feared as much or more than death. Patient-reported outcome measures (PROMs), reflecting individuals' own assessment of their health or well-being, without interpretation by a clinician or anyone else, may be as relevant to many people as mortality.[7] Patients also value information about the experiences of other patients, including friends or family, for example about whether their pain was controlled, whether they were listened to and whether a nurse came when called.[8]

Thus, even if mortality data are reported, other measures are also needed.

Data considerations, appropriateness of measures, and registries

Whatever measures are reported, it is important that the data are accurate, valid and meaningful. Measures should be specific, sensitive, timely, and easy to collect (ideally as part of routine care).[9] Risk adjustment is necessary to account for case complexity. The benefits should outweigh the costs.[10]

Having selected suitable measures of performance and approaches to risk adjustment, the statistical requirements for identifying change over time, differences between individuals, or between one individual and a given standard, are:

1. A sufficiently high rate of the relevant outcome (eg, mortality, stroke or infection) and a high enough case load for adequate statistical power;
2. An understanding of the prior probability of the condition to be identified (eg, poor performance).

However, the typical caseloads of most individual clinicians for many procedures are inadequate to generate enough statistical power to reliably identify potential poorer performers, or to avoid substantial risk of false positives.[11]

Cardiac surgery is more suitable for this type of reporting than most other specialties. In particular, first-time coronary-artery surgery is relatively common and relatively standardised. Mortality is currently slightly more than 1% (ie, deaths are reasonably common). Good methods of risk adjustment are well established.

However, on an annual basis, UK cardiac surgeons would have to perform three times the number of procedures they typically do to generate enough statistical power to detect a poor performer eight times out of ten.[11] The New Zealand situation is essentially similar. (Indeed, it adds perspective to note that as of November 2015, there were only 29 doctors in a vocational scope of cardiothoracic surgery with a current practising certificate on the New Zealand medical register (pers comm, A Cullen, Medical Council of New Zealand, 17 Nov 2015).) Furthermore, the balance between case load and mortality produces much lower statistical power for most other procedures. Lengthier reporting periods (one solution to the problem of insufficient statistical power) may result in long delays in detecting problems, and the process risks losing relevance.[11]

An alternative solution is to aggregate to the team, unit or hospital level, which increases statistical power without losing immediacy.[11,12] Even then, some units may be too small. For procedures that carry substantial risk (eg, >1% mortality rates), consideration should be given to amalgamation to ensure that all surgeons operate within groups ("teams") that collectively have sufficient volumes to provide reliable estimates of outcome.

In hospitals with only one surgeon in a particular field, we strongly recommend aggregation of the "lone" surgeon's hospital data with that of a major centre. The arrangements should include peer support, clinical audit, professional development, case review, internal quality assurance and so forth. Clinicians should not work in isolation, and collegial relationships can be facilitated by modern means of communication, notably video-conferencing. Inclusion of geographically isolated surgeons into larger teams is also an appropriate way of avoiding unintended disclosure of an individual's data.

In addition to limitations in monitoring outcome, there is at least some evidence to suggest that volume itself may be a factor in determining outcome.[13-15]

Collection and registries

Clinical registries are structured ongoing collections of personal health data from all patients in a clinically-defined population. Registries can provide benchmarked, risk-adjusted outcomes, and can be used as the basis of public reporting.[16] They are work-intensive and expensive.[8,9,16] Currently, New Zealand has a few established clinical registries (including registries to monitor the postoperative infection rates of certain procedures, such as hip and knee arthroplasties), but most data currently available for public reporting are derived from administrative datasets and lack the depth and detail of registry data.

Bridging administrative data collection and clinical data collection is difficult, and attempts to do this have largely failed in the UK NHS.[17,18] Though there is a strong argument for building more registries, in the long run information technology (IT) systems that capture the required information as part of routine care are needed, and investment in this approach is more prudent. Relevant work by and with the National Health Information Technology Board (NHITB) is ongoing.

Informed consent and the autonomy of patients or consumers

There is no clear legal or ethical consensus on the importance of information about individual surgeons' performance to informed consent. In the US, case law is evolving with conspicuous differences between states.[13,19,20] In the UK and Australia, the courts have lately moved away from a standard of disclosure determined by the profession to one determined by what 'the prudent patient' would want to know in the given circumstances.[21] The latter part of this test implies that context is important and the matter needs to be decided on a case-by-case basis, rather than in a universal or general way.

In New Zealand, the Code of Health and Disability Services Consumers' Rights 1996 ('the Code') is the key source of law on informed consent supplemented by other legislation and case law. Informed consent is typically viewed as a continuum and a process of information sharing.[22] Under the Code, a patient has the right to be fully informed, but also to effective communication. Thus, the precise information that is

best suited to help any particular patient in making a decision will depend on context.

There are grounds that there is no ethical obligation to provide patients with clinicians' performance information for informed consent because of imprecision of measurement: the individual surgeon's performance alters depending on the team and institution they operate in,[23] and measures are too late and not accurate enough.[20,24] Given the practical and statistical limitations discussed above on the reporting and interpreting of surgical results, there is a real risk of misleading or overburdening patients, rather than informing them in a way that would truly assist in making important decisions. A more general assurance that measures are in place to ensure acceptable competence is probably more appropriate in most cases.

Even if data were provided on some selected specialities, as with cardiac surgery in the UK, many patients may have insufficient statistical knowledge to interpret the information correctly—appropriate displays (such as funnel plots, for example) are quite complex, although commentary may assist. The limitation in choice within our public hospitals is also relevant. It is true that patients unable to choose between surgeons may still decline treatment altogether, but it would be unfortunate if misinterpretation of data resulted in patients refusing treatment that would in fact be of value to them.

Importantly, there should be no grounds for this if our health system is operating adequately—all practitioners should be achieving acceptable results. However, this whole debate has presumably been stimulated by anxiety that this might not be true, so perhaps the most useful information for most patients would simply be that adequate processes are in place to ensure the competence of all practitioners (see Accountability below).

Using data to drive improved outcomes and improve quality

To change outcomes, behaviour has to change. Public reporting may change behaviours by patients or providers.

Patients may:

- choose better quality providers and force lower quality providers to improve or leave the "market";
- gain or lose trust and thus potentially respond with more or less compliance with treatment regimens;
- interpret or access published information differently, potentially leading to increased inequity in outcomes.

Providers (whether individual or institutional) may:

- improve the quality of services;
- cease to provide lower-quality services;
- respond perversely—for example, by reorganising services to reduce exposure to riskier patients, or changing data-recording practices to give the impression of a riskier case mix and thus better relative outcomes.

Changed behaviours by patients or consumers

The evidence is mixed, but suggests consumer decision making is not usually substantially influenced by public reporting on health care quality.[25,26] Though consumers and the public are in favour of public reporting, in practice they tend not to know about[27] or search for the information.[28] They sometimes fail to understand it,[6,29] and/or mistrust the source agencies.[30] They make little use of it in actual decisions, partly because choice is not always a feasible option.[30-32] Indeed, consumer choice of physician has been described as a 'black box'—in effect, inexplicable.[33] There is, however, some evidence that thoughtful presentation of relevant information may result in choice of better-rated providers.[12,34] Differential access to such reports, perhaps because of differences in health literacy, may have led to inequities by ethnicity and socioeconomic status in certain jurisdictions.[9,35] This is not an argument against reporting, but rather one for ensuring that reporting is in appropriate forms and accessible and understandable to all.

Quality improvement and public reporting

Evidence shows public reporting of performance data stimulates quality improvement activity at the provider

level, but not at an individual level.[34-36] Public reporting is more likely to be associated with changes in health care provider behaviour than with selection of health services providers by patients or families.[30,31,34,35,37] Improvement after public reporting seems to be driven by reputational concerns: institutions that report publicly rather than internally tend to put more quality improvement projects in place, and tend to improve, regardless of any efforts to game such systems.[34,37-39]

The New York State Cardiac Surgery Reporting System (NYS CSRS), the longest-running and most-studied such programme in the US, is a clinical registry with a quality improvement focus and a public reporting feature. Hospitals were the unit of reporting until a lawsuit forced reporting by individual surgeon. The NYS CSRS was associated with a 41 percent state-wide fall in in-hospital mortality rates for coronary artery bypass graft (CABG) surgery in three years,[8,9,15,40] though the causes have been debated.[41-43] Other similar state-wide public reporting programmes, particularly in California, have been associated with improved outcomes for cardiac surgery.[44,45] Over the same period, mortality has steadily improved in many units around the world, in cardiac surgery and in surgery generally, so many factors may be at play.[46]

Public reporting of individual surgeons' outcomes in the UK was stimulated by the paediatric cardiac surgery scandal at Bristol Royal Infirmary and subsequent inquiry.[47] The Department of Health informed consultants of their intention to publish performance information at the level of consultant teams.[17] The Society for Cardiothoracic Surgery in Great Britain & Ireland (SCTS) responded quickly, having data systems in place.[48] The Dr Foster organisation published mortality rates for coronary artery surgery by hospital in 2001, and a Freedom of Information Act request in 2005 led to publication of mortality data for coronary artery surgery for all UK surgeons, named individually. Outcomes have clearly improved in the National Health Service (NHS) since then,[49,50] despite an increasing complexity of case mix, but a causal link has not been established, and, as indicated above, results have also improved in other countries over this time period.

Concerns remain over the potential for surgeons to become risk-averse and avoid high-risk patients,[51] or for gaming to occur, with patients scored as higher risk to create the impression of better outcomes, for example, or patients treated non-surgically even when the optimal treatment for the illness is surgery—among other options.[52] Gaming behaviour has been considered a sign that incentives are strong and a measure is effective in discerning performance,[52] and if systems of performance measurement are taken seriously, and are designed to have an effect, then approaches to counter gaming ought to be integral to the design.[53]

Teams versus individuals in determining patient outcomes

There is increasing evidence that outcomes of surgery are less attributable to any single individual than to the multidisciplinary teams and on the collaborative and institutional context in which surgery is done.[20] Failures in teamwork and communication underpin a high proportion of adverse events.[54,55] Outcomes have been shown to vary by the institution and team in which a surgeon works.[23] This is because many aspects of care other than the surgeon's performance are involved, and outcomes are dependent on the influence of anaesthetists, nurses, intensivists, and many others involved in postoperative care, among other considerations. The importance of "failure to rescue" has become increasingly apparent in recent years.[38,56,57]

The US Veterans Health Administration has discouraged reporting of surgeon-specific outcomes as they believe that the performance of individuals cannot be separated from that of the institution.[58] Teamwork and training were shown to reduce both morbidity and mortality in surgery and improve processes.[58]

Enquiries into failures of care at Bristol Royal Infirmary and Stafford Hospital in the UK revealed lack of leadership, teamwork and the ability to work together effectively for the interests of patients as the key failings.[46,59]

Publishing the results of individual surgeons seems likely to promote individualistic, rather than team-oriented, practices and behaviours. In contrast, publishing by

unit is more likely to drive a culture in which all members of the unit will want to ensure that not only themselves but also all their team members are performing as well as possible. We want good practitioners to have a strong incentive to help their colleagues achieve equally good results, rather than to gain by comparison with those not doing quite so well. Inappropriate variation in practice is a recognised barrier to excellent and cost-effective practice in health care. Variation should reflect differences between individual patients: in fact it often reflects unjustifiable differences in the approaches of individual practitioners. In general, if one practitioner's approach is truly the best, then it should be adopted by all; otherwise, the least expensive approach should be used by all. Reporting by unit should encourage appropriate standardisation and strengthen efforts to monitor, maintain and improve the competence of all practitioners.

If it is team-based medicine that is to be encouraged, it does not seem sensible to publish data based on individual members of the team (M Seddon, personal communication, 6 July 2015).[12,36] Given that team level reporting is also more likely to achieve meaningful statistical power and allow timelier pick-up of issues[11,12] the grounds for publication at team or organisation level are compelling.

Accountability

Health care practitioners, providers and regulators, and professional bodies are accountable to the public that services provided are safe and of high quality. The public rightly expects staff to be technically competent, use evidence-informed treatments, work ably within teams, have good communication skills, be caring, and maintain these skills over time.[5] It is reasonable to expect that the relevant authorities will make the proper checks to ensure that health care professionals remain competent and fit to practice.[5,60]

Various processes are currently used to attempt to demonstrate doctors' ongoing competence continuously throughout their medical careers. The Council of Medical Colleges, the Medical Council of New Zealand and the Ministry of Health are working to better align and strengthen these processes.

There is room for more visible evidence of participation and of the criteria used to assess acceptable performance. Though there is no legal binding requirement under the Health Practitioners Competence Assurance Act 2003 for health care professionals to raise concerns about a colleague's competence or performance, acting on concerns where there is risk of patient harm is considered an ethical responsibility and "encouraged" by the Medical Council, which provides guidelines to assist decision making. Under the Act, the health care professional's registering authority has a mandatory requirement to provide written notice to the Accident Compensation Corporation, Director-General of Health, and the Health and Disability Commissioner where there is risk of harm to the public.[61,62]

Use of appropriate data on the performance of individual practitioners has a role in assuring standards *within* institutions or units. Techniques, such as variable life-adjusted CUSUM (cumulative sum control chart)[63] to monitor outcomes (mortality, infection, and many others) on a case-by-case basis may be useful. The aim should be the early detection of trends, to enable appropriate responses before serious problems become embedded. There is a strong argument for the holistic interpretation of performance within units, with a focus on early intervention to maintain and improve standards rather than on waiting for statistically significant red flags to identify problems after many patients have been harmed. There is evidence that publicly reported surgeon rankings of quality have not correlated with disciplinary rates and complaint rates, and quality measures may not pick up behaviours that lead to discipline.[64] Breaches of the code of patient rights, and appearances before disciplinary committees should be tracked, and recurrence of these events should lead to careful review.[60]

The Commission's view (see Box)

Increased transparency and openness are among the Commission's core values. Most consumers and clinicians concur. Transparency and openness are best achieved by the public reporting of judiciously chosen,

adequately risk-adjusted measures at the team, unit or organisational level. Reporting at an individual level is likely to be statistically unsound and counterproductive by undermining the teamwork we wish to encourage. Reporting data at the level of the unit (with appropriate amalgamation to deal with small units) would be a much more statistically robust step towards providing the necessary reassurance to the public while contributing to improvement in the quality of our health care services. It could also lead to a meaningful national data set from which risk and benefit could be determined for common procedures, and assist in planning investment in health systems.

Publication needs to be in a manner that is meaningful and understandable to a wide range of people. Context must be explained. Results should be presented in different formats and media to ensure that inequalities are not increased through failure to address differences in health literacy and access to information. Consumers, colleges, professional bodies and employers should work together to select and define outcome and process measures suitable for each specialty group.

Once appropriate measures have been agreed upon, information should be collected in a nationally standardised way. Reporting by DHB should be via their websites and in their Quality Accounts. The Commission already reports many carefully selected measures of the performance of our health care system, such as the Quality and Safety Indicators and the New Zealand Atlas of Healthcare Variation. The new measures should be chosen to complement these and all measures should be kept under review and revised when necessary as part of the quality improvement journey.

Cost is important—money spent on measuring and reporting represents an opportunity cost in relation to other priorities for improving the quality of our health services. An assessment of what data are currently available and of what reporting could be undertaken currently from registries or other data sets should be made. Building more registries may address the medium-term need, but in the long run, IT systems that capture the required information as part of routine care are needed and investment in these may be more cost-effective. The NHITB must be integral to this process.

The Commission supports the direction that the Council of Medical Colleges, the Medical Council of New Zealand and the Ministry of Health are taking in strengthening and aligning processes to demonstrate doctors' ongoing competence. These processes should be made more visible to the public. We suggest that organisations should be asked to attest to the presence of such processes and to their confidence that all practitioners are participating and achieving acceptable standards.

Public reporting is a complex and challenging area that has been brought into focus by a seemingly simple and obvious request—to *know*. There are pitfalls and also opportunities ahead. The Commission supports increased transparency. But we must build, not destroy or divide. If we are to construct windows to facilitate greater transparency we must make the right decisions early on and proceed in a phased, consistent way, as architects and builders might. There is a danger in optics—illusions are easily produced. We need windows that are well made and well placed to shine a clear light to guide us in ensuring that the care of our patients is safe, and that it continues to improve.

Box: An extract from the position paper of the Health Quality and Safety Commission.

The Commission recommends:

- the public reporting of judiciously chosen, adequately risk-adjusted measures at the team, unit or organisational level rather than the individual level;
- development of agreed national standards of data collection, relevant definitions and measures across New Zealand, and agreed risk adjustment models to account for case complexity and risk;
- that publication should include clear explanations of context, and of the limitations and interpretation of the data, in different formats and media to ensure that the information is accessible to people of all levels of health literacy;
- further evaluation of the cost effectiveness of investment in clinical registries weighed against accelerated investment in IT systems that could capture the same information as part of routine care.

To these ends the Commission suggests:

- that consumers, colleges, professional bodies and employers together define a simple group of outcome and process measures for each specialty group that will serve to assure safety and drive improvement. These measures should reflect the different needs of the interested parties: we suggest one outcome and process measure each that is consumer-focused, clinician-focused and organisation-focused.

Further, the Commission supports:

- the work under way to strengthen and align the processes within organisations to demonstrate doctors' ongoing competence: we recommend that these processes are made more transparent and that boards of health care organisations should be asked to attest to their presence, and to their confidence that all practitioners are participating and achieving acceptable standards;
- increased education and training focused on enhancing teamwork within organisations.

Acknowledgements:

This paper incorporates feedback from the Accident Compensation Corporation, Association of Salaried Medical Specialists, Australian and New Zealand College of Anaesthetists, Counties Manukau DHB Clinical Directors, Ministry of Health, National Chief Executives, National Council of Medical Colleges group, New Zealand Medical Association, New Zealand Nurses Organisation, New Zealand Public Service Association, Royal Australasian College of Physicians, Royal Australasian College of Surgeons, Royal New Zealand College of General Practitioners, Southern DHB clinicians, and Waitemata DHB.

Author information:

Richard Hamblin, Director of Health Quality Evaluation, Health Quality & Safety Commission, Wellington; Carl Shuker, Principal Advisor, publications, Health Quality & Safety Commission, Wellington; Iwona Stolarek, Medical Advisor, Health Quality & Safety Commission, Wellington; Janice Wilson, Chief Executive Officer, Health Quality & Safety Commission, Wellington; Alan F Merry, Chair of the Board of the Health Quality & Safety Commission, and head of the School of Medicine at the University of Auckland, and specialist anaesthetist, Auckland City Hospital.

Corresponding author:

Alan F Merry, Faculty of Medical and Health Sciences, University of Auckland, Private Bag 92019, Auckland.

a.merry@auckland.ac.nz

URL:

www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6842

REFERENCES:

1. Keogh B. 2008. Presidential Message: A decade of immunisation. Society for Cardiothoracic Surgery in Great Britain & Ireland. URL: www.scts.org/_userfiles/pages/file/Presidential%20address-Keogh.pdf (accessed September 2015).
2. Chaudhry M, Gauld R, Horsburgh S. 2012. Hospital quality-of-care performance measurement and reporting: what New Zealand can learn from the United States and United Kingdom. NZ Med J 125(1366): 51–63.
3. Davies H, Marshall MN. 1999. Public disclosure of

performance data: does the public get what the public wants? The Lancet 353(9165): 1639–40.

4. Bridgewater B, Hickey GL, Cooper G, et al. 2013. Publishing cardiac surgery mortality rates: lessons for other specialties. BMJ 346(feb28): f1139.
5. Health Quality and Safety Commission; Ministry of Health. Consumer workshop. 3 July 2015.
6. Minami CA, Dahlke A, Bilimoria KY. 2015. Public Reporting in Surgery. Annals of Surgery 261(2): 241–2.
7. Greenhalgh J, Long AF, Flynn R. 2005. The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory? Soc Sci Med 60(4): 833–43.
8. Hannan EL, Cozzens K, King SB 3rd, et al. 2012. The New York State cardiac registries: history, contributions, limitations, and lessons for future efforts to assess and publicly report healthcare outcomes. J Am Coll Cardiol 59(25): 2309–16.
9. Shahian DM, Edwards FH, Jacobs JP, et al. 2011. Public Reporting of Cardiac Surgery Performance: Part 1–History, Rationale, Consequences. Ann Thorac Surg 92(3): S2–S11.
10. Neil DA, Clarke S, Oakley J. 2007. Against the Informed Consent Argument for Surgeon Report Cards. Informed Consent and Clinician Accountability. Cambridge: Cambridge University Press. p 147–56.
11. Walker K, Neuburger J, Groene O, et al. 2013. Public reporting of surgeon outcomes: low numbers of procedures lead to false complacency. The Lancet 382(9905): 1674–7.
12. Godlee F. 2012. Measure your team's performance, and publish the results. BMJ 345: e4590.
13. Banja JD. 2015. Disclosure of experience as a risk factor in informed consent for neurosurgery: the case of Johnson v. Kokemoor. Virtual Mentor 17(1): 69–73.
14. Birkmeyer JD, Stukel TA, Siewers AE, et al. 2003. Surgeon volume and operative mortality in the United States. N Engl J Med 349(22): 2117–27.
15. Hannan EL, Siu AL, Kumar D, et al. 1995. The decline in coronary artery bypass graft surgery mortality in New York State. The role of surgeon volume. JAMA 273(3): 209–13.
16. University of Melbourne. 2013. Registry Science Handbook. Melbourne: University of Melbourne.
17. Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995. UK: Department of Health.
18. Maughan A. 2010. Six reasons why the NHS National Programme for IT failed. ComputerWeekly.com. URL: http://www.computerweekly.com/opinion/Six-reasons-why-the-NHS-National-Programme-for-IT-failed (accessed September 2015).
19. Bal BS, Choma TJ. 2012. What to disclose? Revisiting informed consent. Clin Orthop Relat Res 470(5): 1346–56.
20. Burger I, Schill K, Goodman S. 2007. Disclosure of individual surgeon's performance rates during informed consent: ethical and epistemological considerations. Annals of Surgery 245(4): 507–13.
21. Sokol DK. 2015. Update on the UK law on consent. BMJ 350: h1481.
22. Governor-General. 1996. Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations (SR 1996/78). Wellington: Governor-General.
23. Huckman RS, Pisano GP. 2006. The firm specificity of individual performance: evidence from cardiac surgery. Management Science 52(4): 473–88.
24. Lagu T, Goff SL, Hannon NS, et al. 2013. A mixed-methods analysis of patient reviews of hospital care in England: implications for public reporting of health care quality data in the United States. Jt Comm J Qual Patient Saf 39(1): 7–15.
25. Henderson A, Henderson S. 2015. Provision of a surgeon's performance data for people considering elective surgery. Cochrane Database Syst Rev 2: CD006327.
26. Ketelaar NA, Faber MJ, Flottorp S, et al. 2011. Public release of performance data in changing the behaviour of healthcare consumers, professionals or organisations. Cochrane Database Syst Rev (11): CD004538.
27. Schneider EC, Epstein AM. 1998. Use of public performance reports: a survey of patients undergoing cardiac surgery. JAMA 279(20): 1638–42.
28. Mannion R, Goddard M. 2003. Public disclosure of comparative clinical performance data: lessons from the Scottish

experience. J Eval Clin Pract 9(2): 277–86.

29. Donelan K, Rogers RS, Eisenhauer A, et al. 2011. Consumer Comprehension of Surgeon Performance Data for Coronary Bypass Procedures. Ann Thorac Surg 91(5): 1400–06.
30. Marshall MN. 2004. How do we maximize the impact of the public reporting of quality of care? Int J Qual Health Care 16(suppl_1): i57–i63.
31. Marshall MN, Shekelle PG, Leatherman S, et al. 2000. The public release of performance data: what do we expect to gain? A review of the evidence. JAMA 283(14): 1866–74.
32. Seddon M. 2012. Reporting hospital performance – a balancing act between accountability and quality improvement. NZ Med J 125(1366): 5–8.
33. Schlesinger M, Kanouse DE, Martino SC, et al. 2013. Complexity, public reporting, and choice of doctors: a look inside the blackest box of consumer behavior. Med Care Res Rev 71(5 Suppl): 38S–64S.
34. Hibbard JH, Stockard J, Tusler M. 2005. Hospital performance reports: impact on quality, market share, and reputation. Health Affairs 24(4): 1150–60.
35. Fung CH. 2008. Systematic review: the evidence that publishing patient care performance data improves quality of care. Ann Intern Med 148(2): 111.
36. Totten AM, Wagner J, Tiwari A, et al. 2012. Closing the quality gap: revisiting the state of the science (vol. 5: public reporting as a quality improvement strategy). Evid Rep Technol Assess (Full Rep) (208.5): 1–645.
37. Contandriopoulos D, Champagne F, Denis JL. 2014. The multiple causal pathways between performance measures' use and effects. Med Care Res Rev 71(1): 3–20.
38. Hamblin R. 2007. Publishing 'quality' measures: how it works and when it does not? Int J Qual Health Care 19(4): 183–6.
39. Hibbard JH, Stockard J, Tusler M. 2003. Does publicizing hospital performance stimulate quality improvement efforts? Health Aff (Millwood) 22(2): 84–94.
40. Chassin MR. 2002. Achieving and sustaining improved quality: lessons from New York State and cardiac surgery. Health Aff (Millwood) 21(4): 40–51.
41. Omoigui NA, Miller DP, Brown KJ, et al. 1996. Outmigration for coronary bypass surgery in an era of public dissemination of clinical outcomes. Circulation 93(1): 27–33.
42. Epstein AJ. 2006. Do cardiac surgery report cards reduce mortality? Assessing the evidence. Med Care Res Rev 63(4): 403–26.
43. Narins CR, Dozier AM, Ling FS, et al. 2005. The influence of public reporting of outcome data on medical decision making by physicians. Arch Intern Med 165(1): 83.
44. Carey JS, Danielsen B, Junod FL, et al. 2006. The California Cardiac Surgery and Intervention Project: evolution of a public reporting program. Am Surg 72(10): 978–83.
45. Romano PS, Marcin JP, Dai JJ, et al. 2011. Impact of public reporting of coronary artery bypass graft surgery performance data on market share, mortality, and patient selection. Medical Care 49(12): 1118–25.
46. Weiser TG, Semel ME, Simon AE, et al. 2011. In-hospital death following inpatient surgical procedures in the United States, 1996-2006. World J Surg 35(9): 1950–6.
47. Kennedy I. 2001. The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: learning from Bristol. ("The Kennedy report".) URL: http://webarchive.nationalarchives.gov.uk/20090811143745/http:/www.bristol-inquiry.org.uk/final_report/the_report.pdf (accessed September 2015).
48. Keogh B, Kinsman R. 2002. National adult cardiac surgical database report 2000-2001. Society of Cardiothoracic Surgeons of Great Britain and Ireland. London: Society of Cardiothoracic Surgeon of Great Britain and Ireland.
49. Bridgewater B, Grayson AD, Brooks N, et al. 2007. Has the publication of cardiac surgery outcome data been associated with changes in practice in northwest England: an analysis of 25 730 patients undergoing CABG surgery under 30 surgeons over eight years. Heart 93(6): 744–8.
50. Brown KL, Crowe S, Franklin R, et al. 2015. Trends in 30-day mortality rate and case mix for paediatric cardiac surgery in the UK between 2000 and 2010. Open Heart 2(1): e000157–e57.
51. Boseley S. 2015, 30 January. Surgeons ask NHS England to rethink policy of publishing patients' death rates. Guardian. URL: http://

www.theguardian.com/society/2015/jan/30/surgeons-nhs-england-patients-death-rates-bruce-keogh-jeremy-hunt-health (accessed September 2015).

52. Mears A. 2014. Gaming and targets in the English NHS. Universal Journal of Management 2(7): 293–301.

53. Bevan G, Hamblin R. 2009. Hitting and missing targets by ambulance services for emergency calls: effects of different systems of performance measurement within the UK. J R Stat Soc Ser A Stat Soc 172(1): 161–90.

54. Joint Commission. 2006. Joint Commission 2006 Sentinel Event Statistics 1995–2005. Washington: Joint Commission.

55. Wahr JA, Prager RL, Abernathy JH 3rd, et al. 2013. Patient safety in the cardiac operating room: human factors and teamwork: a scientific statement from the American Heart Association. Circulation 128(10): 1139-69.

56. Glance LG, Kellermann AL, Hannan EL, et al. 2015. The impact of anesthesiologists on coronary artery bypass graft surgery outcomes. Anesth Analg 120(3): 526–33.

57. Westaby S, De Silva R, Petrou M, et al. 2014. Surgeon-specific mortality data disguise wider failings in delivery of safe surgical services. Eur J Cardiothorac Surg 47(2): 341–5.

58. Neily J, Mills PD, Young-Xu Y, et al. 2010. Association between implementation of a medical team training program and surgical mortality. JAMA 304(15): 1693.

59. Francis R. 2013. The Mid Staffordshire NHS Foundation Trust Public Inquiry. URL: http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffspublicinquiry.com/report (accessed September 2015). London: The Mid Staffordshire NHS Foundation Trust Public Inquiry.

60. Paterson R. 2012. The Good Doctor. Auckland: Auckland University Press.

61. Health Practitioners Competence Assurance Act 2003. http://www.legislation.govt.nz/act/public/2003/0048/latest/DLM203312.html.

62. Medical Council of New Zealand. What to do when you have concerns about a colleague. December 2010. https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Concerns-about-a-colleague.pdf.

63. Kang N, Tsang VT, Gallivan S, et al. 2006. Quality assurance in congenital heart surgery. Eur J Cardiothorac Surg 29(5): 693–7; discussion 97–8.

64. Roberts RG, Friedsam D, Beasley JW, et al. 2006. The state of quality reports: comparing states by their rankings. WMJ 105(8): 60–6.

The proposed change to primary HPV screening in New Zealand: reasons for caution

Peter Fitzgerald, Brian Cox, Andrew Miller, Sandy Hall, Jim Reid

It is likely that the National Screening Unit (NSU) will recommend to the Minister of Health that the screening test for cervical cancer should be changed from liquid-based cytology (LBC) to a molecular based human papillomavirus (HPV) test in 2018. However, New Zealand's pathway to primary HPV screening has been very different to countries with similar highly successful cytology-based cervical cancer screening programs. The lack of wide consultation and haste in which this major change in policy is to be introduced is cause for disquiet.

We believe that while primary HPV screening shows promise, particularly in de novo screening programs, implementation in New Zealand in 2018 is premature and wrong. This decision could reduce the current level of cervical cancer protection and increase unnecessary referrals for assessment and treatment. The potential physical and psychological cost to women is unknown. Financial projections suggesting savings for the government are optimistic and the proposed change may cost more. The public sector colposcopy services are currently stressed and unlikely to meet future demand without considerable extra resourcing. All of this uncertainty and transition risk is unnecessary and could be avoided by co-testing with cytology and HPV.

Since 2008, the collection of cervical screening samples in New Zealand has been into a vial of proprietary preservative fluid. This liquid-based solution is suitable for both cytology and molecular (HPV) analysis. Cytology is currently done on all samples. A subset of women with low-grade cytology have HPV testing. Primary HPV screening reverses the sequence with all women having HPV testing and a subset with high-risk virus having additional cytology. Co-testing is when cytology and HPV testing are done together as the screening test.

The UK's NHS has the most similar cytology-based screening program to New Zealand. The NHS has, over a period of many years, kept its stakeholders closely informed about possible changes to cervical screening. In New Zealand, the proposed changes to primary screening were first made publicly known in September 2015 and a public consultation document was produced by the NSU in October 2015.[1] The document favoured primary HPV screening, the authors were not stated, and it contained a number of errors, suggesting that it had been hastily drafted. Stakeholders were given 3 weeks to respond using a template of directed specific questions. The NSU hosted public meetings in October, but the short notice and limited circulation meant overall attendance was poor. The NSU gave no indication as to how stakeholder feedback would be evaluated.

This process marks a significant change from earlier consultation on the development of the screening program in New Zealand, which was extensive, wide-ranging and considered.

Given the inadequate consultation, it is likely that the recommendations forwarded to the Minister of Health will be little changed from the 2015 consultation document.[1] The move to primary HPV testing, as proposed by the NSU, is not merely a simple change of the primary laboratory test, but requires multiple changes to most aspects of cervical screening.

© NZMA

While the recommendation to change to Primary HPV testing is based on a large body of international clinical trial evidence and population-based modelling,[2-8] no data is yet available on primary HPV screening performance in national cervical screening programs. In the UK, large multi-centre pilot studies were set up in 2013 in order to: compare the results of primary HPV screening with liquid-based cervical cytology; assess the safety of proposed follow-up protocols for women testing positive for high-risk HPV; determine whether extending the screening interval to 5-yearly HPV testing is safe; review the change in logistics required to successfully implement primary HPV testing; and check the acceptability of HPV screening to different ethnic groups.[10]

This data is essential to ensure correct decisions are made about if and when to change from a highly successful primary cytology screening program to a primary HPV screening program. In New Zealand, there have been no pilot studies to guide this decision. The NSU "Technical appendix to the public consultation paper" simply noted that:

> *Rather than 'reinventing the wheel', the National Screening Unit is using the considerable knowledge that has been built internationally, and is working closely with the Australian renewal program.*[1]

However, Australia is not the same as New Zealand. Conventional cytology, not semi-automated LBC is the publicly funded screening test.

Simulation models of policy change use trial data and various assumptions about the natural history of the disease detected, test performance outside of the trials, and patient acceptability to estimate the possible outcomes and service demands of changes in screening policy. The population simulated must include all those who are currently being screened and not just a screening naïve group. Simulation models are a poor substitute for actual observations of the effects of screening in practice. Where practicable, health service observations of the effects of potential changes in screening policy are strongly advised.

Despite the large body of research data presented on the topic in the New Zealand consultation document, the safety of HPV testing at extended screening intervals is not certain.[11,12] The clinical trials used to model the safety of primary HPV screening are all largely dependent on CIN3 as an end point to justify screening performance and clinical safety. However, CIN3 only progresses in a subset of patients and is therefore only a surrogate for invasive cancer.[12-14] Therefore, there is great interest in the performance of primary HPV screening to prevent invasive cancers.[15]

The available results are not reassuring. Four large European clinical trials provide much of the data used for modelling primary HPV screening. In these clinical trials, 8 of 19 invasive carcinomas tested were negative for HPV 2.5–8 years prior to the diagnosis of invasive carcinoma—a false negative rate for invasive carcinoma of 42%.[8] Three of the 4 European studies used conventional cytology not LBC, and so their cytology performance is not applicable to New Zealand, where LBC has been the standard since 2008.

In the UK-based ARTISTIC (A Randomised Trial In Screening To Improve Cytology) study, the cytology protection from invasive carcinoma was significantly superior to primary HPV screening. All 5 of the women who developed invasive carcinoma had negative HPV tests at baseline. There were no women with invasive carcinoma in the cytology arm.[8]

Real life performance of HPV screening protection from invasive cancer using extended screening intervals is now beginning to emerge.[16] Baseline HPV test negative rates of up to 40% in invasive carcinoma should raise concerns about the safety of extended screening intervals. There are multiple possible reasons for this lower than expected HPV screening performance, but a significant factor is that even when the complete tumour is available for examination, more than 10 percent cannot be shown to have detectable HPV by current technology.[17-20] The proportion is higher for adenocarcinoma of the cervix.

Questions should also be raised about the low cytology performance in some of the influential clinical trials which conclude HPV is the more accurate screening test. Where LBC cytology is done to high standard, there is no significant difference

between HPV and cytology test sensitivity. The orthodoxy is that HPV must be more sensitive than cytology. This is not true.[21] It depends on the quality of the cytology. The detection of a sexually transmitted infection rather than a significant cytological abnormality is a major change in the aim of screening. This may reduce screening participation. Any reduction in screening coverage will reduce protection from cervical cancer.

Primary HPV screening may harm women through excessive referral to colposcopy and consequent over treatment. HPV screening will detect high-grade squamous intraepithelial lesions (HSIL) earlier, but this will not necessarily reduce overall invasive cancer, as persistent HSIL would have been detected later by cytology before it became invasive.[22] Because the HPV test is less specific than cytology, more women without any identifiable cervical cancer precursor must be sent to colposcopy to find each HSIL. The likelihood of over treatment will be highest in women less than 30 years of age.[23]

Most HPV positive women will have no abnormality on either colposcopy or histology.[23] This will create a new category of HPV positive, but colposcopy negative, women. The risk of developing cervical cancer in these women is low, as most of these HPV-positive tests will represent either transient infections or small non-progressing squamous intra epithelial lesions. Managing these abnormal, but low risk, test results will be difficult for both clinicians and women. Inevitably at some point persisting HPV infection may generate a recommendation to treat the cervix by excision.

There is no debate about whether or not there will be extra colposcopy referral, diagnostic biopsies and treatments as a result of primary HPV compared to current cytology screening. The debate is only around how much extra and whether the New Zealand health service can cope with the increased demand for these services. Without a considerable increase in already stressed colposcopy resources, waiting times for colposcopy are likely to increase considerably when HPV testing is introduced. Because of this, we believe it is possible the primary HPV new screening algorithm may cost the New Zealand Government more than it currently spends on cervical screening.

So how can we do better? First, acknowledge that primary HPV screening creates risk for our well-established, high-quality screening program. Second, recognise that co-testing can safely provide the New Zealand data necessary to address any uncertainty with respect to primary HPV screening cancer protection (sensitivity) and over treatment (specificity). The need to model screening scenarios from overseas clinical trials would no longer exist. The feasibility and acceptability of primary HPV screening for New Zealand women would be established, or not, in a staged process that would allow for full and equal stakeholder participation.

The current haste by the NSU to implement primary HPV screening is difficult to understand. The semi-automated LBC cervical screening test is designed to continue to provide a high level of test accuracy for years to come despite unconvincing suggestions that incomplete national vaccination will undermine test performance in the short term. While the test is robust, the highly skilled workforce required to maintain the cytology service is fragile as a result of the poorly managed NSU change process. Co-testing would stabilise the work force through a well-defined transition period and reduce the risk of early loss of cytology capacity.

We believe, on the evidence available, that co-testing with LBC and HPV is the best way of assessing the contribution of HPV testing to cervical screening in New Zealand and to evaluate its implementation. Recent New Zealand experience with HPV vaccination provides a good example of poor implementation of Ministry of Health policy. The undue haste with which the NSU seeks to introduce primary HPV screening in New Zealand places women at unnecessary risk and may produce a deterioration in the effectiveness of the screening program for the unvaccinated (vast majority) or women with infection with non-vaccination oncogenic HPV types.

Acknowledgements:
Associate Professor Cox is supported by funds from the Director's Cancer Research Trust.

Author information:
Peter Fitzgerald, Cytopathologist, Southern Community Laboratories, Dunedin; Brian Cox, Specialist in Public Health Medicine, Hugh Adam Cancer Epidemiology Unit, Department of Preventive and Social Medicine, University of Otago, Dunedin; Andrew Miller, Senior Lecturer, Department of Pathology, Christchurch School of Medicine, University of Otago, Christchurch; Sandy Hall, Policy Analyst and Researcher, Women's Health Action, Auckland; Jim Reid, General Practitioner and Deputy Dean, Dunedin School of Medicine, University of Otago, Dunedin.

Corresponding author:
Peter Fitzgerald, Southern Community Laboratories, Plunket House, 472 George Street, Dunedin 9016, New Zealand.
Peter.Fitzgerald@sclabs.co.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6827

REFERENCES:

1. Kitchener HC, Almonte M, Gilham C, Dowie R, Stoykova B, Sargent A, et al. ARTISTIC: A randomised trial of human papillomavirus (HPV) testing in primary cervical screening. Health Technol Assess 2009; 13: 1-126.
2. Kitchener HC, Almonte M, Thomson C, Wheeler P, Sargent A, Stoykova B, et al. HPV testing in combination with liquid-based cytology in primary cervical screening (ARTISTIC): a randomised controlled trial. Lancet Oncol 2009; 10: 672-82.
3. Kitchener HC, Gilham C, Sargent A, Bailey A, Albrow R, Roberts C, et al. A comparison of HPV DNA testing and liquid based cytology over three rounds of primary cervical screening: Extended follow up in the ARTISTIC trial. Eur J Cancer 2011; 47: 864-71.
4. Bulkmans N, Berkhof J, Rozendaal L, van Kemenade F, Boeke A, Bulk S, et al. Human papillomavirus DNA testing for the detection of cervical intraepithelial neoplasia grade 3 and cancer: 5-year follow-up of a randomised controlled implementation trial. Lancet 2007; 370: 1764-72.
5. Ronco G, Giorgi-Rossi P, Carozzi F, Confortini M, Palma PD, Del Mistro A, et al. Efficacy of human papillomavirus testing for the detection of invasive cervical cancers and cervical intraepithelial neoplasia: a randomised controlled trial. Lancet Oncol 2010; 11: 249-57.
6. Naucler P, Ryd W, Tornberg S, Strand A, Wadell G, Elfgren K, et al. Human papillomavirus and Papanicolaou tests to screen for cervical cancer. New Eng J Med 2007; 357: 1589-97.
7. Dillner J, Rebolj M, Birembaut P, Petry KU, Szarewski A, Munk C, et al. Long term predictive values of cytology and human papillomavirus testing in cervical cancer screening: Joint European cohort study. BMJ 2008; 337: 969-72.
8. Ronco G, Dillner J, Elfstrom KM, Tunesi S, Snijders PJF, Arbyn M, et al. Efficacy of HPV-based screening for prevention of invasive cervical cancer: Follow-up of four European randomised controlled trials. Lancet 2014; 383: 524-32.
9. Kitchener HC. Report to the National Screening Committee. June 2015. 1-19 (legacy.screening.nhs.uk/policydb_download.php?doc=555, accessed 9 Feb 2016).
10. Ministry of Health, National Cervical Screening Programme: Changing the primary laboratory test. Technical appendix to the public consultation paper. October 2015 (www.nsu.govt.nz/system/files/page/ncsp_technical_appendix.pdf, accessed 9 Feb 2016)
11. Kinney W, Wright TC, Dinkelspiel HE, Defrancesco M, Thomas Cox J, Huh W. Increased cervical cancer risk associated with screening at longer intervals. Obstet Gynecol 2015; 125: 311-5.

12. Austin RM, Onisko A. Increased cervical cancer risk associated with extended intervals after negative human papillomavirus test results: Bayesian risk estimates using the Pittsburgh Cervical Cancer Screening model. J Am Soc Cytopathol 2016 5, 9-14.
13. Stoler MH, Austin RM, Zhao C. Point-counterpoint: Cervical cancer screening should be done by primary human papillomavirus testing with genotyping and reflex cytology for women over the age of 25 years. J Clin Microbiol 2015; 53: 2798-804.
14. Austin RM. HPV primary screening: Unanswered questions. Cytopathology 2016; 27: 73-4.
15. Blatt AJ, Kennedy R, Luff RD, Austin RM, Rabin DS. Comparison of cervical cancer screening results among 256,648 women in multiple clinical practices. Cancer Cytopathol 2015; 123: 282-8.
16. Pirog EC, Lloveras B, Molijn A, Tous S, Guimer√† N, Alejo M, et al. HPV prevalence and genotypes in different histological subtypes of cervical adenocarcinoma, a worldwide analysis of 760 cases. Modern Pathology 2014; 27: 1559-67.
17. Hopenhayn C, Christian A, Christian WJ, Watson M, Unger ER, Lynch CF, et al. Prevalence of human papillomavirus types in invasive cervical cancers from 7 us cancer registries before vaccine introduction. J Low GenitTract Di 2014; 18: 182-9.
18. Wu Y, Chen Y, Li L, Yu G, Zhang Y, He Y. Associations of high-risk HPV types and viral load with cervical cancer in China. J Clin Virol 2006; 35: 264-9.
19. Sykes P, Gopala K, Tan AL, Kenwright D, Petrich S, Molijn A, et al. Type distribution of human papillomavirus among adult women diagnosed with invasive cervical cancer (stage 1b or higher) in New Zealand. BMC Inf Dis 2014; 14.
20. Elfstrom KM, Smelov V, Johansson ALV, Eklund C, Naucl√©r P, Arnheim-Dahlstr√∂m L, et al. Long term duration of protective effect for HPV negative women: Follow-up of primary HPV screening randomised controlled trial. BMJ (Online) 2014; 348.
21. Zhou H, Mody R, Luna E, Armylagos CT, Xu J, Schwartz MR. et al. Clinical performance of the Food and Drug Administration - approved high-risk HPV test for the detection of high-grade cervicovaginal lesions. Cancer (Cancer Cytopathol) 2016 (online, DOI: 10.1002/cncy.21687, accessed 12 Feb 2016).
22. Wright TC, Stoler MH, Behrens CM, Sharma A, Zhang G, Wright TL. Primary cervical cancer screening with human papillomavirus: End of study results from the ATHENA study using HPV as the first-line screening test. Gynecol Oncol 2015; 136: 189-97.
23. Woodard A, Austin RM, Li Z, Beere J, Zhao C. Prevalence of HPV 16/18 genotypes and histopathologic follow-up outcomes in women with negative cytology and positive high-risk HPV test results. J Am Soc Cytopathol 2015; 4: 261-6.

Current management of acute diverticulitis: a survey of Australasian surgeons

Rebekah Jaung, Jason Robertson, David Rowbotham, Ian Bissett

ABSTRACT

AIMS: To evaluate the current practice and degree of consensus amongst Australasian surgeons regarding non-surgical management of acute diverticulitis (AD) and to determine whether newer approaches to management are being translated into practice.

METHODS: An online survey was distributed to all Australasian colorectal surgeons and all general surgeons in the Auckland region. Responses were collected over two months and analysed to identify points of consensus and areas of significant difference in opinion between these groups.

RESULTS: Responses were received from a total of 99 of 200 (49.5%) colorectal surgeons, and 19 of 36 (52.7%) general surgeons. The Hinchey Classification was the most commonly used measure of disease severity, used by 67 (95.7%) colorectal surgeons and 12 (92.3%) general surgeons. There was lack of consensus around important aspects of AD management, including antibiotic therapy, and use and modality of follow-up imaging. Selective antibiotic therapy and use of anti-inflammatory medication as adjuncts to treatment were practised by a minority of those surveyed.

CONCLUSIONS: Newer approaches to management were being utilised by some respondents. The lack of consensus regarding management of AD may be a consequence of a paucity of high-level evidence to support specific management approaches, particularly in patients with uncomplicated AD.

Left colon diverticulosis is the most commonly found abnormality on colonoscopy.[1] Current estimates are that less than 10% of people under 40 years old, and 50–60% of people over 85, have diverticulosis.[1] Ten to twenty-five percent of those with diverticulosis will experience some form of diverticular disease (DD) and 15–20% of those with symptomatic disease are diagnosed with acute diverticulitis (AD).[2]

Data from New Zealand also show an increasing trend in the number of acute admissions for DD, from 1,443 admissions in 2001 to 2,701 admissions in 2011.[3] Data from North America also indicate that hospital admissions due to AD are increasing, although rates of admission for perforation from AD have remained stable.[4,5]

The bulk of diverticulitis admissions are for uncomplicated AD (evidence of inflammation without abscess, perforation or peritonitis based on the modified Hinchey Classification).[6,7] A single bout of uncomplicated AD confers minimal long-term or serious health risks to patients.[5] Currently there is a shift towards a more conservative approach to uncomplicated AD with the aim of reducing unnecessary interventions and ensuring the efficient use of limited healthcare resources. Recent studies have demonstrated that patients with uncomplicated AD can be safely managed in the outpatient setting [8-10] and with limited use of antibiotic therapy.[10,11] This approach is supported in recently published clinical guidelines.[12]

The aim of this survey was to evaluate the current practice of colorectal specialists in Australasia, and general surgeons in New Zealand, regarding the medical management of AD in order to assess whether newer approaches to management were being translated into practice, and to provide context for further local research into AD.

© NZMA

Table 1: Absolute indicators for hospital admission, responses from New Zealand surgeons only. A p-value <0.05 was considered to be significant. Bold indicates positive consensus.

Admission variable	NZ colorectal surgeons (%)	General surgeons (% positive)	p-value
First episode of acute diverticulitis	2 (9.5)	7 (36.8)	0.039
Patient age	0 (0.0)	0 (0.0)	-
Patient comorbidity	8 (38.1)	6 (35.3)	-
Temperature <36 °C or >38 °C	14 (66.7)	15 (78.9)	-
Heart rate >90 per minute	11 (52.4)	13 (68.4)	-
Respiratory rate >20 per minute	14 (66.7)	13 (68.4)	-
Signs of hypovolaemia	**20 (95.2)**	14 (73.7)	-
Localised peritonism	12 (57.1)	12 (63.2)	-
PR bleeding	4 (19)	5 (26.3)	-
Need for intravenous analgesia	**20 (95.3)**	15 (78.9)	-
Not tolerating oral intake	**18 (85.7)**	**17 (89.5)**	-
White blood cells <4x109/L or >12x109/L	6 (28.6)	7 (36.8)	-
CRP > 10	0 (0.0)	2 (10.5)	-
CRP >40	0 (0.0)	7 (36.8)	0.002
CRP >100	10 (47.6)	8 (42.1)	-

Method

Ethics approval for this study was obtained from the University of Auckland Human Participants Ethics Committee (#012408), as well as Auckland, Counties Manukau and Waitemata District Health Boards, prior to distribution of surveys. The web-based survey was distributed by email to all members of the Colorectal Surgery Society of Australia and New Zealand (CSSANZ) and to general surgery consultants at the three tertiary centres in Auckland. The survey was open for 2 months, with a reminder email sent out at the end of the first month.

The survey aimed to collect information about how often respondents managed patients with AD, followed by a series of questions regarding: rationale for hospital admission; assessment of severity; current management of uncomplicated and complicated AD; and the utilisation of selective use of antibiotics and anti-inflammatory agents. Uncomplicated AD was defined as AD with evidence of inflammation without abscess or perforation on CT scan (modified Hinchey criteria Ia).[6] Some questions required yes/no answers, while others asked for responses on a 5-point Likert scale, with 1 meaning always, 3 sometimes, and 5 never. Consensus was defined as ≥80% agreement at either end of this scale (1/2 consensus, or 4/5 consensus). Additionally, there were a number of questions where qualitative information was gained through free-text responses.

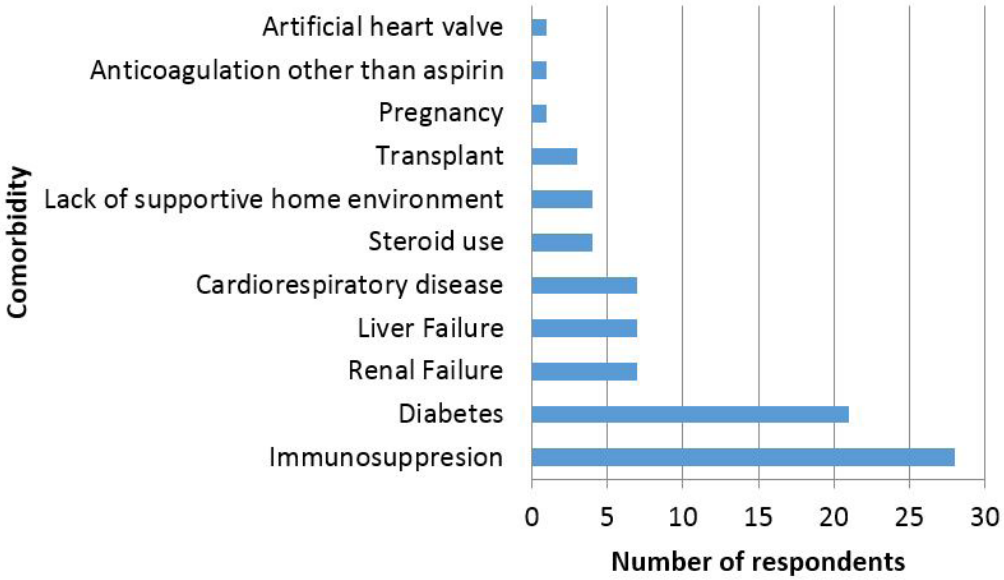
Statistical analysis

Statistical analysis was performed using SPSS for Windows (Version 19; SPSS, Chicago, Illinois, US). Descriptive statistics and figures were used to summarise the data. Univariate analysis was carried out using the chi-squared test for categorical data; one-way analysis of variance (ANOVA) for parametric continuous data, and the Mann-Whitney U and Kruskal-Wallis test for non-parametric data.

Results

Responses were received from a total of 99 of 200 (49.5%) colorectal surgeons, and 19 of 36 (52.7%) general surgeons who were approached to participate in the study. Of the colorectal surgeons, 78 (78.8%) were based in Australia and 21 (21.2%) were based in New Zealand—the response rate for New Zealand members of CSSANZ was 65.6%. The majority of both groups saw patients with AD at least once a month (91.9% in the colorectal group and 84.2%

Figure 1: Absolute indicators for hospital admission.



in the general surgeon group). The median number of patients seen per week was 2 (1–5) and 5 (2–6.5) patients, respectively.

Admission criteria

Factors seen as an absolute indication for hospital admission are listed in Table 1. General surgeons were more likely to select first episode of AD and a moderately raised CRP as indications for admission than colorectal surgeons. There were no significant differences between the responses of New Zealand and Australian colorectal surgeons.

Comorbidities that were considered absolute indicators for admission by either group are displayed in Figure 1.

Assessment of severity

Twenty-eight (28.6%) colorectal surgeons and six (35.3%) general surgeons stated that there was a severity score they routinely used when assessing patients with AD. The majority of clinicians in both groups stated that they used the Hinchey Classification (67 (95.7%) of colorectal surgeons and 12 (92.3%) of general surgeons). The Mannheim Peritonitis Index (1 (1.4%) of colorectal surgeons and 1 (7.7%) of general surgeons) and Acute Physiology and Chronic Health Evaluation II (APACHE II) (10 (7%) of colorectal surgeons and 1 (7.7%) of general surgeons) were used by a minority of respondents. There were no significant differences in the responses of the two groups.

Management of uncomplicated AD

There was a wide variety of practice amongst the respondents. The use of inpatient colonoscopy met a 4/5 consensus, (rarely or never used) and was the only aspect of management where consensus was reached. The general surgeon group reached a 1/2 consensus (always or usually) regarding intravenous antibiotics, with 82.4% of respondents reporting their frequent use in managing uncomplicated AD.

Management of complicated AD

Both groups used bowel rest, intravenous fluids and intravenous antibiotics. The colorectal surgeon group met consensus for the use of follow-up colonoscopy.

Selective antibiotic therapy

Forty-three colorectal surgeons and 7 general surgeons stated that they sometimes did not use antibiotics in the management of diverticular disease. There was no statistically significant difference between the two groups or between colorectal surgeons working in differing countries. This question included the option to provide a free-text response. Similar replies are summarised into Figure 2.

Anti-inflammatory medications

Thirty-three (34%) colorectal surgeons and 10 (58.8%) general surgeons responded that they have used anti-inflammatory agents in the management of diverticular disease of any kind. There was no

Table 2: Management of uncomplicated AD, responses from New Zealand surgeons only. A p-value <0.05 was considered to be significant.

	Median Likert Scale Score (% agreement of 1 or 2)		p-value
	New Zealand colorectal surgeons	General surgeons	
Bowel rest (NBM or clear fluids)	2 (57.1)	3 (41.1)	-
IV fluids	2 (61.9)	2 (64.7)	-
Oral antibiotics	3 (42.9)	3 (23.5)	-
IV antibiotics	2 (57.1)	2 (82.4)	-
Inpatient colonoscopy*	5 (0.0)	5 (0.0)	-
Follow-up colonoscopy	2 (71.4)	3 (17.6)	-
Follow-up CT colonography	5 (9.5)	2 (52.9)	-

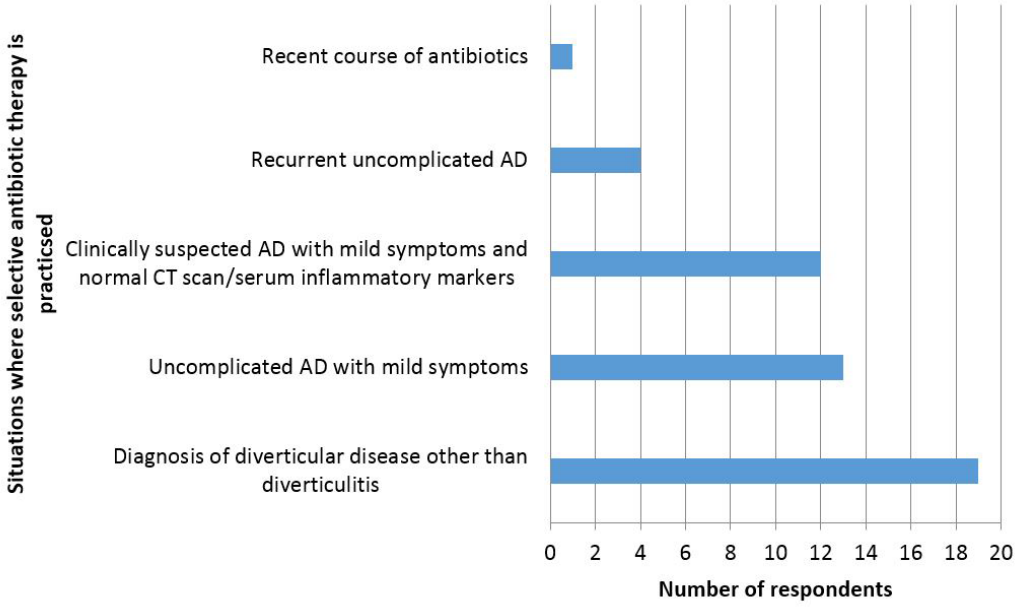
*Indicates that there was >80% agreement of 4 or 5

Table 3: Management of complicated AD, responses from New Zealand surgeons only. A p-value <0.05 was considered to be significant. Bold indicates positive consensus.

	Median Likert Scale Score (% agreement of 1 or 2)		p-value
	New Zealand colorectal surgeons	General surgeons	
Bowel rest (NBM or clear fluids)	**2 (85.7)**	1 (76.5)	-
IV fluids	**1 (95.2)**	1 (84.4)	0.001
Oral antibiotics	4 (20.0)	4 (12.5)	-
IV antibiotics	**1 (100)**	**1 (100)**	-
*Inpatient colonoscopy	5 (0.0)	5 (0.0)	-
Follow-up colonoscopy	**2 (81.0)**	**2 (41.2)**	0.001
Follow-up CT colonography	4 (14.3)	4 (43.75)	0.001

* Indicates that there was >80% agreement of 4 or 5

Figure 2: Rationale for selective antibiotic therapy.



statistically significant difference between country or specialty. Non-steroidal anti-inflammatory drugs (NSAIDs) were the most commonly named agents amongst the free-text responses (4 responses) and analgesia was the most frequently stated purpose for the use of anti-inflammatory agents (8 responses). Four surgeons had used an anti-inflammatory agent in the management of segmental colitis with associated diverticulosis (SCAD). Recurrent or refractory acute diverticulitis and symptomatic uncomplicated diverticular disease (SUDD) were both mentioned once.

A separate question enquired about the use of corticosteroids in any kind of diverticular disease. None of the respondents had used corticosteroids in this setting.

Discussion

This survey describes current practice and provides insight into the decision-making processes of clinicians who are managing patients with AD in Australasia.

Responses to this survey provided some information about the rationale for selecting inpatient care of patients with AD. Notably, serum markers of inflammation did not appear to weigh heavily on the decision to admit a patient. A minority of clinicians stated that age was an absolute indicator for admission, with a wide range of ages that were considered to be a reason to admit patients. Immunosupression in general—as well as diabetes, steroid therapy, transplant, and organ failure—were specified as comorbid conditions that were absolute indicators for hospital admission.

In our survey, there was little consensus regarding the management of uncomplicated AD. Routine use of antibiotics for patients with uncomplicated AD was still practised by a majority of respondents, and there was no consensus regarding this approach. This lack of consensus has also been reported internationally. A recent Delphi study demonstrated that, while there is expert consensus regarding the acceptability of outpatient management of patients with uncomplicated AD, there does not appear to be agreement regarding the important issue of selective antibiotic use in this patient group.[13]

Follow-up colonoscopy for patients with uncomplicated AD was practised 'most of the time' by both of the groups surveyed. This is an area of some contention, as several systematic reviews,[14-17] a retrospective study,[18] and one large epidemiological study,[19] have demonstrated that there are little data to support routine follow-up imaging in this patient group, other than as part of age-appropriate screening or in the management of patients with symptoms suggestive of an alternative diagnosis.

Responses to the focused question regarding the role of selective antibiotic therapy in diverticular disease showed that this approach was considered for non-inflammatory manifestations of the disease, as well as for mild AD. It would be interesting to observe whether these practices had changed or will proceed to change significantly over time. In the aforementioned international survey, a majority of respondents answered that there was a lack of high-level evidence to support the use of antibiotics in these patients,[13] a factor which is likely to explain—at least in part—why consensus is lacking.

The responses to the question regarding anti-inflammatory medication use reflect the uncertainties and new developments that have been made in this area. Anti-inflammatory agents are currently being considered for use in the management of select sub-types of DD. Mesalazine in particular, has been reported to be a helpful adjunct in the treatment of SUDD[20,21] and SCAD.[22,23] There is a small and as yet inconclusive amount of data suggesting that it may be of use in uncomplicated AD by reducing damage caused by inflammation and aiding earlier resolution of the inflammatory response and associated symptoms. To date, mesalazine has been shown to improve time to resolution of endoscopic and histologic evidence of inflammation following an episode of AD, and also reduce the rate of recurrence.[24,25]

The most significant limitation of this study was the sub-optimal response rate. This may be in part due to self-selection by clinicians who do not treat patients with DD and felt that the survey was not relevant to their clinical practice. The number of responses could have been increased by surveying all New Zealand general

surgeons, however, this was found to be logistically impractical due to the inability to gain access to all general surgeons, either from the college or through the District Health Boards. Despite these limitations, the results of this study are still useful for informing future local research into DD.

AD is a frequent indication for hospital admission under the general surgery service, and the patients who are affected make up a heterogeneous group, with variable disease severity. After taking this into account, there is still a striking lack of consensus regarding the approach to and management of AD, particularly the more common uncomplicated presentation. This lack of consensus may be explained by the paucity of high-level evidence in this group of patients. Expansion of the existing knowledge base and ability to utilise this new information in a cohesive, evidence-based approach to management will improve the efficiency and quality of care for patients presenting with this common condition.

Competing interests:
Rebekah Jaung reports grants from the Auckland Medical Research Foundation during the conduct of the study.

Author information:
Rebekah Jaung, Department of Surgery, The University of Auckland, New Zealand; Jason Robertson, Department of Surgery, The University of Auckland, New Zealand; David Rowbotham, Department of Gastroenterology & Hepatology, Auckland City Hospital, New Zealand; Ian Bissett, Department of Surgery, The University of Auckland, New Zealand and Department of Surgery, Auckland City Hospital, New Zealand.

Corresponding author:
Ian Bissett, Department of Surgery, The University of Auckland, New Zealand and Department of Surgery, Auckland City Hospital, New Zealand.
i.bissett@auckland.ac.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6828

REFERENCES:

1. Stollman N, Raskin JB. 'Diverticular Disease of the Colon', Lancet, 363 (2004), 631-9.
2. Parks TG, 'Natural History of Diverticular Disease of the Colon. A Review of 521 Cases', Br Med J, 4 (1969), 639-42.
3. Vather R, Broad JB, Jaung R, Robertson J, Bissett IP. 'Demographics and Trends in the Acute Presentation of Diverticular Disease: A National Study', ANZ J Surg (2015).
4. Ricciardi R, Baxter NN, Read TE, Marcello PW, Hall J, Roberts PL. 'Is the Decline in the Surgical Treatment for Diverticulitis Associated with an Increase in Complicated Diverticulitis?', Diseases of the Colon & Rectum, 52 (2009), 1558-63.
5. Li D, de Mestral C, Baxter NN, McLeod RS, Moineddin R, Wilton AS, Nathens AB. 'Risk of Readmission and Emergency Surgery Following Nonoperative Management of Colonic Diverticulitis: A Population-Based Analysis', Ann Surg, 260 (2014), 423-30; discussion 30-1.
6. Wasvary H, Turfah F, Kadro O, Beauregard W. 'Same Hospitalization Resection for Acute Diverticulitis', Am Surg, 65 (1999), 632-5; discussion 36.
7. Hinchey EJ, Schaal PG, Richards GK. 'Treatment of Perforated Diverticular Disease of the Colon', Adv Surg, 12 (1978), 85-109.
8. Alonso S, Pera M, Pares D, Pascual M, Gil MJ, Courtier R, Grande L. 'Outpatient Treatment of Patients with Uncomplicated Acute Diverticulitis', Colorectal Disease, 12 (2010), e278-82.
9. Biondo S, Golda T, Kreisler E, Espin E, Vallribera F, Oteiza F, Codina-Cazador A, Pujadas A, Flor B. 'Outpatient Versus Hospitalization Management for Uncomplicated Diverticulitis: A Prospective, Multicenter Randomized Clinical Trial (Diver Trial)', Ann Surg, 259 (2014), 38-44.
10. Isacson D, Thorisson A,

Andreasson K, Nikberg K, Smedh K, Chabok A. 'Outpatient, Non-Antibiotic Management in Acute Uncomplicated Diverticulitis: A Prospective Study', Int J Colorectal Dis (2015).

11. Chabok A, Pahlman L, Hjern F, Haapaniemi S, Smedh K. 'Randomized Clinical Trial of Antibiotics in Acute Uncomplicated Diverticulitis', Br J Surg, 99 (2012), 532-9.

12. Vennix S, Morton DG, Hahnloser D, Lange FJ, Bemelman WA. 'Systematic Review of Evidence and Consensus on Diverticulitis: An Analysis of National and International Guidelines', Colorectal Dis, 16 (2014), 866-78.

13. O'Leary DP, Lynch N, Clancy C, Winter DC, Myers E. 'International, Expert-Based, Consensus Statement Regarding the Management of Acute Diverticulitis', JAMA Surg (2015).

14. de Vries HS, Boerma D, Timmer R, van Ramshorst B, Dieleman LA, van Westreenen HL. 'Routine Colonoscopy Is Not Required in Uncomplicated Diverticulitis: A Systematic Review', Surg Endosc, 28 (2014), 2039-47.

15. Daniels L, Unlu C, de Wijkerslooth TR, Dekker E, Boermeester MA, 'Routine Colonoscopy after Left-Sided Acute Uncomplicated Diverticulitis: A Systematic Review', Gastrointest Endosc, 79 (2014), 378-89; quiz 498-98 e5.

16. Sai VF, Velayos F, Neuhaus J, Westphalen AC. 'Colonoscopy after Ct Diagnosis of Diverticulitis to Exclude Colon Cancer: A Systematic Literature Review', Radiology, 263 (2012), 383-90.

17. Sharma PV, Eglinton T, Hider P, Frizelle F. 'Systematic Review and Meta-Analysis of the Role of Routine Colonic Evaluation after Radiologically Confirmed Acute Diverticulitis', Ann Surg, 259 (2014), 263-72.

18. Westwood DA, Eglinton TW, Frizelle FA, 'Routine Colonoscopy Following Acute Uncomplicated Diverticulitis', Br J Surg, 98 (2011), 1630-4.

19. Huang WY, Lin CC, Jen YM, Chang JY, Hsiao CW, Yang MH, Lin CS, Sung FC, Liang JA, Kao CH. 'Association between Colonic Diverticular Disease and Colorectal Cancer: A Nationwide Population-Based Study', Clin Gastroenterol Hepatol, 12 (2014), 1288-94.

20. Gatta L, Di Mario F, Curlo M, Vaira D, Pilotto A, Lucarini P, Lera M, Enkleda K, Franze A, Scarpignato C. 'Long-Term Treatment with Mesalazine in Patients with Symptomatic Uncomplicated Diverticular Disease', Internal & Emergency Medicine, 7 (2012), 133-7.

21. Di Mario F, Aragona G, Leandro G, Comparato G, Fanigliulo L, Cavallaro LG, Cavestro GM, Iori V, Maino M, Moussa AM, Gnocchi A, Mazzocchi G, Franze A. 'Efficacy of Mesalazine in the Treatment of Symptomatic Diverticular Disease', Digestive Diseases & Sciences, 50 (2005), 581-6.

22. Ierardi E, Hassan C, Zullo A, De Francesco V, Valle ND, Prencipe S, Rosania R , Morini S, Panella C, 'Segmental Colitis Associated with Diverticula: A Rare Clinical Entity and a New Challenge for the Gastroenterologist', Digestive & Liver Disease, 41 (2009), 794-7.

23. Imperiali G, Meucci G, Alvisi C, Fasoli R, Ferrara A, Girelli CM, Rocca F, Saibeni S, Minoli G. 'Segmental Colitis Associated with Diverticula: A Prospective Study. Gruppo Di Studio Per Le Malattie Infiammatorie Intestinali (Gsmii)', American Journal of Gastroenterology, 95 (2000), 1014-6.

24. Tursi A, Elisei W , Giorgetti GM, Inchingolo CD, Nenna R, Picchio M, Maiorano M, Penna A, Lecca PG, BrandimarteG. 'Effectiveness of Different Therapeutic Strategies in Preventing Diverticulitis Recurrence', Eur Rev Med Pharmacol Sci, 17 (2013), 342-8.

25. Stollman N, Magowan S, Shanahan, Quigley EM and Diva Investigator Group. 'A Randomized Controlled Study of Mesalamine after Acute Diverticulitis: Results of the Diva Trial', J Clin Gastroenterol, 47 (2013), 621-9.

Overnight transfusions in New Zealand hospitals: potential risk to patients

Rachel Donegan, Angela Wright, Louise Bobbitt, Richard Charlewood, Hilary Blacklock

ABSTRACT

AIMS: This audit aimed to assess how frequently overnight transfusions were taking place and compare it to the previous 2004 audit.

METHOD: All red cell units transfused between 20:00 and 08:00 hours in low acuity areas over 4 weeks in 2010 in 8 of New Zealand's largest public hospitals were identified prospectively, followed by review of clinical notes and laboratory results by the hospital Transfusion Nurse Specialist (TNS).

RESULTS: 535 red cell units were transfused overnight, or 9% of the total units administered over the study period. Indications for transfusion were symptomatic anaemia, active bleeding or haemolysis (66%), but 16% of patients were asymptomatic.

Of the non-urgent overnight transfusions (OTs), 42% were assessed as non-essential during the night. 49% of post-transfusion haemoglobin (Hb) levels were >100 g/L indicating a liberal transfusion practice. Although frequently cited as a reason for OT, only 16% of patients were discharged the following day.

The median interval from pre-transfusion haemoglobin testing and starting the OT was approximately 9 hours, far exceeding the time needed to obtain routine full blood results.

Adherence to recommended best transfusion practice was poor at night, with 12% of transfusions exceeding the 4 hour recommendation. End of transfusion observations fell to less than 80%, with the lowest compliance rate (69%) occurring at 06:00 hours. In addition to the 4 adverse reactions reported to the Haemovigilance programme, another 9 unreported reactions were identified by the auditors from the clinical notes.

CONCLUSIONS: This audit has shown an improvement from 22% to 9% in the rate of OT compared to the 2004 audit. Nevertheless, 42% of transfusions were not considered appropriate based on current guidelines, and there is therefore room for improvement. A mean delay of 9 hours from haemoglobin sampling to transfusion suggests that reasons for this delay could be explored to help optimise transfusion start time. Some aspects of OT were worse than previously, with 12% of the OT exceeding 4 hours duration, double the rate of the previous audit. Results showing poor documentation and a high rate of unreported transfusion reactions (69% of reactions) suggest if an adverse transfusion reaction occurs overnight, there is a significant risk that it is less likely to be recognised, treated and/or reported.

Non-urgent overnight transfusion (OT) interrupts the sleep of the recipient and of neighbouring patients. Sleep deprivation has been identified as a physiological stressor, potentially with poorer outcomes for the patient.[1] Also, OT monitoring may be inadequate because of lower staffing levels and lighting. This is a similar problem to the 'weekend effect', where reduced services inside and outside the hospital are associated with an increased risk of death.[2] All participating hospitals have policies recommending that OTs should be avoided unless clinically essential. The aim of this audit was to ascertain the frequency of overnight transfusion (OT) and to compare the results with the New Zealand Blood Service (NZBS) audit, undertaken in 2004 in 5 of the 8 hospitals reported here.[3]

Method

The main public hospitals in 8 of the largest DHBs (Auckland, Christchurch, Dunedin, Middlemore, North Shore, Palm-

Table 1: NHMRC Guidelines for red cell transfusions used to group audit patients.[4]

Hb: <70 g/L	Transfusion of red cells is usually indicated. A lower threshold may be acceptable in patients without symptoms and/or where specific therapy is available.
Hb: 70–100 g/L	Transfusion is likely to be appropriate during surgery associated with major blood loss or if there are signs of symptoms of impaired oxygen transport.
Hb: <80 g/L	Transfusion may be appropriate to control anaemia-related symptoms in a patient on a chronic transfusion regime or during bone marrow suppression therapy.
Hb: >100 g/L	Transfusion is not likely to be appropriate unless there are specific indications.

erston North, Waikato and Wellington) were audited.

The audit was undertaken by the Transfusion Nurse Specialists, each based within the hospital being audited, over a 4-week period (28 nights per centre). Each overnight transfusion was identified by reviewing the preceding night's issues using the national blood management system, eProgesa, supported by information from the blood bankers. A direct clinical notes review, including relevant laboratory data, was then conducted.

The study period was divided into two blocks of two weeks, separated by 0–7 weeks, during March to May 2010. Gaps between the two blocks were the result of pre-approved leave requests. The total number of red cells transfused for each hospital was extracted by the NZBS data analyst from eProgesa.

Audit data collected

Data collected included: patient demographics and clinical specialty; transfusion details; pre and post transfusion haemoglobin (Hb) (with time and date); availability of blood and details of any delays (as well as documentation of the clinical indications for transfusion); symptoms; and significant co-morbidities. Compliance with recordings at baseline, 15 minutes from starting, and at completion of the OT was also checked. The occurrence of any adverse reactions and discharge date/time were also noted.

Criteria and rationale

Each unit of red cells issued to non-acute areas between the hours of 20:00 and 08:00 hours was audited. Issues to high acuity areas (Emergency Department, Intensive or High Care units, Theatres and Delivery Suites) were excluded because of the higher nurse-to-patient ratio overnight, and therefore ability to monitor appropriately.

The clinical reason for each OT was assessed according to National Health and Medical Research Council (NHMRC) guidelines (Table 1), taking into consideration patient-related factors, such as cardiopulmonary function, volume of blood loss, oxygenation, atherosclerosis and haemoglobin level. [4]

The transfusion rationale was classified by the Transfusion Nurse Specialist (TNS) into 4 groups based on the notes review using the National Health Service Blood and Transplant (NHSBT) OT audit criteria (2008):[5]

1. **Acute Clinical Need:** Patient with active bleeding or haemolysis at time of transfusion and/or patient with low Hb and symptoms;
2. **Less Acute Clinical Need:** Patient transfused to raise Hb prior to surgery/procedure;
3. **Pragmatic Need:** Patient transfused for discharge same/next day, and/or oncology/haematology patient with limited line time;
4. **Other:** Patient with low Hb but no symptoms; transfused for reasons not in the above categories.

Analysis and reporting

The Transfusion Nurse Specialists assessed the appropriateness of each unit transfused, based on the clinical indication for transfusion and the circumstances surrounding it. This was subjective to each Transfusion Nurse Specialist, and not standardised between DHBs. However, each episode was reviewed by a single co-ordinating Transfusion Medicine Specialist (TMS) and queries resolved between the TNS and TMS. Data were entered into a secured Microsoft Access database. The co-ordinating TMS conducted the final analysis using both Microsoft Access and

Table 2: Indications for overnight transfusions per hospital.

	ACUTE CLINICAL NEED		LESS ACUTE	PRAGMATIC	OTHER
	Active bleeding/ Haemolysis %	Anaemia with symptoms %	Pre-surgery %	Discharge/ Line access %	Anaemia, no symptoms %
Transfusions	23%	43%	11%	6%	16%
Appropriate	87%	67%	47%	46%	10%
Mean pre-transfusion Hb (g/L)	78	72	80	79	82

Excel. Identifying information regarding patients or staff was excluded from the audit report. The audit was presented to the Hospital Transfusion Committees of the participating DHBs for comment and action.

Results

Three hundred and fifty-nine patients, mean age 64 years (range <1–99 years) received 535 red cell units overnight, an average of 1.5 units per recipient. The proportion of overnight units to total units transfused in 24 hours ranged from 4% to 12% per DHB. A lower rate of OTs in Palmerston North and Dunedin may be influenced by the absence of a 24-hour blood bank.

OTs were more often given on mid-week days (17% Wednesdays, 18% Thursdays) compared with an average of 13% on other days (chi-square test, p=0.06). The patients were mainly in general medicine (23%), general surgery (21%), orthopaedic (14%) or haematology (10%) wards, with the remaining 32% spread over a wide range of disciplines.

The rationale for most of the OTs was symptomatic anaemia (43%), followed by active bleeding/haemolysis (23%). Of concern, a significant number of patients (16%) had asymptomatic anaemia (Table 2). This latter group also had a higher mean pre-transfusion Hb of 82 g/L, in comparison to 72 g/L in the symptomatic anaemia group (t-test, p<0.0001).

The appropriateness of each transfused unit was assessed against the clinical indication using both NHMRC criteria[4] and clinical symptoms. Overall, 58% of the 535 episodes were assessed as appropriate with a wide range (30–79%) between DHBs.

Most patients (68%) were still in hospital ≥48 hours after the transfusion, with only 16% of patients discharged within 24 hours of the transfusion. Sixty-two percent of units transfused to patients discharged early were assessed as appropriate, not significantly different from the group overall. Twelve deaths occurred in ≤48 hours post transfusion, none were related to OT.

More OTs started between 21:00 and 22:00 hours, and again around 01:00 hours, with fewer transfusions commencing between 04:00 and 05:00 hours (Figure 1). Ninety-one percent of units transfused finished after midnight (Figure 2). The transfusion start times appeared to correlate to shift changes and the new staff on shift commencing the transfusions. Shift changes typically occur at 19:00 and 24:00.

Delays in blood availability due to the need to recollect a pre-transfusion sample occurred with 1% of all units, and an additional 2% were blood bank related (ie, the time needed to identify red cell antibodies or sourcing of blood from other hospitals).

The median time from taking the pre-transfusion Hb to the OT start time was 9 hours, where both times were known. Most pre-transfusion Hb levels (88%) were taken on the same day as the OT, between 08:00 and 21:00 hours (Figure 3).

Similarly, the median time from taking the pre-transfusion group and screen sample to the OT start time was 9.2 hours, where both times were known.

The transfusion of a red cell unit should be completed within 4 hours of leaving refrigerated storage in the blood bank (4-hour rule)[6]. Twelve percent of red cell units audited exceeded this recommendation (ie, the time from issue to transfusion completion was >4 hours). Where times were provided, the average transfusion duration (time taken to infuse the unit) was 2.7 hours, but 4% of red cell units were administered over 4 hours, exceeding the

Figure 1: Time of commencement where the unit was the first unit following a haemoglobin check.

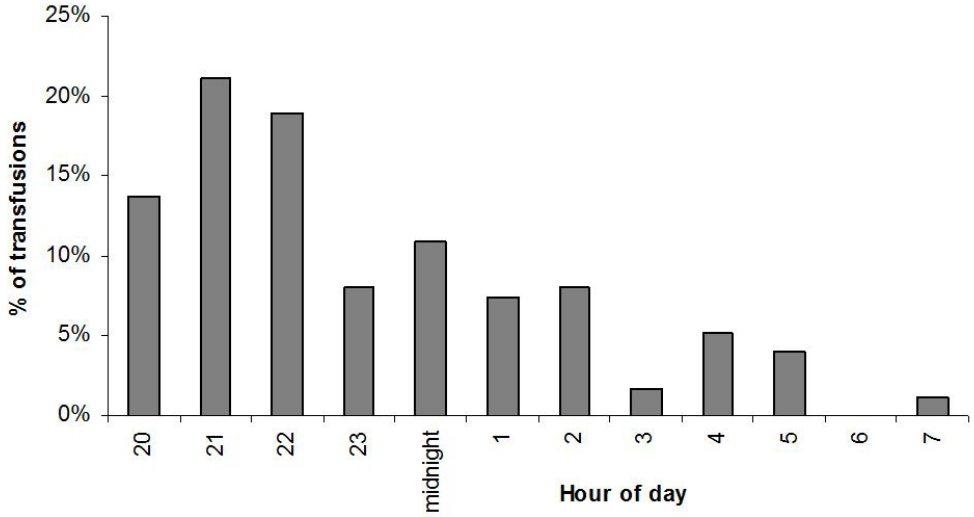


Figure 2: Time of completion of units transfused.

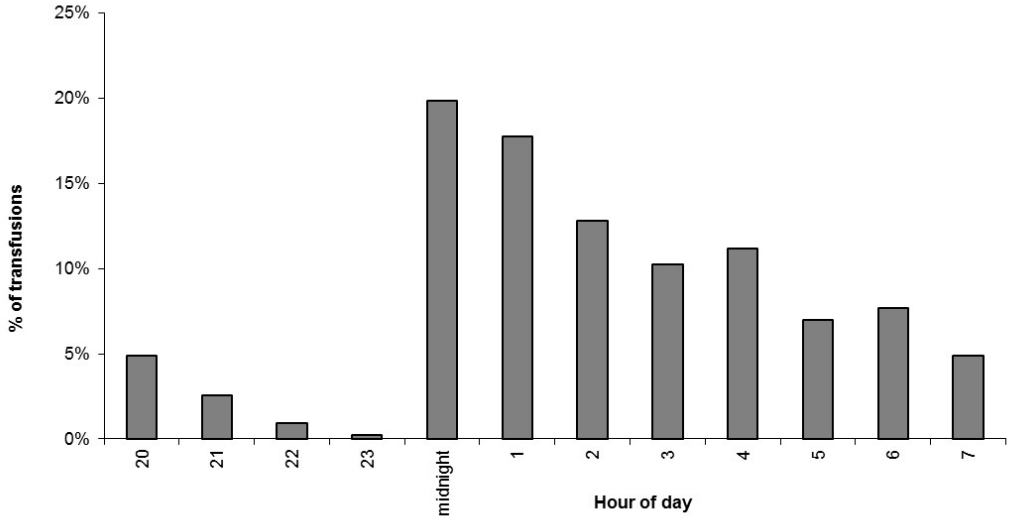


Figure 3: Timing of pre-transfusion haemoglobin level.

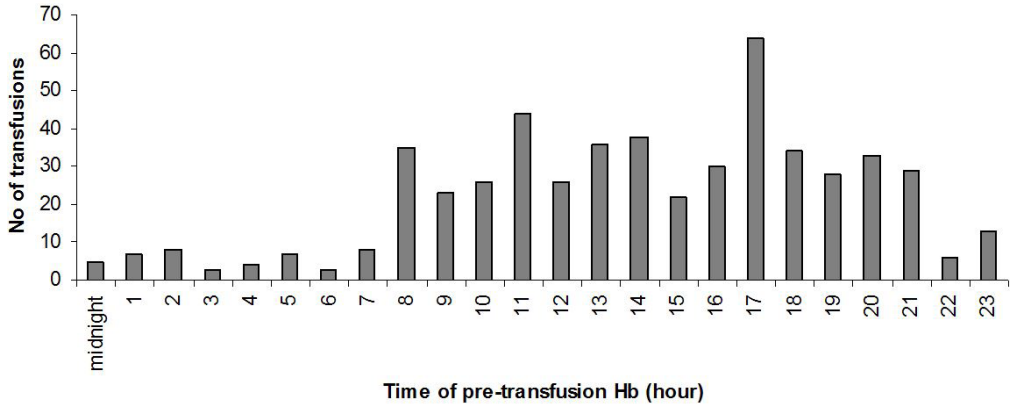


Table 3: Reported and unreported adverse reactions to blood.

Type of reaction	Reactions identified by auditors	Reactions reported to blood bank
Transfusion Associated Circulatory Overload	6	1
Transfusion Associated Dyspnoea	2	0
Unclassifiable Complication of Transfusion	2	2
Allergic Reaction	2	1
Febrile non-Haemolytic Transfusion Reaction	1	0
Overall	13	4

4 hour rule, without taking transport time from blood bank into account.

Baseline observations (temperature, pulse, respiratory rate, BP) were close to 100% compliance, whereas those at the 15-minute interval ranged between 80–100% compliance; the end-of-transfusion observations fell to less than 80% compliance. The lowest compliance rate (69%), also for end-of-transfusion observations, occurred at 06:00 hours.

Of concern, the auditors noted that only 31% of adverse reactions (4 of 13 documented in the patient notes) were reported to the Blood Bank (Table 3).

Audit limitations

This audit provides only a snapshot of documented activity between March–May 2010, in non-acute areas in New Zealand's largest hospitals.

Transfusions in operating theatres or emergencies, including massive transfusions, were not included in this audit. However in these areas, OTs are less likely to be a major, or the only, cause of interrupted sleep.

Variance in data collection is inherent to multi-centre auditing. Despite using a standard data collection form, and having regular meetings (via telephone or face-to-face), differences in how each of the 8 TNSs reported findings were still evident, most notably the subjective assessments as to whether the OTs were clinically appropriate or not.

The audit did not assess the clinical outcome, other than adverse effects, thus it was not possible to assess any morbidity or mortality caused by inappropriate OTs.

Discussion

Best practice guidelines state that OTs in stable patients should be avoided, unless clinically essential.[6,7] During the study period, only 9% of issued units were transfused overnight (22:00–08:00 hours). This is a better result than reported in a large UK study, where 28.5% of red cell units were transfused out of day-time hours, or another UK audit that reported 25%.[8,9] It is also an improvement in comparison to the OT rate of 22% in the smaller NZBS audit, suggesting that education and hospital policies with respect to OTs have had some impact.[3] The 8 hospitals that took part in this audit have policies which encourage routine transfusions to be completed by 22:00 hours. Two of the hospitals operate an on-call service after midnight which may discourage non-essential OTs at their institutions.

The proportion of OT patients with an acute clinical need for transfusion (66%) is similar to that found in the NHS audit (58%).[5] The acute clinical need group was made up of patients with symptomatic anaemia (43%), and active bleeding/haemolysis (23%). Although the rationale to transfuse was assessed as appropriate, the auditors noted that in 13% of the actively bleeding group and 33% of the symptomatic anaemia group, the transfusions could have started earlier in the day, or the patient had stabilised and further units could have been delayed until the subsequent day.

Reasons as to why a patient receives an OT outside high acuity areas may include timing issues, such as a patient moving from the ward for X-rays, or intravenous lines being used for other treatments. A small number of additional delays were also identified due to unavoidable blood bank issues, including the length of time needed to identify difficult red cell antibodies. In other cases, the issue seemed to be organisational such as the decision to transfuse being made on the morning ward round,

but the prescription not being completed until late in the day. The median intervals between taking the pre-transfusion Hb sample and transfusion, and taking the group and screen sample and transfusion were 9.0 and 9.2 hours respectively, again consistent with a problem in initiating the transfusion earlier in the day. Most of the OTs commenced before 23:00 hours (consistent with other audits), but were not completed until after midnight. If there was an urgent need for the transfusion, one would expect to see a more even spread of transfusions over the whole night.

Overall, 58% of transfusions were considered appropriate by subjective assessment, in contrast to the 2004 NZBS audit and a single-centre UK audit, when only 15% and 20% of transfusions were considered appropriate.[3,10] Our audit also compares favourably with another multi-centre audit in the UK, which assessed 33% to be appropriate.[9] These results, in conjunction with the reduction in the proportion of units transfused overnight, suggests an improvement in OT-related practice in the major New Zealand hospitals.

It is of concern that 16% of the patients receiving an OT had asymptomatic anaemia, which is seldom an appropriate clinical indication. The fact that this group had higher average pre-transfusion Hb levels than the symptomatic patients is in keeping with the lack of symptoms and supports the assessment that only 10% of these OTs were likely appropriate. Post-transfusion Hb checks were performed frequently, typically the day after the previous testing and mostly after 2 units. 49% of post-transfusion Hb levels were >100 g/L, suggesting a high degree of liberal transfusion. This is a disappointing result. It is now more than a decade after the landmark TRICC intensive care unit study which showed that a restrictive transfusion practice (with a trigger of 70 g/L and an endpoint of 70–90 g/L) was as safe as a liberal transfusion strategy in an intensive care setting.[11] This finding, prompting a restrictive strategy to be adopted, has now been supported by multiple studies in a variety of clinical settings.

'Discharge the following morning' is sometimes given as the reason why a patient receives an OT. However, only 16% of patients were discharged within 24 hours of their OT, similar to a UK audit finding of 10%.[10]

Although the Australian and New Zealand Society for Blood Transfusion (ANZSBT) guidelines recommend that the reason for each transfusion should be documented, it was commented on by the TNS that this was often omitted, making both the auditing difficult, and potentially making it difficult for night-shift nursing and medical staff to know whether to transfuse overnight or not.[6] Also, documentation of vital signs—a further ANZSBT recommendation—decreased as the OT progressed, potentially putting the patient at risk. A study on post-transfusion monitoring reported a continuing failure to monitor vital signs appropriately at night, despite interventional education.[12] Lower staff numbers at night, poor lighting, and a reluctance to wake the patient, may be reasons why observations are not recorded. Reduced available staff is especially significant at certain times of the night, eg at 06:00 hours, the nadir of post-transfusion observations.[10,13]

The OTs lasted 2.7 hours on average. However, at least 4% exceeded the 4-hour limit intended to protect patients from bacterial complications, double the frequency (2%) noted in a previous New Zealand audit, and consistent with the decreased nocturnal attention to the transfusion.[3] These findings emphasise the importance of rapid transport from blood bank to ward and prompt commencement of the transfusion upon receipt into the clinical environment.

Thirteen adverse reactions (2% of 535 OT units) were identified when the case notes were examined by the auditors, with only 4 of these 13 (31%) being reported to Blood Bank. For comparison, a previous New Zealand audit of daytime transfusions showed a reporting rate of 60%.[14] This suggests OT adverse reactions are not being properly assessed or treated, perhaps due to reduced staff or transfusion skills overnight. Adverse reactions are just as likely to occur from units transfused at night as in the day. Performing non-emergency transfusions in a setting of reduced staffing levels and a reduced skill-set of medical staff increases risk for patients. The New Zealand Haemovigilance programme found

that 16% of the adverse reactions reported to the New Zealand Haemovigilance programme in 2008 occurred overnight.[15]

This audit shows a reduction in OT rate when compared to the 2004 audit. Nevertheless, a significant proportion of these transfusions appear to have taken place at night because of a systematic failure to get the blood transfused during the day, combined with a liberal transfusion strategy. The poorer transfusion practice at night, as evidenced by an increased percentage of transfusions running over the 4-hour recommendation, evidence of decreased monitoring and lower adverse reaction reporting, adds support for ongoing action to reduce the potential risk to patient safety.

As a consequence of these findings, we recommend that DHBs further restrict non-essential OTs and improve systems to initiate transfusions earlier in the day, when possible. Also, night clinical staff should receive ongoing education with respect to monitoring OTs and investigating/treating/reporting adverse reactions when these occur.

Competing interests:
Nil

Acknowledgements:
Auditors also included the following Transfusion Nurse Specialists: Christopher Corkery (NZBS Waikato), Fiona King (NZBS Wellington), Suzi Rishworth (NZBS Dunedin), Liz Thrift (NZBS MidCentral), Jacqueline Raynes (Middlemore Hospital); as well as Carolyn Jeffrey (NZBS Data Analyst) and John Dagger (NZBS Technical Advisor).

Author information:
Rachel Donegan, Transfusion Nurse Specialist, New Zealand Blood Service, Auckland District Health Board, Auckland; Angela Wright, Transfusion Nurse Specialist, New Zealand Blood Service, Canterbury District Health Board, Christchurch; Louise Bobbitt, Transfusion Nurse Specialist, Waitemata District Health Board, Auckland; Richard Charlewood, Transfusion Medicine Specialist, New Zealand Blood Service, Auckland; Hilary Blacklock, Haematologist, Counties Manukau DHB, Auckland.

Corresponding author:
Rachel Donegan, Transfusion Nurse Specialist, New Zealand Blood Service, Private Bag 92071, Auckland 1142, New Zealand
Rachel.Donegan@nzblood.co.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6829

REFERENCES:

1. Xu T, Wick EC, Makary MA. Sleep deprivation and starvation in hospitalised patients: how medical care can harm patients. BMJ Qual Saf. 2015 Sep 8;(September):bmjqs – 2015–004395.
2. Aylin P. Making sense of the evidence for the "weekend effect." BMJ. 2015 Sep 5;4652(September):h4652.
3. Donegan R, Corkery C, Hammond C, Wright A, Rishworth S. Overnight transfusion audit within five centres in New Zealand. Auckland, New Zealand; 2004. Available from: https://www.clinicaldata.nzblood.co.nz/resourcefolder/audits/Overnight Transfusion Audit Report April 2004.pdf
4. Rubin G, Carter C, Davies M, Dean M, Farrugia A, Fordham R, et al. Clinical Practice Guidelines on the Use of Blood Components (red blood cells, platelets, fresh frozen plasma, cryoprecipitate). Canberra, Commonwealth of Australia; 2001. Available from: http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cp78.pdf
5. Hawkins T, Davies T, Ambler L, Tinegate H, Lowe D, Dalton D, et al. National Comparative Audit of Overnight Red Blood Cell Transfusion. Birmingham, United Kingdom; 2008. Available from: http://hospital.blood.co.uk/media/26879/nca-national_comaprative_audit_overnight_transfusion_st-_elsewheres_hospital.pdf

6. Australian and New Zealand Society of Blood Transfusion. Guidelines for the administration of blood products. Sydney, Australia; 2011. Available from: http://www.anzsbt.org.au/publications/documents/ANZSBT_Guidelines_Administration_Blood_Products_2ndEd_Dec_2011_Plain_Tables.pdf
7. Harris AM, Atterbury CLJ, Chaffe B, Elliott C, Hawkins T, Hennem SJ, et al. Guideline on the Administration of Blood Components. London, United Kingdom; 2009. Available from: http://www.bcshguidelines.com/documents/BCSH_FMH_bcsh_sept2009.pdf
8. Tinegate HN, Thompson CL, Jones H, Stainsby D. Where and when is blood transfused? An observational study of the timing and location of red cell transfusions in the north of England. Vox Sang. 2007 Oct;93(3):229–32.
9. Stevenson T. The safe administration of blood transfusions at night. Nurs Times. 2007;103(5):33.
10. Ambler E. P25 Overnight Transfusions Expose Patients to Unnecessary Risk and Seldom Facilitate Next Day Discharge. Transfus Med. 2006 Oct;16(s1):35–35.
11. Hebert PC, Wells G, Blajchman MA, Marshall J, Martin C, Pagliarello G, et al. A Multicenter, Randomized, Controlled Clinical Trial of Transfusion Requirements in Critical Care. N Engl J Med. 1999 Apr; 340(13):409-17.
12. Clark P, Rennie I, Rawlinson S. Quality improvement report: Effect of a formal education programme on safety of transfusions. BMJ. 2001 Nov 10;323(7321):1118–20.
13. Stainsby D, Jones H, Asher D, Atterbury C, Boncinelli A, Brant L, et al. Serious hazards of transfusion: a decade of hemovigilance in the UK. Transfus Med Rev. 2006 Oct;20(4):273–82.
14. Charlewood R, Wright A, Donegan R. Bedside Transfusion Practice Audit: An audit in eight New Zealand Hospitals. Auckland; 2009. Available from: https://www.clinicaldata.nzblood.co.nz/resourcefolder/audits/Bedside Transfusion Practice Audit Final Report.pdf
15. Dagger J. The New Zealand Haemovigilance programme - Unpublished data. Wellington, New Zealand; 2008.

Management of gestational trophoblastic disease: a survey of New Zealand O&G practice

Maria Kladnitski, Diane Kenwright

ABSTRACT

AIM: The aim of the study was to obtain information on pathways for diagnosis and management of molar pregnancy/gestational trophoblastic disease (GTD) across New Zealand, the protocols used, and, in addition, to consider the view of O&G Specialists on a national GTD reference centre.

METHOD: An electronic survey approved by the RANZCOG Continues Professional Development Committee was distributed amongst registered O&G Specialists currently working in New Zealand. Data were analysed using Microsoft Excel 2011. Frequency distributions were used to determine the percentage of participants responding to the listed alternatives for each question.

RESULTS: There were 234 potential responders, but only 68 complete questionnaires were received and available for analysis. The diagnosis of GTD requires histopathological analysis of pregnancy tissue, however only 79.7% of participants request this test routinely. Sixty-five percent of Fellows thought that a number of molar pregnancies can be missed with increasing proportion of medically-managed miscarriages, reliance on ultrasound and appearance of the tissue being contributing factors. Sixty-six percent of specialists were directly involved in the management of patients with GTD to various degrees. Follow-up responsibilities were divided between designated O&G specialists (52.3%), specialised gynaecology clinics (29.2%), acute assessment units (13.8%), nurse specialists (12%), O&G registrars (10.8%), GPs (6.2%), and others (6.2%). NZGCG guidelines were used by the majority of responders (54.8%), followed by local (29%) and RCOG (27.4%) guidelines. Seventy-two percent of specialists felt that some form of centralisation in the management of GTD is needed.

CONCLUSION: In spite of the low response rate, our research demonstrates existing practice heterogeneity at every level of care. It also confirms that there is a desire for some form of centralisation in diagnosis and management of GTD, and a definite need for data collection in the form of a national register.

Background

Gestational trophoblastic disease (GTD) comprises a spectrum of interrelated conditions originating from the placenta. Histologically distinct disease entities include complete and partial mole, invasive mole, gestational choriocarcinoma, and placental site trophoblastic tumours.

Although estimates for the incidence of various forms of GTD vary, molar pregnancy is the most common subtype. For example, in the US, hydatidiform moles are observed in approximately 1:600 therapeutic abortions and 1:1,500 pregnancies.[1] Data from the UK are slightly different. The incidence of complete hydatidiform mole is around 1:1,000 pregnancies and 3:1,000 for partial hydatidiform mole.[2] There is also evidence of ethnic variation. Women from Asia, for instance, have a higher incidence than non-Asian women; 1:125 pregnancies in Taiwan versus 0.6–1.1:1,000 pregnancies in Europe.[3] Furthermore, incidence is higher at the extremes of the reproductive spectrum; in women younger than 15, and older than 40.[3]

Estimates for the incidence of hydatidiform moles/GTD in New Zealand are not currently available as the entity is not registered, but it was not always the case. The Trophoblastic Disease Register was established in New Zealand in late 1979,

Table 1: Survey Questions.

1	Do you routinely send products of conception for histopathological analysis?
2	What influence your decision on sending obtained products of conception to histopathological analysis?
3	Do you think that some number of molar pregnancies are missed and, if so, why?
4	Are you involved in the management of molar pregnancies /GTD in your hospital /practice and, if YES, to what degree?
5	What guidelines do you follow in your DHB?
6	Do you agree with your local guidelines? If you disagree, is there anything you would like to change?
7	In your hospital/region/practice who is responsible for follow up of the patients with molar pregnancies?
8	There is some evidence that creation of a Trophoblastic Disease Reference centre is desirable to improve treatment of patients with GTD. Do you agree?
9	There is no such centre in New Zealand at present. Do you think that the diagnosis and treatment of GTD should be centralised?
10	In your opinion, what would be the best option?

and since 1982 it was under the auspice of the Royal New Zealand College of Obstetricians and Gynaecologists. The aims of the register were to collect epidemiological data on trophoblastic disease, to facilitate early detection of malignant trophoblastic disease, and thus to optimise management.

Two studies conducted in New Zealand shortly after introduction of the register, gave the incidence of trophoblastic disease between 1:1,497 pregnancies and 1:400 deliveries. According to Duff, [4] 70% of cases were reported to the register (notification from some smaller centres in both the North and South Islands were below average at 42–58%). The clinical information obtained at the time revealed no difference in incidence of GTD between the three main ethnic groups, which make up the New Zealand population: New Zealand European, Māori and Asian.

Unfortunately the register no longer exists, and the incidence of GTD in New Zealand at present is not known. However, the indication that the Asian population is rising[5] and maternal age at conception is increasing in New Zealand (in 1962, 26.5 years; in 2009, 32.1 years[5]) suggests that New Zealand incidence may currently be higher compared with European countries.

Most women with GTD can be cured and their reproductive function can be preserved, but it is important that the initial management and follow-up of a patient be timely and appropriate. Currently, there is no information regarding the mode of referral, the initial assessment, and the management of patients with molar pregnancies or GTD in New Zealand. Although there are guidelines available,[6] it is not known if they are used across the country as a single source of information.

Where there is variation in clinical practice or concerns about ineffective practice, guidelines can be a useful way to improve the quality of health care, and assist clinicians in the management of specific conditions. Moreover, the advantages of centralisation of cases have long been recognised as essential to improve the management of patients with rare diseases.

In the UK, there are three National Centres for Trophoblastic Disease, which has been functioning for many years now. Thorough follow-up and centralised management have achieved impressive results with cure rate of 98–100%, and low chemotherapy rates.[7]

Brewer reported as far back as 1971, that both the morbidity and mortality of GTD patients was nine times lower at a centre staffed by physicians experienced in the management of trophoblastic disease compared with the ‘occasional’ physician treating this entity.[8]

Countries such as France, the US, Sweden, the Netherlands, Norway and Hungary have the registration and management of GTD centralised.

The Philippines, and some parts of India, also try to implement centralised management. It appears to be a good time to consider reviving the National GTD Register in New Zealand, and a creation of a reference centre as a next step.

The overarching aim of the present study was to better understand how New Zealand O&G specialists currently approach GTD management with the view to initiate improvement in the assessment, diagnosis, and treatment of this condition in New Zealand.

Method

In May 2013, a link to an electronic survey was sent via email to registered O&G Specialists currently working in New Zealand, using the RANZCOG mailing list. A reminder email was sent 2 weeks later.

The survey was comprised of ten questions examining current clinical practice related to the diagnosis and management of patients with GTD (Table 1).

There were also sections allowing responders to explain their answers.

A total of 244 surveys were distributed. Nine surveys failed to be delivered; one responder was no longer practicing, leaving 234 potential responders.

The RANZCOG's Continuing Professional Development Committee approved the survey for distribution. Ethical approval was not sought, as this was a survey of practice and opinions.

Results

Data were analysed using Microsoft Excel 2011. Frequency distributions were used to determine the percentage of participants responding to the listed alternatives for each question. Descriptive statistics are presented in Tables 2 through 4 below.

In total, 75 responses were received (32% response rate). Of those, 29% (68) responses were completed questionnaires available for analysis, and 2.9 % (7) responses were from participants opting out, indicating that they were not involved in the care of patients with GTD.

Specialists were asked: a) if they routinely submit obtained products of conception for histopathological analysis; b) what influences their decision; and c) their opinion regarding missed molar pregnancies. Survey showed that 79.7% (51) of specialists always send tissue, irrespective of the results of pre-operative investigations, 7.8%(5) do not, 12.5%(8) do it sometimes, and 5.8%(4) skipped the question. Out of those who do not submit tissue for histological analysis, 80% of specialists base their decision on the ultrasound scan (USS) report, 80% on the appearance of the tissue, and 60% on clinical presentation. Out of those who submit tissue sometimes, 87% rely on USS report, 62% on the appearance, and 75% on clinical presentation. Other factors mentioned included previous molar pregnancy. The percentages add up to more than 100%, as responders were able to choose more than one response.

As can be seen from the above data, 20% of products of conception are not always sent to histology, and various methods are used to determine if histology is required. Sixty-five percent (41) of Fellows thought that GTD is being missed through current referral practices. 69.8% (44) of specialists mentioned an increasing number of medically-managed miscarriages was the main reason GTD had been missed. 20.6 % (13) and 12.7% (8) respectively think that reliance on USS and gross appearance of the tissue contributes to missed diagnosis.

We were interested in the extent to which O&G specialists are involved in the care of patients with GTD once it is diagnosed. Among the responders, there were 10% (7) gynaecologists or oncologists who provide consultations and treatment of persistent GTD. Involvement of generalists includes performing D&C and following bHCG levels post procedure, supervision of junior staff, clinical advice and signing histology reports. Overall, 66% (45) of generalists were directly involved in patient's care. The data from question seven are summarised in Table 2.

In order to obtain an accurate diagnosis and provide appropriate treatment to patients with GTD, one must use current, evidence-based guidelines. At the time of the survey there were several guidelines available and Fellows were asked what guidelines they use in their decision making, and whether they agree with the guidelines or would like some changes to be

Table 2: Follow-up responsibilities.

Clinical role	N	%
Nurse specialist	8	12
Acute assessment unit	9	13.8
Specialised gynaecology clinic	19	29.2
Designated O&G specialist	34	52.3
O&G registrar	7	10.8
GP	4	6.2
Other	4	6.2

The designation of 'other' has not been specified.

Table 3: Guidelines used in the management of GTD in New Zealand.

Guidelines	N	%
RCOG	17	27.4
ACOG	3	4.8
NZGCG	34	54.8
Local guidelines	18	29
NSWGTD	0	0

Table 4: View of O&G specialists on a Trophoblastic Disease Reference Centre.

Opinion	N	%
Centralisation needed	48	72.7
Centralisation not needed	18	26.4
Few named centres	35	53
Single national centre	26	39.4
Joined Australian & New Zealand centre	6	9.1

made. Responders were given five options, including RCOG, ACOG, NZGCG Guidelines, NSW Gynaecological Cancer Guidelines and local DHB's guidelines (Table 3) Of note, the RANZCOG statement for the management of GTD was not included at the time as it had become available only in November 2013.

Majority of the responders 93% (54) agreed with the guidelines, and 8.6% (5) of specialists indicated that they would like some changes to be introduced, including the use of unified national guidelines by all involved.

The view of O&G specialists on a Trophoblastic Disease Reference Centre is presented in Table 4.

Discussion

GTD is a type of neoplasia derived from a pregnancy. Approximately 10–20% of patients will develop malignant sequela, requiring administration of chemotherapy after evacuation of hydatidiform moles.[1]

In New Zealand, generalist obstetrician-gynaecologists are the most likely practitioners to be involved in the care of women with hydatidiform moles, which comprise nearly 70% of all GTD. O&G consultants are expected to diagnose, follow-up, and evaluate a patient's risk status to allow appropriate referrals and treatment. Currently in New Zealand, 66.1% (45) of specialists indicated that they are directly involved in the management of patients with GTD, of them 10% (7) were gynaecologists/oncologists.

As with any other medical condition, a patient's journey begins when the diagnosis is made. GTD is diagnosed much earlier now than 20 years ago. The most common presenting symptom is abnormal bleeding. Ultrasound examination has replaced all other non-invasive means of establishing the diagnosis. Molar tissue is typically identified as a mixed echogenic pattern replacing the placenta, the appearance produced by expanded villi and intrauterine blood clots.

Multiple soft USS markers, including cystic spaces in the placenta, and a ratio of transverse to anterior-posterior dimension of the gestational sac of greater than 1.5 are required for the reliable diagnosis of a partial molar pregnancy.[10] However, according to the several retrospective studies, when USS is used in the first and early second trimester, only 40–60% molar

pregnancies are correctly identified as such, with the rest being mislabelled as miscarriages.[11,12] The combination of USS findings with elevation of bHCG above expected for gestational age and clinical presentation with vaginal bleeding are highly suggestive of a molar pregnancy, but not diagnostic.

In our survey, the appearance and amount of tissue play some role in the decision making, but the majority of responders, who do not perform routine histopathological exam, rely mainly on the preoperative USS report and clinical presentation.

As there are difficulties in making a diagnosis of a molar pregnancy before evacuation, the histopathological assessment of material obtained from the surgical management of incomplete/missed miscarriage is recommended by all major guidelines on GTD and early pregnancy loss.[6,10,16,17] Yasemin Tasci evaluated the histopathological findings related to tissue samples obtained via surgical evacuation in patients who were admitted to the early pregnancy clinic with the diagnosis of incomplete/missed miscarriage, or anembryonic pregnancy.[13] Histology revealed RPOC in 69.7%; partial molar pregnancy in 2.1%; complete molar pregnancy in 0.43%; exaggerated placental site and placental site trophoblastic nodule in 0.12%; and decidual tissue in 16.9%.

Of note, all the patients had an USS and bHCG prior to evacuation, but not a single one had a diagnosis of GTD prior to the operation.

Another study looked at the value of histological examination of product of conception. In a retrospective review of case notes of 23 patients diagnosed with molar pregnancy in Birmingham City Hospital, in 11/23 (48%) of cases there was no suspicion at having molar pregnancy before histological diagnosis.[14]

In our survey, 79.7% of responders routinely send products of conception to histology, 12.5% do it sometimes and 7.8% do not send obtained tissue to histology. It was very reassuring to learn that majority of RANZCOG Fellows routinely sent tissue to histology and some commented on importance of histopathological analysis.

However, it is concerning that in about 20% of cases, products of conception are not examined routinely, with reasons why not being stated. Both lack of submission of tissue and medical management of non-viable pregnancies are considered to contribute to missing GTD. 69.8% (44) of specialists thought increasing number of medically-managed miscarriages was the main reason.

El-Refaey states that as many as 20% of women expressed a strong preference for medical management, in order to avoid general anaesthesia and to feel being more in control.[15] Women who miscarried at home should be strongly advised to take any tissue passed to the hospital, so that histological examination can be arranged.[16] However, it is a difficult task, as some tissue passed cannot be recognised as such, and women are not willing to retrieve and transport blood clots and tissue. Alternative management can include measurement of bHCG 3 weeks after completion of treatment, or at least urine pregnancy test.[17] 20.6%(13) and 12.7% (8) of Fellows respectively think that relay on USS and gross appearance of the tissue contributes to missed diagnosis.

Once GTD is diagnosed, appropriate counselling and follow-up should be arranged. The question of follow-up is an important one, because it is time when persistent GTD is unmasked and decision on further treatment and referral to a gynaecologist/oncologist is to be made. Different hospitals have different modes of follow-up, with various health professionals with different level of training, being involved in the process. The majority of patients are seen either by an O&G specialist or in the specialised clinic (52.3% and 29.2% respectively). The rest were divided between nurse specialists, registrars, GPs and others. Once again, practice heterogeneity becomes obvious when health professionals with different level of training and experience are involved in the care of patients with GTD.

One way to avoid mistakes when managing patients with rare conditions is to use guidelines and follow protocols. Various guidelines are used around the country. The majority of participants (54.8%) are using NZGCG guidelines on management of trophoblastic disease, which were updated and published online in January 2014.[6] Out of the remaining participants, 29% use local guidelines, and 27.4% use the RCOG guide-

Table 5: Comments.

"GTD should be managed via an oncology service with clear guidance on follow up via a local clinic. Centralisation makes access for some people very difficult secondary to transport issues"
"Very rural areas in NZ. Perhaps follow-up and treatment management in consultation with centralised centre"
"Not practical a present, but national approach should be considered"
"Population too small and too widespread"
"If there is evidence of poor treatment/outcomes then that should be addressed by education. If a national service could be shown to be cost effective then it could be considered"
"I think the diagnosis should be recorded in the national register for audit and quality control purposes"
Nevertheless some form of advice and guidance from a local gynaecology oncology services or MDT appears to be necessary in majority of cases. The following comments support the statement:
"MDT management by off-site conferencing could be helpful"
"The current medical oncologist in Christchurch provides a useful reference source of information and advice. May be her role should be formalised?"
"Central case discussion with submission of all cases would be good and an annual report on number of cases and outcomes"

lines. A small number of specialists are using the ACOG guidelines (4.8%). The use of RANZCOG Guidelines was not questioned, as it was not available at the time of the survey.

The lack of information or any form of registration of patients with GTD in New Zealand makes it impossible to collect data or conduct an audit to determine standards of care. This is a serious deficiency in care in New Zealand.

Available literature suggests that a national approach to registration and treatment of GTD in the form of a Register or a National Reference Centre can improve the quality of care delivered to patients with GTD, and majority of participants surveyed (92.5% (62)) agree with the statement. However, opinions on the creation of such a centre in New Zealand were divided. 72.7 % (48) of Fellows indicated that some form of centralisation, or at least registration of patients with GTD, is desirable. On the other hand, 27.3% (18) of specialists expressed an opinion that centralisation is not necessary, or is not possible, at present. Among the arguments were comments about small population size, remoteness of some rural areas associated with transport issues, and lack of data on adverse outcomes, which make it difficult to implement improvements. Table 5 shows some comments.

A National GTD Register was mentioned several times as a good starting point in the centralisation. It will help to conduct audit and provide quality control, which is lacking at present. It is difficult to determine what form of centralisation will be achieved in New Zealand. Opinions are divided between a single centre (39.4%), few named centres (53%), or even joined Australia- New Zealand Centre (9.1%).

Conclusion

The most recent literature on the incidence of trophoblastic disease in New Zealand dates back to 1986. It appears that the pathways for the initial diagnosis and the follow-up arrangements vary widely between specialists, hospitals, and DHBs. This may impact on detection and management of GTD. Moreover, a lack of data at the national level makes it impossible to monitor quality of care and improve outcomes.

Therefore, the first step to the unified management of GTD should be the use of a single guideline across all DHBs. The majority of Fellows already use NZGCG guidelines, which were recently updated and are now easily available on the Ministry of Health website. We suggest that it can be used as a National guideline.

The second step should be the establishment of a national registry. The RANZCOG Statement for the management of Gestational Trophoblastic Disease, which became available at the end of 2013, mentions a New Zealand Registry, but to our knowledge one does not exist at present.

The NZGCG guidelines recommend the establishment of local registries to capture all GTD patients, but it is not known how many are in use at present. Furthermore, creation of multiple registries may lead to fragmentation of care.

In contrast, the establishment of only a few registries with shared database under the supervision of regional gynaecology-oncology services will aid in the collection of reliable data on GTD in New Zealand and provision of quality care.

One notable limitation of the present study was a modest response rate of 32%. It is therefore likely that the results represent only a small snapshot of the knowledge and experiences of O&G specialists. While a higher participation rate would have been desirable, it is rarely achieved in surveys of medical practitioners. Participation bias by those most interested in the topic cannot be excluded. A possible explanation for the low response rate is the degree of involvement of O&G specialists in GTD care. It may be the case that the specialists who are not involved in the care opted not to complete the survey. Therefore, future research should consider a survey of O&G registrars, who tend to be more actively involved in the management of early pregnancy complications.

In conclusion, our research shows existing practice heterogeneity, and practitioner's call for re-establishing national data collection in the form of a registry/registries, and some degree of consistency in the diagnosis and management of GTD under the supervision of the oncology services. Although the results should be interpreted with caution, we believe that the survey reflects current practice in the management of trophoblastic disease.

Competing interests:
Nil

Author information:
Maria Kladnitski, O&G Fellow, St Vincent's Hospital, Sydney, NSW, Australia; Diane Kenwright, Head of Department for Pathology and Molecular medicine, University of Otago, Wellington, New Zealand.

Corresponding author:
Maria Kladnitski, Department of O&G, St Vincent's Hospital, 390 Victoria Street, Darlinghurst, NSW 2010, Australia.
mkladnitski@gmail.com

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6830

REFERENCES:

1. Berkowitz RS, Goldstein DP. Gestational trophoblastic disease. In Hoskin WJ, Perez CA, Young RC, editors. Principals and practice of gynaecological oncology. 3rd ed. Philadelphia (PA): Lippincott Williams & Wilkins; 200: 1117-37
2. Newlands ES, Paradinas FJ, Fisher RA. Recent advances in gestational trophoblastic disease. Hematol Oncol Clin North Am 1998; 13:225-44
3. RS Berkowitz, DP Goldstain. Current management of gestational trophoblastic disease. Gynecology Oncology 112(2009) 654-662
4. Duff, G. B. (1989). Gestational trophoblastic disease in New Zealand, 1980-1986. Australian and New Zealand Journal of Obstetrics and Gynaecology 29(2): 139-142.
5. Projections overview www.stats.govt.nz
6. Gestational Trophoblastic Disease: New Zealand Gynaecologic Cancer Group guidelines 2014 http://www.health.govt.nz/publication/gestational-trophoblastic-disease-new-zealand-gynaecologic-cancer-group-guidelines
7. Hancock BW, Newlands ES, Berkowitz RS. Gestational trophoblastic disease. 2nd edition Sheffield
8. Brewer JI, Eckman TR, Dolkart RE, et al. Gestational trophoblastic disease. A comparative study of the results of therapy in patients with

invasive mole and with choriocarcinoma. Am J Obstet Gynecol 1971; 109:335-40

9. Tham BW, Everard JE, Tidy JA, Hancock BW. Gestational trophoblastic disease in the Asian population of Northern England and Northern Wales. BJOG 2003; 110:555-9
10. RCOG guideline N 38 "Gestational Trophoblastic Disease" http://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg38/
11. Fowler DJ, Lindsay I, Seckl MJ, Sebire NJ. Routine pre-evacuation USS diagnosis of hydatidiform mole. Obstet Gynecol 2006; 27:56-60
12. Johns JN, Greenwood S Buckley E A prospective study of ultrasound screening for molar pregnancy in missed miscarriages Ultrasound in Obstet gynec 2005; 25:493-497
13. Yasemin Tasci, Serdar Dilbaz, Ozlem Secilmis, Berna Dilbaz, Ahmet Ozfutty and Ali Haberal. Routine histopathological analysis of product of conception following first trimester spontaneous miscarriage J. Obstetric. Gynaecol. Res.Vo 31 N 6: 579-582, December 2005
14. Thirumagal B, Sinha D, Raghavan R & Bhatti N. Gestational trophoblastic disease: Are we compliant with the standards? J of Obstetric Gynaecol, July2009; 29(5): 434-436
15. El-Rafaey. Medical management of missed abortion and anembrionic pregnancy (Br Medical Journal 1992: 305: 1399)
16. RCOG guidelines N25 "Early Pregnancy Loss, Management http://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg25/
17. NICE Guideline 154 "Ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage", Recommendation 1.5 .16 http://www.nice.org.uk/guidance/cg154
18. Lowe B, Vant M. Hydatidiform moles at Waikato Women's Hospital 1971-85. NZ Med J 1986; 99:624-626

Accuracy of frozen sections for breast cancer sentinel lymph node biopsies within a peripheral New Zealand hospital

James PL Tan, Lesley Joblin, Emily Davenport

ABSTRACT

AIM: Intra-operative frozen section is a commonly-used technique for evaluating sentinel lymph node biopsies in breast cancer to determine the need for an axillary node dissection (AND). Frozen section does have drawbacks, including cost and uncertainty around operating time. In addition, recent studies have questioned the benefit of AND in certain cases. The aim of this study was therefore to evaluate the accuracy of frozen section at our institution.

METHODS: All patients who had a sentinel node biopsy for breast cancer in the Hawke's Bay District Health Board region over a 1-year period were included in the study. Results of intra-operative frozen section were compared to routine paraffin histological analysis.

RESULTS: Eighty patients were eligible. Eighteen had a positive frozen section. There were two false negatives. The sensitivity of frozen section for metastases was 90%, specificity was 100%, and the false negative rate was 2.5%.

CONCLUSIONS: The accuracy of frozen section section for sentinel lymph node biopsies in breast cancer at Hawke's Bay District Health Board is acceptable by international standards. However, as further evidence against axillary node dissections in those with sentinel node positive disease mounts, their use in the future may be limited.

Sentinel lymph node biopsy (SLNB) is now standard practice for staging of early breast cancer. It allows avoidance of axillary node dissection (AND) in patients with sentinel node negative disease, thereby significantly reducing potential morbidity.[1]

Intra-operative frozen section (FS) is one option for evaluation of the SLN providing a rapid result (within 20–30 minutes). Although patients benefit by proceeding directly to AND if positive, and therefore only requiring one operation, there are downsides such as false negatives, increased pathology time and cost, and uncertainty around planning operating theatre time. In addition, recent evidence has questioned the benefit of AND in patients with limited SLNB positive disease,[2-4] leaving management decisions in this group highly controversial. These decisions may be more appropriately made in a multidisciplinary meeting setting rather than intra-operatively, with subsequent delayed AND where appropriate. In this era of current controversy, audit of practice is more important than ever to justify the ongoing use of frozen section for SLNB.

The aim of our study was therefore to examine the accuracy of frozen section for breast cancer SLNB at a peripheral hospital in New Zealand, and to compare these results to internationally accepted standards.

Methods

All patients with breast cancer who underwent an intra-operative frozen section SLNB between 1 January 2014 and 31 December 2014 in the Hawke's Bay region

Table 1: Patient characteristics (n=80).

Median age (years)	63 (range 43–86)
Female gender	79 (99%)
Histological type	
Invasive ductal carcinoma	57 (71%)
Invasive lobular carcinoma	10 (13%)
DCIS	4 (5%)
Papillary carcinoma	3 (4%)
Other	6 (8%)
Number of sentinel nodes removed	
1	29 (36%)
2	32 (40%)
3	15 (19%)
4 or more	4 (5%)
Tumour size	
T(is)/T(mi)	7 (9%)
T1a	2 (3%)
T1b	15 (19%)
T1c	41 (51%)
T2	14 (18%)
T3	1 (1%)
Tumour grade	
I	31 (39%)
II	28 (35%)
III	15 (19%)
N/A (e.g. DCIS)	6 (8%)

(public and private hospitals) were analysed in this prospective, observational study.

All patients had pre-operative scintigraphy to allow localisation of the sentinel node with a hand-held gamma probe. Patent Blue V Dye was also administered in a peri-areolar fashion prior to incision. The sentinel node/nodes were excised in a standard fashion.

Sentinel nodes were sent for immediate frozen section. Frozen sections were prepared using a standard protocol and results relayed to the operating consultant surgeon who proceeded with immediate AND in those with a positive result. All SLNs were then subjected to routine paraffin sectioning with haematoxylin and eosin staining and immunohistological examination. Frozen section results were compared with paraffin section results and sensitivity, specificity and accuracy calculated.

Results

Eighty-one patients were eligible for inclusion in the study. One patient was excluded as the cryostat machine was unavailable at the time of the operation. Summary data is shown in Table 1. Of the eighty SLNBs performed during the 1-year study period, 20 were positive for metastases on paraffin section. Of these, 18 were positive on frozen section. There were two false negatives; one a micro-metastasis and the other a macro-metastasis. There were no false positives.

The sensitivity of frozen section in this study was 90% (95% CI = 68.3%–98.8%);

Figure 1: Paraffin section of a sentinel node with metastatic ductal carcinoma.

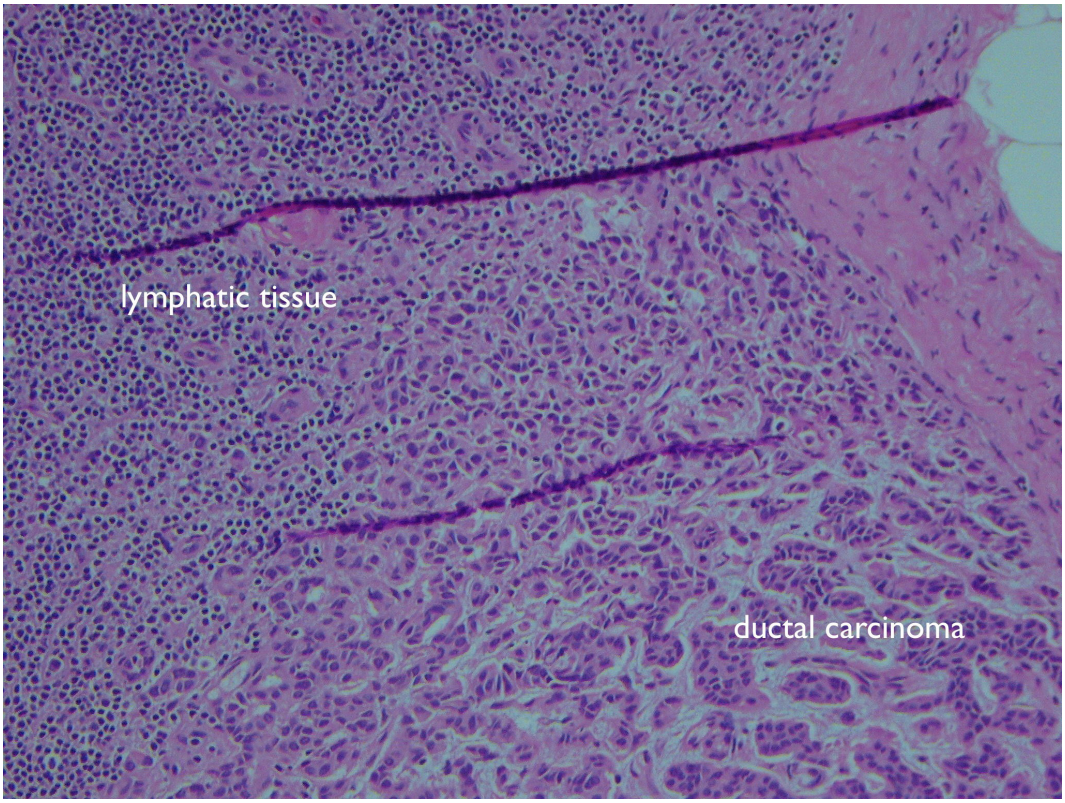
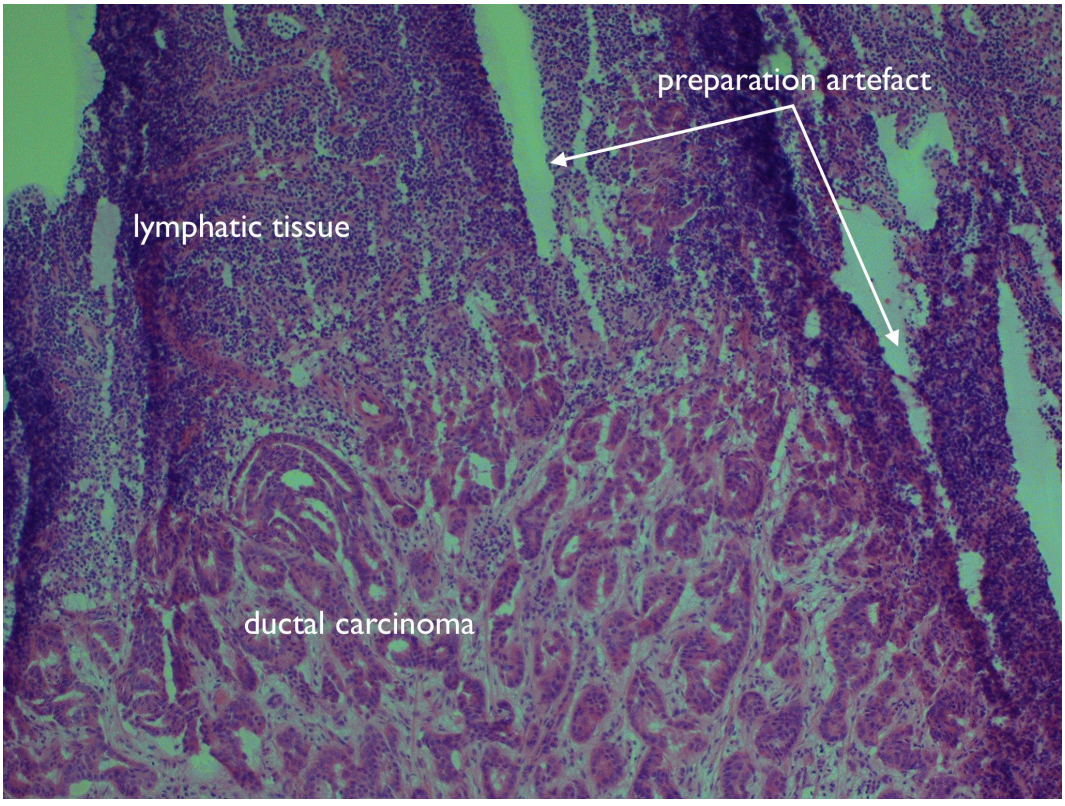


Figure 2: Frozen section of a sentinel node with metastatic ductal carcinoma. Note the preparation artefact.



specificity was 100% (95% CI = 94.0%–100%). The negative predictive value of frozen section was 96.8% (95% CI = 88.8%–99.6%). The false negative rate was 2.5% and therefore the accuracy of frozen section in this study was 97.5%.

Discussion

Frozen section provides a timely result, allowing intra-operative decision making and limiting surgery to a single operation for the majority of patients. However, there are significant trade offs.

Frozen sections are prone to artefact (eg, overlapping of the specimen, frozen water droplets) during preparation, which makes interpretation more difficult (Figure 1). The quality of the slide is also operator dependant. This can lead to inaccuracy in interpretation. Of particular concern is a false negative result, which can falsely reassure patients leading to significant psychological trauma when the final result is explained on top of the need for a second operation. Paraffin sections (Figure 2) are generally of a higher quality, but take longer to prepare without the option of an intraoperative result, therefore resulting in AND as a second procedure in approximately one quarter of patients.

The false negative rate of frozen sections at our institution in this study was 2.5%. This is well within international standards (false negative rates reported between 2.8% and 4.9%).[5,6] Of the two false negatives, one was a micro-metastasis and therefore would not have proceeded to AND in our institution. Therefore, only one patient of 80 (1.25%) had management affected by inaccuracy of FS, while FS allowed 18 patients (22.5%) to proceed to immediate AND and therefore avoid the need for a second operation.

Performing frozen section can put a strain on resources. There is a significant amount of pathologist and laboratory technician time required for the procedure. In addition, accurate planning of operating list time is difficult, as the length of the procedure is determined by the outcome of the frozen section. This can result in either under-utilisation of theatre, or overrun lists. Overall however, the resources saved by avoiding a second operation for a substantial number of patients by utilising frozen section likely outweighs other concerns.

In recent years, deciding which patients should proceed to AND has become less clear. Evidence from the American College of Surgeons Oncology Group Z0011 trial,[2] and the International Breast Cancer Study Group Trial 23-01[3] suggests that, in patients with low volume SLNB metastases, there is no benefit from AND in terms of disease-free survival. The patients who underwent AND had a higher rate of complications. In addition, the AMAROS trial[4] has recently demonstrated non-inferiority of axillary radiotherapy compared with AND in terms of axillary recurrence in patients with low-volume SLN disease, but with a lower incidence of lymphoedema in the radiotherapy arm. Radiotherapy may therefore provide a valid alternative to surgery in suitable patients. Based on these trials, some centres have abandoned AND in selected patients with low-volume SLN disease. In our centre, we no longer routinely proceed to AND in patients with micro-metastases. Others argue that trial flaws, in particular underpowering, high rates of adjuvant treatment and poor description of radiotherapy protocols, mean that further evidence is required before changing practice.

Given current controversies, the decision of whether to proceed with AND for an individual patient may be better made in a formal multidisciplinary setting rather than intra-operatively. In the future, this may limit the use of intra-operative frozen section.

In summary, use of FS for SLNB in patients with breast cancer at Hawke's Bay Hospital meets internationally accepted standards. Although not without problems, the overall benefit to patients outweighs these and ongoing use can be justified at present. As evidence mounts against routine AND for those with SLN-positive disease, the role of intra-operative FS may be limited in the future.

Competing interests:
Nil

Author information:
James Tan, Surgical Registrar, Department of General Surgery, Hawke's Bay District Health Board, Hastings, New Zealand; Lesley Joblin, Pathologist, Department of Pathology, Hawke's Bay District Health Board, Hastings, New Zealand; Emily Davenport, General Surgeon, Department of General Surgery, Hawke's Bay District Health Board, Hastings, New Zealand.

Corresponding author:
James Tan, Department of General Surgery, Level 2, Hawke's Bay Hospital, 398 Omahu Road, Frimley, Hastings 4120, New Zealand.
James.Tan@hawkesbaydhb.govt.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6831

REFERENCES:

1. Veronesi U, Paganelli G, Galimberti V, et al. Sentinel-node biopsy to avoid axillary dissection in breast cancer with clinically negative lymph-nodes. Lancet. 1997;349(9069):1864-7.
2. Giuliano AE, Hunt KK, Ballman KV, et al. Axillary dissection vs no axillary dissection in women with invasive breast cancer and sentinel node metastasis: a randomized clinical trial. JAMA. 2011;305(6):569-75.
3. Galimberti V, Cole BF, Zurrida S, et al. Axillary dissection versus no axillary dissection in patients with sentinel-node micrometastases (IBCSG 23–01): a phase 3 randomised controlled trial. Lancet Oncol. 2013;14(4):297-305.
4. Donker M, van Tienhoven G, Straver ME, et al. Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer (EORTC 10981-22023 AMAROS): a randomised, multicentre, open-label, phase 3 non-inferiority trial. Lancet Oncol. 2014;15(12):1303-10.
5. Lim J, Govindarajulu S, Sahu A, et al. Multiple step-section frozen section sentinel lymph node biopsy–A review of 717 patients. Breast. 2013;22(5):639-42.
6. Poling JS, Tsangaris TN, Argani P, Cimino-Mathews A. Frozen section evaluation of breast carcinoma sentinel lymph nodes: a retrospective review of 1,940 cases. Breast Cancer Res Treat. 2014;148(2):355-61.

An exploratory study of the health harms and utilisation of health services of frequent legal high users under the interim regulated legal high market in central Auckland

Chris Wilkins, Jitesh Prasad, KC Wong, Thomas Graydon-Guy, Marta Rychert

ABSTRACT

AIMS: To explore health problems and the accessing of health services by frequent legal high users under an interim regulated legal market in central Auckland.

METHOD: Frequent legal high users (monthly+) were recruited from outside eight randomly-selected, licensed, legal high stores in central Auckland from 23 April–7 May, 2014. Eligible participants were emailed a unique invitation to complete an on-line survey; 105 completed the survey.

RESULTS: Twenty-seven percent had suffered mental illness during their lifetimes. Eighty percent used synthetic cannabinoids (SC), and 20% 'party pills'. Forty-seven percent of SC users used daily or more often. Other drugs used included alcohol (80%), cannabis (59%), 'ecstasy' (18%) and methamphetamine (15%). Fifty-eight percent of SC users were classified as SC dependent. The most common problems reported from SC use were: insomnia (29%); 'vomiting/nausea' (25%); 'short temper/agitation' (21%); 'anxiety' (21%); 'strange thoughts' (16%); and 'heart palpitations' (14%). The health services most commonly accessed by SC users were: a 'doctor/GP' (9%); 'counsellor' (9%); 'DrugHelp/MethHelp' websites (7%); 'Alcohol & Drug Helpline' (4%); 'ambulance' (3%); 'A&E' (3%); and hospitalisation (3%).

CONCLUSIONS: Frequent use of interim licensed SC products was associated with health problems, including dependency. Further research is required to determine the health risks of these products.

The enactment of the *Psychoactive Substances Act* (PSA) in New Zealand on 17 July 2013 created the world's first regulated legal market for 'low-risk' psychoactive products (ie, 'legal highs').[1] A temporary interim regulatory regime was established immediately following the passage of the PSA to allow time for the development of further regulation required for the full PSA regime, including product testing standards, and to prevent the emergence of a black market for existing products.[2] During the interim period, the continued sale of existing legal high products was permitted subject to new retail restrictions (ie, R18 age restriction, no sale from convenience stores or petrol stations, and licensed sellers), provided they had not attracted any official reports of adverse effects in the 3 months prior to the passage of the PSA.[2] Forty-one existing legal high products received interim licenses, of which 35 were smoking synthetic cannabinoid (SC) products.[3,4] The interim PSA regime was brought to abrupt end on May 7 2014, following ongoing reports of adverse effects and dependency related to legal high products.[2,5] Regulatory work on the full PSA regime continues.[3]

© NZMA

SC include a wide range of compounds that bind to cannabinoid CB1 and CB2 receptors in the brain, and mimic the effects of delta-9-tetrahydrocannabinol (THC) in natural cannabis, although often with greater affinity.[6-8] Case reports and case series have reported adverse effects from SC including tachycardia, vomiting, agitation, drowsiness, psychosis, hallucinations, anxiety, headache, seizures and suicidal ideation.[6,9-15] Acute SC intoxication has resulted in emergency department (ED) admissions requiring supportive care, benzodiazepines, and fluids, with severe cases resulting in hospitalisation for up to 2 weeks.[6,16] Some cases of dependence on SC have been reported after chronic use.[6,17-19]

Studies of SC users outside of clinical settings are currently limited to a very small number of on-line and other convenience studies completed in other countries.[10,15,19,20] To date, there have been no similar studies of SC users in New Zealand, and little is known about patterns of use, the extent of adverse effects, levels of other drug use, and the accessing of health services of this group. The New Zealand retail environment under the interim PSA regime was unique, as it involved the sale of a restricted number of legal high products from licensed retail outlets under new retail restrictions.

We therefore undertook an exploratory study of frequent legal high users in central Auckland during the interim PSA period to identify the extent of health problems and utilisation of health services to inform further research. Frequent users of a drug are often the subject of exploratory research as their high-use patterns provide early warning of health risks.[21] Central Auckland was a natural location to conduct our study as it had a high concentration of licensed legal high retail outlets.[22]

Methods

The aim of our study was to explore the patterns of use, health harms, extent of substance dependency, and utilisation of health services of frequent legal high users during the interim regulatory regime in central Auckland.

Frequent legal high users were recruited from outside of all eight interim licensed legal high stores in central Auckland from 23 April to 7 May, 2014. They were invited to complete an on-line survey examining their legal high and other substance use during the previous 6 months. All of the central Auckland legal high stores were open 7 days a week, with many staying open past midnight during mid-week and weekends (eg, typically 2am from Wednesday onwards and 4am Friday/Saturday). The recruiters were present outside of two randomly selected shops during each of seven shift times per day (ie, 9–10am, 10–12pm, 12–2pm, 3–5pm, 5–7pm, 9–11pm and 11pm–1am). Recruitment after 1am was deemed to pose a personal safety risk. The interviewers completed a total of 161 recruitment shifts over 3 weeks. The lunchtime and early evening shifts were by far the busiest times for the stores, but in the interest of recruiting a broad cross-section of buyers, we ensured interviewers were present outside of stores even at times and days when there were very few patrons. Furthermore, not all store patrons were engaged in buying legal highs. The importance of legal high sales varied from store to store, with some primarily set up to sell legal highs while others sold legal highs as part of a range of other retail business. All the stores sold other retail items, such as hemp products, t-shirts, smoking pipes and smoking paraphernalia. Consequently, the recruiters screened patrons to ascertain they were eligible for the study.

Patrons were approached as they exited stores and provided with a brief explanation of the study, and asked two screening questions about the frequency of their legal high use and purchase in central Auckland. To be eligible, patrons had to have used and purchased legal highs approximately monthly or more often over the past six months in central Auckland. Those who were eligible were emailed a unique invitation to complete an on-line survey. The eligibility questions were repeated at the beginning of the on-line survey, with those not meeting the criteria exited. The survey was programmed and managed using IBM™ SPSS data collection package. One hundred and five surveys were completed. Respondents were offered a $20 food voucher to compensate them for their time. The study was approved by the Massey University Human Subjects Ethics Committee.

Measures

Demographics

Participants were asked a range of demographic questions, including current and previous history of mental illness (eg, 'depression, psychosis, schizophrenia, anxiety'), and whether they had "ever been a patient in a psychiatric ward or hospital for an overnight stay or longer."

Patterns of substance use

Participants were asked how frequently they had used a list of 24 drug types in the previous 6 months, including three general categories of legal highs ('synthetic cannabis', 'party pills' and 'other legal highs').

Dependency on legal highs

Dependency on SC and 'party pills' was assessed using a five-question validated Severity Dependency Scale (SDS) with a cut-off score of four or greater for the five enumerated questions indicative of drug dependency.[23,24]

Physical and psychological problems

The frequent legal high users were asked if they had experienced any of a list of 21 acute physical and psychological problems from their substance use in the previous six months, and to name the substance(s) responsible for each problem.

Life impacts

The frequent legal high users were asked if they had experienced any of a list of 12 adverse life impacts from their substance use in the previous six months, and to name the substance(s) responsible for each problem.

Help-seeking

The frequent legal high users were asked if they wanted help to reduce their substance use, and to name the substance(s) they wanted help for.

Accessing health services

The frequent legal high users were asked if they had accessed any of 10 health and information services in relation to their substance use in the previous six months, and to name what substance(s) was involved in each instance.

Results

Demographics

Seventy-six percent of the frequent legal high users were male with a mean age of 29 years (median 27 years, range 18–52 years). Fifty-four percent were New Zealand/European, 23% were Māori, 9% were Indian, 7% were British, 5% were Pacific, 5% were Middle Eastern and 4% were Asian. Sixty-two percent were in full-time/part-time employment, 13% were students, 11% were on a sickness benefit, and 10% were unemployed. Fifty-three percent had a university degree or diploma, 23% a high school qualification, and 16% a trade qualification. Five percent had no educational qualifications.

History of mental illness

Twenty-seven percent had suffered from a mental illness at some point in their lives. Eight percent were 'currently', and 10% had 'previously', received treatment or medication for a mental illness. Five percent had been a patient in a psychiatric ward or hospital overnight or longer.

Legal high and other drug use

The frequent legal high users had used a mean of four drug types in the previous six months (median 4, range 1–12). The drug types most commonly used were alcohol (80%), 'synthetic cannabis' (80%), tobacco (69%), cannabis (59%), 'party pills' (20%), 'ecstasy' (18%), methamphetamine (15%), anti-depressants (12%), nitrous oxide (10%), salvia divinorum (9%) and amphetamines (9%). Eighty percent of the SC users used SC weekly or more often, 47% used daily or more often, and 32% used 'more than once per day'. Only 12% of party pill users used party pills weekly or more often; none used daily.

Dependency on legal highs

Fifty-eight percent of the SC users were categorised as dependent on SC. Twenty-five percent of the party pill users were dependent on party pills.

Physical and psychological adverse effects from SC

The adverse effects most commonly reported from SC were: 'trouble sleeping' (29%); 'vomiting/nausea' (25%); 'short temper/agitation' (21%); 'anxiety' (21%); 'strange thoughts' (16%); and 'heart palpitations' (14%) (Table 1). Six percent reported

Table 1: Proportion of frequent legal high users who attributed acute physical and psychological problems to different substances in the previous six months

Physical and psychological problems	Synthetic cannabinoids (n=70)	Party pills (n=19)	Alcohol (n=80)	Cannabis (n=58)	Tobacco (n=69)
Trouble sleeping	29%	5%	4%	2%	0%
Vomiting/nausea	25%	5%	17%	2%	4%
Short temper/agitation	21%	0%	8%	3%	4%
Anxiety	21%	6%	5%	4%	4%
Strange thoughts	16%	0%	4%	4%	0%
Heart palpitations	14%	24%	5%	0%	0%
Skin problems	13%	0%	4%	0%	1%
Drowsiness	13%	0%	8%	7%	1%
Paranoia	12%	6%	3%	7%	3%
Weight loss	12%	19%	1%	6%	2%
Depression	11%	6%	11%	4%	0%
Shortness of breath	10%	0%	3%	7%	12%
Blurred vision	9%	0%	9%	4%	0%
Fainting/passing out	7%	0%	6%	2%	0%
Chest pains	7%	0%	0%	2%	4%
Tremors	6%	0%	3%	2%	0%
Suicidal thoughts	6%	0%	3%	0%	0%
Fits/seizures	6%	0%	0%	0%	1%
Hallucinations	4%	0%	0%	2%	0%
Teeth problems	3%	0%	4%	2%	3%
Other problems	1%	0%	0%	0%	0%
Overdose	0%	6%	1%	0%	0%

experiencing ‘suicidal thoughts’ and ‘fits and seizures’ in relation to SC use. Those reporting adverse effects from SC reported a mean of four problems (median 3, range 1–18). The most common adverse effects from party pills were ‘heart palpitations’ (24%) and ‘weight loss’ (19%). The most common adverse effect from alcohol was vomiting (17%).

Life problems

The most common life problems from SC were: ‘spending too much money’ (51%); ‘damaging a friendship or relationship’ (29%); ‘reduced work/study performance’ (21%); and ‘arguing with others’ (21%) (Table 2). Fifteen percent reported “losing their job or quitting study” as a result of their SC use. Those reporting life problems from SC reported a mean of three life problems (median 2, range 1–10). The most common life problem reported by the party pill users was ‘spending too much money’ (32%). Drinkers and smokers also commonly reported financial pressure, with drinkers also reporting damaging relationships (31%) and reduced work/study performance (16%).

Help seeking and accessing health services

Fifty-one percent of the frequent legal high users reported they wanted help to reduce their substance use. The drug types they wanted help with were: SC (61%); alcohol (32%); tobacco (18%); cannabis (16%); and ‘party pills’ (4%). Approximately one-in-ten SC users accessed a ‘counselling service’ (9%) and a ‘doctor/GP’ (9%) in relation to their SC use (Table 3). Three percent had accessed an ‘ambulance’, ‘Accident and Emergency Department’ and

Table 2: Proportion of frequent legal high users who attributed life problems to different substances in the previous six months.

Life problem	Synthetic cannabinoids (n=70)	Party pills (n=19)	Alcohol (n=80)	Cannabis (n=58)	Tobacco (n=69)
Spent too much	51%	32%	35%	16%	27%
Damaged a friendship/relationship	29%	0%	31%	7%	3%
Had reduced work/study performance	21%	6%	16%	7%	3%
Argued with others	21%	5%	10%	7%	1%
Couldn't remember the night before	17%	5%	10%	5%	1%
Lost job/quit study	15%	0%	9%	2%	0%
Physically hurt yourself	4%	0%	9%	2%	0%
Got arrested	3%	5%	6%	2%	0%
Damaged someone's property	1%	0%	4%	0%	0%
Physically hurt someone else	1%	0%	3%	0%	0%
Other problem	1%	0%	3%	0%	0%
Were sexually harassed	0%	0%	1%	0%	0%

Table 3: Proportion of frequent legal high users who accessed health services in relation to different substances in the previous six months.

Health service	Synthetic cannabinoids (n=70)	Party pills (n=19)	Alcohol (n=80)	Cannabis (n=58)	Tobacco (n=69)
GP/doctor)	9%	0%	5%	0%	0%
Counselling services	9%	0%	8%	5%	0%
DrugHelp/MethHelp	7%	0%	3%	0%	0%
Alcohol & Drug Helpline	4%	0%	3%	0%	0%
Ambulance	3%	0%	1%	0%	0%
Accident & Emergency	3%	0%	3%	0%	0%
Hospitalisation (admitted)	3%	0%	0%	0%	0%
Other	3%	0%	0%	0%	0%
First Aid	0%	5%	1%	0%	1%
Pharmacy	0%	0%	4%	2%	1%

had been 'admitted to hospital' as a result of SC use. Those accessing health services for SC had accessed a mean of two services (median 2, range 1–6). One party pill user had accessed 'First Aid'. Eight percent of drinkers had accessed a counsellor in relation to their alcohol consumption.

Discussion

Approximately a quarter of our sample of frequent legal high users reported suffering from mental illness, and this is of concern as legal highs have been associated with inducing psychotic relapse, as well as triggering new psychotic events.[11,14]

We found approximately half of SC users used SC daily or more often and were categorised as dependent on SC. The frequency of SC use and level of dependency found in our study greatly exceeds the levels found in overseas studies (see[10,15,19,20]) and this reflects the less frequent recruitment criteria in these studies (ie, 'last year' or 'lifetime' use). The proportion of SC users classified as dependent on SC in our study is higher than the proportion of frequent

ecstasy users (monthly+) classified as dependant on ecstasy (9%) (using the same SDS scale), and is in fact closer to the proportion of frequent methamphetamine users (monthly+) classified as dependent on methamphetamine (66%) in New Zealand.[25] The utilisation of ED services in relation to SC in our sample (3%) was very close to the rate found by Winstock and Barratt[16] among last year SC users (2.4%).

The new PSA regime was modelled on the assumption that the patterns of use of legal highs would be similar to those previously seen with legal BZP party pills during the mid-2000s.[2] However, a national population survey of BZP use in 2006 found only 16% of monthly BZP users used BZP weekly or more often, and none reported daily use.[26] The sales turnover of the BZP legal high market was estimated to be $28 million per year, while the recent interim legal high market generated an annual turnover of $140 million.[2] These differences illustrate the important implications of what type of legal high products gain licenses under a legal regime.

Our findings suggest that alcohol and other drug use may have played a part in the substance-related problems experienced by the frequent legal high users, and this requires further research. Barrett et al[15] found those who used SC concurrently with alcohol reported more side-effects, while those who used SC with cannabis did not. A previous study of BZP legal high users in New Zealand found concurrent use of cannabis and other drugs, taking large quantities of BZP party pills in a single session, concurrently using 5-hydroxytryptophan (5-HTP) recovery pills, and being female, were all independent predictors of experiencing adverse effects from BZP.[27]

Although the interim PSA regime ended in May 2014, regulatory work on the full PSA regime has continued, with new regulations and discussion documents released in early November 2014,[28,29] and further retail regulations scheduled for release in mid-2016. As outlined earlier, the legal high products sold during the interim regime were not subject to any formal product testing as originally intended by the PSA. Discussion documents indicate the product testing standards which are being considered for the full regulatory regime will essentially be the same as the international agreed standards for medicines (ie, International Conference Harmonisation [ICH] guidelines).[28,29] Consequently, there is good reason to believe the legal high products approved under the full regime will pose a lower health risk than those sold during the interim regime.[29] They are unlikely to include traditional smoking products, for example.[29] However, even approved medicines can cause adverse reactions if they are used: by vulnerable individuals; at higher than recommended dosage levels; via high risk modes of administration, such as injection; or in conjunction with substances which can amplify adverse effects, such as alcohol. The hedonistic consumption patterns associated with recreational alcohol and other drug use may accentuate the adverse health risks from clinically-tested legal high products, and clinical testing should seek to recreate these real world conditions to fully identify risks.[1] Finally, while many of the frequent legal high users in our study had histories of mental illness, a recent evaluation suggests the interim PSA regime may have reduced legal high-related mental illness by reducing the availability of these products to licensed rather than convenience outlets.[31]

We acknowledge a number of limitations with this study. While we recruited from randomly selected legal high stores in central Auckland, the sample is not a representative sample of frequent legal high users in central Auckland or other parts of New Zealand. Central Auckland may be different from other parts of the country in important ways, including the concentration of legal high stores and other late night nightlife venues. Participants needed to be able to access the internet to complete the survey. Although internet usage is very high in New Zealand (eg, only 1% those under 40 years do not use the internet[30]) and the survey could be completed via smart phone or tablet, difficulties with accessing the internet may have excluded more vulnerable users. Nevertheless, 11% of our sample was on a sickness benefit and a further 10% were unemployed. The low numbers of respondents in our sample reporting 'party pill' use indicate these results should be treated with caution. We had planned a larger sample size, but recruitment was brought to an unexpected halt by the banning of all interim licensed products. The incidence of

adverse effects, and the substances deemed responsible, were self-reported and not supported by urine or blood analysis. The use of illegal drugs may have been under-reported to some extent due to social stigma or fear of prosecution. Although, our sample reported very high levels of illegal drug use compared to surveys of the general population.

In conclusion, our exploratory study suggests frequent use of interim licensed SC products was associated with health risks, including drug dependency. Further research is required to more precisely identify the health risks including general random population surveys and larger sample studies to identify specific risk factors. Our study illustrates the importance of post-approval research of legal high products which describe use patterns and adverse effects in natural settings to better understand harms.

Competing interests:
Nil
Acknowledgements:
Funding for this research was provided by Auckland Council and Massey University.
Author information:
Chris Wilkins, Researcher, SHORE & Whariki Research Centre, College of Health, Massey University, Auckland; Jitesh Prasad, Project Manager, SHORE & Whariki Research Centre, College of Health, Massey University, Auckland; KC Wong, Statistician, SHORE & Whariki Research Centre, College of Health, Massey University, Auckland; Marta Rychert, Doctoral Student, SHORE & Whariki Research Centre, College of Health, Massey University, Auckland; Thomas Graydon-Guy, Technical Officer, SHORE & Whariki Research Centre, College of Health, Massey University, Auckland.
Corresponding author:
Chris Wilkins, SHORE & Whariki Research Centre, Massey University, PO Box 6137, Wellesley Street, Auckland.
c.wilkins@massey.ac.nz
URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6832

REFERENCES:

1. Wilkins C. A critical first assessment of the new pre-market approval regime for new psychoactive substances (NPS) in New Zealand. Addiction. 2014;109:1580-6.
2. Ministry of Health. Regulatory Impact Statement: Amendment to the Psychoactive Substances Act 2013. 2014. Available at: http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/amendment-psychoactive-substance-act-2013. (accessed 11 March, 2015).
3. Ministry of Health. Regulatory Impact Statement: Psychoactive Substances Regulations. Wellington: 2015. Available at: http://www.treasury.govt.nz/publications/informationreleases/ris/pdfs/ris-moh-psr-jul14.pdf. (accessed 10 March, 2015).
4. Wilkins C. The interim regulated legal market for NPS ('legal high') products in New Zealand: The impact of new retail restrictions and product licensing. Drug Testing Anal. 2014;6:868-75.
5. Wilkins C. Recent developments with the establishment of a regulated legal market for new psychoactive substances ('legal highs') in New Zealand [Letter]. Drug Alcohol Rev. 2014;33:678-80.
6. Castaneto M, Gorelick D, Desrosiers N, et al. Synthetic cannabinoids: epidemiology, pharmacodynamics, and clinical implications. Drug Alcohol Depend. 2014;144:12-41.
7. Aung M, Griffin G, Huffman J, et al. Influence of the N-1 alkyl chain length of cannabimimetic indoles upon CB(1) and CB(2) receptor binding. Drug Alcohol Depend. 2000;60:133-40.
8. Hermanns-Clausen M, Kneisel S, Szabo B, et al. Acute toxicity due to the confirmed consumption of synthetic cannabinoids: clinical and laboratory findings. Addiction. 2013;108:534-44.
9. Harris C, Brown A. Synthetic cannabinoid intoxication: A case series

and review. J Emerg Med. 2013;44:360-6.

10. Winstock A, Barrett M. Synthetic cannabis: A comparison of patterns of use and effect profile with natural cannabis in a large global sample. Drug Alcohol Depend. 2013;131:106-11.
11. Glue P, Al-Shaqsi S, Hancock D, et al. Hospitalisation associated with use of the synthetic cannabinoid K2. NZ Med J. 2013;126:18-23.
12. Every-Palmer S. Warning: legal synthetic cannabinoid-receptor agonists such as JWH-018 may precipitate psychosis in vulnerable individuals. Addiction. 2010;105:1859-60.
13. 13. Schep L, Slaughter R, Temple W. Synthetic cannabinoid use in New Zealand: A brief evaluation of enquiries to the New Zealand National Poisons Centre. NZ Med J. 2011;124:99-101.
14. Every-Palmer S. Synthetic cannabinoid JWH-018 and psychosis: An explorative study. Drug Alcohol Depend. 2011;117:152-7.
15. Barratt M, Cakic V, Lenton S. Patterns of synthetic cannabinoid use in Australia. Drug Alcohol Rev. 2013;32:141-6.
16. Winstock A, Barratt M. The 12-month prevalence and nature of adverse experiences resulting in emergency medical presentations associated with the use of synthetic cannabinoid products. Human Psychopharmacol. 2013;28:390-3.
17. Zimmermann U, Winkelmann P, Pilhatsch M, et al. Withdrawal phenomena and dependence syndrome after the consumption of "Spice Gold". Dtsch Arztebl Int. 2009;106:464-7.
18. Nacca N, Vatti D, Sullivan R, et al. The synthetic cannabinoid withdrawal syndrome. J Addict Med. 2013;7:296-8.
19. Vandrey R, Dunn K, Fry J, et al. A survey study to characterize use of Spice products (synthetic cannabinoids). Drug Alcohol Depend. 2012;120:238-41.
20. Kelly B, Wells B, Pawson M, et al. Novel psychoactive drug use among younger adults involved in US nightlife scenes. Drug Alcohol Rev. 2013;32:588-93.
21. Breen C, Topp L, Longo M. Adapting the IDRS Methodology to Monitor Trends in Party Drug Markets: Findings of a Two-Year Feasibility Trial. Sydney, National Drug and Alcohol Research Centre, University of New South Wales, 2002. (NDARC Technical Report Number 142).
22. Auckland Council. Local Approved Products Policy. 2015. Available at: http://www.aucklandcouncil.govt.nz/en/planspoliciesprojects/councilpolicies/localapprovedproductspolicy/Pages/localapprovedproductspolicy.aspx. (accessed 10 March, 2015).
23. Gossop M, Darke S, Griffiths P, et al. The Severity of Dependence Scale (SDS): psychometric properties of the SDS in English and Australian samples of heroin, cocaine and amphetamine users. Addiction. 1995;90:607-14.
24. Martin G, Copeland J, Gates P, et al. The Severity of Dependence Scale (SDS) in an adolescent population of cannabis users: reliability, validity and diagnostic cut-off. Drug Alcohol Depend. 2006;83:90-3.
25. Wilkins C, Jawalkar S, Parker K. Recent trends in illegal drug use in New Zealand 2006-2012: Findings from the 2006, 2007, 2008, 2009, 2010, 2011 and 2012 Illicit Drug Monitoring System (IDMS). Auckland, SHORE and Whariki Research Centre, Massey University, 2013.
26. Wilkins C, Girling M, Sweetsur P, et al. Legal party pill use in New Zealand: Prevalence of use, availability, health harms and 'gateway effects' of benzylpiperazine (BZP) and triflourophenylmethylpiperazine (TFMPP). Auckland, Centre for Social and Health Outcomes Research and Evaluation (SHORE) & Te Ropu Whariki, Massey University, 2006, June.
27. Wilkins C, Sweetsur P, Girling M. Patterns of benzylpiperazine/ trifluoromethylphenylpiperazine (BZP/TFMPP) party pill use and adverse effects in a population sample in New Zealand. Drug Alcohol Rev. 2008;27:633-9.
28. New Zealand Government. Psychoactive Substances Regulations. Wellington, 2014. (Order in Council 2014/243). http://www.legislation.govt.nz/regulation/public/2014/0243/latest/DLM6203143.html.
29. Office of the Psychoactive Substances Regulatory Authority. Psychoactive Substances Product Approval Guidelines. Wellington, 2014. (Draft).
30. Gibson A, Miller M, Smith P, et al. The Internet in New Zealand 2013. Auckland, Institute of Culture, Discourse & Communication, AUT University, 2013.
31. Glue, P., Courts, J., MacDonald, M., Gale, C., Mason, E. Implemnetation of the 2013 Psychoactive Substances Act and mental health harms from synthetic cannabinoids. NZ Medical Journal. 2015; 128 (1414):15-8.

Social and spatial inequalities in Rotaviral enteritis: a case for universally funded vaccination in New Zealand

Christopher Bowie, Malcolm Campbell, Paul Beere, Simon Kingham

ABSTRACT

AIMS: Rotaviruses have long been recognised as the most common cause of diarrhoea-related childhood morbidity and mortality worldwide. The benefits of national rotavirus vaccination programmes have been proven, with estimates of the reduction in hospital stays ranging from 70% to 90%. Previous work has found spatial variation in rotaviral rates between areas in Australia and Germany. This study sought to identify spatial and spatio-temporal variation in clustering of high and low neighbourhood rates of paediatric hospital admissions for RV disease in Auckland, New Zealand for the period 2006–2011.

METHODS: Annual clusters of rotavirus hospitalisations were identified using a Local Moran's I Index from ArcGIS. Spatio-temporal variation during the study period used a retrospective spatial variation in temporal trends scan statistic in SatScan.

RESULTS: Annual clusters of high and low rotavirus rates were identified for each year of the study and the spatio-temporal scan statistic confirmed that spatial clustering of rotavirus rates had shifted significantly during the study period.

CONCLUSIONS: This research suggests that targeted rotaviral intervention is inappropriate and supports the introduction of a fully funded rotavirus vaccine in New Zealand in 2014.

Rotaviruses (RV) have long been recognised as the most common cause of diarrhoea-related childhood morbidity and mortality worldwide.[1] Previous estimates of over 525,000 annual deaths due to RV have been made, most of these occurring in non-industrialised nations.[2] There remains a considerable clinical, economic, and social burden of RV disease in industrialised countries, despite improvements in hygiene, sanitation and access to clean water.[3–5] Previous New Zealand research found RV hospitalisation rates, adjusted for age and season, to be 634/100,000 per annum among children aged 3 years and under.[6] Estimates of the associated health sector cost due to RV in New Zealand were $7.07million, or $22.17 for every child younger than 5 years old in the country.[7] Hospital admissions are not the only economic burden factored into cost analyses with medical care; family stress, and lost working days for parents also being important factors.[3,7]

Both international and New Zealand-based studies have consistently found an absence of association between RV and both socio-economic status (SES) and ethnicity.[2,6,8,9] There are a number of social risk factors for RV, including premature birth, requirement of neonatal care, low birth weight, malnutrition, and immunosuppression.[4,8] These are often not specific to deprived/non-deprived groups and so are not significant enough to drive socio-economic inequalities in RV rates. Studies which have found some variation between social or ethnic groups in RV hospitalisations cite differences in access to care and the cost of vaccination and/or treatment as the reason for these inequalities.[8,10] Spatial

variation in RV hospitalisations has previously been demonstrated in Australia and Germany. In Australia, rates varied at the state level and there was some evidence of ethnic variation for Aboriginal communities in the Northern Territory.[11] This was potentially due to seasonal differences between states and the isolation of indigenous communities from health care services in northern areas.[10] In Germany, a neighbourhood-level analysis in Berlin showed that rates varied across the urban area. Again, poverty as a barrier to healthcare was cited as the reason for these differences.[9] RV vaccination in a national programme is widely considered to be the only public health measure capable of controlling RV across all population groups.[8,12]

The World Health Organization has previously stated that "rotavirus vaccines should be included in all national immunisation programmes and considered a priority".[13] This position was supported by the Paediatric Society of New Zealand, who recommended that the Government include a fully funded RV vaccine to the national immunisation schedule.[14] The National Immunisation Advisory Committee in New Zealand has also long recommended the introduction of this vaccine, and in July 2014, an oral vaccine was added to the National Immunisation Schedule.[15] The vaccine is given orally at 6 weeks, 3 months and 5 months of age. Prior to this, there were two vaccines for RV available in New Zealand, Rotarix and RotaTeq, which cost approximately NZ$100 for a full round.[16–18]

The benefits of national RV vaccination programmes have been proven in overseas settings through reductions in hospitalisations and emergency department visits, medical practitioner visits, and RV-related laboratory testing.[3,5] Estimates of reductions in RV-related hospital stays due to vaccination programmes are relatively consistent across studies conducted in Europe, Australia, and the US, ranging from 70% to 90%.[3,11,19] Vaccination for RV has been shown to reduce the disease burden of all gastroenteritis infections, and not just those caused by RV pathogens.[12,14,20] When high rates of RV immunisation are achieved in the national population, herd immunity is a significant protective factor in reducing rates of RV illness among the un-immunised.[14,21] A cost-benefit analysis of including a RV vaccine on the national immunisation schedule found a cost per quality-adjusted life-year gained of $46,092.[7] This was deemed to be modest by international standards, and lower than the cost associated with the Meningococcal B vaccination programme. In countries where RV vaccination requires families to pay themselves, it is possible that inequalities in RV illness are based on socially constructed factors due to their ability to pay rather than aetiology of the disease itself. However, more than 90% of children are infected with RV by age 3, regardless of their socio-economic or ethnic background.[22]

This study aims to identify spatio-temporal variation in clustering of high and low neighbourhood rates of paediatric hospital admissions for RV in Auckland, New Zealand, prior to the introduction of a fully-funded vaccine. Annual clustering of high and low hospital admission rates within geographic units was examined to identify spatial RV trends during the period 2006–2011.

Methods

Case and population data

Paediatric (0–4 years) RV hospitalisations were obtained from the Ministry of Health's National Minimum Dataset. This contains discharge information for both public and private hospitals in New Zealand and includes both clinical and day patient records. Only cases coded as A08.0 under the International Classification of Diseases version 10 were included for analysis. These data were spatially referenced to each patient's home Census Area Unit (CAU). A census area unit is a non-administrative census boundary that in urban areas contains 3,000–5,000 people. Both age and ethnicity were included for each case, and only individuals aged 0–4 years were included in the final analysis.

The geographic area of interest was Auckland City, as seen in Figure 1. The central city area is in the middle of this map exert, South Auckland to the south-east and Waitakere/Henderson and the North Shore to the west and north respectively. The population of Auckland is made up of 64% European, 19% Asian, 14% Pacific and 11% Māori.

Individuals in the hospital admissions dataset were counted once per calendar year, with an age-group specific rate calculated using the final counts as the numerator, and estimated CAU population aged 0–4 years as the denominator. Population estimates were sourced from the NZ.Stat tool on the Statistics New Zealand website.[23]

Spatial Analyses

To identify annual hot and cold clusters of RV rates, an Anselin Local Moran's I index (ref original) was calculated using the Spatial Statistics toolbox in ArcGIS. This index identified spatial clustering of areas with high and low hospitalisation rates. Hot and cold clusters are defined as geographic areas with a significantly higher, or lower, rate of RV among children compared to the overall trend of the entire geographic region of interest. This analysis was run separately for each year 2006–2011 to identify any variation in spatial clustering of RV hospitalisations over the study period.

Spatial variation in temporal trends during the study period was examined using a discrete Poisson distribution in SaTScan to identify areas which had a statistically significant change in RV hospitalisations from the beginning to the end of the study period. This analysis determined which clusters have a temporal trend that is least likely to be the same as the temporal trend outside the cluster. Time trends inside and outside of the cluster are plotted on a log-linear scale and report percentage increase or decrease that is constant over time. SatScan parameter settings to identify significant clusters were: scanning for areas with high or low trend; 50% of the population at risk as the maximum spatial cluster size; a circular spatial window shape; and a Standard Monte Carlo test statistic (with 9,999 repetitions as there was a relatively small number of CAUs in the study area). This analysis was adjusted for seasonal variation in RV hospitalisations.

Neither the annual or spatial-temporal analyses were adjusted for covariates, as the study aimed to identify areas where vaccination may have the greatest impact on RV hospitalisations, so the pattern of cases was of most interest.

Descriptive Statistics

Following the detection of annual RV hospitalisation clusters, the underlying demographics of the CAUs which make up hotspots in each year were described. The proportion of, and temporal changes to, the total population classified as European, Māori, Pacific, and Asian, were examined to identify any evidence of variation in the underlying populations at risk. The same was calculated for SES using the New Zealand Deprivation Index 2006 (NZDep06), a decile index based on New Zealand census variables, where decile 1 represents the least deprived, and decile 10 the most deprived. CAUs were grouped into three classes—high SES (1–3), medium SES (4–7) or low SES (8–10)—and the proportion of CAUs within each category from each annual hotspot was plotted over the study period.

Results

Annual RV clustering results

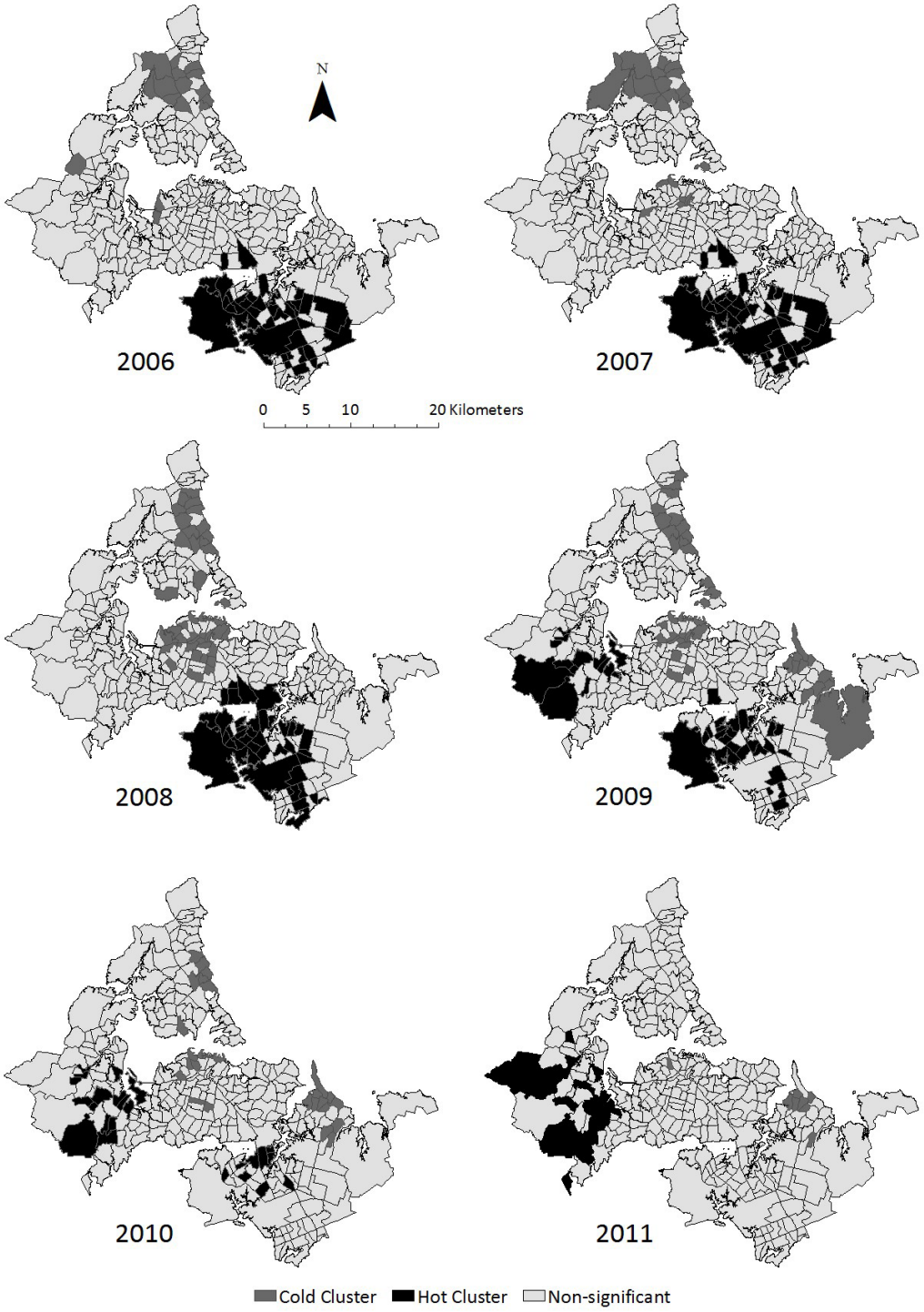
Hot and cold clusters of RV hospitalisations were detected for all years 2006–2011, with evidence of spatial variation over the study period (Figure 1). For the years 2006–2008, hotspot clustering was confined mainly to the southern part of the study area. In 2009, a second hot cluster developed in the western part of the study area. From 2010–2011, the hot cluster of RV hospitalisations in the south first decreased, and then disappeared, leaving a single hot cluster located to the west of the city.

Annual cold clustering of RV hospitalisations varied geographically during the study period, with an initial cluster located in the northern part of the study area in 2006. The following year, some isolated secondary cold clustering of RV hospitalisations appeared in the central city and in 2008, there was evidence of a two prominent cold clusters of RV hospitalisations in the northern and central regions of the city. In 2009, a third cold cluster of RV hospitalisations emerged in eastern regions of the study area. All three cold clusters reduced in size in 2010, and in 2011 only a small cold cluster of RV hospitalisations remained in the east.

Cluster description

Both the number of CAUs that form annual hot and cold clusters, identified by the Local Moran's I Index, along with neighbourhood and population level demographics, varied throughout the study period (Tables 1 & 2). The spatial

Figure 1: Annual hot and cold clusters of paediatric RV hospitalisations, Auckland 2006–2011.



NZMJ 11 March 2016, Vol 129 No 1431
ISSN 1175-8716 © NZMA

Table 1: Descriptive statistics of underlying CAU demographics within hot clusters over time, 2006–2011.

		2006	2007	2008	2009	2010	2011
Number of CAUs in hot cluster		111	108	120	114	72	69
Ethnic composition of CAUs in hot clusters (%)	**European**	28.7	29.2	26.2	32.7	39.9	59.4
	Māori	20.1	20.1	20.1	17.6	15.1	13.2
	Pacific	44.7	44.3	48.5	42.3	33.7	17.3
	Asian	16.2	16.1	15.2	15.6	17.6	13.3
Socio-economic spread of CAUs in hot clusters (%)	**High 1–3**	5.4	8.3	0.0	5.3	8.3	21.7
	4–7	8.1	8.3	7.5	13.2	29.2	43.5
	Low 8–10	86.5	83.3	92.5	81.6	62.5	34.8

NB: Socio-economic status based on NZDep06 decile rankings (1=least deprived, 10=most deprived)

Table 2: Descriptive statistics of underlying CAU demographics within cold clusters over time, 2006–2011

		2006	2007	2008	2009	2010	2011
Number of CAUs in cold cluster		48	69	123	126	75	24
Ethnic composition of CAUs in cold clusters (%)	**European**	63.9	64.4	64.1	66.2	65.5	58.8
	Māori	5.1	5.8	5.9	5.1	4.1	3.8
	Pacific	3.5	3.1	5.8	4.1	3.0	2.7
	Asian	21.9	21.9	21.3	20.7	22.6	30.1
Socio-economic spread of CAUs in cold clusters (%)	**High 1–3**	50.0	56.5	43.9	57.1	80.0	75.0
	4–7	43.8	30.4	43.9	35.7	20.0	25.0
	Low 8–10	6.3	13.0	12.2	7.1	0.0	0.0

NB: Socio-economic status based on NZDep06 decile rankings (1=least deprived, 10=most deprived)

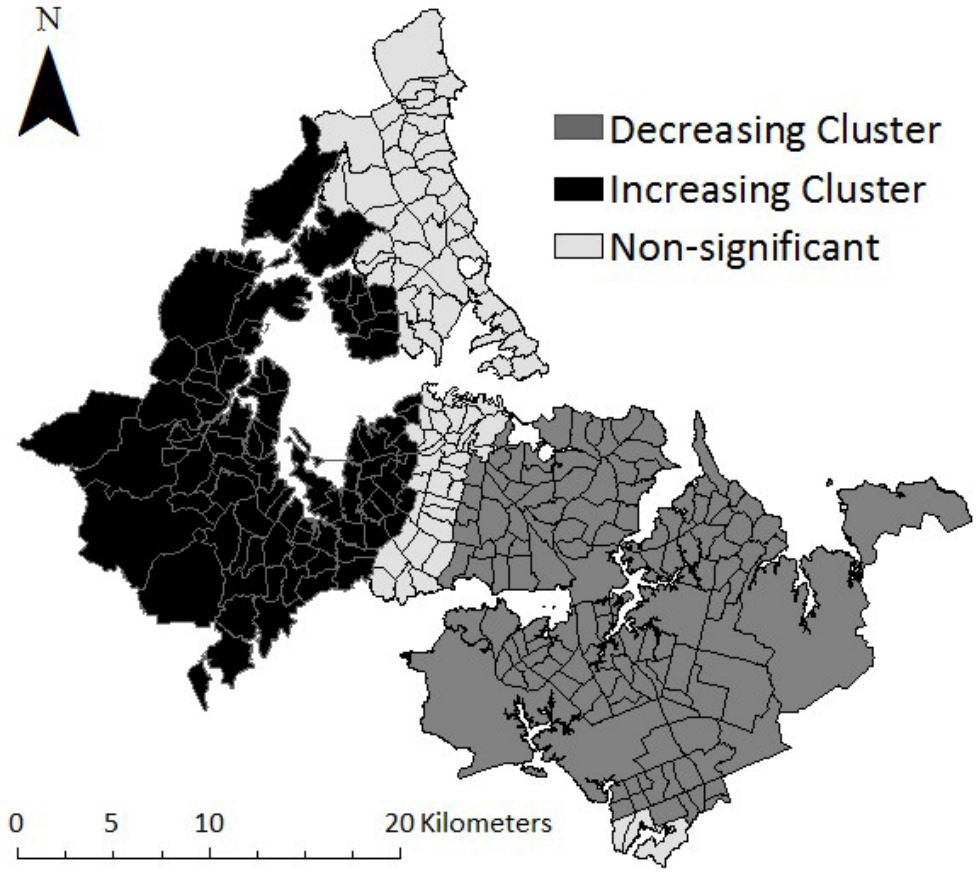
shift in cluster locations has seen hot clusters of RV hospitalisations move from neighbourhoods with large proportions of Pacific and Māori people to more European-dominated areas. A large shift in the SES of neighbourhoods is evident, as over twenty percent of neighbourhoods in hot clusters in 2011 were from among the least deprived CAUs, compared to just over five percent in 2006. The most deprived neighbourhoods, which in 2006 represented over 86% of CAUs in hot clusters in 2006, only account for approximately 35% at the end of the study period.

The ethnic and socio-economic demography of CAUs in cold clusters changed over time, but not to the same degree as was seen in hot clusters (Table 2). The ethnic composition of area populations remained relatively stable for most groups, with a slight decrease in European, Māori, and Pacific representation, and a rise in Asian ethnic groups. Neighbourhood SES changed more markedly, with a large rise in the number of least deprived CAUs evident. This was offset by a decline in areas with mid-range deprivation rankings. Throughout the study period, the most deprived neighbourhoods are a minority in low RV hospitalisation rate clusters, and do not feature at all after 2009.

Spatial variation in temporal trends scan statistic results

Analysis of spatial variation in the temporal trends identified in Figure 1 confirmed that RV hospitalisations were increasing during the study period (2006–2011) in the west Auckland region, and decreasing in the eastern, central and southern regions (Figure 2). RV hospitalisations in the most likely cluster with an increasing trend were rising at a constant rate of 18.32% (Log likelihood-ratio: 21.40, $p<0.001$) over the study period, while in the most likely cluster with a decreasing trend, RV hospitalisations were falling at a rate of 8.7% (Log likelihood-ratio: 20.44, $p<0.001$).

Figure 2: Spatial variation in temporal trends of paediatric RV hospitalisations: most likely increasing and decreasing clusters, Auckland 2006–2011.



Discussion

This study sought to identify spatial and spatio-temporal variation in clustering of high and low neighbourhood rates of paediatric hospital admissions for RV in Auckland, New Zealand, for the period 2006–2011. The results suggest that cases of RV hospitalisations have shifted spatially over time within the Auckland City urban environment and support the inclusion of RV vaccination to the national immunisation schedule as a means to reduce the health burden of RV across all social and ethnic groups in New Zealand. The geographic movement of high and low rates of RV hospitalisations has been accompanied by a change in the socio-demographics of populations living in these clusters. This has been particularly evident in hot cluster neighbourhoods, where the largest change in underlying ethnic composition and neighbourhood SES has been found.

The hot clustering of RV hospitalisations evident at the beginning of the study period occurred in the southern Auckland region. This area can be characterised as being home to a relatively large representation of minority ethnic groups, as well as families and neighbourhoods with low SES. Traditionally in New Zealand, low SES, Māori, and Pacific groups are over-represented in infectious disease statistics.[24] Previous research in Auckland has found high rates of meningococcal disease among Māori and Pacific groups,[24] as well as both tuberculosis and acute rheumatic fever in low-socio economic settings.[26,27] Much of this increased risk among these groups is attributed to substandard and crowded living conditions, high smoking rates, and lower ability to access and afford quality medical care.[28]

As hot clustering of RV hospitalisations shifted from east to west across Auckland city, the populations living in these clusters also changed quite markedly. High rates of RV hospitalisations at the end of the study period were clustered in the areas of Auckland that have a relatively larger European and lower Māori and Pacific composition compared to the beginning of the study period. The SES of these areas was overall much less deprived in western compared to eastern clusters. This finding

of comparatively higher rates of RV hospitalisations in areas of relative affluence and low composition of minority ethnic groups is in contrast to previous Auckland disease literature.

Cold clustering of RV hospitalisations shifted spatially throughout the study period also. However, the underlying demographics of neighbourhoods in these clusters remained relatively affluent, and with a high European and Asian population. These groups have traditionally had better outcomes in New Zealand health statistics and it is unsurprising that this remains so here. As an infectious disease, there are certain steps that will reduce risk, such as improved living conditions, hygiene, and sanitation. The increased ability of the groups to seek out and afford medical treatment during the early stages of infection before hospitalisation is required is also likely to factor into this trend.

As the national uptake of RV vaccination was just 2.5% in 2011,[29] the inequalities in RV hospitalisations are unlikely to have be driven by variation in access to vaccines before the universal programme was introduced in 2014. Further, there is also no evidence of a targeted public health campaign in Auckland that would explain the spatial shift in RV hospitalisations seen during the study period. These results support previous research that suggests RV infection and outbreaks in developed countries cannot be attributed to a particular social or ethnic group.[9] Therefore, the authors posit that targeted rotaviral intervention is likely to be ineffective in reducing RV hospitalisations. The findings reported here support the recent introduction of a fully funded rotavirus vaccine in New Zealand after a period of strong support from the medical community and the National Immunisation Advisory Committee. This research suggests that blanket vaccination coverage will be the most effective tool for reducing rates of RV hospitalisations in New Zealand.

Competing interests:
Nil

Author information:
Christopher Bowie, GeoHealth Laboratory, Department of Geography, University of Canterbury, Christchurch, New Zealand; Malcolm Campbell, GeoHealth Laboratory, Department of Geography, University of Canterbury, Christchurch, New Zealand; Paul Beere, GeoHealth Laboratory, Department of Geography, University of Canterbury, Christchurch, New Zealand; Simon Kingham, GeoHealth Laboratory, Department of Geography, University of Canterbury, Christchurch, New Zealand.

Corresponding author:
Christopher Bowie, GeoHealth Laboratory, Department of Geography, University of Canterbury, Private Bag 4800, Christchurch 8140, New Zealand.
Christopher.Bowie@canterbury.ac.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6833

REFERENCES:

1. Roberts L. Rotavirus Vaccines' Second Chance. Science (80-). 2004;305(5692):1890–3.
2. Parashar U, Burton A, Lanata C, Boschi-Pinto C, Shibuya K, Steele D, et al. Global Mortality Associated with Rotavirus Disease among Children in 2004. J Infect Dis. 2009;200(Supplement 1):S9–15.
3. Giaquinto C, Dominiak-Felden G, Van Damme P, Htar Myint T, Maldonado Y, Spoulou V, et al. Summary of effectiveness and impact of rotavirus vaccination with the oral pentavalent rotavirus vaccine. A systematic review of the experience in industrialized countries. Hum Vaccin. 2011;7(7):734–48.
4. Tajiri H, Takeuchi Y, Takano T, Ohura T, Inui A, Yamamoto K, et al. The burden of rotavirus gastroenteritis and hospital-acquired rotavirus gastroenteritis among children aged less than 6 years in Japan: a retrospective, multicenter epidemiolog-

ical survey. BMC Pediatr. 2013;13(83):1–8.

5. Krishnarajah G, Demissie K, Lefebvre P, Gaur S, Sheng Duh M. Clinical and cost burden of rotavirus infection before and after introduction of rotavirus vaccines among commercially and Medicaid insured children in the United States. Hum Vaccines Immunother. 2014;10(8):2255–66.
6. Grimwood K, Sue Hang Q, Cohet C, Gosling I, Hook S, Teele D, et al. Rotavirus hospitalisation in New Zealand children under 3 years of age. J Paediatr Child H. 2006;42(4):196–203.
7. Milne R, Grimwood K. Budget Impact and Cost-Effectiveness of Including a Pentavalent Rotavirus Vaccine in the New Zealand Childhood Immunization Schedule. Value Heal. 2009;12(6):888–98.
8. Huppertz H, Salman N, Giaquinto C. Risk Factors for Severe Rotavirus Gastroenteritis. Pediatr Infect Dis J. 2008;27(1):S11–9.
9. Wilking H, Hohle M, Velasco E, Suckau M, Eckmanns T. Ecological analysis of social risk factors for Rotavirus infections in Berlin, Germany, 2007–2009. Int J Heal Geogr. 2012;11(37).
10. Newall A, MacIntyre R, Wang H, Hull B, Macartney K. Burden of severe rotavirus in Australia. J Paediatr Child H. 2006;42(9):521–7.
11. Macartney K, Porwal M, Dalton D, Cripps T, Maldigri T, Isaacs D, et al. Decline in rotavirus hospitalisations following introduction of Australia's national rotavirus immunisation programme. J Paediatr Child H. 2011;47(5):266–70.
12. Pockett R, Adlard N, Carroll S, Rajoriya F. Rotavirus Vaccination as a Means of Reducing Health and Social Inequality in England. Public Health International Conference 2011. London; 2011.
13. WHO. Rotavirus Vaccines. WHO position paper - January 2013. Weekly epidemiological record. Geneva; 2013.
14. PSNZ. Paediatric Society Position Statement on Rotavirus Immunisation [Internet]. 2013 [cited 2013 May 17]. Available from: http://www.paediatrics.org.nz/files/2013/Rotavirus Immunisation Position FINAL 2013.pdf
15. Ministry of Health. Rotavirus and the RotaTeq vaccine. Wellington; 2014.
16. Ministry of Health. Rotavirus. Immunisation Handbook. Wellington: Ministry of Health; 2011.
17. Immunisation Advisory Centre. Rotavirus: FactSheet for Parents and Caregivers. 2011.
18. GlaxoSmithKline New Zealand. Instructions for General Practice on the Patient Access Programme for Rotarix. Auckland; 2012.
19. Department of Public Health. New vaccine to help protect babies against rotavirus [Internet]. [cited 2013 May 15]. Available from: https://www.gov.uk/government/news/new-vaccine-to-help-protect-babies-against-rotavirus
20. Tate J, Parashar U. Rotavirus vaccines in routine use. Clin Infect Dis. 2014;59(9):1291–301.
21. Anderson E. Time to begin a new chapter and expand rotavirus immunization. Clin Infect Dis. 2014;59(7):982–6.
22. Velazquez F, Garcia-Lozano H, Rodriguez E, Cervantes Y, Ovalle J, Torres J, et al. Diarrhea Morbidity and Mortality in Mexican Children: Impact of Rotavirus Disease. Pediatr Infect Dis J. 2004;23(10):S149–55.
23. Statistics New Zealand. NZ.Stat: Population Estimates [Internet]. [cited 2013 Mar 28]. Available from: http://nzdotstat.stats.govt.nz/wbos/index.aspx
24. Baker M, Telfar Barnard L, Kvalsvig A, Verrall A, Zhang J, Keall M, et al. Increasing incidence of serious infectious diseases and inequalities in New Zealand: a national epidemiological study. Lancet. 2012;379(9821):1112–9.
25. Baker M, McNicholas A, Garrett N, Jones N, Stewart J, Koberstein V, et al. Household crowding a major risk factor for epidemic meningococcal disease in Auckland children. Pediatr Infect Dis J. 2000;19(10):983–90.
26. Baker M, Das D, Venugopal K, Howden-Chapman P. Tuberculosis associated with household crowding in a developed country. J Epidemiol Community Heal. 2008;62(8):715–21.
27. Jaine R, Baker M, Venugopal K. Acute Rheumatic Fever Associated With Household Crowding in a Developed Country. Pediatr Infect Dis J. 2011;30(4):315–9.
28. Kerdemelidis M, Lennon D, Arroll B, Peat B, Jarman J. The primary prevention of rheumatic fever. J Paediatr Child H. 2010;46(9):534–48.
29. Rich M. Personal Communication July 5th 2013.

Stroke care delivery at North Shore Hospital, Waitemata District Health Board 2014

Jennifer Yeo, Lifeng Zhou, Yogini Ratnasabapathy

ABSTRACT

AIM: To audit the current delivery of stroke care, including post-discharge community rehabilitation, in a consecutive group of acute stroke patients admitted to North Shore Hospital (NSH), Waitemata District Health Board.

METHODS: A retrospective audit from 1 January 2014 to 28 February 2014 conducted at North Shore Hospital.

RESULTS: The clinical care of 72 patients was reviewed. Longer delays for initial key multidisciplinary stroke assessments are seen in this audit compared to the Royal College of Physicians, Sentinel Stroke National Audit Programme (RCP SSNAP 2013). Results for therapy intensity for physiotherapy compare less favourably with the RCP SSNAP. Prescription rates for oral anticoagulation for atrial fibrillation (AF) at final discharge from hospital is lower in this audit in comparison to the RCP SSNAP audit (54%, 95% CI=33%–73% vs 75.6%). Results for mortality rate and rate for new institutionalisation on discharge are comparable to the RCP SSNAP (11%, 95% CI=5%–20% vs 14.8% and 7%, 95% CI=2%–15% vs 8% respectively). The median number of days to community physiotherapy and occupational therapy follow up were 29 days and 25 days respectively.

CONCLUSION: Key areas for improvement in stroke care identified in this audit are anticoagulation for stroke prevention in AF, time to key multidisciplinary stroke assessments and access to community rehabilitation.

Stroke is a major health problem in New Zealand. It is the second leading cause of health loss in older adults aged 75 years and above, after coronary heart disease.[1] Since 1980, mortality rates from cerebrovascular disease have declined, reflecting improvements made in stroke care in the last few decades.[2] Although the incidence of cerebrovascular disease is also declining, it is projected that the burden from stroke will rise in the future as a consequence of the ageing population.[3]

Methods

This is a retrospective audit from 1 January 2014 to 28 February 2014 conducted at North Shore Hospital (NSH). Cases were identified using the NSH Stroke Registry, an inpatient prospective record of all stroke referrals received by the Stroke Service, and a search through the hospital discharge summary database.

The types of stroke included in the study were ischaemic strokes and spontaneous intracerebral haemorrhage. Transient ischemic attacks (TIAs), subarachnoid haemorrhage, subdural or extradural haemorrhage, haemorrhage into a cerebral tumour or post-traumatic intracerebral haemorrhage were excluded from the study.

The audit covered five main domains (casemix, processes of care in the first 72 hours, discharge results, therapy intensity and post discharge community cares). The audit form used to assess the first four domains was a comprehensive checklist based on a compilation of forms used in previous local audits, as well as the RCP SSNAP. Post discharge data were collected until 31 October 2014. Clinical data were sourced from inpatient notes, as well as the Clinical Notes & Electronic Records (Concerto).

Results in this audit are compared with previous local audits undertaken at NSH,

the latest UK RCP SSNAP clinical audit from the period October to December 2013, and the Australian National Stroke Audit of Rehabilitation Services from the period March to May 2014.

For categorical variables, proportions (%) are reported and 95% confidence intervals were calculated based on binomial distribution for rates. P-values were calculated using the chi-square test. For continuous variables, results are presented as medians unless otherwise stated, and 95% confidence intervals were produced using distribution-free methods. The Wilcoxon Rank-Sum statistical test was used for comparisons. Results were considered significant at the 5% level.

'Clock start' is defined as time of arrival to the Emergency Department (ED). 'Eligible' is defined as those who did not decline or were medically unwell at time of screening.

Results

Description of current audit

Casemix

Seventy-two cases met the inclusion criteria. Ninety-six percent of cases were ischaemic strokes. Fifty-three percent of patients were female. The median age on arrival to hospital was 79 years. Thirty-two percent of patients had known atrial fibrillation (AF) and 10% had newly detected AF on admission. Twenty-two percent of patients had a previous history of stroke or TIA.

Prior to the stroke, the majority of patients were functionally independent (93% had a modified Rankin Scale score (mRS) of 1 or less). The median NIHSS score was 3.

Processes of care in the first 72 hours

The proportion of patients scanned within 1 hour of clock start was 43%. The median time from clock start to scan was 1 hour 16 minutes. The first ward of admission was the Stroke unit (74%) followed by a Medical ward (24%) and HDU/ICU (3%).

Six percent (n=4) of all stroke patients received thrombolysis. All of eligible patients were given thrombolysis. The median time between clock start and thrombolysis was 1 hour 46 minutes. For thrombolysis cases, the median time from clock start to scan was 44 minutes. The median time from scan to thrombolysis was 1 hour 7 minutes.

The proportion of patients eligible to have swallow screening within 4 hours was 82%, however only 5% of these patients had a swallow screen performed within 4 hours. The median time from clock start to swallow screening was 13 hours 12 minutes.

Forty-seven percent of patients were assessed by a stroke specialist consultant within 24 hours of clock start. The median time between clock start and assessment by a stroke consultant was 21 hours 39 minutes. The median time between clock start and assessment by OT and PT were 43 hours 42 minutes and 33 hours and 29 minutes respectively.

Discharge results

The median length of stay from clock start to final inpatient discharge was 6 days. Rehabilitation in the AT+R unit was required in 21% of stroke admissions. The median length of stay in the AT+R unit was 17 days. Eighty-nine percent of patients were discharged alive. Thirteen percent of patients were discharged to a care home. Seven percent of patients were newly institutionalised on discharge. Of those discharged alive, 42% required help with activities of daily living (ADL) through formal home support services. The proportion of patients discharged alive from hospital who were in AF was 41%. Fifty-four percent (n=14) of these patients were on anticoagulants by discharge, 35% (n=9) on anti-platelet therapy, while 12% (n=3 [n=2 cerebral amyloid angiopathy, n=1 haemorrhagic transformation]) were on no anti-thrombotic therapy.

Therapy intensity

The proportion of patients reported as requiring therapy was 88% (OT), 90% (PT) and 47% (SLT). The median number of minutes per day on which therapy was received is 40 minutes (OT), 30 minutes (PT) and 25 minutes (SLT). The median percentage of days as an inpatient on which therapy was received is 37% (OT), 50% (PT) and 26% (SLT).

Post discharge community cares

The proportion of stroke survivors followed up in an outpatient clinic was 55%. The median number of days to clinic review from discharge was 96 days. Thirty-eight percent of patients required follow up from the community rehabilitation services.

Table 1: Post discharge rehabilitation services

	Current audit
Physiotherapy (PT)	
Proportion of patients requiring follow up	25%
Number of days from final discharge from hospital to first contact	29 days
Number of days to discharge from the community team*	70 days
Direct sessions	
Number of sessions	6.5
Minutes of therapy per session	45m
Occupational therapy (OT)	
Proportion of patients requiring follow up	16%
Number of days from final discharge from hospital to first contact	25 days
Number of days to discharge from the community team*	40 days
Direct sessions	
Number of sessions	3
Minutes of therapy per session	51m
Speech and Language therapy (SLT)	
Proportion of patients requiring follow up	9%
Number of days from final discharge from hospital to first contact	6 days
Number of days to discharge from the community team	57 days
Direct sessions	
Number of sessions	2
Minutes of therapy per session	60m

* By the end of the data collection period, 6% (n=1) and 20% (n=2) of patients were receiving ongoing rehabilitation input for PT and OT respectively

Table 2: Casemix

	2007	**2008/09**	**2009/10**	**Current audit**	**P-value**
Number of patients	486	73	70	72	
Average age (years)	73.8	73.5	76.4	76	.4685
Female (%)	51	44	60	53	.3856
Ischemic stroke (%)	88	90	81	96	.0066
Risk Factors (%)					
• Hypertension	57	64	66	64	.8199
• Dyslipidemia	32	38	49	42	.4084
• Previous stroke / TIA	40	37	36	22	.0761
• Ischemic heart disease	19	36	34	13	.0021
• Arial fibrillation	26	19	24	43	.0181
• Diabetes mellitus	16	12	24	10	.0206

The P-value calculated compares results between the 2009/10 audit and the current audit; The median age for the 2009/10 audit was 82 years and 79 years in the current audit.

Table 3: Key performing indices

	2007	2008/09	2009/10	Current audit	P-value
Treated for more than 90% of stay in a stroke unit (%)	Data not available	Data not available	13	47	<.0001
CT scan within 24 hours of admission	59	81	93	96	.4904
Physiotherapy assessment within 72 hours	84	70	82	90	.1296
Swallow screening within 24 hours	72	65.5	56	45	.1793
Rehabilitation goals agreed by MDT (%)	86	52	65	59	.4276
OT assessment within 4 days	66	74	74	94	.0009

The P-value calculated compares results between the 2009/10 audit and the current audit.

Marked delays in access to post-discharge rehabilitation services by stroke survivors particularly for PT and OT are demonstrated (Table 1). The median number of days to community PT and OT follow up were 29 days and 25 days respectively.

Comparison with previous audits conducted at North Shore Hospital

Comparison with the 2009/10 audit for baseline characteristics (Table 2) show a significantly greater proportion of patients in this audit with ischaemic strokes, 96% vs 81% (P-value=0.0066) and atrial fibrillation, 43% vs 24% (P-value =0.0181). Significant improvements are seen in the proportion of stroke patients spending more than 90% of their stay in a stroke unit, 47% vs 13% (P-value <.0001).

Comparison with Royal College of Physicians Sentinel Stroke National Audit Programme (RCP SSNAP) Oct–Dec 2013

The baseline characteristics, including age, gender and stroke severity, are comparable with a few significant differences observed (Table 4). In this current audit, there was a higher proportion of patients with AF (42%, 95% CI=30%–54% vs 20.8%), and ischaemic strokes (96%, 95% CI=88%–99% vs 87.9%). A greater proportion of the stroke patients in the UK audit at baseline had a higher degree of disability and dependence in the daily activities compared to this current audit (proportion of patients with a mRS 3,4 or 5 in this audit was 6%, 95% CI = 2%–14% vs 18.2%).

The results of brain scanning were comparable between the two audits (Table 5). There was better performance in the thrombolysis timings in the UK audit however a major limitation is that this audit only included 4 cases of stroke thrombolysis (Table 5). The RCP SSNAP results for time from clock start to swallow screening (13h 12m, 95% CI=7h 52m–15h 58m vs 1h 42m) and to initial key assessments by a stroke consultant (21h 39m, 95% CI=19h 3m–25h 49m vs 13h 52m), OT (43h 42m, 95% CI=30h 11m–51h 48m vs 24h) , PT (33h 29m, 95% CI=26h 59m–49h 3m) and SLT for formal swallow assessments (23h 30m, 95% CI=21h 29m–37h 3m) were superior compared to this current audit (Table 5).

Discharge results (Table 6) were comparable to the UK audit for median length of inpatient stay (6 days, 95% CI=4 days–8 days in this audit vs 7.2 days), median length of stay on a stroke unit (4 days, 95% CI=4 days–7 days in this audit vs 6.2 days) and rate of new institutionalisation on discharge (7%, 95% CI=2%–15% vs 8%). There was no significant difference in the dependency of patients on discharge as indicated by the median mRS on discharge (mRS=2, 95% CI=1–2 vs mRS=2). UK patients were more likely to have spent greater than 90% of their hospital stay in a stroke unit (47%, 95% CI=35%–59% vs 83.5%). A greater proportion of patients discharged alive in this audit were in AF (41%, 95% CI=26%–54% vs 21.8%), while UK patients in AF on discharge were more likely to receive anticoagulation (54%, 95% CI=33%–73% vs 75.6%).

Table 4: Casemix

	Current audit (95% CI)	RCP SSNAP Oct–Dec 2013[5]
Number of stroke patients included in report		
Number of stroke patients	72	18,839
Patients newly arriving in hospital	94% (86%–98%)	94.7%
Patients already in hospital at time of stroke	6%	5.3%
Gender		
Male patients	47% (35%–59%)	49.5%
Female patients	53% (41%–65%)	50.5%
Median age on clock start		
Age (years)	79 (75–83)	77
Male patients	78 (69–83)	74
Female patients	81 (76–83)	81
Atrial fibrillation		
Proportion of patients with atrial fibrillation	42% (30%–54%)	20.8%
Known	77% (58%–90%)	Not available
New	23% (10%–42%)	Not available
If patient is in Atrial Fibrillation, what combination of anticoagulant and antiplatelet medication was the patient on prior to admission?		
Anticoagulant AND antiplatelet medication	0% (0%–12%)	5.3%
Anticoagulant medication only	35% (12%–46%)	33.1%
Antiplatelet medication only	30% (10%–42%)	35.5%
Neither medication	35% (12%–46%)	26%
Stroke Type		
Infarction	96% (88%–99%)	87.9%
Intracerebral haemorrhage	4% (1%–12%)	10.9%
Unknown (not scanned)	0%	1.3%
Modified Rankin Scale score before stroke		
0 (no symptoms)	85% (74%–92%)	57%
1 (no significant disability)	8% (3%–17%)	15.5%
2 (slight disability)	1% (0.04%-8%)	9.2%
3 (moderate disability)	4% (0.9%–12%)	10.2%
4 (moderately severe disability)	1% (0.04%–8%)	5.8%
5 (severe disability)	0% (0%–5%)	2%
Groups		
1 or 2	10% (4%–19%)	24.7%
3, 4 or 5	6% (2%–14%)	18.2%
Number of NIHSS components completed		
1 (only the compulsory LOC)	12% (6%–22%)	14.9%
2–14	0% (0%–5%)	9.6%
15 (all components)	88% (78%–94%)	75.5%
If NIHSS fully completed, severity groups:		
0	8% (0%–6%)	6.4%
1 to 4 = minor stroke	48% (35%–60%)	43.9%
5 to 15 = moderate stroke	38% (26%–51%)	35.4%
16 to 20 = moderate / severe stroke	5% (0.1%–13%)	6.7%
21 to 42 = severe stroke	2% (0.04%–9%)	7.6%
If NIHSS fully completed		
Median	3 (2–5)	4
Mean	5.3	7.2
Palliative Care Decisions		
Has it been decided in the first 72hrs that the patient is for palliative care?	5.6% (2%–14%)	4.5%

Table 5: Processes of care in the first 72h.

	Current audit (95% CI)*	**RCP SSNAP Oct–Dec 2013[5]**
Timings (median) from onset (using both precise and best estimate times)		
Time from onset to arrival	2h 6m (1h 18m–4h 7m)	2h 30m
Time from onset to scan	3h 48m (2h 11m–6h 16m)	4h 13m
Time from onset to thrombolysis	3h 27m (2h 25m–4h 45m)	2h 25m (1h 50m–3h 9m)
Timings from clock start (median)		
Time from clock start to first arrival on a stroke unit	10h 9m (6h 40m–12h 57m)	3h 36m
Time from clock start to scan	1h 16m (54m–2h 3m)	1h 23m
Time from clock start to thrombolysis	1h 46m (57m–2h 22m)	58m
Brain scanning		
Proportion of patients scanned within 1 hour of clock start	43% (32%-56%)	41.7%
Proportion of patients scanned within 12 hours of clock start	91% (82%-97%)	84.8%
Proportion of pts scanned within 24h of clock start	97% (90%-100%)	Not available
Median time from clock start to scan	1h 16m (54m–2h 3m)	1h 23m
Median time from onset to scan	3h 48m (2h 11m–6h 16m)	4h 13m
Stroke unit		
Proportion of patients directly admitted to a stroke unit within 4 hours of clock start	15% (4%-34%)	58.1%
Median time between clock start and arrival on stroke unit	10h 9min (6h 40m–12h 57m)	3h 36m
First ward of admission		
Stroke Unit (ward 2)	74% (61%–84%)	73.8%
Medical ward	24% (14%–35%)	20.5%
HDU/ICU	3% (0.4%–10%)	1.9%
Other (unacceptable)	0% (0%–5%)	3.9%
Thrombolysis		
Proportion of all stroke patients given thrombolysis	6%	11.3%
Proportion of eligible patients given thrombolysis (according to the RCP guideline minimum threshold)	100%	74.7%
Proportion of patients who were thrombolysed within 1 hour of clock start, if thrombolysed	25%	52.8%
Median time between clock start and thrombolysis	1h 46m	58m
Thrombolysis timings (median)		
Time from clock start to thrombolysis	1h 46m (range = 57m–2h 22m)	58m (range = 39m–1h 26m)
Time from onset to thrombolysis	3h 27m (range = 2h 25m–4h 45m)	2h 25m (range = 1h 50m–3h 9m)
If thrombolysed, time from onset to clock start	2h 14m (range = 23m–3h 23m)	1h 17m
If thrombolysed, time from clock start to scan	44m (range = 34m–47m)	22m
If thrombolysed, time from scan to thrombolysis	1h 7m (range = 13m–1h 35m)	31m
Thrombolysis complications if patient received thrombolysis		
Patient had complications	0%	8.8%

Table 5 (cont): Processes of care in the first 72h

	Current audit (95% CI)*	RCP SSNAP Oct–Dec 2013[5]
NIHSS 24h after thrombolysis, if patient received thrombolysis		
Known	75%	78.2%
Not known	25%	21.8%
If NIHSS 24h after thrombolysis is known, severity groups:		
0	0%	16.4%
1 to 4 = minor stroke	67%	30.3%
5 to 15 = moderate stroke	33%	33.6%
16 to 20 = moderate / severe stroke	0%	10.5%
21 to 42 = severe stroke	0%	9.2%
Swallow screening within 4h and 24h		
Proportion of patients eligible to have swallow screening within 4h	82% (71%–90%)	88.4%
Proportion of eligible patients who had swallow screening in 4h	5% (1%–14%)	64.2%
Proportion of eligible patients who had swallow screening in 24h	45% (32%–58%)	Not available
Median time from clock start to swallow screening	13h 12m (7h 52m–15h 58m)	1h 42m
Formal swallow assessment by an SLT within 72 hours		
Proportion of eligible patients who had formal swallow assessment within 72 hours	96% (78%–100%)	79.3%
Median time from clock start to formal swallow assessment	23h 30m (21h 29m–37h 3m)	19h 52m
Assessment by Stroke Consultant		
Proportion of patients who were assessed by a stroke specialist within 24h of clock start	47% (35%–60%)	74.8%
Median time between clock start and being assessed by stroke consultant	21h 39m (19h 3m–25h 49m)	13h 52m
Assessed by an OT within 72h of Clock Start		
Proportion of eligible patients who were assessed by an OT within 72h of clock start	90% (79%–96%)	86.3%
Median time between clock start and being assessed by OT	43h 42m (30h 11m–51h 48m)	24h
Assessed by a PT within 72h of Clock Start		
Proportion of eligible patients who were assessed by a PT within 72h of clock start	90% (95%CI: 79%–96%)	93.5%
Median time between clock start and being assessed by PT	33h 29min (95%CI: 26h 59m–49h 3m)	22h 25m
Assessed by an SLT within 72h of Clock Start (for communication and swallow)		
Proportion of eligible patients who were assessed by a SLT within 72h of clock start	93% (77%–99%)	Not available
Median time between clock start and being assessed by SLT	26h 15m (22h 3m–44h 30m)	Not available

*Unless stated.

Table 6: Discharge results

	Current audit (95% CI)*	**RCP SSNAP Oct–Dec 2013[5]**
Modified Rankin Scale (mRS) score at discharge		
0 (no symptoms)	10% (4%–19%)	18.8%
1 (no significant disability)	38% (26%–50%)	19.5%
2 (slight disability)	19% (11%–30%)	13.8%
3 (moderate disability)	6% (2%–14%)	14.5%
4 (moderately severe disability)	14% (7%–24%)	12.2%
5 (severe disability)	3% (0.3%–10%)	6.5%
6 (dead)	11% (5%–20%)	14.8%
Modified Rankin Scale (mRS) score (median)		
mRS score before stroke	0 (0 to 0)	0
mRS score at discharge	2 (1 to 2)	2
Change in mRS score	+1 (+1 to +2)	+1
Median length of stay		
Length of stay from clock start to final inpatient discharge including death	6 days (4 days–8 days)	7.2 days
Length of stay on a stroke unit	4 days (4 days–7 days)	6.2 days
Is over 90% of a patient's stay in hospital spent on a stroke unit?		
Yes	47% (35%–59%)	83.5%
No	54%	16.5%
Delays in discharging patients who no longer require inpatient rehabilitation		
Median number of days from patient no longer requiring inpatient rehabilitation to hospital discharge	0 days (range = 0 to 8 days)	0 days
Discharge destination		
Discharged alive from inpatient care	89% (79%–95%)	85.2%
Discharged to a care home	13% (6%–23%)	10.9%
Discharged home	67% (54%–78%)	54.1%
Discharged somewhere else	20% (11%–32%)	6.9%
Transferred to an ESD/community team	Not applicable	13.3%
If discharged home		
Living Alone	30% (17%–46%)	26.6%
Not living alone	67% (51%–81%)	69.9%
Not known	2% (0.06%–12%)	3.5%
If discharged to a care home		
Previously a resident	38% (9%–76%)	37.6%
Not previously a resident	63% (25%–91%)	62.4%
If discharged alive from inpatient care		
Newly institutionalised (discharged to a care home where not previously a resident)	7% (2%–15%)	8%
If newly institutionalised:		
Temporary	0%	20.1%
Permanent	100%	79.9%
If discharged alive, required help with activities of daily living (ADL)		
Yes	42% (28%–57%)	37.2%
No	58% (43%–72%)	62.8%

Table 6 (cont): Discharge results

If patient required help with ADL, no of social service visits per week		
0 visits	0% (0%–17%)	17.1%
At least one visit per week	80%	23.1%
1 to 6 visits	45% (23%–68%)	1.2%
7 to 13 visits	30% (12%–54%)	13.6%
14 to 20 visits	5% (0.1%–25%)	5.2%
21 to 27 visits	0% (0%-17%)	3.8%
28+ visits	Not applicable	9.4%
Not known	20% (0%–44%)	59.8%
If discharged alive, is patient in Atrial Fibrillation (AF)		
Patient in Atrial Fibrillation	41% (29%–54%)	21.8%
Patient not in Atrial Fibrillation	59% (46%–71%)	78.2%
If in AF, patient given anticoagulation		
Yes	54% (33%–73%)	75.6%
No	35% (17%–56%)	6.7%
No but (given neither anticoagulation nor antiplatelet therapy but with a justifiable reason)	12% (2%–30%)	17.7%
Rehabilitation goals agreed within 5 days of clock start		
Proportion of eligible patients who have rehabilitation goals agreed within 5 days of clock start	59% (45%–72%)	81%

*Unless stated.

Table 7: Therapy intensity

	Current audit (95% CI)	**RCP SSNAP Oct–Dec 2013[5]**
Occupational Therapy (OT)		
Proportion of patients reported as requiring OT	88% (78%–94%)	81.2%
Median number of minutes per day on which OT is received	40m (38m–53m)	40m
Median % of days as an inpatient on which OT is received	37% (33%–50%)	45.3%
Physiotherapy (PT)		
Proportion of patients reported as requiring PT	90% (81%–96%)	86.2%
Median number of minutes per day on which PT is received	30m (30m–35m)	31.9m
Median % of days as an inpatient on which PT is received	50% (43%–50%)	55.4%
Speech and language therapy (SLT)		
Proportion of patients reported as requiring SLT	47% (35%–59%)	47.8%
Median number of minutes per day on which SLT is received	25m (18m–45m)	30m
Median % of days as an inpatient on which SLT is received	26% (17%–38%)	27.9%

Table 8: Secondary prevention measures on discharge

	Current audit	Australian national stroke audit 2014[8]
On anti-thrombotics on discharge*	100% (94%–100%)	97%
On anti-hypertensives on discharge^	78% (63%–86%)	82%
On lipid-lowering therapy on discharge*	75% (61%–85%)	84%

*For ischaemic strokes only if treatment was neither contraindicated nor declined; ^ For all stroke patients if treatment was not contraindicated.

In this audit, the results for the proportion of patients reported as requiring therapy (OT, PT and SLT) and the median number of minutes per day on which therapy is received are comparable to the UK audit (Table 7). Therapy intensity are also similar for OT and SLT between the two audits with a significant difference observed for PT favouring UK patients (median percentage of days as an inpatient on which therapy is received is 50%, 95% CI=43%–50% vs 55.4%).

Comparison of secondary prevention measures on discharge with the Australian National Stroke Audit of Rehabilitation Services 2014

See Table 8.

Discussion

This audit provides an overview of the delivery of stroke care in a New Zealand hospital. Since the last local audit cycle was undertaken in 2009/10, there has been a significant improvement in the proportion of stroke patients spending more than 90% of their stay in a stroke unit. This can be explained by further developments within the Stroke Service at NSH that include early identification of stroke admissions to NSH and an increase in the number of dedicated acute stroke beds; from 4 beds in 2009 to 10 (up to 18 beds) in 2014. The acute stroke swallowing screen procedure at Waitemata DHB can be administered by trained health professionals. Compared to the last 2009/10 local audit cycle, the rate of swallow screen remains low at 45%. A similar low rate of 56% was also reported in the 2013 Australian Clinical Audit report.[4] This audit finding shows that further work is still needed to provide timely screening for acute stroke patients at NSH.

In this audit, more than 50% of patients with known AF on admission were on either anti-platelet therapy alone or no anti-thrombotic therapy, and raises concern of the possible underuse of oral anticoagulation therapy in eligible patients in the community to prevent thromboembolic events. Similar results were also seen in the recent RCP SSNAP audit (Table 4).[5] In this audit, where oral anticoagulation was prescribed, most patients (75%) were prescribed warfarin, with the remaining being on the newer oral anticoagulant, dabigatran. This prescribing practice is similar to that seen in Australia, where warfarin has a prescribing rate of at least three times that of dabigatran.[6] It is concerning to see that a higher proportion of UK patients with AF on discharge were discharged on oral anticoagulation compared to this audit (54%, 95% CI=33%–73% vs 75.6%).[5]

The importance of secondary prevention has been highlighted by evidence showing survivors of strokes are at significantly increased risk for a recurrence with the risk remaining elevated for several years after the event.[7] It is encouraging to see that results in this audit for therapy for secondary prevention measures on discharge are comparable to the results from the 2014 Australian National Stroke Audit of Rehabilitation Services (Table 8).[8]

A dedicated stroke unit has been defined as a stroke team or ward providing a service for the care of stroke patients in a designated area.[9] It has been shown that stroke unit care offers significant benefits in survival, dependency and the need for institutional care when compared to general medical wards, so it is encouraging to see that in this audit, 74% of patients were admitted directly to the stroke unit as the first ward of admission.[9,10] The result is

comparable to the UK audit (Table 5) and approaches the 80% target that has been set nationally.[5,11,12] The significant difference seen between this and the UK audit in the proportion of patients spending more than 90% of their inpatient stay in a stroke unit most likely reflects the difference in the development of designated stroke beds. At NSH, patients requiring at least 7 days of inpatient rehabilitation are transferred to designated stroke beds on a mixed assessment/rehabilitation unit for those aged ≥65 years or to non-designated beds at Rehab Plus for those under 65 years of age.

This audit has demonstrated significantly longer delays for initial key multidisciplinary stroke assessments compared to the UK audit. The primary reason for this is the absence of a dedicated Stroke Service provided by Stroke Service physicians and therapists during weekends and public holidays at NSH.

It has been shown that rehabilitation is necessary for about 30% of stroke admissions.[13] Stroke rehabilitation is therapy intensive and one of the unresolved discussions has been around the issue of therapy intensity in the acute period following a stroke. It is a common recommendation across national stroke guidelines that patients undergo as much therapy as they are willing and able to participate in and that are appropriate to their needs. To provide quantifiable targets, the NICE guidelines recommend offering initially at least 45 minutes of each stroke rehabilitation therapy for at least 5 days per week, while the New Zealand guidelines recommend providing physical therapy (PT and OT) for a minimum of 1 hour of practice per day, and at least 5 days a week.[14,15] These recommendations are based on the general consensus by experts that increased intensity of therapy is helpful. The results in this audit fall short of the New Zealand recommendations and is consistent with the finding from a 2013 New Zealand national survey, where it was found that less than 50% of primary rehabilitation units provide 1 hour active practice per day of physical therapy (at least 5 days a week).[16] Although individual studies suggest that therapy intensity is important, two separate literature reviews assessing therapy intensity and effects on motor recovery concluded that the current evidence base cannot support a specific recommendation regarding therapy intensity during inpatient rehabilitation following stroke.[17,18]

This is the first audit at North Shore Hospital to assess the community arm of stroke rehabilitation. NICE guidelines recommend that following transfer of care from hospital, people with disabilities after stroke (including people in care homes) should be followed up within 72 hours by the specialist stroke rehabilitation team.[15] A 2013 survey of stroke rehabilitation services in New Zealand showed a mean delay of 14 days in patients accessing post-discharge rehabilitation services.[16] Of concern is that this audit reveals a significant delay in patient access to community rehabilitation, particularly for physiotherapy and occupational therapy, before continuing their rehabilitation (average delay of 44 days and 34 days respectively). Only 12% of patients have their first contact with the community team in less than a week, while for 48% of patients, this takes longer than 4 weeks. This is in contrast to our Australian counterparts, where 45% of hospitals on average were able to provide access to community-based rehabilitation within a week, 29% within one to two weeks and only 3% of hospitals had on average more than 4 weeks delay in access to this service.[8] Further exploration into the extended waiting times demonstrated in this current audit appears warranted.

Community rehabilitation can be delivered either at home (home-based therapy) or at an outpatient clinic at a local hospital (center-based therapy). At NSH, both delivery models are used. A meta-analysis in 2010 of randomised controlled trials assessing both types of services for community dwellers affected by stroke found that home-based rehabilitation was superior to centre-based rehabilitation for functional benefits (using the Barthel Index, a measure for functional independence) at 6 weeks (P=0.03) and 3–6 months (P=0.01).[19] The median duration of intervention of therapy received in the community by stroke survivors has been described in this audit. At present, the current practice of rehabilitation intervention focuses mainly on the first 6 months of stroke as this is within the timeframe in which studies have shown beneficial

effects of augmented exercise therapy time following a stroke.[20] When home-based rehabilitation services are extended to more than 1 year post stroke, results from a Cochrane review was inconclusive in influencing any relevant patient or carer outcome.[21] The strengths of this audit are the detailed data collection covering multiple domains and the extended data collection period post discharge. The main limitation of the audit is the small sample size. The total number of thrombolysis cases included in the audit were small, so results may not be entirely reflective of the stroke thrombolysis service at NSH. To better assess this area of stroke care and to ensure that national (6% per annum) and regional targets (8% per annum for Northern Regional DHBs for 2014/15) for acute stroke thrombolysis are met, an audit specifically dedicated to this area would be beneficial.[11,12]

This audit has revealed strengths in stroke care delivery at NSH, but also highlights areas that require further attention and development of strategies for improvement; in particular, time to initial key multidisciplinary assessments, prescription rates for oral anticoagulation for secondary stroke prevention and access to community rehabilitation services. It is important that waiting times for community rehabilitation are minimised in order for stroke survivors to continue to make functional gains, or at least maintain the gains made during inpatient therapy. At this current point, specific guidance on intensity of therapy and duration of community therapy post stroke cannot be made and this reflects how strokes are heterogeneous in nature and its multifaceted effects create the need for a flexible treatment approach.

Competing interests:
Nil

Acknowledgments:
We thank the dedicated staff at North Shore Hospital who participated in this audit.

Author information:
Jennifer Yeo, Registrar, Older Adults and Home Health Department, North Shore Hospital, Auckland; Lifeng Zhou, Senior Epidemiologist, Planning & Funding, Waitemata and Auckland DHBs; Yogini Ratnasabapthy, Consultant Geriatrician and Stroke Rehabilitation Lead Physician, Older Adults and Home Health Department, North Shore and Waitakere Hospitals.

Corresponding author:
Jennifer Yeo, Older Adults and Home Health Department, North Shore Hospital, Shakespeare Road, Takapuna, Auckland 0622, New Zealand.
jennifer.yeo@waitematadhb.govt.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6834

REFERENCES:

1. Ministry of Health. 2013. Health loss in New Zealand: A report from the New Zealand Burden of Diseases, Injuries and Risk factors Study, 2006-2016. Wellington: Ministry of Health. http://www.health.govt.nz/system/files/documents/publications/health-loss-in-new-zealand-final.pdf Accessed 7 Feb 2015.
2. Ministry of Health. 2013. Mortality and Demographic Data 2010. Wellington:Ministry of Health. http://www.health.govt.nz/system/files/documents/publications/mortality-demographic-data-2010.pdf Accessed 7 Feb 2015.
3. Feigin V, Forouzanfar M, Krishnamurthi R, et al. Global and regional burden of stroke during 1990-2010: findings from the Global Burden of Disease Study 2010. Lancet 2014; 383:245-55.
4. National Stroke Foundation – Australia. National Stroke Audit Acute Services: Clinical Audit Report 2013. https://strokefoundation.com.au/~/media/strokewebsite/resources/treatment/nsf838_clinicalexec_summaryweb3.ashx?la=en Accessed 18 Oct 2015.

5. Royal College of Physicians, Clinical Effectiveness and Evaluation Unit on behalf of the Intercollegiate Stroke Working Party. 2014. Sentinel Stroke National Audit Programme (SSNAP). Clinical audit October – December 2013 public report. https://www.rcplondon.ac.uk/sites/default/files/ssnap_public_report_oct-dec_2013.pdf Accessed 7 July 2014.
6. The Royal Australian College of General Practitioners. 2014. Pradaxa investigation raises importance of drug safety infrastructure in general practice. http://www.racgp.org.au/yourracgp/news/fridayfacts/08-08-2014/ Accessed 7 Feb 2015.
7. Hillier S, Inglis-Jassiem G. Long-term risk of recurrent stroke after a first-ever stroke. The Oxfordshire Community Stroke Project. Stroke 1994 Feb; 25(2):333-7.
8. National Stroke Foundation. National Stroke Audit: Rehabilitation Services Report 2014. Melbourne, Australia. http://strokefoundation.com.au/site/media/NSF1044_Rehab-Audit-2014_FINALweb.pdf Accessed 7 Feb 2015.
9. Stroke Unit Trialists' Collaboration. Collaborative systematic review of the randomised trials of organised inpatient (stroke unit) care after stroke. BMJ 1997; 314:1151.
10. Stroke Unit Trialists' Collaboration. Organised inpatient (stroke unit) care for stroke. Cochrane Database of Systematic Reviews 2007, Issue 4. Art. No.: CD000197. DOI: 10.1002/14651858.CD000197.pub2.
11. Northern Region Health Plan 2014/2015. http://www.adhb.govt.nz/documents/NRHP-%20Minister%20Approved%202-7-14.pdf Accessed 25 Feb 2015.
12. Health Improvement and Innovation Resource Center. Policy Priorities PP20: Improved management for long term conditions (CVD, Diabetes and Stroke). http://www.hiirc.org.nz/page/40085/clarification-of-pp20-indicators-for-diabetes/?q=policy%20priorities%20PP20&highlight=policy%20priorities%20pp20&section=10538 Accessed 25 Feb 2015.
13. Willems D, Salter K, Meyer M, et al. Determining the need for in-patient rehabilitation services post-stroke: Results from eight Ontario hospitals. Healthc Policy 2012 Feb; 7(3): e105-e118. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3298025/ Accessed 23 August 2015.
14. Stroke Foundation of New Zealand and New Zealand Guidelines Group. Clinical Guidelines for Stroke Management 2010. Wellington: Stroke Foundation of New Zealand; 2010. http://www.stroke.org.nz/resources/NZClinicalGuidelinesStrokeManagement2010ActiveContents.pdf Accessed 7 February 2015.
15. National Institute for Clinical Excellence (UK) 2013. Stroke Rehabilitation: Long-term rehabilitation after stroke. https://www.nice.org.uk/guidance/cg162 Accessed 7 Feb 2015.
16. McNaughton H, McRae A, Green G, et al. Stroke rehabilitation services in New Zealand: a survey of service configuration, capacity and guideline adherence. NZMJ 2014; 127(1402):10-19.
17. Foley N, Pereira S, Salter K, et al. Are recommendations regarding inpatient therapy intensity following acute stroke really evidence-based? Top Stroke Rehabil 2012 Mar-Apr; 19(2):96-103.
18. S Sehatzadeh. Effectiveness of increased intensity of rehabilitation in post-stroke patients: a rapid review. Toronto, ON: Health Quality Ontario; 2013 Jan. 24p. http://www.hqontario.ca/Portals/0/Documents/eds/rapid-reviews/post-stroke-effectiveness-increased-intensity-rehabilitation-130314-en.pdf Accessed 7 Feb 2015.
19. Hillier S, Inglis-Jassiem G. Rehabilitation for community-dwelling people with stroke: home or centre based? A systematic review. Int J Stroke 2010 Jun; 5(3):178-86.
20. Kwakkel G, van Peppen R, Wagenaar R, et al. Effects of augmented exercise therapy time after stroke: A meta-analysis. Stroke 2004; 35:2529-2536.
21. Aziz NA, Leonardi-Bee J, Philips M, et al. Therapy-based rehabilitation services for patients living at home more than one year after stroke. Cochrane Database of Systematic Reviews 2008, Issue 2. Art. No.:CD005952. DOI: 10.1002/14651858.CD005952.pub2.

Valuing embryos as both commodities and singularities

Michael Legge, Ruth Fitzgerald

ABSTRACT

An argument put forward against gamete and embryo donation, sale and research, is that to do so would treat the gametes or embryos as objects with no intrinsic value as human. Instead, gametes and embryos created and used for donation, sale or research, can be considered more like a commodity created and traded for economic exchange—something that is valuable only for the amount of money or other goods and services that others are willing to exchange. While Kant asserts that humans have dignity rather than object worth, the provision of human gametes and embryos are progressively becoming utilities for resolving childlessness and for certain research investigations. In this paper we discuss the commodity market and the relationship to human reproduction material.

In New Zealand, the Human Assisted Reproductive Technology Act (2004) establishes two committees: Advisory Committee on Assisted Reproductive Technology (ACART, www.acart.govt.nz); and the Ethics Committee on Assisted Reproductive Technology (ECART, www.ecart.govt.nz). The former having responsibility for establishing policy and providing ministerial advice relating to assisted reproductive technologies (ART), and the latter overseeing the ethical compliance, which fall outside of 'Established Procedures' (a range of ART procedure deemed to be routine and not requiring ethical approval as laid out in the Human Assisted Reproductive Technologies Order, 2005). Typically, procedures such as extended storage of gametes and embryos (beyond the current 10-year period), gamete and embryo donations, and certain surrogacy arrangements, would require ECART consideration. Neither committee has a regulatory role as in the UKs Human Fertilisation and Embryology Act (2007). As the HART Act establishes what is not permissible, such as financial transactions to take place for reproductive material or services (eg, payment for gametes and embryos), those that are donated may be viewed as a 'gift' rather than a commodity.

The deliberative ethics regulatory style that marks New Zealand's contemporary operating standards for innovative reproductive procedures actively diminishes commodity trading in relation to HART procedures, such as surrogacy and donation of gametes. While reimbursement of costs are permitted for the provision of such services, the 2004 HART Act sets out prison sentences and financial penalties for those involved in the offer or uptake of financial inducements towards either of these procedures. This is in opposition to more *laissez faire* regulatory approaches found in other countries.[1] More recently however, New Zealand television, radio and print media has featured 'true-life dramas' from folk taking issue with the deliberative ethics regulatory approach to HART, suggesting some dissatisfaction; for example, that options such as sex selection or commercial surrogacy arrangements are not made available (other than through reproductive tourism), along with calls for consideration of the benefits of payment for gamete donation (*New Zealand Herald*, 8 August, 2010; *New Zealand Herald*, 30 August, 2010). Such popular reimagining of where the 'good' in commercialised HART procedures may be found suggest the need for a more

© NZMA

careful consideration of the moral qualities of exchange within reproduction.

The commodity market

The argument about the moral use of things is a very important one to consider because when the use of gametes or embryos is compared to the moral world of commodity trading, there is a deeply embedded set of cultural beliefs about that world. These include such truisms as 'let the buyer beware', the market will 'take care of itself', and the value of any object is 'what the market can stand'. The commodity market (as captured in this cultural rendering) offers a cold and ruthless world of constantly shifting values, where crafty speculators make a profit from the careless and overly trusting. However, the discipline of business ethics[2] teaches that the moral world of markets also relies on trust, the honouring of contracts and social responsibility in the pursuit of profit, but in the popular imagination these ethical aspects are diminished to emphasise the market's tainted and speculative identity. Anthropological study of exchange systems suggests that economic exchange is far more complex and fascinating, and hinges on the notion of value—a term which can comprise moral, sacred and economic aspects. Early twentieth century anthropologists, such as Mauss,[3] considered many of these ideas regarding the commodity market, while also gathering evidence that non-industrialised societies exchanged their goods in different ways. This alternative exchange system was called gift exchange, and was originally placed in opposition to the commodity market as a more pristine moral world of exchange in which the objects people exchanged in their community were understood to be gifts or special treasures. In opposition to the commodity market, such a trading system did not appear to emphasise trickery and guile in order to accumulate a vast surplus, instead the object of gift exchange was to circulate precious objects so that all people could have the experience of the objects for a certain time. Each object was considered so unique and precious that the term "singularity" was coined, rather than 'gift', to describe their existence which seems to capture better the manner in which such an object would be valued (that there is only one and no other).[4] When the manner in which objects are being valued, such a gift (or in modern terms 'reciprocal') exchange system, clearly indicates that they are being treated as ends in themselves—rather like the way that Kant suggests human beings should be valued.[5] The parallel which New Zealanders have drawn with gamete and embryo donation, or research and commercialised surrogacy, holds that either is morally tainted for its association with the market (the commodity exchange system) and the fluctuating value, which such an exchange system places on humans. This is a powerfully expressed cultural belief and is a very potent force in the construction of romanticised views of the idealised nuclear family. For instance Dolgin has noted in her review of the development of the family in the US, that the ideology of the nuclear family and the private sphere was created as a haven and an antidote to the 'callous' world of the market place.[6]

Economic exchange and moral values

Such ideologies, however, presume that a complete distinction can be made between these two moral value systems of economic exchange (commodities vs gifts or singularities). More recent anthropological theorising about exchange systems has clarified the romanticised earlier writings on 'gift' economies and would disagree that such a clean distinction is possible. For instance, guile and self-interest does manage to appear in gift exchange systems, while ethical behaviour can mark contemporary business transactions. Contemporary anthropological thought suggests no neat dividing line exists between the world of commodities and the world of singularities.[7] Instead, all communities simultaneously engage in both types of transactions, although the popular imaginings of their different moral worlds continues. If it is possible to demonstrate that many people tolerate the manner in which humans and human material circulate both as commodities and as singularities in their contemporary

world, then the moral argument against gamete and embryo donation, or research for its capacity to treat them as a mere commodity, loses much of its force (or the very least demonstrates an inconsistent thinking in this regard). Kopytoff refers to the contemporary field of reproductive medicine as an example of the blurring of the understanding of humans and human material simultaneously as both commodities and as singularities.[4] His argument is that it is possible to slip constantly between these understandings of the value of both gametes and embryos; often treating them as commodities in order to gain them as singularities ('our babies') is most persuasive. To deny completely the possibility of gamete and embryo donations and research is to deny the manner in which reproductive medicine is built on a foundational understanding of humans as (simultaneously) both commodities and singularities.

Trade in human reproductive material

Reproductive medicine is based on the trade in human reproductive materials, such as sperm, oocytes and embryos, all of which are in short supply. While in some countries such a supply is managed through donations, it has been noted in a study of the trade in male gametes in the US, such 'donations' are in fact rather closer to commodity trading in the market place than altruistic individuals making the 'gift' of life.[7] An extreme example of the commoditisation of human gametes are the website auctions of sperm and oocytes (www.ronsangels.com/index2.html) where it is stated "the only website that provides you with the unique opportunity to bid on eggs from beautiful, healthy and intelligent women". In relation to oocyte 'donation', Howley's thoughtful episode of investigative journalism in which she diaries her experience of accepting $10,000 compensation for the difficulties of the 'donation' of twelve ripe oocytes is an excellent discussion of what she herself begins to identify as the 'grey area' between donation and commodity trading for human reproductive material (www.reason.com/news/show/36867.html).[8] It has been reported, however, that New Zealand women participating in donor-assisted conception discussed the individual creation of moral identities as an ethical subject during the bodily gift-giving process.[9] Such gifts may be perceived as rewards appreciated as a future life of a new individual with no preconceived expectation of reciprocity.

A further variation to this donation and trading of human reproductive material occurs when people move with their gametes intact within them to different geographical locations in order to make use of reproductive techniques not available or disallowed in their home countries. This intriguing phenomenon and the relevance to our argument is the instrumental and calculating manner in which such people pursue the best chances of the market place to obtain their child.[10,11] In highlighting this process we do not suggest that such people then regard the child as a commodity, however their manner of acquiring the child is rather reminiscent of the market place and certainly involves parting with a great deal of money. To take a related example, the international adoption trade is called trade for a very explicit reason, and while many countries stipulate now that children may not be sold for adoption, the associated industries, which have sprung up to facilitate visas, normalise introductions to the child, etc, are indeed trading for profit. Furthermore, in commercial surrogacy people enter legal contracts with the express aim of purchasing the 'results of a pregnancy' no matter how the contract is worded. Disputes arising from disinclination to hand the child over, or the subsequent neglect of the child by the arranging parents, or the dissolution of their marriage, are heard in the US under contract law not family law,[6] and reinforce the idea that children arising from reproductive technology procedures are commodities. This modern commoditisation of the child is analogous to the hundreds of years of trade in breast milk and wet nurses,[12] and vindicates Kopytoff's insightful reference to reproduction as a blurry exchange system *pas excellence*.[4]

Conclusion

In summary, Shaw[13,14] argues that a range of social relationships between

New Zealand givers and receivers varies depending on the organ or tissue being transferred from anonymity to intimate social relationships. There is also a contrast with New Zealand women whose gift-relationships with their donated ova range from wishes for future relationship with possible offspring to regarding the donated ova as waste.[13] There are also divergent ethical resolutions to reproductive dilemmas in New Zealand, with disputes over the uses of PGD or surrogacy arrangements in the highly-regulated, deliberative ethics environment of New Zealand, versus the opportunities to purchase such services through reproductive travel. In considering these and the views of others, can a complete distinction be made between the two moral systems of economic exchange, ie, commodities versus gifts or singularities? As consumers, prospective parents wish for success and hold high expectations of the competencies of the personnel with their field of expertise. While clearly wishing for children as singularities (priceless and incapable of being traded), such people may also simultaneously pursue the obtaining of a child with an eye to 'quality of the product', thereby investing in a commodity. Context is everything to understand the morality of exchange system as Kopytoff [4] described so long ago, we need to consider commodity candidacy, phase and context. At the very least there seems to be a difference between when a State considers these matters and when individual families decide what is 'best' in their circumstances.

Competing interests:
Nil

Acknowledgements:
We acknowledge with thanks the funding for this project from the University of Otago (UORG) and from the Marsden Fund administered by the Royal Society of New Zealand.

Author information:
Michael Legge, Biochemistry, University of Otago, Dunedin, New Zealand; Ruth Fitzgerald, Anthropology and Archaeology, University of Otago, Dunedin, New Zealand.

Corresponding author:
Michael Legge, Biochemistry, University of Otago, Dunedin, New Zealand.
mike.legge@otago.ac.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6835

REFERENCES:

1. Nuffield Council on Bioethics. Human bodies: donation for medicine and research. 2011, London. Nuffield Council on Bioethics.
2. Singer AE. Business ethics and strategy. 2007, Aldershot, England, Ashgate Publishing Co.
3. Mauss M. The gift. The form and reason of exchange in archaic societies.1950, London. Routledge.
4. Kopytoff I. The cultural biography of things: commodification in cultural perspective. In: A.Appadurai (Ed). Social life of things: commodities in cultural perspective 1986, pp 64-91. New York: Cambridge University Press.
5. Manninen B. Are human embryos Kantian persons? Kantian considerations in favor of embryonic stem cell research. Philosophy, Ethics and Humanities in Medicine. 2008; 3. doi: 10.1186/1747-5341-3-4.
6. Dolgin J. Defining the family law: Technology and reproduction in an uneasy age. 1999, New York: New York University Press.
7. Tober DM. Semen as a gift, semen as goods: reproductive workers and the market in altruism. 2001; Body and Society. 7; 137-160.
8. Howley K. Ova for sale [internet]. Available from: http://reason.com/archives/2006/10/01/ova for sale. (Accessed 16 October 2015).

9. Shaw R. The gift-exchange and reciprocity of women in donor-assisted conception. 2007;The Sociological Review.55: 293-310.
10. Pennings G. Legal harmonization and reproductive tourism in Europe. 2005; Human Reproduction. 19: 2689-2694.
11. Provoost V, Pennings G, De Sutter P. et al. Infertility patients' beliefs about their embryos and their disposition preferences. 2009; Human Reproduction. 24: 896-905.
12. Golden J. Gender, class and the meaning of breast milk in the twentieth century. 1996; Historian 59: 75-88.
13. Shaw R. The notion of the gift in the donation of body tissues. 2008a; Sociological Research Online http://www.socresonline.org.uk/13/6/4.html. (accessed 16 October 2015).
14. Shaw R. Rethinking gifts as body projects. 2008b; Sociology. 42: 11-28

Decision-making in an era of cancer prevention via aspirin: New Zealand needs updated guidelines and risk calculators

Nick Wilson, Vanessa Selak, Tony Blakely, Josh Knight, Nhung Nghiem, William Leung, Philip Clarke, Rod Jackson

ABSTRACT

Based on new systematic reviews of the evidence, the US Preventive Services Task Force has drafted updated guidelines on the use of low-dose aspirin for the primary prevention of both cardiovascular disease (CVD) and cancer. The Task Force generally recommends consideration of aspirin in adults aged 50–69 years with 10-year CVD risk of at least 10%, in who absolute health gain (reduction of CVD and cancer) is estimated to exceed absolute health loss (increase in bleeds). With the ongoing decline in CVD, current risk calculators for New Zealand are probably outdated, so it is difficult to be precise about what proportion of the population is in this risk category (roughly equivalent to 5-year CVD risk ≥5%). Nevertheless, we suspect that most smokers aged 50–69 years, and some non-smokers, would probably meet the new threshold for taking low-dose aspirin. The country therefore needs updated guidelines and risk calculators that are ideally informed by estimates of absolute net health gain (in quality-adjusted life-years (QALYs) per person) and cost-effectiveness. Other improvements to risk calculators include: epidemiological rigour (eg, by addressing competing mortality); providing enhanced graphical display of risk to enhance risk communication; and possibly capturing the issues of medication disutility and comparison with lifestyle changes.

The United States Preventive Services Task Force (USPSTF) has issued draft recommendations for the use of aspirin for the prevention of cardiovascular disease (CVD) and cancer—with public comment invited by October 2015.[1] These recommendations combine the use of low-dose aspirin for the primary prevention of both CVD and colorectal cancer, and give consideration to both life expectancy and addressing potential benefit versus harms depending on personal preferences. The specific text is detailed in Table 1, but in summary the USPSTF generally recommends aspirin in adults aged 50–69 years with 10-year CVD risk of at least 10% (roughly equivalent to 5-year CVD risk ≥5%).

Possible implications for the New Zealand population

To explore the potential implications of the USPSTF recommendations for the New Zealand population, we used an online CVD risk calculator designed specifically for the New Zealand population: "Know Your Numbers".[2] This calculator uses Framingham Risk Equations, modified for the New Zealand setting, to estimate 5-year risk of CVD events. However, the equations currently used almost certainly overestimate CVD risk because of the ongoing downward trend in CVD risk for the whole New Zealand population (and as projected into the future[3]). However, even if the USPSTF threshold for recommending aspirin in primary prevention is doubled to accommodate this overestimate of CVD risk (ie, to 5-year CVD risk >10%), this is half the threshold of current New Zealand guidelines and, apart from European women, most smokers aged 50–69 years would probably meet the new USPSTF threshold for taking low-dose aspirin (Appendix: Table A).

© NZMA

Table 1: United States Preventive Services Task Force (USPSTF) recommendations on aspirin for the prevention of CVD and cancer (as of September 2015)[1].

Population	Recommendation	Grade of evidence
Adults aged 50 to 59 years	"The USPSTF recommends low-dose aspirin use for the primary prevention of cardiovascular disease (CVD) and colorectal cancer in adults ages 50 to 59 years who have a 10% or greater 10-year CVD risk, are not at increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years."	"The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial."
Adults aged 60 to 69 years	"The decision to use low-dose aspirin to prevent CVD and colorectal cancer in adults ages 60 to 69 years who have a greater than 10% 10-year CVD risk should be an individual one. Persons who are not at increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years are more likely to benefit. Persons who place a higher value on the potential benefits than the potential harms may choose to use low-dose aspirin."	"The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small."
Adults younger than age 50 years	"The current evidence is insufficient to assess the balance of benefits and harms of aspirin use to prevent CVD and colorectal cancer in adults younger than age 50 years."	"The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined."
Adults age 70 years and older	"The current evidence is insufficient to assess the balance of benefits and harms of aspirin use to prevent CVD and colorectal cancer in adults age 70 years and older."	As above.

Updated guidelines for New Zealand are needed

Current New Zealand guidelines are that "aspirin and other antiplatelet agents are not generally recommended for people with a risk lower than 20 percent",[4] a much higher threshold than the draft USPSTF recommendations. However, the New Zealand guidelines are based on older reviews (from the early 2000s) and do not take into account the effect of aspirin on colorectal cancer. Overall, the quality of the draft USPSTF recommendations appears to be high. The recommendations are based on a microsimulation model of the lifetime net benefits of daily use of low-dose aspirin in terms of life-years and quality-adjusted life-years (QALYs).[5] The effects of aspirin on CVD, colorectal cancer and major bleeding outcomes have been taken into account using effect estimates obtained from three recent systematic reviews.[6-8] However, the microsimulation model is designed to be representative of the US population and only takes into account two factors (age and sex) in its estimate of (untreated) absolute bleeding rates. This is a limitation because there is considerable variation in absolute bleeding risk according to many of the same risk factors as for absolute CVD risk.[9] Hence, any updated local guideline development around the use of low-dose aspirin needs to consider the unique aspects of New Zealand's demography and population health status, and also to adequately consider net health gain and cost-effectiveness as detailed further below.

Determining net QALYs gained

A plausible bottom line with regular use of a preventive pharmacotherapy, such as low-dose aspirin, is the expectation of consumers of gaining extra years of

healthy life on average. New guidelines could therefore consider QALYs gained for the use of low-dose aspirin after taking into account: age, sex, ethnicity, CVD risk reduction, colorectal cancer prevention and risk of bleeding (gastric and intracranial).

Cost-effectiveness

The issue of cost-effectiveness is relevant for policy-makers who should be striving to get the maximum health gain from the taxpayer-funded public health budget. So guideline development should ideally reflect the intervention costs involved with taking aspirin (supermarket purchase or on-prescription) and the impacts on health system costs from both diseases prevented and adverse effects caused, eg, from gastric bleeding. We suspect, given some existing international literature,[10] that aspirin use in adults aged 50–69 may generally be cost-effective (approximately US$ 5,000 per QALY for 55-year-old men with a 10% CVD risk over 10 years), but ideally such an analysis should be done with New Zealand data (given the very different health system costs in New Zealand versus the US). Furthermore, in an earlier study by the same authors,[11] adding proton pump inhibitor co-therapy versus aspirin alone was found to be *not* cost-effective, for 55- and 65-year-old men with a 10% CVD risk over 10 years and average gastric bleeding risk, but may be cost-effective for selected men at increased risk for gastric bleeding. A comprehensive economic evaluation of low-dose aspirin, with and without proton pump inhibitor co-therapy, in primary prevention considering the main therapeutic endpoints (CVD and selected cancers) and adverse effects (including medication disutility) is yet to be published.

The cost-effectiveness of enhancing uptake of low-dose aspirin should also be compared with other New Zealand-specific results suggesting the cost-saving nature of additional tobacco control interventions (eg, further raising tobacco tax[12]), and cost-saving dietary salt reduction interventions.[13]

Considering *H. pylori* infection

Really sophisticated New Zealand guidelines would take into account the likelihood that the adverse effects of aspirin may be worse in Māori and Pacific peoples (given higher rates of *H. Pylori* infection and hence higher risk of gastric bleeding [14]). A systematic review has reported that "eradication of *H. pylori* infection before aspirin use could reduce the incidence of upper GI [gastrointestinal] complications by 25–30%."[15]

Improving CVD risk calculators for clinical decision-making with patients

If updated guidelines suggest that low-dose aspirin is a cost-effective intervention for at least some 50–69 year olds in New Zealand, the next step is to consider updated risk calculator development that can inform decision-making by clinicians alongside patients. At present, a large number of online CVD risk calculators currently exist (eg, see these reviews[16,17]). They do not provide highly precise risk estimates,[16] but their use appears to have some beneficial impact (eg, stimulating lifestyle changes[18]). Nevertheless, some researchers have highlighted the complex responses of users and suggest that such calculators "may best be used in conjunction with health professionals who can guide the user through the calculator".[19]

The free, online New Zealand CVD risk calculator ("Know Your Numbers" [2]) has a number of desirable features (see Appendix: Table B). However, to optimally make use of such calculators (including in the light of the new USPSTF recommendations on aspirin), they could benefit from the following improvements.

Background epidemiological refinements

As discussed above, there is a need for upgraded risk calculators to be adjusted for the latest CVD risk information given the ongoing downward trend in CVD risk in New Zealand (and as projected into the future[3]). Socioeconomic status is another possible refinement, eg, derived using the latest NZDep scores for small-area level deprivation, based on a person's residential address.

Although not so relevant to the aspirin issue in the 50–69 year age range, extending the age range of CVD calculators is generally desirable. For example, the current New Zealand calculators are only designed for the <75 year age group. New versions of such calculators could also take into

account "competing mortality" in terms of the increased risk of death from other causes at older years. This particular issue probably starts to matter quite a lot for older people in their 80s and 90s.[20]

Incorporating cancer and bleeding risks

Ideally, absolute bleeding risk (gastric and intracranial) and colorectal cancer risk would be estimated alongside absolute CVD risk, with integrated results being produced (eg, net QALYs gained or lost). While CVD risk calculators are abundant, there is a paucity of bleeding and cancer-risk equations that would be suitable for use in primary prevention populations (but some work in this area is proceeding[21]).

Graphical display of risk

To assist with understanding risk by patients, it is probably desirable to show graphically how many cases of CVD events plus colorectal cancer events are prevented "in 100 people like me" who adopt risk reduction efforts, such as aspirin use. This is already being done for non-specific CVD risk reduction in some such calculators (eg, for QRisk2,[22] and a Mayo Clinic calculator for statin use[23]). The JBS3 risk calculator[24] graphically displays the average survival time that is free of a CVD event, and how this can be extended with reductions in blood pressure etc. Again, these estimates should ideally be upgraded to allow for competing mortality risk.

Medication disutility

Some people simply don't like the idea of taking daily preventive medications, as described in the literature on "medication disutility".[25-27] This issue is likely to apply to low-dose aspirin, particularly when it is the only daily medication being taken. So really sophisticated calculators could allow users to incorporate various levels of such medication disutility. For example, a threshold analysis result could be a possible output: "to outweigh the health benefit of taking daily aspirin for a year, you would have to regard taking daily aspirin as worse than losing 'x' days of life per year".

Lifestyle change comparisons

Other than quitting smoking, it may be difficult for individuals to adopt the dietary and physical activity changes that would equate to the benefit of taking low-dose aspirin. Nevertheless, a really sophisticated calculator would provide information on how the health gain from low-dose aspirin might compare with that from quitting smoking, increasing physical activity, adopting a Mediterranean diet,[28-30] and reducing consumption of processed meat or red meat (given the association with colorectal cancer[31]).

Conclusions

Based on the USPSTF draft recommendations, it seems likely that some (albeit a still unclear) proportion of New Zealanders aged 50–69 years might obtain net benefit from the use of low-dose aspirin for the prevention of CVD and cancer. This group is especially likely to include smokers. But to inform appropriate New Zealand guidelines, updated risk estimates are needed to account for the ongoing decline in CVD risk. Good decision-making also requires data on absolute net health gain (in QALYs per person) and cost-effectiveness. Along with this, improvements could be made to New Zealand-specific risk calculators to improve their epidemiological rigour (eg, by addressing competing mortality), capture other important aspirin-related aspects (cancer prevention and risk of bleeding), provide enhanced graphical display of risk to enhance risk communication, and possibly capture the issues of medication disutility and comparison with lifestyle changes.

Appendix

Table A: The probably out-of-date (over-estimated) 5-year risk of a CVD event in different demographic groups estimated using the current New Zealand specific risk calculator "Know Your Numbers".[2*]

Demographic group	5-year CVD event risk using the online calculator (range generated by using each year of age)**	
	Smokers	Non-smokers
European men		
50–54 years	9–11	***4–6***
55–59 years	12–15	***6–8***
60–64 years	16–19	9–11
65–69 years	20–22	11–13
Māori men		
50–54 years	14–16	9–11
55–59 years	17–19	11–13
60–64 years	21–24	14–15
65–69 years	24–27	16–18
European women		
50–54 years	***5–6***	2–3
55–59 years	***6–7***	3
60–64 years	***8–10***	4–5
65–69 years	10–12	***5–6***
Māori women		
50–54 years	10–11	7–8
55–59 years	11–13	8–9
60–64 years	14–16	9–10
65–69 years	16–18	10–11

* Dark shading indicates overall >20% 5-year risk of a CVD event; lighter shading indicates 10–20% risk; font in bold and italics indicates 5–9% risk.

** Using average blood pressure data (systolic/diastolic) from the 2008/2009 Adult Nutrition Survey[32] and the total cholesterol (TC) to HDL ratio from the same survey.[33] All risks calculated assuming "no diabetes" and "no family history" of CVD, which will result in some under-estimation of the true risk. On the other hand, this particular risk calculator is very likely to over-estimate the risks given the on-going decline in CVD incidence in New Zealand since it was designed, and because competing mortality is not built into the calculator (a common design limitation of such calculators).

Table B: Comment on selected features of the online "Know Your Numbers" CVD risk calculator designed for the New Zealand setting.*

Domain	Further detail
Time horizon	This New Zealand-specific calculator provides 5-year risk—which seems to us to be more relevant for clinical decision-making than the 10-year timeframe used by most such CVD risk calculators (for more details see this article by Jackson, et al[34]).
Ethnicity	Relatively detailed ethnicity input options are available (ie, Māori, various Pacific and Asian populations). Nevertheless, adding in the New Zealand-based Chinese population could be a good addition.
Graphical features	The output provides projections in a graphic form and there are also dynamic graphic options that show current risk and future risk at different settings. Furthermore, there is also a comparison with an 'ideal trajectory and also what the likely trajectory is for the person if no CVD risk reduction efforts are made. But further improvements are possible in graphical display (see main text).
Calculator tools	The calculator has sliding scales to allow the user to see the implications of reductions in blood pressure (BP) and cholesterol ratio (TC/HDL) changes on their CVD risk. This can be used to demonstrate visually the relatively large importance of high BP in influencing CVD risk.
'Heart age'	The calculator estimates the person's 'heart age'. It is possible that this might help motivate some people, but more research on this is probably needed on this issue. For example, one study found that participants told that they had an older heart age found it 'confronting'.[18]
Recommendations	For those at high CVD risk, the calculator provides information about seeing a doctor about CVD medications. The user can also proceed to creating a somewhat personalised "heart health plan". There is also discussion of the importance of stopping smoking and making dietary changes.

* An earlier version of this table along with some of the ideas in the main text were previously included in a blog that some of the authors wrote.[35] We note that one of the authors (RJ) was involved in epidemiological aspects of developing this "Know Your Numbers" calculator.

Competing interests:
Nil

Acknowledgements:
The BODE[3] Programme is funded by the Health Research Council of New Zealand (HRC), Grant 10/248. Vanessa Selak is also funded by the HRC for the development of an aspirin harm benefit calculator (Grant 15/165).

Author information:
Nick Wilson, Public Health, University of Otago, Wellington; Vanessa Selak, Epidemiology and Biostatistics, University of Auckland, Auckland; Tony Blakely, Public Health, University of Otago, Wellington; Josh Knight, Epidemiology & Biostatistics, University of Auckland, Auckland; Nhung Nghiem, Public Health, University of Otago, Wellington; William Leung, Public Health, University of Otago, Wellington; Philip Clarke, Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Australia; Rod Jackson, Epidemiology and Biostatistics, School of Population Health, University of Auckland, Auckland.

Corresponding author:
Nick Wilson, Public Health, University of Otago, Wellington.
Nick.Wilson@otago.ac.nz

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6836

REFERENCES:

1. US Preventive Services Taskforce. Draft Recommendation Statement: Aspirin to Prevent Cardiovascular Disease and Cancer (September 2015). http://www.uspreventiveservicestaskforce.org/Page/Document/draft- recommendation-statement/aspirin-to-prevent-cardiovascular-disease-and- cancer.
2. Heart Foundation. Know Your Numbers. http://www.knowyournumbers.co.nz/. 2012.
3. Ministry of Health. Health loss in New Zealand: A report from the New Zealand Burden of Diseases, Injuries and Risk Factors Study, 2006–2016. Wellington: Ministry of Health, 2013.
4. Ministry of Health. Cardiovascular Disease Risk Assessment: New Zealand Primary Care Handbook 2012 (updated 2013). Wellington: Ministry of Health, 2013.
5. Dehmer SP, Maciosek MV, Flottemesch TJ. Aspirin Use to Prevent Cardiovascular Disease and Colorectal Cancer: A Decision Analysis: Technical Report: Rockville (MD): Agency for Healthcare Research and Quality (US), 2015.
6. Chubak J, Kamineni A, Buist DSM, et al. Aspirin Use for the Prevention of Colorectal Cancer: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force: Rockville (MD): Agency for Healthcare Research and Quality (US), 2015.
7. Guirguis-Blake JM, Evans CV, Senger CA, et al., Aspirin for the primary prevention of cardiovasular events: a systematic evidence review for the US Preventive Services Task Force. Evidence synthesis No. 131. AHRQ Publication No. 13-05195-EF-1. 2015, Agency for Healthcare Research and Quality: Rockville, MD.
8. Whitlock EP, Williams SB, Burda BU, et al., Aspirin use in adults: cancer, all- cause mortality, and harms. A systematic evidence review fo the US Preventive Services Task Force. Evidence synthesis No. 132. AHRQ Publication No. 13-05193-EF-1. 2015, Agency for Healthcare Research and Quality: Rockville, MD.
9. Antithrombotic Trialists' (ATT) Collaboration, Baigent C, Blackwell L, et al. Aspirin in the primary and secondary prevention of vascular disease: collaborative meta- analysis of individual participant data from randomised trials. Lancet 2009;373:1849-60.
10. Pignone M, Earnshaw S, McDade C, et al. Effect of including cancer mortality on the cost-effectiveness of aspirin for primary prevention in men. J Gen Intern Med 2013;28:1483-91.
11. Earnshaw SR, Scheiman J, Fendrick AM, et al. Cost-utility of aspirin and proton pump inhibitors for primary prevention. Arch Intern Med 2011;171:218-25.
12. Blakely T, Cobiac LJ, Cleghorn CL, et al. Health, health inequality, and cost impacts of annual increases in tobacco tax: Multistate life table modeling in New Zealand. PLoS Med 2015;12:e1001856.
13. Nghiem N, Blakely T, Cobiac LJ, et al. Health and economic impacts of eight different dietary salt reduction interventions. PLoS One 2015;10:e0123915.
14. McDonald AM, Sarfati D, Baker MG, et al. Trends in Helicobacter pylori infection among Maori, Pacific, and European Birth cohorts in New Zealand. Helicobacter 2015;20:139-45.
15. Thorat MA, Cuzick J. Prophylactic use of aspirin: systematic review of harms and approaches to mitigation in the general population. Eur J Epidemiol 2015;30:5-18.
16. Allan GM, Garrison S, McCormack J. Comparison of cardiovascular disease risk calculators. Curr Opin Lipidol 2014;25:254-65.
17. Allan GM, Nouri F, Korownyk C, et al. Agreement among cardiovascular disease risk calculators. Circulation 2013;127:1948-56.
18. Bonner C, Jansen J, Newell BR, et al. I don't believe it, but i'd better do something about it: patient experiences of online heart age risk calculators. J Med Internet Res 2014;16:e120.
19. Nolan T, Dack C, Pal K, et al. Patient reactions to a web-based cardiovascular risk calculator in type 2 diabetes: a qualitative study in primary care. Br J Gen Pract 2015;65:e152-60.
20. Liew SM, Jackson R, Mant D, et al. Should identical CVD risks in young and old patients be managed identically? Results from two models. BMJ Open 2012;2:e000728.
21. Hippisley-Cox J, Coupland C. Predicting risk of upper gastrointestinal bleed and intracranial bleed with anticoagulants: cohort study to derive and validate the QBleed scores. BMJ 2014;349:g4606.
22. ClinRisk Ltd. Welcome to the QRISK®2-2015 risk

calculator: http://qrisk.org

23. Mayo Clinic. Statin Choice Decision Aid (2015). http://statindecisionaid.mayoclinic.org/index.php/statin/index.
24. Joint British Societies for the Prevention of Cardiovascular Disease. JBS3 Cardiovascular Risk Calculator (2014). http://www.jbs3risk.com/pages/risk_calculator.htm.
25. Gage BF, Cardinalli AB, Owens DK. The effect of stroke and stroke prophylaxis with aspirin or warfarin on quality of life. Arch Intern Med 1996;156:1829-36.
26. Hutchins R, Viera AJ, Sheridan SL, et al. Quantifying the utility of taking pills for cardiovascular prevention. Circ Cardiovasc Qual Outcomes 2015;8:155- 63.
27. Fontana M, Asaria P, Moraldo M, et al. Patient-accessible tool for shared decision making in cardiovascular primary prevention: balancing longevity benefits against medication disutility. Circulation 2014;129:2539-46.
28. Sleiman D, Al-Badri MR, Azar ST. Effect of mediterranean diet in diabetes control and cardiovascular risk modification: a systematic review. Front Public Health 2015;3:69.
29. Schwingshackl L, Hoffmann G. Mediterranean dietary pattern, inflammation and endothelial function: a systematic review and meta-analysis of intervention trials. Nutr Metab Cardiovasc Dis 2014;24:929-39.
30. Schwingshackl L, Hoffmann G. Adherence to Mediterranean diet and risk of cancer: an updated systematic review and meta-analysis of observational studies. Cancer Med 2015;4:1933-47.
31. Bouvard V, Loomis D, Guyton KZ, et al. Carcinogenicity of consumption of red and processed meat. Lancet Oncol 2015;16:1599-600.
32. McLean RM, Williams S, Mann JI, et al. Blood pressure and hypertension in New Zealand: results from the 2008/09 Adult Nutrition Survey. N Z Med J 2013;126:1-14.
33. University of Otago and Ministry of Health. A Focus on Nutrition: Key findings of the 2008/09 New Zealand Adult Nutrition Survey. Wellington: Ministry of Health. http://www.health.govt.nz/publication/focus-nutrition-key- findings-2008-09-nz-adult-nutrition-survey, 2011.
34. Jackson R. Lifetime risk: does it help to decide who gets statins and when? Curr Opin Lipidol 2014;25:247-53.
35. Wilson N, Nghiem N, Blakely T, et al. Calculating cardiovascular risk with online calculators – scope for improvement? Public Health Expert [Blog] (21 September 2015). https://blogs.otago.ac.nz/pubhealthexpert/2015/09/21/calculating- cardiovascular-risk-with-online-calculators-scope-for-improvement/.

Perforated sigmoid colon carcinoma within a left inguinal hernia with associated necrotising infection

Suheelan Kulasegaran, Marcel Fernando, Brendon Fraser-Jones, Hisham Hammodat

It is extremely rare for colon cancer to perforate within an inguinal hernia and be associated with necrotising soft tissue infection. This case highlights the importance of a thorough history in the context of an inguinal hernia and discusses management options.

Case Report

A 66-year-old man presented to the emergency department following an episode of syncope. He reported a 6-week history of left iliac fossa pain that was increasing in intensity and had been constipated for 3 days. He was still passing flatus. He did not exhibit any signs of sepsis, and his vital signs were normal. He had a large, incarcerated, tender left inguinal hernia with surrounding swelling and erythema. Blood tests revealed a white cell count of 13.3 x 10^9/L and a C-reactive protein level of 279 mg/L. Abdominal and chest plain films were unremarkable. An ejection systolic murmur was heard on examination and echocardiogram confirmed severe aortic stenosis, with an ejection fraction of 75%. He was taken to theatre immediately. A left inguinal skin crease incision was the initial approach of choice. An obstructed large left inguinal hernia was found. Further dissection and opening of the hernia sac revealed perforated sigmoid colon with faecal contamination. In addition to this, there were signs of a severe necrotic infection of the surrounding soft tissue, extending into the femoral triangle. After mobilising the involved bowel, a sigmoid colectomy was performed using a bowel-stapling device. Resected ends were reduced into the peritoneal cavity with orchidectomy and spermatic cord resection to the level of the internal ring.

Following this, the infected soft tissue was debrided from an area of 20 x 20 cm. A midline laparotomy was subsequently performed to further mobilise and resect bowel. The proximal bowel was brought out as a colostomy in the left hypochondrium. He required five further debridements and coverage with VAC dressing before split skin graft.

Histology and CT staging revealed a low-grade adenocarcinoma (T3, N0, M0) with no evidence of metastasis.

Discussion

Inguinal hernias are common, and 10% of inguinal hernias become incarcerated.[1] Malignant tumours within hernia sacs are rare and found in less than 0.4% of excised sacs.[2] These tumours are divided into two main categories; saccular tumours, such as mesothelioma, or intra-saccular tumours, most commonly sigmoid cancer, although ascending colon and caecal involvement has been reported.[3] Inguinal hernias containing perforated sigmoid adenocarcinoma with associated necrotising skin infection are extremely rare. A literature review found 31 cases describing tumours within an inguinal hernia, with only 5 of these patients having perforated cancers.[1-5] Perforated colorectal

© NZMA

cancer is generally associated with a poorer prognosis. Prognosis is better if the perforation is within the hernia sac without peritoneal contamination. A delay in diagnosis or management can result in necrotising infections of the genitalia and mortality rates of 7–45%.[6]

There are several management options available to the surgeon. This includes a midline laparotomy, groin incision or commonly, both.[1] One approach involves the construction of a double-barrelled colostomy through an inguinal hernia incision. This is a potentially effective approach in a critically ill surgical patient.[4] In our case, both left groin and midline incisions were utilised. Subsequent to this, a secure open hernia repair was performed. The patient required repeat debridement and VAC placement.

The underlying principles apply for all cases. These include good oncological clearance and a secure hernia repair. In patients who develop necrotising skin infections, early and aggressive debridement and re-look washouts with VAC placement need to be strongly considered before final skin coverage.

Competing interests:
Nil

Author information:
Suheelan Kulasegaran, General Surgery, North Shore Hospital, Auckland; Marcel Fernando, General Surgery, North Shore Hospital, Auckland; Brendon Fraser-Jones, General Surgery, North Shore Hospital, Auckland; Hisham Hammodat, General Surgery, North Shore Hospital, Auckland.

Corresponding author:
Suheelan Kulasegaran, General Surgery, North Shore Hospital, Auckland.
suheelan.kulasegaran@gmail.com

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6837

REFERENCES:

1. Boormans JL, Hesp WL, Teune TM, Plaisier PW. Carcinoma of the sigmoid presenting as a right inguinal hernia. Hernia : the journal of hernias and abdominal wall surgery. 2006;10(1):93-6. Epub 2005/09/01.
2. Ko KH, Yu CY, Kao CC, Tsai SH, Huang GS, Chang WC. Perforated sigmoid colon cancer within an irreducible inguinal hernia: a case report. Korean journal of radiology. 57 2010;11(2):231-3. Epub 2010/03/02.
3. Tan GY, Guy RJ, Eu KW. Obstructing sigmoid cancer with local invasion in an incarcerated inguinal hernia. ANZ journal of surgery. 2003;73(1-2):80-2. Epub 2003/01/22.
4. Kouraklis G, Kouskos E, Glinavou A, Raftopoulos J, Karatzas G. Perforated carcinoma of the sigmoid colon in an incarcerated inguinal hernia: report of a case. Surgery 62 today. 2003;33(9):707-8. Epub 2003/08/21.
5. Ruiz-Tovar J, Ripalda E, Beni R, Nistal J, Monroy C, Carda P. Carcinoma of the sigmoid colon in an incarcerated inguinal hernia. Canadian journal of surgery Journal 65 canadien de chirurgie. 2009;52(2):E31-2. Epub 2009/04/29.
6. Flanigan RC, Kursh ED, McDougal WS, Persky L. Synergistic gangrene of the scrotum and penis secondary to colorectal disease. The Journal of urology. 1978;119(3):369-68 71. Epub 1978/03/01.

Time to establish a New Zealand/Aotearoa Twin Registry?

Frank Houghton, Jeremy Toms, Bruce Duncan

New Zealand is often described as 'punching above its weight' in international health.[1] There are many reasons for this success, including the Government's approach to tobacco control[1] and the impact of the Dunedin Multidisciplinary Health & Development Study.[2] In order to continue maximising this potential, New Zealand should consider initiating the establishment of a national longitudinal geocoded National Twin Registry. This should involve a study of development, health, wellbeing and illness, as well as a focus on individual, familial, social, and environmental factors, backed up by biological samples.

The Twin Method, which dates back to the work of Galton[3] over one hundred years ago, formerly compares the similarity of identical (monozygotic, (MZ)) twins with fraternal (dizygotic, (DZ)) twins. Twin studies therefore represent an incredible and unique resource through which to examine the impact of genetics, as well as shared and unshared environments.[4-5] Although historically focusing more on genetics, contemporary research using twin studies has started to investigate epigenetic factors,[6] as well as explorations of wider environmental factors[7] such as socio-economic deprivation,[8] social capital,[9-11] walkability[12] and green space.[13]

New Zealand has developed a particular expertise that is critical to the success of a venture such as the establishment of a Twin Registry. Evidence of this can be seen in the Dunedin Study,[2] which is recognised as one of the most successful and highly cited longitudinal studies in the world. Some indication of the significant contribution made to contemporary understandings of health and disease resulting from this longitudinal study can be seen in the substantial volume of publications that have resulted from it (at least 776 published refereed journal articles, as well as almost 500 other publications).[14] Part of its success rests on the remarkable ongoing participation rate, which remains in excess of 90%. Poulton et al have recently outlined the factors behind this impressive rate, which includes good systems, good recruitment staff, removing barriers to participation, engaging assessments, noticeable research outputs, and appropriate resources.[2] However, the authors state that although these factors are necessary, they are not sufficient to ensure such a high response rate. They suggest that their guiding philosophy of treating people as you would like to be treated yourself, combined with 'professionalism, courtesy and persistence' and a sustained focus on the researcher-participant relationship to build participant loyalty are the essential factors.[2]

Although the Twin method is not without its critics,[15] and has both a controversial[16-25] and tainted[26-31] history, it still offers an unparalleled opportunity to gain insight into the effects of gene-environment interactions on health, well-being and disease. Twin registries now exist in more than 20 different countries, with some countries hosting a number of such registries (for example there are 9 in the US).[4-5] Neighbouring Australia established their Australian Twin Registry (ATR) in 1981.[32-33] Hur & Craig also noted in 2013 that "during the past 10 years, the number of twin registries has increased rapidly across the globe".[4] The International Network of Twin Registries (INTR) has also been established in recent years to help foster international cooperation between registries.[34]

The timing is opportune for New Zealand to establish such a registry. Rising rates of fertility treatment in New Zealand have resulted in increased twinning rates. In 2015, 1,620 twins were born out of a total of 61,038 births (up from 1,136 out of 56,639 births 40 years earlier).[35] Establishing a Twin Registry is undoubtedly expensive and will require considerable planning and preparation. Some of these operational costs may be offset by access fees for investigators.[36]

While results from twin studies elsewhere can be applied here, there are features unique to the New Zealand population which would enhance the value of a locally-based twin registry. The year 2020 is fast approaching. Given popular understanding of the term '20-20' to indicate clear vision, aiming for this as the launch date, and incorporating this term in the title of such a registry might fortuitously offer an opportunity to generate popular widespread understanding of and support for the aims of the project.

Author information:
Frank Houghton, MPH Program Director, Department of Public Health & Health Administration, Eastern Washington University, Spokane, Washington, USA; Jeremy Toms, Graduate Student Assistant, Department of Public Health & Health Administration, Eastern Washington University, Spokane, Washington, USA; Bruce Duncan, Medical Officer of Health, Hauora Tairawhiti, Gisborne, New Zealand.

Corresponding author:
Frank Houghton, Program Director MPH & HSAD, Eastern Washington University, Rm 232, Phase 1 Building, 668 N. Riverpoint Blvd., Spokane, Wa, 99202, USA
fhoughton@ewu.edu

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6838

REFERENCES:

1. McCool J1, Bullen C. "Punching above its weight": why New Zealand must maintain leadership in global health. N Z Med J. 2011;124(1345):64-8.
2. Poulton R, Moffitt TE, Silva PA. The Dunedin Multidisciplinary Health and Development Study: overview of the first 40 years, with an eye to the future. Social Psychiatry & Psychiatric Epidemiology. 2015;50(5):679–693.
3. Galton F. The history of twins as a criterion of the relative powers of nature and nurture. Royal Anthropological Institute of Great Britain and Ireland Journal. 1876;6:391-406.
4. Hur Y-M, Craig JM. Twin Registries Worldwide: An Important Resource for Scientific Research. Twin Research and Human Genetics. 2013;16(1):1-12. doi: 10.1017/thg.2012.147
5. Busjahn A, Hur Y-M. Twin Registries: An Ongoing Success Story. Twin Research and Human Genetics. 2006;9, 6:705.
6. Bell JT, Spector TD. A twin approach to unraveling epigenetics. Trends Genet. 2011;27(3):116–125.
7. Strachan E, Hunt C, Afari N, Duncan G et al. University of Washington Twin Registry: Poised for the Next Generation of Twin Research. Twin Research and Human Genetics. 2012;16(1):455-462.
8. Watson NF, Horn E, Duncan GE, Buchwald D, Vitiello MV, Turkheimer E. Sleep Duration and Area-Level Deprivation in Twins. Sleep. 2016 Jan 1;39(1):67- 77. doi: 10.5665/sleep.5320.
9. Fujiwara T, Kawachi I. Social capital and health. A study of adult twins in the U.S. Am J Prev Med. 2008:35(2): 139-44.
10. Diez Roux AV. The Effects of Social Capital on Health: What twin studies can tell us. Am J Prev Med. 2008:35(2):182-3.
11. Goldberg J, Bogart A, Gonzales AA. Comment: Social capital and health. A study of adult twins in the U.S. Am J Prev Med. 2009;36(3):280-2.
12. Duncan GE, Cash SW, Horn EE, Turkheimer E. Quasi-causal associations of physical activity and neighborhood walkability with body mass index: a twin study. Prev Med. 2015;70:90-5. doi: 10.1016/j.ypmed.2014.11.024.

13. Cohen-Cline H, Turkheimer E, Duncan GE. Access to green space, physical activity and mental health: a twin study. J Epidemiol Community Health. 2015;69(6):523-9. doi: 10.1136/jech-2014-204667.
14. McCann M. 2015. Dunedin Multidisciplinary Health & Development research Unit, Department of Otago, University of Otago, Dunedin (personal correspondence).
15. Joseph J. The Use of the Classical Twin Method in the Social and Behavioral Sciences: The Fallacy Continues. The Journal of Mind and Behavior. 2013;34(1):1-40.
16. Kamin LJ. The science and politics of IQ. Lawrence Erlbaum Associates: Potomac, MD, 1974.
17. Gillie O. Crucial data was faked by eminent psychologist. Sunday Times: London, 24th October, 1976.
18. Hearnshaw L. Cyril Burt: Psychologist. Cornell University Press: Ithaca, NY, 1979.
19. Joynson RB. The Burt affair. Routledge: New York, 1989.
20. Fancher RE. The Burt Case: Another Foray: Review of R. Fletcher's Science, Ideology, and the Media: The Cyril Burt Scandal. Science. 1991; 253, 1565-1566.
21. Zenderland L. Review of Burt Again. Science. 1990;248:884-886.
22. Jensen AR. IQ and science: the mysterious Burt affair. Public Interest. 1991;105:93-106.
23. Hothersall D. History of Psychology. McGraw-Hill: New York, 1995.
24. Mackintosh NJ. Cyril Burt: Fraud or framed? Oxford University Press: New York, 1995.
25. Tucker WH. Re-reconsidering Burt: Beyond a reasonable doubt. Journal of the History of the Behavioral Sciences. 1997;33(2):145-162.
26. Müller-Hill B. The Blood from Auschwitz and the Silence of the Scholars. History and Philosophy of the Life Sciences. 1999;21(3):331-365.
27. Seidelman WE. Nuremberg lamentation: for the forgotten victims of medical science. BMJ. 1996; 313:1463-7.
28. Teo T, Ball LC. Twin research, revisionism and metahistory. History of the Human Sciences. 2009;22(5):1-23.
29. Weingart P. German Eugenics between Science and Politics. Osiris. 1989;5:260-282.
30. Mozes Kor E. Nazi Experiments as Viewed by a Survivor of Mengele's Experiments. In AL Caplan (ed.) When Medicine Went Mad, pp. 3-8. Humana Press: Totowa, NJ, 1992.
31. Segal NL. Twin Research at Auschwitz- Birkenau: Implications for the Use of Nazi Data Today. In AL Caplan (ed.) When Medicine Went Mad, pp. 281-300. Humana Press: Totowa, NJ, 1992.
32. Hopper JL, Treloar SA, de Klerk NH, Morley R. Australian Twin Registry: A Nationally Funded Resource for Medical and Scientific Research, Incorporating match and WATCH. Twin Research and Human Genetics. 2006;9(6):707-711.
33. Hopper JL, Foley DL, White PA, Pollaers V. Australian Twin Registry: 30 Years of Progress. Twin Research and Human Genetics. 2012;16(1):34-42.
34. Buchwald D, Kaprio J, Hopper JL, Sung J, et al. International Network of Twin Registries (INTR): Building a Platform for International Collaboration. Twin Research and Human Genetics. 2014;17(6):574-577.
35. Mair R. 2016. Statistics New Zealand Tatauranga Aotearoa, Christchurch (personal correspondence).
36. Chulada PC, Corey LA, Vannappagari V, Whitehead NS, Blackshear PJ. The Feasibility of Creating a Population-Based National Twin Registry in the United States. Twin Research and Human Genetics. 2006;9(6):919-926.

Colon cancer screening: the devil is in the details

James Church

Dear Sir,

I read with interest the editorial by Professor Brian Cox in the February 19 edition of the *Journal*. His plea for a flexible sigmoidoscopy screening program for colorectal cancer in New Zealand is based on a sound analysis of relevant data, but it only tells a part of the story.[1] I write in an attempt to fill in some of the gaps.

Colorectal cancer is such a frustrating disease because it is largely preventable and curable. Every cancer arises in a premalignant lesion and so there is the opportunity to prevent cancer by removal of that lesion. Even if cancer has already developed, it is commonly curable if diagnosed at an early stage.[2] The question for those at risk for the disease is "how best to prevent it or diagnose it early?" The answer is to screen, so that asymptomatic patients with polyps or Stage I or II cancer are discovered and treated. So far, so good. The next question is "how should the screening be done?", and here the answer is contentious. The preferred screening option varies according to the individual risk of the patient and the characteristics of the various tests. In particular, screening tests differ in their availability, their sensitivity and specificity, their tolerability and adverse effects, and their financial implications for the patient and the healthcare system of the country. The implications of an individual approach may be considerably different to that for a population. Thus, the attraction of flexible sigmoidoscopy screening is in the context of screening a population.[1] Here, a compromise in the ability to prevent and detect cancer is allowable in the interest of minimising cost and maximising availability. From the viewpoint of an individual patient and their caregivers however, this sort of compromise is often less acceptable.

There are significant downsides to flexible sigmoidoscopy that are best understood by those who have performed or received the test. These include an unpredictable result from one or two phosphate enemas, especially in patients with sigmoid diverticulosis; the cramping and pain that is common when no sedation or analgesia is given, and an unpredictable depth of insertion that is dictated by the skill of the endoscopist, the tortuosity, fixity and spasticity of the colon, and the tolerance of the patient.[3] In addition, there is the undeniable concern that at best the test examines only half of the colon. While flexible sigmoidoscopy would prevent 88 or 102 cancer deaths a year—depending on the level of participation—colonoscopy would be expected to prevent many more.

Colorectal cancer is no longer a left-sided disease, as shown by brief review of my own unpublished data from colonoscopy screening in average risk patients over the age of 50 years during the last 3 years. Two hundred and eighteen patients out of 427 who were screened had polyps (51%). In 111 patients (51%), the polyps were only proximal to the splenic flexure, and the left colon and rectum were normal. There were left-sided polyps in 107 patients; 55 (25%) had only left-sided polyps and 52 had polyps on both sides of their colon (24%). Thus, flexible sigmoidoscopy would detect lesions in half of the patients at most—the other half would be blissfully unaware of their increased risk. Flexible sigmoidoscopy is not even guaranteed to reach the splenic flexure. In fact, the scope often does not traverse the entire sigmoid as the sigmoid colon is notoriously the most difficult part of the colon to intubate, and in unsedated patients the examiner often has to bail out.[3] Despite these limitations imposed by polyp

© NZMA

distribution and limited depth of insertion, the assumption that only 5% of patients receiving flexible sigmoidoscopy would need a colonoscopy is an underestimate, depending on the indications for referral used by the program. If the finding of any polyp is an indication for colonoscopy, then about 25% of patients will be referred, as about 25% of patients at average risk have left-sided polyps (55+52/427). Just over half of these polyps will be hyperplastic, but there is still debate about the association between distal hyperplastic polyps and proximal neoplasms, especially sessile serrated adenoma/polyps (SSA/P).[4] Discussion of colorectal cancer screening is not complete without consideration of SSA/P. These flat, pale lesions are hard to see, are typically right-sided and account for as many as 18% of colorectal cancers. They are precursors in the promoter methylation route to CIMP high colorectal cancers (CIMP = CpG Island Methylator Phenotype).[5] Flexible sigmoidoscopy will detect almost none of these dangerous lesions.

Colonoscopy is not a perfect screening tool either, and there is evidence that colonoscopy screening is not protective against death from right-sided colorectal cancer.[6] This raises the issue of the quality of the exam, an issue that applies equally (if not more so) to flexible sigmoidoscopy. However, a recent meta-analysis of studies looking at the effect of colonoscopy on colon cancer incidence and mortality shows an 89% reduction in incidence compared to no colonoscopy (RR: 0.11; 95% CI: 0.08–0.15).[7] From a patient point of view, if screening is to be invasive then the test ought to be as comfortable and as thorough as possible, and so in the context of a single patient, colonoscopy is the better choice. However, colonoscoping all the eligible population of New Zealand is clearly not possible, logistically or financially. There are some new alternatives however.

Faecal DNA testing became a commercial test in US last year, based on a paper published in the *New England Journal of Medicine* that showed 92.3% sensitivity for cancer, 69.2% sensitivity for adenomas containing high-grade dysplasia, and 42.4% sensitivity for SSA/P (compared to faecal immunochemical blood testing (FIT) with a sensitivity of 73.8% for cancer, 46.2% for adenomas with high-grade dysplasia and 5.1% for SSA/P).[8] The cost of the test is approximately $600US, and the recommended screening interval is 3 yearly. This program is reimbursed by Medicare and many private payers. Another option may soon be a blood test for a new cancer marker, CA 11-19, which has recently been reported to detect colorectal cancer with 98% sensitivity.[9] In the meantime, colorectal surgeons and gastroenterologists are increasingly concerned about the rising incidence of colorectal cancer (and rectal cancer in particular) in young patients who fall outside any of the screening guidelines.[10] The newer, non-invasive tests may be a Godsend to clinicians worried about the changing demographics of the disease.

So in the face of conflicting ideas and different emphases in the selection and interpretation of data, what must we do? Given that colonoscopy remains the most sensible and effective tool for colorectal cancer detection and prevention, the strategy must be to use this tool optimally. This means maximising yield, and one way to do this is to stratify patients by risk for colorectal cancer. The importance of a family history of colorectal cancer and polyps cannot be over emphasised. This is a red flag that must be responded to by scheduling a colonoscopy at an appropriate age (10 years prior to the age at diagnosis of the youngest affected relative, or age 50, whichever is younger). A personal history of premalignant polyps should lead to a colonoscopic surveillance program, as should a history of endometrial cancer in a patient or a relative, especially at a young age. Secondly, the symptom of rectal bleeding cannot be ignored or attributed to benign causes. It is an indication for a prompt colonoscopy. In the majority of patients who are at average risk without symptoms, some sort of screening is required. Faecal DNA testing and blood tests for cancer markers are very promising in terms of comfort, safety, high sensitivity and lower cost, but are not yet ready to be rolled out on a population level. Our commitment to FIT has already been shown to be effective in its pilot study and although data for flexible sigmoidoscopy screening show it to be effective also,[1] there are problems and issues with both of these compromise

tools. For the individual patient, colonoscopic screening remains the preferred way to clear the colon. To the Minister of Health I would advise patience, and continue with investments already made in the realisation that progress will soon make the issue of colorectal cancer screening much less contentious.

Competing interests:
James Church is a paid speaker for Exact Sciences, the company producing Cologuard faecal DNA test.

Author information:
James Church, Director of the Sandford R. Weiss MD Center for Hereditary Colorectal Neoplasia, Digestive Diseases Institute, Cleveland Clinic Foundation, Cleveland, Ohio, USA.

Corresponding author:
James Church, Director of the Sandford R. Weiss MD Center for Hereditary Colorectal Neoplasia, Digestive Diseases Institute, Cleveland Clinic Foundation, Cleveland, Ohio, USA.
cyclax@aol.com

URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6839

REFERENCES:

1. Cox B. Flexible sigmoidoscopy is the best approach for a national bowel screening programme. NZ Med J 2016;129: 14-17.
2. Liang J, Fazio V, Lavery I, Remzi F, Hull T, Strong S, Church J. Primacy of surgery for colorectal cancer. Br J Surg 2015; 102: 847-52.
3. Painter J, Saunders DB, Bell GD, Williams CB, Pitt R, Bladen J. Depth of insertion at flexible sigmoidoscopy: implications for colorectal cancer screening and instrument design. Endoscopy. 1999; 31: 227-31.
4. Dodou D, de Winter JC. The relationship between distal and proximal colonic neoplasia: a meta-analysis. J Gen Intern Med. 2012; 27: 361-70.
5. Rex DK, Ahnen DJ, Baron JA, Batts KP, Burke CA, Burt RW, Goldblum JR, et al. Serrated lesions of the colorectum: review and recommendations from an expert panel. Am J Gastroenterol. 2012 Sep;107(9):1315-29.
6. Baxter NN, Goldwasser MA, Paszat LF, Saskin R, Urbach DR, Rabeneck L. Association of colonoscopy and death from colorectal cancer. Ann Intern Med 2009; 150: 1-8.
7. Jun Pan, Lei Xin, Yi-Fei Ma, Liang-Hao Hu, Zhao-Shen Li. Colonoscopy Reduces Colorectal Cancer Incidence and Mortality in Patients With Non-Malignant Findings: A Meta-Analysis. Am J Gastroenterol advance online publication 12 January 2016; doi: 10.1038/ajg.2015.418
8. Imperiale TF, Ransohoff DF, Itzkowitz SH, Levin TR, Lavin P, Lidgard GP, Ahlquist DA, Berger BM. Multitarget stool DNA testing for colorectal-cancer screening. N Engl J Med. 2014; 370: 1287-97.
9. Overholt BF, Wheeler DJ, Jordan T, Fritsche HA. CA11-19: a tumor marker for the detection of colorectal cancer. Gastrointest Endosc. 2016; 83: 545-51.
10. Amri R, Bordeianou LG, Berger DL. The conundrum of the young colon cancer patient. Surgery 2015;158: 1696-703.

Medication review and deprescribing method for hospitalised older patients receiving multiple medications

The authors of this study note that the prescription of multiple medications in older patients poses risks of adverse drug reactions. The aim of their study was to determine whether a structured approach to deprescribing—identifying and discontinuing unnecessary medications—in the inpatient setting is feasible and reduces medication burden.

Their 5-step deprescribing protocol included absence of valid indication, little likelihood of benefit, risk of harm outweighing benefit, no effect on symptoms or treatment burden unacceptable to patient. Among 50 patients of median age 82.5 years and six co-morbidities, 186 of 542 (34.3%) regular medications were discontinued, representing a significant decrease in the median number of medications per patient at discharge compared with presentation. Statins, gastric acid suppressive agents, angiotensin-converting enzyme inhibitors/angiotensin receptor antagonists and inhaled bronchodilators were the most frequently ceased medications.

At follow-up (median 78 days) only 5 of 413 (1.2%) ceased medications were recommenced in three patients because of symptom relapse. The authors conclude that a standardised method of medication review and deprescribing may significantly reduce medication burden in a cohort of older hospitalised patients.

Internal Medicine Journal 2016,46,35-42

Anaemia in elective orthopaedic surgery

Anaemia in elective surgery, including orthopaedic surgery, carries several risks including increased transfusion rates, length of hospital admission, mortality and post-operative infection. It has been estimated that blood loss for both total knee and total hip replacements is of the order of 1.5L, with just over half the loss being visible and the remainder invisible.

Hence an anaemia clinic was established at the Royal Adelaide Hospital to improve the management of patients scheduled for arthroplasty. Seventeen percent of patients scheduled for elective surgery were found to be anaemic. Of the 100 patients who attended, approximately half were found to be iron deficient and the remainder had anaemia of chronic disease. Serum ferritin <30 µg/L alone did not identify iron deficiency in 80% of patients with iron deficiency. Patients with iron deficient anaemia were able to be treated, in all cases, to achieve a significant increase in preoperative haemoglobin.

The researchers conclude that such a screening clinic is able to improve preoperative haemoglobin levels and reduce perioperative transfusion rates and should improve patient outcome.

Internal Medical Journal 2016, 46, 96-101

ISSN 1175-8716
© NZMA

Trouble in an hospital: honorary staff resigns

February 1916

DR. T. H. A. VALINTINE, M.R.C.S., L.R.C.P., D.P.H. (*NZ Truth*, 30 November 1912). Alexander Turnbull Library, Wellington, New Zealand. http://natlib.govt.nz/records/3865325

A difference between the Timaru Hospital Board and the honorary medical staff came to a head recently. Some time ago the board set up a committee to inquire into the way the store book had been kept, and the committee, it is alleged, found that the matron had been somewhat careless in making entries. The honorary staff, seizing on some expressions made use of, interpreted these as a reflection on the matron's honesty. The matron herself, through her solicitor, asked for a further inquiry, and on this being refused by the board as being unnecessary, the honorary staff and all the other medical men in town signed a letter to the board demanding inquiry, and this being refused, the honorary staff resigned, and all others also signing this letter. They then asked Dr Valintine, Inspector-General, to visit Timaru and conduct an inquiry. Dr Valintine has consented, but cannot come before the end of the month. On this the doctors wrote to the board asking leave to withhold their resignations in the meantime.

The board to-clay questioned the right of the Inspector General to interfere, and by eight votes to three resolved to accept the resignation of the honorary staff, the resident surgeon to make the best arrangements he can for assistance at operations until the board can secure a permanent assistant resident surgeon (who may be allowed outside practice).

Dr Loughnan, late of the honorary staff, who is also an elected member of the board, took part in the discussion, urging the right of the matron to further inquiry, and supporting the doctors in their action, but did not vote.

In the course of the discussion some members of the board indicated that they had a grievance against the honorary staff and other outside doctors, in that they sent to the hospital no patients who could pay them, therefore patients' payments were a small item of the revenue.

© NZMA