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THE NEW ZEALAND MEDICAL JOURNAL

EDITORIAL

Medicolegal Diary

The Journal today runs, for the first time, a section entitled Medicolegal Diary wherein Jonathan Coates addresses the issue of parental rights in refusing medical treatment for their children.

We considered it should be useful to publish brief legal perspectives on medicolegal issues of relevance to the ‘usual’ practise of medicine, or arising from high profile cases in the courts and media.

Constructing brief notes for the easy consumption of medical practitioners by an author trained in law, is no small challenge. Law and medicine differ in so many ways, not least in language. Yet it is vital we understand each other’s perspectives when situations or a particular patient bring the focus of the two professions together.

Jonathan Coates qualified BA/LLB from Otago University and has practised as a solicitor since 1993. He was employed by Hempsons, a leading United Kingdom medical law firm whose clients included the Medical Defense Union and a number of National Health Service Trusts. In late 1999 he completed an MA in Medical Law and Ethics at King’s College, London - with distinction. As part of the MA, he conducted an examination of the General Medical Council and its disciplinary processes. Now he works with Simpson Grierson in Wellington.

Jonathan Coates, with or without a co-author, will construct articles for Medicolegal Diary when he and we agree there is an issue of interest. We are open to suggestions regarding topics and the success or otherwise of the endeavour.

The Editors

Inequalities in health are ultimately caused by social inequalities (in income, wealth, education, and other life chances). If we seriously want to try to reduce inequalities in health we should try to reduce the structured social inequalities which create them, rather than focusing on the immediate short term risks that are manifestations of an unequal society (such as obesity, high cholesterol, poor lung function consequent on many years’ smoking, or early and unplanned pregnancy).


All was quiet in our coronary unit last Sunday morning, when the monitor suddenly showed that one of the temporary pacemakers was accelerating – 70 ... 80 ... 100 ... 120/min. The nurse rushed to the cubicle, where she found the patient half out of bed struggling with the rate-control switch of her pacemaker. They looked at each other for a moment, but the patient took the initiative as she demanded, “How do you get music out of this damn thing?”

Changes in methods of male youth suicide: 1980-95

John Langley, Professor and Director; Shyamala Nada-Raja, Research Fellow; Jonathan Alsop, Biostatistician, Injury Prevention Research Unit, University of Otago, Dunedin.

Abstract

Aims. To determine if there have been changes in the methods used, particularly hangings, for male youth suicides; whether any changes were similar to those for other age groups; and to what degree any changes identified may have impacted on overall suicide rates.

Methods. All males aged fifteen to 24 years of age who died between 1980 and 1995 inclusive, and whose death was assigned one of the WHO external cause codes for “suicide and self-inflicted injury” (E950-E959), were selected from the New Zealand Health Information Services national mortality database.

Results. The rate for suicide by hanging was relatively low and stable in the early 1980’s. By 1985 it had started to increase dramatically up until 1989, at which point it became stable again. The substantive increase in hangings was largely confined to males aged 24 years and younger. The increase in suicide by hanging cannot be attributed to substitution in methods as the rates for all other methods also increased, albeit less dramatically.

Conclusions. Much of the increase in suicide among male youths is due to an increase in hanging. The reasons for the choice of this method are unknown, and warrant study.

New Zealand’s male youth (age fifteen to 24 years) suicide rate is the worst among seventeen OECD countries.1 The rates increased dramatically in the mid 1980s.1 Similar trends have been noted in Australia,2 and England and Wales.3 In Finland, the rate increased somewhat earlier during the period of 1966-1975.4

A summary of the changes in methods used for suicide among sixteen countries from 1960 to 1980 showed that in 1980, New Zealand’s overall rate of suicide by hanging, strangulation, or suffocation was higher than that of Australia, United States, United Kingdom or Venezuela.5 Hanging accounted for about 24% of the suicide rate in New Zealand. A summary of the methods for suicide in Australia showed that there has been a four-fold increase in the rate of male youth suicide by hanging since the early 1980’s.6 At the same time, there was a two-fold increase in car exhaust suicides. In contrast, the rate for firearm related suicides decreased.

A detailed analyses of the trends in methods of suicide for youth for New Zealand has not been published. Such analyses are important since there is evidence that in some situations restricting the availability of a suicide method results in a decline in overall suicide rates. Moreover, the greatest potential for reducing deaths by limiting access to means may be achieved by targeting the methods most commonly employed, especially if the rates of suicide are increasing by those methods.2

Our aims were to determine if there have been changes in the methods used, particularly hangings, for male youth suicides; whether any changes were similar to those for other age groups; and to what degree any changes identified may have impacted on overall suicide rates.

Methods

All males aged fifteen to 24 years of age who died between 1980 and 1995 inclusive, and whose death was assigned to one of the WHO external cause codes for “suicide and self-inflicted injury” (E950-E959) were selected from New Zealand Health Information Services national mortality database. The classification of methods of suicide was based on the external cause codes. Age specific rates were calculated for fifteen to 24 year olds, and 25 years and over age groups using Statistics New Zealand Population estimates.

Results

For the period 1980-95 inclusive there were 1684 suicides among 15-24 year olds, 82% (n=1384) of which involved males. The most common methods of male 15-24 year old suicide were: hanging (44%), firearms (21%), gas/exhaust (18%) and other (16%).

Figure 1 shows that the suicide by hanging rate was relatively low and stable in the early 1980’s. Around 1985 it started to increase dramatically until 1989, at which point it became relatively stable again until 1995 when the rate rose to its highest level for this period. It is apparent that the increase in the rate of suicide by hanging cannot be attributed to substitution in methods as the rates for all other methods have increased, albeit less dramatically.

Discussion

The results show that youth suicide by hanging increased dramatically between 1980 and 1995 and that most of this...
increase occurred from the mid to late 1980's. While a similar pattern was observed for males 25 years of age and over it was less dramatic. There were increases in rates for other methods but collectively their impact on the overall suicide rates has been less dramatic, especially for those aged 15-24 years of age.

Figure 2. Male hanging suicide rate, 1980-95.

New Zealand’s youth suicide by hanging rate increased a comparable amount to that reported for Australia. What is of more significance is that New Zealand’s 1980 rate was approximately three times that of Australia and remained approximately three times the Australian rate by the mid 1990’s.

An increase in suicide hangings has been observed in Britain. It has been suggested that the increase in rates may have been attributable to the abolition of capital punishment by hanging and thus the stigma associated with this method. Given that the last legal hanging in New Zealand occurred in 1957, this seems an unlikely explanation for New Zealand. It seems unlikely also that the availability of the means of hanging, for example ropes, has increased to any significant degree over this period. Thus the increase in hanging cannot be explained by an increase in availability of the means. The only likely remaining explanation is increasing acceptability of hanging as a means of taking ones life. This may be due to increased media attention on this method, or reference to it in music. The latter explanation is consistent with younger people finding it more acceptable than older persons. While we have no New Zealand data to support this hypothesis a Finnish study suggested that the movie “Force Play” had been influential in the increase in suicides by automobile exhausts among teenagers in Finland.

Another possible explanation for the increase in hangings could be the contribution of suicides in custody, where hanging is usually the only possible method. A New Zealand study showed that of 429 suicides by hanging in men aged fifteen to 49 years for the period 1980-8, 10% occurred in prisons or police cells. Of the 38 suicides by hanging in Maori men aged fifteen to 49 years, 71% occurred in custody. If suicide in custody has increased in the late 1980's this could contribute to the increase in hanging, although it would only account for a small part of the total hanging burden.

The potential to limit hangings by reducing the availability of means in other contexts is extremely limited. That being the case, we need to improve our performance on generic approaches to reduction (eg early identification and treatment of mental disorders).

A study of suicide attempters, similar to that conducted by Skopek and colleagues, designed to explore the sociocultural influences on the choice of a particular method, in particular hanging, may identify further opportunities for preventing what has become a persistent and significant public health problem in New Zealand.

Acknowledgments. The Injury Prevention Research Unit is funded by the Health Research Council of New Zealand and the Accident Compensation Corporation. The second author was supported by the Community Trust of Otago. We thank Keren Skegg and Dorothy Begg for their comments on earlier versions of this paper.

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The Freestyle aortic bioprosthesis is a stentless porcine bioprosthesis that has haemodynamic advantages over stented prostheses, implant versatility and manufacturing features which potentially enhance durability. The porcine aortic root provides the implant options of scalloped subcoronary implantation, semi-scaled subcoronary implantation, inclusion cylinder aortic valve replacement (AVR) and root replacement with coronary reimplantation. Implantation techniques have been described previously. The bioprosthesis features 'physiologic' root fixation at 40 mmHg pressure while leaflet fixation in glutaraldehyde is at zero-pressure and antimineralisation treatment is with alpha-amino-oleic acid, all features affording enhanced durability.

We report on our initial experience with this bioprosthesis with early and medium term haemodynamic and clinical follow-up.

Methods

The study group included all 40 patients in whom a Freestyle aortic bioprosthesis was implanted at either Green Lane Hospital or the Mercy Hospital between February 1993 and December 1998. Implantation was by one of two cardiac surgeons. When consent for operation was obtained, ongoing clinical and echocardiographic follow-up was discussed and agreed to by all patients. Use of the bioprosthesis was according to surgeon preference, based on clinical grounds including age, aortic root size, and the desire to decrease prosthetic-valve morbidity and anticoagulation requirements. The first ten patients were part of the initial world-wide clinical trial of this valve in accordance with United States Federal Drug Administration requirements and for which local ethics committee approval was obtained.

The mean age of the patients at implant was 71.4±9.7(SD) years (range 33.6 to 84.1, median 74.1), with 25 (63%) aged greater than 75 years. 29 (72%) were females. The primary indication for surgery was aortic valve replacement in one (3%) and subaortic myectomy (with CVG) in one (3%). The mean patient age was 71.4±9.7 (SD) years, with 29 (72%) females. Pre-operative left ventricular systolic function was impaired in four (10%) patients with the ejection fraction 35-50%. The echocardiographic mean left ventricular end-diastolic dimension was 52.6±7.2 (SD) mm and left ventricular hypertrophy was present in eleven of the fifteen (73%) patients who had the appropriate measurements.

Surgery was elective in all cases. The method of implantation, valve-size used and operative times are shown in Table 1. Concomitant procedures were carried out in 21 (53%) patients and comprised coronary bypass grafting in eighteen (36%), aortic root enlargement in two (5%), mitral valve replacement in one (3%) and subaortic myectomy (with CVG) in one (3%).

The first ten patients were included in the international clinical trial, the protocol requiring that six received anticoagulation with warfarin in the first six post-operative weeks. Thereafter antithrombotic therapy in the immediate post-operative period was according to the surgeon's preference (based on factors which included atrial arrhythmias, volume of suture material and left ventricular function). 22 (55%) patients received warfarin, eight (20%) aspirin and ten (25%) patients had no antithrombotic therapy.

Between March and May 1999, all patients underwent follow-up clinical review with those having the operation within three years also undergoing echocardiography. Information of previous clinical and echocardiographic follow-up of all patients was obtained. Clinical data recorded included NYHA symptomatic class and valve complications. Echocardiographic examinations included two-dimensional inspection of the valve and root for abnormalities in calcification, thickness, stability or structure. Doppler examination assessed mean valve gradient, peak velocity and effective orifice area and the degree of regurgitation was quantified. Left ventricular mass index was calculated by the American Society of Echocardiography (ASE) cube method. Survival follow-up was 100%. Mean duration of follow-up was 29.5±25.5(SD) months (range 4.6 to 75.6 months, median 17.5 months) and totalled 101.6 patient years.

Results

Survival and complications. There were no early (<30 days) deaths. One late death (3%) occurred nine months after operation from non-cardiac carcinoma. Three (8%) patients required re-exploration in the initial post-operative period because of excessive bleeding. One further patient underwent formation of a pericardial window three months after AVR and internal mammary grafting for persistent pericardial effusion. To date there have been no re-operations on the study valve.

At latest follow-up, two (5%) patients were anticoagulated with warfarin (one patient having atrial fibrillation and one cerebrovascular event, one haemorrhagic complication and one case of valve dysfunction. At follow up (range 4.6 to 75.6 months, mean 29.5±25.5) there has been one (3%) late death which was non valve related, one (3%) episode of study-valve endocarditis, and three (8%) thromboembolic episodes. NYHA Class I or II in all but one survivor. Echocardiographic follow-up has shown no further instances of valve dysfunction with satisfactory haemodynamic parameters at 24-months post-operation, and a significant and sustained regression of left ventricular mass.

Conclusions. The initial experience with the Freestyle valve is that it results in good clinical and haemodynamic performance, suggesting it as an ideal bioprosthesis for this patient group.
having had concomitant mitral valve replacement), eighteen (46%) were on aspirin alone (all having concomitant coronary disease), one patient was on dipyridamole alone (due to aspirin intolerance) and two (5%) were on aspirin and dipyridamole (both having had transient ischaemic attacks).

There was one early neurological event occurring at nine days post-operation and consisting of a right homonymous hemianopia one day after the patient was cardioverted for atrial fibrillation. At the time, therapy included aspirin and warfarin with an International Normalised Ratio (INR) of 2.2. Late (>30 days) neurological events have occurred in three (8%) patients - none of whom were on warfarin - all experiencing transient ischaemic attacks. Echocardiographic examination excluded an intracardiac source of thrombus in two and dipyridamole therapy was added to aspirin. The third patient had a suspected cerebral event with a normal CT brain examination and has been maintained on aspirin therapy with no further events. One patient suffered gastrointestinal bleeding from a peptic ulcer one week after operation whilst on warfarin therapy (INR 3.1). A four-unit red blood cell transfusion was required. Another patient also had significant gastrointestinal bleeding from a peptic ulcer one week after operation whilst on warfarin therapy with an International Normalised Ratio (INR) of 2.6. There was one episode of endocarditis from Streptococcus bovis diagnosed two months after AVR and treated with six weeks of intravenous antibiotics. Transoesophageal echocardiography and subsequent transthoracic scans have shown normal bioprosthetic function with no evidence of vegetations or abnormal valve thickening.

Follow-up assessment. At latest follow-up, 30 (77%) surviving patients were in NYHA class I, seven (18%) in class II (all but one of these having improved following AVR) and one patient was in class III - with breathlessness predominantly from mitral stenosis (mean class 1.2). In one further patient, NYHA class could not be assessed (wheelchair bound).

37 (93%) patients had post-operative echocardiography - the three exceptions have deceased, emigrated or declined the investigation. The mean duration to the latest post-operative echocardiography was 22.5±16.7 months (range 4.6 to 72.1 months). 33 patients had follow-up studies within twelve months of operation, 20 patients at 24 months and fourteen at 48 months. Serial postoperative studies have been carried out in only 20 patients with the duration between scans variable. Thus analysis of parameters over time has not been undertaken. At early post-operative examination two patients had central regurgitation - one trivial and one mild. The mild lesion has progressed to mild-moderate at the 48 month post-operative scan but without deterioration in left ventricular end-diastolic dimension (pre-operative 58 mm, at three months after operation 48 mm and at 48-months, 50 mm). There has been no clinical deterioration. A further patient had trivial central regurgitation seen at the 24 month post-operative scan.

For all valve sizes, the haemodynamic parameters at latest follow-up were as follows: peak velocity 1.9±0.6 m/s; mean gradient 6.2±4.4 mmHg; effective orifice area 2.0±0.7 cm²; and effective orifice area indexed to body surface area 1.2±0.4 cm²/m². The haemodynamic parameters over time are shown in Table 2. There was significant change in these parameters over time.

Table 1. Operative data.

<table>
<thead>
<tr>
<th>Implantation method</th>
<th>Inclusion</th>
<th>Scalloped</th>
<th>Semi-scalloped</th>
<th>Root replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>11 (33%)</td>
<td>9 (21%)</td>
<td>7 (18%)</td>
<td>11 (28%)</td>
</tr>
<tr>
<td>Valve size (mm)</td>
<td>19 ± 16</td>
<td>21 ± 19</td>
<td>23 ± 19</td>
<td>27 ± 16</td>
</tr>
<tr>
<td>Number</td>
<td>2 (5%)</td>
<td>2 (10%)</td>
<td>11 (28%)</td>
<td>11 (28%)</td>
</tr>
<tr>
<td>Operative time (mins)</td>
<td>Isolated AVR</td>
<td>AVR + Concomitant procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aortic cross clamp</td>
<td>129 ± 24</td>
<td>145 ± 22</td>
<td>145 ± 22</td>
<td></td>
</tr>
<tr>
<td>Cardiopulmonary bypass</td>
<td>152 ± 30</td>
<td>168 ± 27</td>
<td>168 ± 27</td>
<td></td>
</tr>
</tbody>
</table>

AVR: aortic valve replacement. Operative times are mean ± SD.

Table 2. Haemodynamic parameters over time.

<table>
<thead>
<tr>
<th>Time post-op</th>
<th>Peak aortic velocity (m/s)</th>
<th>Mean gradient (mmHg)</th>
<th>Effective orifice area (EOA) (cm²)</th>
<th>EOA indexed to BSA (cm²/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early n=21</td>
<td>2.6±1.6</td>
<td>10.0±5.2</td>
<td>1.9±0.1</td>
<td>1.1±0.2</td>
</tr>
<tr>
<td>12 months n=21</td>
<td>2.1±0.8</td>
<td>8.1±6.7</td>
<td>2.1±0.7</td>
<td>1.2±0.4</td>
</tr>
<tr>
<td>24 months n=12</td>
<td>2.2±0.5</td>
<td>7.5±6.8</td>
<td>2.1±0.6</td>
<td>1.1±0.4</td>
</tr>
<tr>
<td>36 months n=12</td>
<td>2.1±0.6</td>
<td>7.9±5.2</td>
<td>2.1±0.7</td>
<td>1.2±0.4</td>
</tr>
</tbody>
</table>

Data are mean ± SD. EOA: effective orifice area. BSA: body surface area.

Table 3. Haemodynamic parameters at latest follow-up according to valve size.

<table>
<thead>
<tr>
<th>Freestyle valve size</th>
<th>Small (19,21 mm) n=14</th>
<th>Large (23,25,27 mm) n=26</th>
<th>p-value</th>
<th>Mean gradient (mmHg)</th>
<th>Effective orifice area EOA(cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.4±0.6</td>
<td>1.7±0.4</td>
<td>&lt;0.001</td>
<td>10.4±7.0</td>
<td>1.7±0.6</td>
</tr>
<tr>
<td></td>
<td>2.6±0.6</td>
<td>4.9±1.1</td>
<td></td>
<td>12.0±0.4</td>
<td>2.2±0.8</td>
</tr>
</tbody>
</table>

Data are mean ± SD. EOA: effective orifice area.

Table 4. Left ventricular mass indexed to body surface area.

<table>
<thead>
<tr>
<th>Time post-op</th>
<th>Pre-op</th>
<th>Early</th>
<th>6 months</th>
<th>12 months</th>
<th>24 months</th>
<th>36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVMI (g/m²)</td>
<td>155 ± 53</td>
<td>133 ± 56</td>
<td>122 ± 36</td>
<td>96 ± 39</td>
<td>98 ± 11</td>
<td>91 ± 24</td>
</tr>
<tr>
<td>Number</td>
<td>15</td>
<td>13</td>
<td>13</td>
<td>12</td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>

Data are mean ± SD. LVMI: left ventricular mass index.
Discussion

There are a variety of options for aortic valve prostheses available for use in New Zealand. These include mechanical valves (for example St Jude’s - bileaflet tilting disk, Medtronic Hall - single tilting disk, Starr Edwards - ball and cage), homograft valves, stented porcine valves, pulmonary autografts (the Ross procedure) and the Freestyle stentless porcine valve. Selection of the appropriate valve depends on a variety of factors including: patient age, comorbidity, anticoagulation issues, surgeon experience, clinical setting (eg endocarditis) and the likelihood of repeat surgery. Mechanical valves allow easier implantation and long-standing durability, but require permanent anticoagulation with higher rates of valve-related morbidity than porcine valves.11 Lack of homograft availability limits its widespread use. Porcine valves lack the durability of mechanical valves, but there is not the need for anticoagulation therapy, and so these valves are particularly suited to the elderly population. Compared to stented valves, the stentless prosthesis such as the Freestyle valve offers several advantages. These include the lack of a stent allowing a more physiologic flow profile with improved haemodynamic parameters. This is illustrated in Table 5 by comparison with our experience of the Intact® and the new generation Mosaic (published observations) porcine stented valves over all valve sizes. Furthermore, although the number of patients with the appropriate echocardiographic measurements is small, the regression in left ventricular mass was significant and sustained. The Freestyle root allows flexibility in implant options. Particular problems in the elderly patient include small diameter aortic roots, calcification and discrepancies between the size of the annulus and the sino-tubular junction.10 A small sized stentless valve provides adequate haemodynamic performance without the need for aortic root enlargement. This valve has been implanted in smaller patients, compared to the Mosaic valve, in our institution (body surface area of Freestyle patients 1.7±0.10 versus Mosaic 1.86±0.18, p<0.001), with females comprising the large majority of patients (72% versus 28%). Whilst the peak velocity and mean gradient for the smaller Freestyle valves are significantly inferior to the larger valves in this series, they remain acceptable in terms of haemodynamic performance. Additionally, post-stenotic dilatation can be handled by minirout replacement using the prosthesis itself, as was the case in 28% of this series. This technique is not possible with stented bioprostheses.

The zero 30-day mortality and low rates of subsequent mortality and overall morbidity in this series compare very favourably with other reported series of Freestyle valves,1-4,10 in which follow-up varied from twelve months4 to 36-48 months.3 30-day mortality in those studies ranged from 3.8 - 6.0%. In the largest series Westaby et al concluded long-term survival of the Freestyle root can be dealt with in a versatile manner.

The potential for improved durability lies in the techniques of leaflet and root fixation and antimineralisation previously mentioned. Furthermore, the absence of a frame reduces leaflet stress. Given the numbers and limited follow-up duration, conclusions on long-term valve durability cannot be made. However, there has been no primary structural valve failure to date. Two patients had early postoperative regurgitation (one mild and one trivial). Of note is that even slight undersizing of this valve will result in the commissures being pulled outwards when the aortic root is pressurised, resulting in insufficient regurgitation.10 A potential disadvantage of the stentless valve is the more complex implantation technique that includes a double suture line and often, coronary re-implantation, with consequently longer surgical times. This is certainly the case in our experience with cardiopulmonary bypass and aortic cross clamp times being significantly longer for the Freestyle than the Mosaic valve. However, there is a learning curve involved in any new technique, and the Freestyle times reflect the first 40 patients undergoing this procedure, whereas the implantation of the newer stented valves is not subject to the same learning curve. Improved cardiopulmonary bypass and cardioprotection techniques mean that prolonged surgical times are not as concerning as previously, and may be acceptable if there is potential for improved long-term haemodynamic valve performance.

In regard to study limitations, the patients included represent a non-consecutive series. While all patients underwent elective aortic valve replacement, the influences on the surgical choice of this valve are not known. Clinical and echocardiographic follow-up was not standardised to any protocol. As a result of this, the mean figures for the haemodynamic parameters at latest follow-up do not reflect an average of the figures for each follow-up period. However, there was no significant difference in twelve month haemodynamic parameters between the first 22 and last eighteen patients, although the numbers in each group are small. The late echocardiographic data will be usefully compared with the haemodynamic performance of future prosthetic aortic valves.

In conclusion, the Freestyle stentless porcine bioprosthesis provides a wider choice for patient and surgeon in aortic valve replacement. In our experience, it has been implanted with zero mortality and low morbidity, and with good clinical and excellent haemodynamic performance to date. In the elderly, where prolonged durability is not essential, it appears as an ideal prosthesis, as the need for anticoagulation is obviated and structural variations in the aortic annulus and root can be dealt with in a versatile manner.

Acknowledgements. The authors gratefully acknowledge the contribution of Mr Paget Milsom, who operated on three of the patients in this series.

Correspondence. Dr Malcolm Legget, Cardiology Department, Green Lane Hospital, Green Lane West, Auckland 1005. Fax: (09) 631 0703; Email: malcolmh@ahs.co.nz

Table 5. Green Lane Hospital porcine aortic valves - haemodynamic parameters at 2 years.

<table>
<thead>
<tr>
<th>Valve</th>
<th>Peak velocity (m/s)</th>
<th>Mean gradient (mmHg)</th>
<th>Effective orifice area (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mosaic</td>
<td>2.6 ± 0.5</td>
<td>13.9 ± 6.4</td>
<td>1.7 ± 0.5</td>
</tr>
<tr>
<td>Intact</td>
<td>2.6 ± 0.4</td>
<td>17.0 ± 5.2</td>
<td>1.6 ± 0.5*</td>
</tr>
<tr>
<td>Freestyle</td>
<td>2.2 ± 0.5</td>
<td>7.5 ± 4.8</td>
<td>2.1 ± 0.6</td>
</tr>
</tbody>
</table>

Data are mean ± SD. *4-years post-op.
Job satisfaction, psychological morbidity and job stress among New Zealand general practitioners

Anthony C Dowell, Professor of General Practice; Stephen Hamilton, Medical Student; Deborah K McLeod, Research Manager for General Practice, Wellington School of Medicine, Wellington.

Abstract

Aim. To assess levels of psychological distress and job satisfaction among New Zealand general practitioners.

Methods. A random sample of general practitioners (GPs) in the central region of the North Island were surveyed using a postal questionnaire. Job satisfaction and psychological distress (twelve-item General Health Questionnaire, GHQ-12) were assessed and compared with similar studies in the UK and Australia.

Results. The response rate was 391/480 (81.5%). Job satisfaction scores were generally high. Rural GPs were less satisfied than urban practitioners and solo practitioners less satisfied than those in group practice. Work was perceived as affecting the physical health of 177 GPs (46%) and 220 (57%) often contemplated leaving general practice. 121 GPs (31.4%) scored >3 on the GHQ-12 showing high levels of psychological symptoms and 39 (9.9%) scored greater than eight, indicating significant psychological distress. Major causes of stress and lack of job satisfaction were: excessive paperwork, health reforms and bureaucratic interference, excessive hours and on-call work.

Conclusions. Overall, GPs were satisfied with their jobs. Levels of psychological symptoms were of concern, particularly in the 10% showing very high levels of psychological distress, and in rural and solo practitioners.

Current developments and the rapid pace of change in general practice are creating new challenges and possible sources of stress for GPs. Internationally there is concern about the health and morale of GPs and the effect that lower levels of job satisfaction may have on recruitment and retention. There is evidence from overseas studies that work related stress is contributing to high levels of psychological symptoms and physical symptoms of ill health among GPs. Little is known, however, about the present situation in New Zealand. A recent study by Richards’ identified stress in 61% of a sample of New Zealand doctors and there is evidence of high levels of burnout in rural practitioners. GPs in New Zealand are being subjected to health reforms and changes in working practice which have been a source of stress in other countries. These sources of stress have characteristically included changes both to organisational and regulatory frameworks associated with general practice, leading to new and changing administrative responsibilities, as well as changes to working practice and workload. In the last decade, New Zealand has witnessed changes in health care which have been as rapid and substantive as in any other industrialised country. Changes in government health policy, the introduction of Independent Practitioner Associations, changes to after hours working arrangements and the introduction of accreditation arrangements have all produced a significant impact on general practice. It is within this context that we aimed to assess levels of psychological distress and job satisfaction among New Zealand GPs and to compare findings with similar studies in the UK and Australia and the general population in New Zealand.

Methods

GPs were sampled from a combined MedMedia and Royal New Zealand College of General Practitioners (RNZCGP) membership database of the central health region plus Gisborne, Te Kuiti and New Plymouth. The database was divided into rural and urban, defined by proximity to a base hospital. 288 urban GPs were randomly sampled from the 492 on the database using a random sampler application in Microsoft Excel. All rural GPs in the locality were included to give a total sample of 517.

Numbered postal questionnaires were used to survey the GPs who were assured anonymity. Responses were returned via a prepaid, addressed envelope. Non-responders were posted a single reminder questionnaire after one month. Facsimile or telephone follow-up was used two months after the original mailout.

A four-part questionnaire was used to collect data on job satisfaction, mental health and demographic characteristics. Job satisfaction was measured using nine items from a possible choice of fifteen in the Warr, Cook and Wall job satisfaction scale. The twelve-item General Health Questionnaire (GHQ-12) was used to identify the presence of psychological disturbance and related physical complaints. Data were also collected on the impact of stress, maintaining competency, continued interest in medicine and remaining in general practice. Seven-point Likert rating scales were used to score each item.

Data were entered into a Microsoft Access database. Descriptive statistics were generated using Epi Info software and chi squared tests. Correlation analysis was performed in SAS and Spearman correlation coefficients were used to investigate associations between job satisfaction and demographic data.

Ethical approval was granted by the Wellington Ethics Committee.

Results

Response rate. 37 of the sampled doctors had died, retired, changed address, were on maternity leave or were not GPs, leaving a final sample size of 480. Thirteen were unable to be contacted by telephone or facsimile because of non-listing in the telephone directory. Completed questionnaires were received from 391 GPs, a response rate of 81.5% (391/480). A further six questionnaires were incomplete and seven were received too late to be included in the analysis. Reasons for not completing the questionnaire included: “too busy and under too much pressure”; “hit the wall regarding questionnaires and surveys” and “the answers are my business”. 385 GPs fully completed the GHQ-12 and 377 fully completed the job satisfaction scale. Numbers of respondents may vary in analyses due to missing data. Table 1 shows demographic characteristics of respondents.

Job Satisfaction. Mean and median scores for each item in the job satisfaction scale and total scores are given in Table 2. New Zealand GPs were most satisfied with the amount of variety in their jobs (mean=5.61) and least satisfied with their hours of work (mean=3.91). Female GPs were significantly more satisfied with their hours of work (χ²=19.76; p<0.003), working fewer sessions per week (mean 6.77, SD=2.43) than male GPs (mean = 8.71, SD=1.84). Female GPs also had on average fewer hours on call per month (mean=4.15, SD=6.33) than males (mean=6.39 SD=7.46) (χ²=49.10; p<0.000). General practitioners who worked on call, when...
considered as a group, were significantly less satisfied with the hours worked (mean=3.73, SD=2.79) than non on-call GPs (mean=6.20, SD=0.70), ($\chi^2=238.7$, p < 0.000). Solo practitioners were significantly less satisfied with the job satisfaction dimension regarding colleagues and fellow workers than GPs in partnerships or group practices ($\chi^2=135.84$, p=0.001). Rural GPs were significantly less satisfied with five out of the possible nine job satisfaction dimensions when compared with urban GPs. Predictors of high job satisfaction were increasing age (r =0.14, n=373, p=0.009) and increasing number of years spent in general practice (r =0.16, n=375, p=0.002). Predictors of low job satisfaction were the increasing number of sessions worked per week (r =-0.10, n=373, p=0.046) and the increasing number of nights spent on-call per month (r =-0.19, n=377, p<0.001).

### Table 1. Demographic profile of general practitioners who completed the questionnaire.

<table>
<thead>
<tr>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>276</td>
</tr>
<tr>
<td>Female</td>
<td>115</td>
</tr>
<tr>
<td>Mean Age (years) (SD)*</td>
<td>45.9(9.2)</td>
</tr>
<tr>
<td>25-34</td>
<td>31</td>
</tr>
<tr>
<td>35-44</td>
<td>163</td>
</tr>
<tr>
<td>45-54</td>
<td>129</td>
</tr>
<tr>
<td>55-64</td>
<td>42</td>
</tr>
<tr>
<td>65+</td>
<td>22</td>
</tr>
<tr>
<td>Years in general practice Mean (SD)*</td>
<td>16.0(8.9)</td>
</tr>
<tr>
<td>&lt;6</td>
<td>41</td>
</tr>
<tr>
<td>6-10</td>
<td>83</td>
</tr>
<tr>
<td>&gt;10</td>
<td>265</td>
</tr>
<tr>
<td>Number of FTE general practitioners in practice*</td>
<td>2</td>
</tr>
<tr>
<td>Solo (half-time)</td>
<td>0.5</td>
</tr>
<tr>
<td>Solo (full-time)</td>
<td>116</td>
</tr>
<tr>
<td>1.1-3.0</td>
<td>142</td>
</tr>
<tr>
<td>3.1+</td>
<td>121</td>
</tr>
<tr>
<td>Number of sessions per week*</td>
<td>8</td>
</tr>
<tr>
<td>Median</td>
<td>53</td>
</tr>
<tr>
<td>Mean</td>
<td>82.2</td>
</tr>
<tr>
<td>&lt;6 (part-time)</td>
<td>53</td>
</tr>
<tr>
<td>&gt;6 (full-time)</td>
<td>333</td>
</tr>
<tr>
<td>Length of appointments (minutes)*</td>
<td>5-10</td>
</tr>
<tr>
<td>67</td>
<td>17.2</td>
</tr>
<tr>
<td>11-15</td>
<td>276</td>
</tr>
<tr>
<td>&gt;15</td>
<td>46</td>
</tr>
</tbody>
</table>

*Number of respondents vary due to non-response to some questions

**FTE**: full time equivalents

### Impact on Physical Health.

177 GPs (46%) felt that work had affected their physical health recently. These GPs were least satisfied with the job satisfaction dimension hours of work ($\chi^2=56.67$, p<0.000). However, there were no differences between the mean number of sessions worked per week or nights spent on-call per month between the GPs who felt that work had affected their physical health recently and other GPs. All nine job satisfaction dimensions scored significantly when compared to those GPs who perceived no affect to their physical health.

**Mental Health.** The median GHQ-12 score for the total sample was one (mean=2.58, SD=3.12, range 0-12). Using the cut-off score of 3/4 to define probable cases of psychological disturbance, 121 (31.4%) GPs in our sample would be classed as cases. 38 (9.9%) had GHQ-12 scores of eight or more, a cut off score indicating the probable presence of a more severe psychological disturbance. More rural (37.4%) than urban (28.4%) GPs were probable cases ($\chi^2=3.3$, p=0.07). There was no significant difference in the proportion of probable cases between male (31.6%), and female (31.0%) GPs ($\chi^2=0.02$, p=0.90), and between solo GPs and those working in partnerships or group practices. 52% (89/173) of those who felt their health had been recently affected by their work were probable cases, compared with 15% (31/209) of those who felt their health had not been affected ($\chi^2=58.9$, p=0.001). GPs in the severe psychological disturbance group (GHQ 8-12) had spent significantly fewer years (mean=12.7) in general practice than both other groups (non-case=16.0, mild-moderate case=17.9). Severe cases had significantly less overall job satisfaction (mean=57.2) than both non-cases (mean=47.1) and mild-moderate cases (mean=41.5).

When responses to individual questions of the GHQ-12 were analysed, 44% of GPs indicated they were under rather more or much more constant strain than usual, 32% indicated they enjoyed their normal day to day activities less or much less than usual, and 23.9% indicated they were feeling rather more or much more unhappy and depressed than usual.

**Role as a general practitioner.** 220 (57%) of all GPs surveyed, indicated they sometimes or always contemplated giving up working as a GP because of work related stress. A further 214 (55%) indicated they sometimes or always felt disinterested in medicine because of work related stress and 122 (32%) indicated they sometimes or always felt unable to remain competent in their role as a GP. These figures increased to 76.9%, 72.7% and 48.8% respectively when data were analysed for those who were classed as probable cases of psychological disturbance (GHQ-12 score >4-12).

**Comments.** 175 general practitioners (45%) provided additional information. Included were comments on the types of stressors as well as sources of job satisfaction. The key themes related to excessive paperwork (mentioned 38 times), health reforms and bureaucratic interference (35), excessive hours (12) and on-call work (11). Typical comments included: “Increasing fragmentation is a source of disenchantment”,”While I feel I have always practiced defensive medicine, I feel that I now am continually having to be more defensive”,”PHARMAC is forcing me to alter my prescribing”,”Poor access to specialist investigations and waiting lists are frustrating” and “Questionnaires and other paperwork increase job stress”. Positive comments were made by 23 GPs reflecting satisfaction with their role, for example: “Rural practice is very demanding but rapport with patients very much deeper”; “I love my job” and “I don’t think I would want any other job”.

**Comparison with general practitioners from other countries.** New Zealand GPs scored significantly higher for job satisfaction dimensions (amount of variety in the job, physical working conditions, freedom to choose own methods of working, recognition received for good work and hours of work) than GPs in a similar study in the UK (Table 3). There were no significantly higher scores for UK GPs.

Using a GHQ cut-off score of >4 to denote psychological distress, there was no difference between New Zealand GPs (31.4%) compared to a similar Australian study (30.7%). Significantly higher proportions of GPs were probable cases than that found in the general population in New Zealand (11.5%, $\chi^2=169.3$, p<0.001) (Table 3). Using a comparable cut-off score of 2/3, in the current study New Zealand had significantly lower proportions of GPs classed as probable cases (39.5%) than the UK study (52%, $\chi^2=10.3$, p=0.001). There were significantly higher proportions of probable severe cases in New Zealand GPs (9.9%) than the general population (3.9%) but significantly lower proportions than Australian GPs (12.8%, $\chi^2=62.5$, p<0.001).
This study aimed to assess levels of psychological distress and job satisfaction among New Zealand GPs. A good response rate of 82% was achieved and comparison of the demographic terms the survey is representative of New Zealand general practice. It has been suggested that non-responders in such situations may be more unwell than respondents and hence, it has been suggested that non-responders in such situations may be more unwell than respondents, and hence, the good response rate in this study might be an indication of the level of concern felt by GPs about this issue.

Despite the overall level of satisfaction, over a half of doctors (57%) in the New Zealand survey indicated they often contemplated leaving general practice. Some aspects of the job satisfaction scores highlight potential concern for workforce planning. GPs were less satisfied with solo practice, rural practice and practice which involves out of hours on call. Moreover, rural practitioners were less satisfied than urban colleagues with factors such as the amount of responsibility they were given and the opportunity to use their ability, features which have traditionally been seen as part of the attraction of rural practice. These findings are in keeping with other recent commentary on New Zealand rural general practice. A recent survey of 160 rural GPs found that large numbers of doctors were suffering from high ‘burnout’, displaying features of emotional exhaustion, depersonalisation and low personal accomplishment. It is clear that rural practice requires more support and research to determine appropriate solutions to these problems. No comparable information was available from the general population.

Table 2. Mean scores on the Warr, Cook and Wall job satisfaction scale.

<table>
<thead>
<tr>
<th>Dimensions*</th>
<th>Present study (n=377) Mean (SD)</th>
<th>UK study† (n=285) Mean(SD)</th>
<th>p value</th>
<th>F Statistic‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of variety in job</td>
<td>5.61 (1.24) 6 (5-7)</td>
<td>5.34 (1.51)</td>
<td>0.012</td>
<td>6.37</td>
</tr>
<tr>
<td>Physical working conditions</td>
<td>5.52 (1.34) 6 (5-6)</td>
<td>5.05 (1.75)</td>
<td>0.001</td>
<td>15.31</td>
</tr>
<tr>
<td>Amount of responsibility given</td>
<td>5.41 (1.42) 6 (5-6)</td>
<td>5.42 (1.61)</td>
<td>0.91</td>
<td>0.01</td>
</tr>
<tr>
<td>Opportunity to use your ability</td>
<td>5.37 (1.46) 6 (5-6)</td>
<td>5.21 (1.43)</td>
<td>0.16</td>
<td>1.98</td>
</tr>
<tr>
<td>Colleagues and fellow workers</td>
<td>5.29 (1.11) 6 (5-6)</td>
<td>5.33 (1.41)</td>
<td>0.71</td>
<td>0.14</td>
</tr>
<tr>
<td>Freedom to choose own method of working</td>
<td>5.23 (1.49) 6 (5-6)</td>
<td>4.86 (1.64)</td>
<td>0.003</td>
<td>9.17</td>
</tr>
<tr>
<td>Recognition you get for your good work</td>
<td>4.31 (1.56) 4 (3-5)</td>
<td>3.63 (1.60)</td>
<td>0.001</td>
<td>28.44</td>
</tr>
<tr>
<td>Amount you earn (rate of pay)</td>
<td>4.23 (1.64) 4 (3-6)</td>
<td>4.15 (1.29)</td>
<td>0.61</td>
<td>0.26</td>
</tr>
<tr>
<td>Hours of work</td>
<td>3.91 (1.70) 4 (2-5)</td>
<td>3.48 (1.79)</td>
<td>0.002</td>
<td>9.93</td>
</tr>
<tr>
<td>Total score</td>
<td>44.88 (8.55)</td>
<td>42.42</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Comparison of GHQ-12 scores and proportions of cases of psychological morbidity.

<table>
<thead>
<tr>
<th>GHQ-12 scores (sd)</th>
<th>U.K† (n=285)</th>
<th>Present study (n=385)</th>
<th>LINZ‡ (n=3140)</th>
<th>Aust§ (n=296)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean GHQ-12 scores (sd)</td>
<td>3.86 (3.6) 2.58 (3.12) 1.14 (2.30)</td>
<td>3.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GHQ-12 score 3-12+</td>
<td>52% 39.5% ND ND</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GHQ-12 score 4-12†</td>
<td>31.4% 11.3% 30.7%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GHQ-12 score 5-12+</td>
<td>9.9% 3.9% 12.8%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Each dimension scored 1 to 7, high score = high satisfaction. †F distribution with 1660 degrees of freedom. A comparison of means was used because only mean data were available from the UK study. ‡Results from 1994; Appleton, House and Dowell. §All uncompleted job satisfaction scales were omitted.

Discussion

This study aimed to assess levels of psychological distress and job satisfaction among New Zealand GPs. A good response rate of 82% was achieved and comparison of the sample characteristics with a national survey suggests that in demographic terms the survey is representative of New Zealand general practice. Response rates from GPs to questionnaire surveys are dropping. The good response rate in this study might be an indication of the level of concern felt by GPs about this issue. It has been suggested that non-responders in such situations may be more unwell than respondents and hence, despite the good response rate, the levels of psychological distress found in the study might be an underestimate of the situation in the whole GP population. Overall, levels of job satisfaction were high, and satisfaction scores were higher in New Zealand than the UK and comparable with those of GPs in Australia. In the UK, the introduction of the new GP contract and the introduction of fundholding was a significant focus of professional anxiety and stress. These surveys represent snapshots of general practice carried out several years apart and there may be cultural factors which affect levels of job satisfaction and response to stress. Despite the overall level of satisfaction, over a half of doctors (57%) in the New Zealand survey indicated they often contemplated leaving general practice.

The large number of general practitioners reporting that work was affecting their physical health (46%) is of concern, particularly given the further association with high GHQ scores in that group. Within the sample there may be a
group of doctors coping with the triad of low job satisfaction, significant psychological distress and poor physical health, each of these factors acting deleteriously on the other two.

An important observation was that those exhibiting the highest level of psychological distress (GHQ >8) had spent significantly fewer years in practice. Those finding it hardest to cope are a cohort of younger doctors who have been in practice for a mean of twelve years. It is not clear whether this represents a ‘mid career crisis’ or whether this particular generation of doctors is affected more than comparable cohorts in previous generations. Also of relevance may be the greater financial pressures facing young doctors as a result of both the increased cost of medical training and the decreasing profitability of general practice.

The additional questions addressing the impact of stress on working life provide perhaps the greatest food for thought. Over a half of those sampled sometimes or always contemplated giving up work as a GP because of work related stress, or they had become disinterested in medicine. One third indicated they sometimes or always felt unable to remain competent in their role as a GP. These figures increased considerably when data were analysed for those GPs who were classed as probable cases of psychological disturbance. It is not known how often contemplation of giving up work leads to action or how often feelings of lack of professional competence may represent a real concern over professional standards. It is nevertheless a matter of concern that such large numbers of doctors feel this way.

The qualitative comments helped to illuminate some of the underlying causes of stress and job dissatisfaction. In keeping with other studies, the major concerns identified were: excessive paperwork, health reforms and bureaucratic interference, rather than matters connected directly with patient care. Excessive hours and on-call work were, however, also regarded as stressful. We did not conduct a second phase psychiatric interview, and cannot conclude that all the probable ‘cases’ were suffering from diagnosable psychiatric disorder. Nevertheless, our result suggests worrying levels of symptoms of distress among GPs.

This study has identified significant sources of job stress and problems in the physical and mental well being of GPs. All have direct consequences for the quality of service for patients. Our study supports other recent work in highlighting current difficulties in general practice and shows that the combination of low job satisfaction, poor mental health and poor subjective physical health is a common experience for many GPs.

No attempt was made in the survey to question GPs about strategies they used to cope with stress. Many would no doubt see the solutions to their problems as lying in the hands of others and the results would seem to indicate that government, health care organisations and even professional bodies should examine the degree to which their policies and paperwork are causing stress among GPs. Two other possible solutions to professional stress and job dissatisfaction should be mentioned. The RNZCGP self-care package16 and the Doctor’s Health Advisory Service (DHAS)17 should be considered by doctors seeking support. It is also important for GPs to have their own doctor. It should also be remembered, however, that overall job satisfaction levels were high and many GPs remain extremely contented with their choice of career.

Acknowledgements. We thank Clare Salmon and Rohyn Green for assistance with statistical analysis, Sue Pullon, Marjan Kjäkovic, Lynn McBain and John Durham, General Practice Department, Wellington School of Medicine for their advice, Maureen Dillon at the RNZCGP, Edwin Whiteside at the DHAS and Peter Herbsin who kindly provided additional data from the LINZ survey. Most importantly thanks to the general practitioners who completed the questionnaire. Stephen Hamilton received a summer studentship grant from the RNZCGPs.

Correspondence. Professor Tony Dowell, General Practice Department, Wellington School of Medicine, PO Box 7343, Wellington South.


The chief executive of each trust and health authority should listen to what people in the workforce say and act on it. Clinicians and nursing staff have clear ideas of what is wrong with the present system - but junior medical staff have great difficulty in getting their voices heard. The fear of the adverse reference and being termed a troublemaker are still potent forces within medicine. Nurses speak with their feet; the problems of nursing recruitment and retention are not only related to pay. Consultants have more and more duties pinned on them, but they find that important, crucial decisions affecting how, when, where, and with whom they work are increasingly made by other people, both inside and outside the workplace. They feel that many of these decisions are eroding their ability to retain professional autonomy even within their clinical practice.

Stereotactic breast biopsies for lesions discovered on routine mammography: experience at the North Shore Hospital

PM Mok, Radiologist; Y Keepin, Radiographer, North Shore Hospital, Auckland.

Abstract

Aim. To review the efficacy of stereotactic breast biopsies performed at the North Shore Hospital.

Method. Out of 118 consecutive biopsies carried out between 1992 and 1998, performed on impalpable lesions found on routine mammography, 102 with adequate follow-up data were reviewed, with particular regard to the sensitivity and accuracy of the technique in the diagnosis of breast cancer. The techniques and equipment employed are described.

Results. The results were comparable to those described in the literature, with a sensitivity of 88.9%, specificity of 97.6% and overall accuracy of 97.1%. The procedure was found to be well-tolerated by patients.

Conclusions. The method was found to be accurate, safe and inexpensive.

It is widely accepted that percutaneous biopsies (with or without image guidance) should be carried out on suspicious breast lesions, for exclusion or confirmation of malignancy, before proceeding to open surgical procedures. The majority of cancer diagnoses should be made this way. Stereotactic breast biopsies have been performed at the North Shore Hospital since 1992. The service was set up from the beginning to be a clinical one, rather than for trial or study purposes. Hence only patients strictly requiring this particular method of biopsy were accepted. These were women with breast lesions (nodules, calcifications, abnormal mammographic ‘densities’) suspicious for malignancy which were not possible to biopsy adequately by other non-surgical means (ie by palpation or ultrasound guidance). The technique we use has evolved through several phases as the operators learned from their experience.

Methods

118 stereotactic breast biopsies were performed at the North Shore Hospital from 1992 to 1998, and 102 were included in this review. Sixteen cases were excluded because of lack of follow-up data. All lesions were impalpable and discovered on routine mammography. All biopsies were performed by the first author (PMM), with the second author (YK) being the principal radiographer (out of six) responsible for the procedure. 25 patients had surgical confirmation and 68 had radiological/clinical follow-up of six months to five years (average seventeen months). The remaining nine had pathological diagnoses which were considered conclusively benign and were discharged to the care of their own doctors.

All biopsies were performed on a General Electric stereotactic device (“Stereotix”), purchased as an inexpensive attachment to a standard mammography machine. Nearly all biopsies were carried out with the patients seated in an erect position. Three patients with a high degree of anxiety were biopsied lying on their sides in decubitus positions. Initially only fine needle aspiration (FNA) biopsies were done for cytology (24 cases). It is now our routine to start with FNA’s, which are immediately assessed by a cytologist on site, and then routinely proceed to 18G core biopsies. The sensitivity of 88.9%. There were two false positives from the early period when only FNA’s were performed – both had cytology interpreted as mildly suspicious for DCIS but had benign excision biopsies. The specificity was 97.6% and overall accuracy 97.1%. The only false negative involved a small group of mildly suspicious microcalcifications which yielded negative cytology and core biopsy histology (“florid epithelial hyperplasia with coarse ductal calcifications”). Excision was carried out on mammographic criteria, revealing the presence of two types of calcifications: malignant calcifications due to DCIS as well as benign calcifications. The case illustrates the point that management must take into account radiological findings and clinical factors, and not be based on biopsy findings alone.

Results

The results are summarised in Tables 1 to 3. Of the seventeen cancers (nine invasive, eight ductal carcinoma-in-situ (DCIS)), sixteen returned positive biopsies for a sensitivity of 88.9%. There were two false positives from the early period when only FNA’s were performed – both had cytology interpreted as mildly suspicious for DCIS but had benign excision biopsies. The specificity was 97.6% and overall accuracy 97.1%. The procedure was found to be well-tolerated by patients.

Conclusions. The method was found to be accurate, safe and inexpensive.

Table 1. Results of biopsies.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>True Positive</td>
<td>16</td>
</tr>
<tr>
<td>True Negative</td>
<td>81</td>
</tr>
<tr>
<td>False Positive</td>
<td>2</td>
</tr>
<tr>
<td>False Negative</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
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</tbody>
</table>

Table 2. Diagnostic Accuracy.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>88.9%</td>
</tr>
<tr>
<td>(16/17)</td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>97.6%</td>
</tr>
<tr>
<td>(83/85)</td>
<td></td>
</tr>
<tr>
<td>Overall accuracy</td>
<td>97.1%</td>
</tr>
</tbody>
</table>

Table 3. Analysis of final pathology.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Benign</td>
<td>85 (83.3%)</td>
</tr>
<tr>
<td>Malignant</td>
<td>17 (16.7%)</td>
</tr>
<tr>
<td>-DCIS</td>
<td>8</td>
</tr>
<tr>
<td>-Invasive</td>
<td>9</td>
</tr>
</tbody>
</table>

DCIS indicates ductal carcinoma-in-situ.

Notably, FNA was positive in fifteen of the sixteen cancers detected. In the remaining one, a small focus of DCIS on the core specimen was in fact an incidental finding, unrelated to the targeted calcifications which were found to be benign. Core specimens did add useful information in two positive cases (invasive nature of carcinomas confirmed) and provided conclusive diagnoses in benign lesions.
Nutritional supplement usage among 26-year-olds

Tracie Allen, Final-year student, School of Pharmacy; W Murray Thomson, Senior Lecturer, Department of Oral Health, School of Dentistry; Lynne M Emmerton, Lecturer, School of Pharmacy; Richie Poulton, Director, Dunedin Multidisciplinary Health and Development Research Unit, School of Medicine, University of Otago, Dunedin.

Abstract

Aims. To estimate the prevalence of use of nutritional supplements among young adults, to examine the source of those supplements and to investigate sex differences in usage.

Methods. Participants in the age-26 years assessments of the Dunedin Multidisciplinary Health and Development Study were asked to bring containers for any medication (including supplements) taken in the previous two weeks. Medication data (including prescription source) were recorded and analysed for 978 of 980 Study members.

Results. The prevalence of supplement use was 16.6%; 20.4% among females and 13.3% for males (p<0.01). Multivitamin preparations were the most widely consumed, followed by water-soluble vitamin supplements (such as folate and vitamin C). Folate use was higher among females and was taken by 35.7% of pregnant females. Most supplements were self-prescribed, although a doctor had prescribed over one-third of the mineral supplements. Most supplements had been taken for weeks or months, rather than years.

Conclusions. Nutritional supplement usage among young adults is reasonably common, and involves a wide range of preparations. The extent of use among younger people suggests a need for regulation of their manufacture, sale and usage, and research to examine their efficacy.
were taking a multivitamin/mineral supplement. Nearly all studies of older people have reported multivitamins or single-vitamin preparations to be the most commonly consumed supplement, although one reported single-mineral preparations to be the most prevalent among older Americans. It has been reported that the use of mega-dose vitamins was common among American nurses. Strong socioeconomic associations with supplement use have been noted, with greater use among those with higher income and education levels.

There are currently no data on supplement use by adults in their mid-twenties, yet there are a number of reasons why such information would be of interest. First, many females in this age group have started or are contemplating having children, and it is generally accepted that periconceptional folate prevents a substantial proportion of neural tube defects. Moreover, folate taken during pregnancy especially during the latter half of pregnancy helps eliminate megaloblastic anaemia in the mother.

Estimation of the extent of folate usage among pregnant females was not possible owing to the lack of information on folate usage, and the duration of use.

Medication data were collected during the general medical examination: participants were asked to bring the containers for all medications (including any supplements) taken in the previous two weeks, and the details were systematically recorded by either a registered nurse or a registered medical practitioner. Where an individual had forgotten to bring his/her medication, either a follow-up phone call was made or the participant was assessed within one month of their third birthdays. Compared to the rest of the New Zealand population, the DMHDS sample is slightly advantaged socio-economically.

Ethical approval for the data collection at 26 years was obtained from the Ethics Committee of the (then) Southern Regional Health Authority. Participants signed an informed consent statement approved by that Committee.

Medication data were collected during the general medical examination: participants were asked to bring the containers for all medications (including any supplements) taken in the previous two weeks, and the details were systematically recorded by either a registered nurse or a registered medical practitioner. Where an individual had forgotten to bring his/her medication, either a follow-up phone call was made or the person’s recall was relied upon. Each medication was assigned a five-digit numeric code using the MedCap system, which was used because of the ease of analysis afforded by its five-digit numeric, hierarchical coding structure. Other details recorded were the prescriber, the source of medication information, the dose (where available) and frequency of usage, and the duration of use.

An estimate of social class was obtained by using data collected at age fifteen years on parental socio-economic status (SES), using the occupation-based Elley-Irving indices which use a six-interval classification (where, for example, a medical doctor scores ‘1’ and a labourer scores ‘6’). The estimate for the male parent was used where possible, and if there was no male parent, or he was unemployed) that for the female parent was used. In the analysis, the scores were used to allocate each participant to a high (code 1 or 2), medium (3 or 4) or low (5 or 6) SES group.

Data were entered into an electronic database and analysed using SPSS. Statistical significance was tested using the Chi-squared test, and the alpha value was set at 0.05.

Results

A total of 980 (96.2%) of the surviving 1019 Study participants were assessed at Phase XXVI of the DMHDS, and data on medication use were collected from 978. There were 479 (49.0%) women and 499 (51.0%) men. Some 162 individuals (16.6%) had taken at least one nutritional supplement in the previous two weeks, and this was higher among females than males (20.4% and 13.1% respectively, p<0.01). There were no significant differences by socioeconomic grouping, with the prevalence of supplement use in Elley-Irving groups 1-2, 3-4 and 5-6 being 19.3%, 17.8% and 15.8% respectively (X²=0.81; 2df; p=0.67). The mean number of supplements taken was 0.24 (SD, 0.62) overall, and 1.46 (SD, 0.73) among those who were taking one or more. Most (106, or 65.4%) of the latter took only one supplement, while 40 (24.7%) took two, and fourteen (8.6%) took three. One participant took four supplements and one consumed five.

The prevalence of use of the various supplement types by sex is shown in Table 1. Multivitamin preparations were the most widely consumed supplement type (8.5% of the total sample, or 51.2% of the 162 supplement users). Water-soluble vitamin preparations were the second most widely consumed type of supplement (5.4 and 32.7% respectively). The third most prevalent supplement type was the mineral supplements (2.6 and 15.4% respectively, followed by the botanical, micro-organism and bee products category (2.5 and 14.8% respectively). None of the remaining supplement forms was commonly reported.

<table>
<thead>
<tr>
<th>Product type</th>
<th>All</th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamin preparations</td>
<td>81 (8.5)</td>
<td>18 (7.6)</td>
<td>63 (9.4)</td>
</tr>
<tr>
<td>Water-soluble vitamin supplements</td>
<td>53 (5.4)</td>
<td>20 (4.0)</td>
<td>33 (6.0)*</td>
</tr>
<tr>
<td>Mineral supplements</td>
<td>25 (2.6)</td>
<td>5 (1.0)</td>
<td>20 (4.2)*</td>
</tr>
<tr>
<td>Botanical, micro-organism and bee products</td>
<td>24 (2.5)</td>
<td>11 (2.2)</td>
<td>13 (2.7)</td>
</tr>
<tr>
<td>Garlic supplements</td>
<td>13 (1.3)</td>
<td>4 (0.8)</td>
<td>9 (1.8)</td>
</tr>
<tr>
<td>Oils</td>
<td>9 (0.9)</td>
<td>3 (0.6)</td>
<td>6 (1.3)</td>
</tr>
<tr>
<td>Bran/fibre supplements</td>
<td>5 (0.5)</td>
<td>1 (0.2)</td>
<td>4 (0.8)</td>
</tr>
<tr>
<td>Other supplements</td>
<td>5 (0.5)</td>
<td>2 (0.4)</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>Fat-soluble vitamin and beta-carotene supplements</td>
<td>2 (0.2)</td>
<td>0 (0.0)</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td>Sports supplements</td>
<td>6 (0.6)</td>
<td>1 (0.2)*</td>
<td>5 (1.0)</td>
</tr>
</tbody>
</table>

*p<0.05, prevalence higher among females than males; †p<0.01 prevalence higher among females than males.

The number of people using the subcategories of the most prevalent supplement categories is presented in Table 2 (it should be noted that the percentages in Tables 1 and 2 do not exactly correspond because some individuals took more than one subcategory of some supplements). Among the water-soluble vitamins, folate and vitamin C were the most widely used, while iron was the most common mineral supplement. Herbal remedies were the most frequent subcategory of the botanical products. The only sex differences were apparent with folate and pharmacological dose iron, which were taken only by females.

31 (6.5%) of the 479 women in the sample were pregnant at the time of the interview, and more of them consumed a mineral supplement than non-pregnant women (12.9% and 3.6% respectively, p<0.05). Iron supplements and pharmacological-dose calcium were the mineral supplements that pregnant women were more likely to consume. The prevalence of watersoluble vitamin supplement consumption was higher among pregnant than non-pregnant women (32.3% and 5.1% respectively, p<0.01). Among those water-
soluble vitamins, folate use was higher among pregnant than non-pregnant women (32.3% and 0.7% respectively, p<0.01). Of the ten pregnant women taking folic acid, five had self prescribed and five had it prescribed by their doctor. Information on the stage of pregnancy was available for eight of the women taking folate: three were in the first trimester and five in the second or third trimesters.

<table>
<thead>
<tr>
<th>Table 2. Prevalence of use of subcategories of the four most prevalent supplements, by sex (%).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product type</td>
</tr>
<tr>
<td>Multivitamin in preparations</td>
</tr>
<tr>
<td>Multivitamins</td>
</tr>
<tr>
<td>Other multinutrient preparations</td>
</tr>
<tr>
<td>Antioxidant nutrient preparations</td>
</tr>
<tr>
<td>Water-soluble vitamin supplements*</td>
</tr>
<tr>
<td>Vitamin B6</td>
</tr>
<tr>
<td>Vitamin B 12</td>
</tr>
<tr>
<td>Folate</td>
</tr>
<tr>
<td>Vitamin B complex</td>
</tr>
<tr>
<td>Vitamin C</td>
</tr>
<tr>
<td>Mineral supplements§</td>
</tr>
<tr>
<td>Calcium</td>
</tr>
<tr>
<td>Pharmacological dose calcium</td>
</tr>
<tr>
<td>Iron</td>
</tr>
<tr>
<td>Pharmacological dose iron</td>
</tr>
<tr>
<td>Zinc</td>
</tr>
<tr>
<td>Botanical, micro-organism and bee products§</td>
</tr>
<tr>
<td>Herbal remedies and other plant extracts</td>
</tr>
<tr>
<td>Spirulina</td>
</tr>
<tr>
<td>Bee product</td>
</tr>
</tbody>
</table>

*No individuals taking thiamin, riboflavin, niacin or pantothenic acid; †p<0.01 prevalence among females than males; ‡No individuals taking magnesium, potassium or selenium supplements; §No individuals taking acidophilus or brewers yeast; ‡P numbers taking subtypes of the herbal remedies were Echinacea (8 individuals), Ginseng (2), St John’s Wort (3), Ephedra (1), Guarana Lift (3), Bach Flower Rescue Remedy (1), Nodouze (2), and Cranberry Concentrate tablets (1).

Discussion

The proportion of participants using a supplement in the two weeks prior to the interview was surprisingly high, at 16.9%. It is possible, however, that the proportion of ‘ever-users’ was somewhat higher because the question used at interview referred only to the previous two weeks. The 1997 New Zealand National Nutrition Survey examined supplement usage within the previous year, and reported that 61.6% of nineteen to 24 year-olds had taken a vitamin/mineral supplement, and other supplement types had been taken by 25.3%, indicating that prevalence estimates for supplement usage are dependent on the approach taken.

That one in six individuals had used supplements in the previous two weeks raises two important issues. First, how appropriate was the choice of those supplements? A recent USA study of over 10 000 individuals reported that supplement users consumed substantially higher levels of some nutrients from dietary sources than non-users, but that only 17% of men and 10% of women supplement users received 80% or more of the recommended daily allowance of five key nutrients. Whether supplement use arises out of medical need remains unanswered from those data. Second, the efficacy of those preparations should be closely examined, but is beyond the scope of this paper. The cohort study design of the DMHDS has the potential to investigate the long-term effects and associations of nutritional supplement use in future data collections.

Multivitamin preparations were the most commonly consumed supplement type, which is consistent with the findings of other studies. However, the prevalence of use in those studies for the 25-34 age group was twice that reported here. This may be due to the difference in age groups or it may reflect differences between New Zealanders and Americans in the use of these preparations. In the current study, a substantial number of the mineral preparations and the mineral supplements.

The finding that more women than men consumed any type of supplement has been reported elsewhere, although the sex difference was not consistently observed in all supplement categories. The higher consumption of mineral supplements by women was due to their greater use of iron and calcium. Water-soluble vitamins were also consumed more by women than men, largely due to the taking of folic acid by pregnant women. It is noteworthy...
that, when the analysis was repeated without the pregnant females, only the mineral supplements showed a significant difference by sex. Sports supplements were the only category in which usage by males exceeded that by females.

This study provides the first New Zealand data on the use of supplements by pregnant women (albeit a small sample). More pregnant participants consumed a water-soluble vitamin than those who were not, and this was due to the use of folate, whether doctor or self-prescribed. It has been shown that periconceptional folate prevents a substantial proportion of neural tube defects, and folate taken during pregnancy, especially during the latter half of pregnancy, helps eliminate megaloblastic anaemia in the pregnant woman. It is not surprising therefore, to find that folate supplement use was observed approximately equally across the trimesters, but there is cause for some concern in the observation that only one-third of pregnant women were taking it. One non-pregnant woman was taking a folate supplement; this may have been in anticipation of pregnancy. More pregnant women were using iron and calcium supplements than non-pregnant women. The iron requirements of pregnancy exceed the iron stores of most women of childbearing age, and the use of such supplements can help prevent a deficiency occurring, especially during the latter half of pregnancy. Pregnancy is also a time of increased calcium demand, as the developing fetus, for its term, will have deposited 30g of calcium in its own skeleton, most of this in the last ten weeks of pregnancy. As most women do not meet their daily calcium needs through diet alone, and pregnancy places an increased demand on stores, it is common for calcium supplements to be taken.

Herbal remedies and other plant extracts were also relatively widely used, and this may be due to popular perceptions of their efficacy as alternatives to conventional medical therapy, particularly for illnesses such as depression. The relatively longer period of usage for oils, garlic, multivitamin/mineral and mineral supplements may be due to their being used as general preventive agents, rather than as treatment for specific conditions.

Although associations between socioeconomic status (SES) and supplement use have been previously reported, no such relationship was observed in the current study, suggesting that either SES is not a modifier of supplement use on young New Zealanders, or perhaps that household SES at age fifteen years is not a robust predictor of future use of medications.

In summary, it is evident that nutritional supplement usage among young New Zealanders is reasonably common, and involves a wide range of preparations. In view of the substantial economic implications of supplement usage, not only for the pharmaceutical and alternative medicines industries but also for the country as a whole, future pharmacoepidemiological research should examine such as the need for regulation of nutritional supplement manufacture, sale and usage, as well as research to examine their efficacy and association with health status.

Acknowledgements. The Dunedin Multidisciplinary Health and Development Research Unit is supported by the Health Research Council of New Zealand. Medication data collection was partially funded by a New Zealand Heart Foundation Grant to Dr Poulton. Data collection was partially supported by US Public Health Service grant MH-45070 from the National Institute of Mental Health. The authors are indebted to former Study Director Dr PA Silva, and to the Study members for their continued support and participation. Tracie Allen was supported by a University of Otago Pharmacy Summer Studentship.

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Book Review

Handbook of Biostatistics: A Review and Text.


The preface to this book begins “Why yet another textbook of Biostatistics?” The author then justifies this text on the basis that the vast majority of textbooks in the area are either too long and technical or too short and superficial. Therefore, there is a need for a text that provides a sufficient “treatise that will explain the specific statistical analyses needed, without going into extreme technical detail”. A genuine dearth is identified and the text very laudably attempts to meet this need. In the main this goal is achieved. It is largely written in an engaging, non-technical style and covers the full spectrum of descriptive and inferential univariate techniques in around 100 pages. The ‘take-home’ messages and questions and worked answers at the end of each chapter usefully highlight key aspects of the text. However, this ‘no-mans land’ between too long and technical and too short and superficial is not an easy place to tread. Some areas (eg power analysis and ANOVA) provide too little explanation and are therefore only likely to confuse, and other areas (eg odds ratios) include perhaps too much detail given the text’s aim.

Despite these inevitable shortcomings, by and large the author (a Professor of Medicine, no-less) achieves his stated aim with a text that can be used as a quick reference or for self-study, rather than as treatment for specific problems. How large the likely readership is for such a text and what purpose it might serve in enhancing statistical standards are perhaps questions worth pondering. Notably, the text contains a number of factual errors (eg confusing p-values and α levels), confusing the processes (eg linear regression and correlation) and many typographical errors, suggesting appropriate statistical editing was not undertaken.

Despite the shortcomings, this text provides an accessible introduction to a comprehensive range of statistical methods. However, it can only really be recommended to those who read, or read about statistics, rather than those intending to practice the noble art.

Dr CM Frampton, Christchurch.
Infectious intestinal diseases are caused by a wide range of microbiological pathogens and their toxins, some of which may be transmitted by food. Foodborne infectious disease is a major public health problem in all countries. In New Zealand the reported number of cases is increasing.\(^1\)

Estimates of the number of cases of foodborne infectious disease are needed to assess their economic impact and the status of food safety generally, and to help prioritise this problem for control purposes. Such estimates are difficult to make due to the high proportion of cases which do not come to the attention of the health system, and the fact that for the potentially foodborne infectious diseases, only a proportion of the cases will have actually been caused by pathogens transmitted by food.

As part of a project to estimate the economic burden of foodborne infectious disease in New Zealand we have gathered information on illnesses caused by potentially foodborne pathogens.

**Methods**

From the pathogens or toxins which may be transmitted by food\(^2\) we identified ten potentially foodborne infectious diseases as particularly important in New Zealand. These are: campylobacteriosis; salmonellosis; shigellosis; yersiniosis; listeriosis; verotoxigenic *Escherichia coli* (VTEC) infection; typhoid fever; hepatitis A infection; illness caused by toxins produced by *Clostridium perfringens*, *Bacillus spp.*, or *Staphylococcus aureus*, as well as unspecified food poisoning; and small round structured virus (SRSV) infection (Norwalk like viruses). The number of cases of these diseases were defined in terms of the following outcomes:

- do not present to the public health system (unreported) and recover in the community
- visit a general practitioner (GP) but not hospitalised, and recover in the community
- hospitalised (assume prior GP visit) with the following outcomes:
  - recover
  - long term illness
  - death

For campylobacteriosis, salmonellosis, yersiniosis, shigellosis, VTEC infection, and illness caused by bacterial toxins, it was assumed that the majority of cases would be self-limiting and unreported, with a proportion requiring a visit to a GP, and a smaller proportion admitted to hospital. For listeriosis, typhoid fever, and hepatitis A, it was assumed that all cases would come to the attention of the health system and there would be no unreported cases. For SRSV infection it was assumed that all cases were either self limiting and unreported, or else only requiring a visit to a GP, that is, no hospitalised cases.

The primary sources of data for this study were communicable disease notifications\(^3\) and Ministry of Health New Zealand Health Information Service (NZHIS) public hospital discharge unit record data. Private hospital data showed very few cases of acute gastrointestineal disease,\(^4\) so were not included.

The intention of this study was to provide a realistic and up to date estimate of the number of cases of foodborne infectious disease in New Zealand. For diseases where the number of cases has increased in recent years (campylobacteriosis, salmonellosis, yersiniosis, VTEC infection) we used the most recent information (1998 notification and 1997 hospitalisation data). For diseases where the number of cases is relatively low (hepatitis A infection, typhoid fever, listeriosis, shigellosis), averages from notification data for 1991-1998, and hospitalisation data from 1991-1997 were used. Numbers of long term illness cases and deaths were averages from NZHIS data for 1991-1997.

The number of hospitalised cases was obtained by examining assigned International Classification of Diseases (ICD) codes in sequence until a relevant disease code was found. Readmissions for the same disease within 365 days were excluded as these might have been for the same episode of infection. The number of long term illness cases was obtained by counting cases with a relevant ICD code, whether or not this occurred in conjunction with a gastrointestinal disease code. Long term illness admissions were considered a separate event after the initial admission for gastrointestinal illness. Long term illness cases, and deaths, were deducted from the hospitalised disease cases, the remainder of which were assumed to recover.

The number of cases of the 'visit a general practitioner but not hospitalised' outcome category was derived by subtracting the number of hospitalised cases from the number of notified cases.\(^1\) An under-notification correction was applied of 10% for salmonellosis, shigellosis and yersiniosis, and 20% for campylobacteriosis, based on isolate typing data\(^5\) and an investigation into *Campylobacter* infection.\(^6\)

The proportion of potentially foodborne infectious disease that does not come to the attention of the public health system was estimated using...
information from a recent prospective study of infectious intestinal disease in England. After a search of the published literature, we considered that this study was the most rigorous assessment of community rates of such illnesses. Studies of this type have not been carried out in New Zealand, and there are many similarities between the New Zealand and United Kingdom infectious disease surveillance systems.

The English study found that the ratio of cases in the community to cases reaching national surveillance depended on the pathogen. For salmonellosis and campylobacteriosis the ratios were 3.2:1 and 7.6:1 respectively. We used the quoted ratios for salmonellosis and campylobacteriosis, and applied the mid-range of those ratios of 5:1 for yersiniosis and shigellosis.

Hospitalised cases of ‘food poisoning’ by the various bacterial toxins were added to cases coded to ‘unspecified food poisoning’ (ICD code 005.9). However, as these are not notifiable diseases, no New Zealand information was available regarding the number of GP visits or community cases. We used the combined rates of disease due to 

\[ \text{Clostridium perfringens} \]

enterotoxin and

\[ \text{Staphylococcus aureus} \]

reported in the English study for the number of community and GP visits (267 and 146 cases per 100 000 population respectively). The same approach was used for infection with SRSV which is also not notifiable in New Zealand (130 community cases and 199 GP visits per 100 000 population).

Information on the number of cases of various outcomes from VTEC infection was taken from a recent detailed analysis of this disease in New Zealand.8

Of the secondary long-term illnesses that can develop after infectious intestinal disease, this study included haemolytic uremic syndrome (HUS) after VTEC infection, reactive arthritis, and Guillain Barré syndrome (GBS).9

It was assumed that 10% of hospitalised reactive arthritis cases were the result of prior infection with a foodborne pathogen, based on previous studies.10,11 These cases were then attributed to each potential triggering pathogen, based on the relative number of notified cases. We assumed that 25% of cases of GBS could be attributed to prior infection with 

\[ \text{Campylobacter jejuni} \]

based on overseas studies.12,13 These proportions are the same as used in a study of the costs of campylobacteriosis in Canterbury in 1995.14

The average length of hospital stay was derived from NZHIS data. It was assumed that both potentially foodborne infectious disease and long term illness patients experienced an equal period of illness outside hospital, before and/or after hospitalisation. Studies in the United States have used either one or two days spent recuperating at home for each day spent in hospital.15 The length of illness for non-hospitalised cases was generally taken as the midpoint of ranges given in standard texts on foodborne pathogens.16,17 In the absence of information on the length of illness for listeriosis and hepatitis A infection we used the same period as for hospitalised cases.

A 1994/95 study of campylobacteriosis in New Zealand found that the duration of illness ranged from one to sixteen days with a median of seven days.18 This matches the period derived here for hospitalised cases, but we chose to use a slightly shorter period of five days for non-hospitalised cases.

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Toxigenic Campylobacter jejuni

\[ \text{Campylobacter jejuni} \]

\[ \text{Salmonella} \]

\[ \text{Shigella} \]

\[ \text{Yersinia} \]

\[ \text{Listeriosis} \]

\[ \text{VTEC} \]

\[ \text{Typhoid} \]

\[ \text{Hepatitis A} \]

\[ \text{Toxins} \]

\[ \text{SRSV} \]

<table>
<thead>
<tr>
<th>Disease</th>
<th>Campylobacteriosis</th>
<th>Salmonellosis</th>
<th>Shigellosis</th>
<th>Yersiniosis</th>
<th>Listeriosis</th>
<th>VTEC</th>
<th>Typhoid</th>
<th>Hepatitis A Toxins</th>
<th>SRSV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially foodborne intestinal disease cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not visit a GP</td>
<td>102 098</td>
<td>6957</td>
<td>693</td>
<td>2920</td>
<td>0</td>
<td>200</td>
<td>0</td>
<td>0</td>
<td>9880</td>
<td>46 019</td>
</tr>
<tr>
<td>Visit a GP but not hospitalised</td>
<td>15 634</td>
<td>2172</td>
<td>139</td>
<td>584</td>
<td>7</td>
<td>23</td>
<td>3</td>
<td>215</td>
<td>5375</td>
<td>7326</td>
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<tr>
<td>Hospitalised and recover</td>
<td>354</td>
<td>93</td>
<td>22</td>
<td>16</td>
<td>9</td>
<td>4</td>
<td>13</td>
<td>44</td>
<td>11</td>
<td>51</td>
</tr>
<tr>
<td>Hospitalised and long term illness</td>
<td>27.5</td>
<td>41</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>25</td>
<td>47.6</td>
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<td>Deaths</td>
<td>0.7</td>
<td>0</td>
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<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
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<td>Total</td>
<td>115 915</td>
<td>9218</td>
<td>854</td>
<td>3520</td>
<td>16</td>
<td>248</td>
<td>16</td>
<td>259</td>
<td>15 256</td>
<td>53 345</td>
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<tr>
<td>Proportion foodborne (%)</td>
<td>65</td>
<td>92</td>
<td>30</td>
<td>65</td>
<td>90</td>
<td>20</td>
<td>80</td>
<td>5</td>
<td>100</td>
<td>33</td>
</tr>
</tbody>
</table>

| Foodborne intestinal disease cases | | | | | | | | | | |
| Do not visit a GP | 66 364 | 6396 | 208 | 1898 | 0 | 40 | 0 | 0 | 9830 | 15 186 | 99 922 |
| Visit a GP but not hospitalised | 8732 | 1998 | 42 | 380 | 6 | 5 | 2 | 11 | 5375 | 2418 | 18 969 |
| Hospitalised and recover | 230 | 86 | 7 | 10 | 1 | 10 | 5 | 1 | 51 | 1 | 405 |
| Hospitalised and long term illness | 17.9 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 21.9 | |
| Deaths | 1.1 | 0.6 | 0 | 0 | 0.4 | 0.2 | 0 | 0 | 0 | 0 | 2.3 |
| Total | 75 345 | 8481 | 257 | 2288 | 14 | 50 | 12 | 13 | 15 276 | 16 704 | 119 320 |

* Data have been rounded to whole numbers of cases except for long term illness and deaths. Because of rounding individual items may not add exactly to the totals shown.

† Illness caused by toxins produced by 

\[ \text{Clostridium perfringens} \]

\[ \text{Bacillus} \]

\[ \text{Clostridium perfringens} \]

\[ \text{Staphylococcus aureus} \]

 Besides as well as unspecified food poisoning.

GP = General Practitioner VTEC = verotoxigenic Escherichia coli SRSV = small round structured virus.

Table 1. Estimated annual number of cases of potentially foodborne infectious disease and foodborne infectious disease in New Zealand.*
intestinal diseases in New Zealand could then be broadly estimated as up to approximately 823 000 cases annually (224 per 1000 population).

Discussion

An estimated 119 000 cases of infectious intestinal disease per year are caused by foodborne transmission of pathogens and this points to a significant public health burden, despite the fact that the vast majority of these illnesses are not severe.

This assessment has a number of limitations. The most important is the extensive use of findings from a study carried out in England that provided data which are not available in New Zealand. The estimates of cases caused by non-foodborne pathogens and cases in which no pathogen is identified are uncertain, although New Zealand rates of notified cases of infection with Cryptosporidium parvum and Giardia intestinalis are similar to those found for England. The estimates of the proportion of potentially foodborne infectious disease that are actually foodborne are derived largely from United States empirical assessments, which may not be appropriate for New Zealand, in particular for campylobacteriosis.

There have been three retrospective New Zealand studies which examined the total prevalence of food poisoning. They found that the percentage of the population who believed they had experienced food poisoning over the previous year was in the range 9-28%. Our estimate of 3.2% seems reasonable given that retrospective surveys tend to give markedly higher estimates of the number of cases of intestinal disease than do prospective studies, and self-reported food poisoning may actually be due to infection by other transmission routes.

There is evidence that gastrointestinal disease from SRSV infection is as common as that caused by bacterial enteric pathogens in New Zealand. SRSV was the most commonly identified pathogen in gastrointestinal disease outbreak cases in New Zealand in 1998. A study of current laboratory investigation practices of GPs in New Zealand indicated that common source outbreaks of viral gastroenteritis are unlikely to be recognised.

The number of days lost to foodborne infections may be an overestimate. The length of illnesses generally relate to the presence of symptoms, and it is likely that many cases will not absent themselves from work for this whole period. Conversely if the number of cases has been underestimated then our estimate of days lost to illness could be very conservative.

These data identify a number of areas where further research would be useful. First, quantification of the incidence of sporadic SRSV infection and food poisoning by bacterial toxins. Second, further investigation into the vehicles for transmission of VTEC. Third, clarification of the importance of different transmission routes for each pathogen. Finally, clarification of the role of infectious intestinal diseases in secondary long term illness.

Acknowledgements

Funding for this work was provided by the Health Research Council of New Zealand. We are grateful to Dr Michael Bates of ESR Kenepuru Science Centre for helpful comments on the manuscript.

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15. Australian Institute of Food Science and Technology. Foodborne microorganisms of public health significance. Australia: Australian Institute of Food Science and Technology (NSW Branch); 1997.
Economic cost to New Zealand of foodborne infectious disease

W Guy Scott, Senior Lecturer, Massey University at Wellington; Helen M Scott, Independent Consultant, Wellington; Robin J Lake, Scientist, Food Group, Institute of Environmental Science and Research Ltd, Christchurch; Michael G Baker, Public Health Physician, Epidemiology Group, Institute of Environmental Science and Research Ltd, Porirua.

Abstract

Aims. To estimate the annual economic cost to New Zealand of foodborne infectious disease.

Methods. Annual incidence rates were combined with unit cost data to derive estimates of the annual economic cost to society of each foodborne infectious disease. Market prices and wages were used as proxies for the unit costs of resource utilisation. A decision analytic model was developed to estimate the costs of each disease and to undertake sensitivity analysis.

Results. There are an estimated 119 320 episodes of foodborne infectious disease per year in New Zealand (3241 per 100 000 population). The total cost of these cases was $55.1 million ($462 per case) made up of direct medical costs of $2.1 million, direct non-medical costs of $0.2 million, indirect cost of lost productivity of $48.1 million, and intangible cost of loss of life of $4.7 million. Campylobacteriosis generated most of the costs. Lost productivity was the major cost component for all diseases. The total cost of potentially foodborne infectious disease was estimated to be $88.8 million. Broad estimates of additional costs due to cases of infectious intestinal diseases caused by non-foodborne pathogens or for which no pathogen is identified could raise the cost to $215.7 million.

Conclusion. The findings imply that resources of $55 million could be devoted to prevention of foodborne infectious disease. Efforts should focus on lowering the incidence of campylobacteriosis as this disease accounts for most of foodborne illness costs.

Our objective was to estimate the economic cost to New Zealand of foodborne infectious disease by type of disease and category of cost.

Methods

Event pathways (Figure 1) were constructed for each potentially foodborne infectious disease using the diseases and outcomes defined in the preceding incidence report. We multiplied the unit cost of each resource used by the volume of resources utilised for each outcome. Costs were broken down into direct medical costs (general practitioner, drugs, laboratory tests and hospital), direct non-medical costs (transport), indirect costs (productivity), and intangible costs (death).

Figure 1. Foodborne infectious disease: event pathways and resources utilised by each event.
Market prices and wages were used as proxies for unit costs of resource utilizations which were measured incrementally, that is, the cost of each disease was compared against the situation in which the disease did not exist. As this study took a societal perspective, all identifiable transfer payments such as goods and services tax (GST) were excluded from the analysis of costs. All costs were measured in 1999 New Zealand dollars (SNZ, NZ$1 = US$0.5528 average mid-rate May 1999).

It was assumed that when a person contracts a foodborne infectious disease they will either treat themselves or consult a general practitioner (GP). We considered (after discussion with pharmacists) that 10% of self treatment cases purchased an over-the-counter (OTC) medicine for electrolyte fluid replacement, and this required transport to and from the pharmacy (two trips).

Each consultation with a GP generated a consultation fee and transport to and from the surgery (two trips). If treated in the community, each episode would require a laboratory test and a prescription for electrolyte fluid replacement (collected on the way home from the surgery).

Each admission to hospital involved: a GP (or hospital emergency department costed as for GP consultation, transport to and from the hospital (two trips) and the relevant diagnosis related group (DRG) hospital cost. If a GP refers a patient to hospital it was assumed that no diagnostic tests were undertaken in the community. Full recovery incurs no further costs. Long term illness generated a further GP consultation fee, transport both to and from the GP, and to and from hospital and a hospital stay (cost evaluated using an average bed day cost). Deaths were quantified using the value of a human life according to willingness to pay criteria. Lost production, based on the length of illness, was evaluated for all cases.

The cost of a GP consultation was $31.40, being the average unsubsidised adult consultation fee (the cost to society is the total fee increased by the proportion paid by the patient out of pocket). Drugs prescribed by GPs for patients treated in the community were assumed to be an electrolyte fluid replacement such as Gastrolyte™. As a prescription for Gastrolyte™ dispensed costs more than the medicine purchased OTC, the OTC unit cost was applied to prescriptions. It was assumed that people self-treating would purchase the same medicine OTC.

The laboratory test for enteric pathogens unit cost was $15.30. Volume and cost data for this test for July 1994 to February 1999 inclusive were obtained (C Taylor, Health Benefits Limited, personal communication, 23 March 1999) to check that our estimated number of tests was realistic and to corroborate the unit cost.

Hospital unit costs were derived from (DRG) costings. This study used Australian National Diagnosis Related Groups (AN-DRGs) version 3.1 which provided the average base contract price paid by the Regional Health Authorities (RHAs) in 1996/97. The respective ICD/s for each diagnostic test were used to identify the most closely related AN-DRGs appearing in the cases identified from the Ministry of Health New Zealand Health Information Service (NZHIS) data sets. A weighted average cost was used if more than one AN-DRGs appeared frequently.

When a hospital patient had a long term illness that was assumed to be caused by antecedent infection with a foodborne pathogen (Guillain–Barré syndrome, reactive arthritis, and haemolytic uraemic syndrome) were calculated using the average public hospital stay multiplied by the average bed day cost of $636.5

The cost of a private motor vehicle was valued at $0.62 per kilometre. A round trip of ten kilometres, was used for a visit to a GP or pharmacy, while a round trip of 20 kilometres, was used for hospital admissions. As most (85%) of New Zealand’s population live in urban areas it was reasonable to assume that patients would on average live within these distances of a pharmacy, GP or hospital. In some cases an ambulance would be used, thus increasing costs. Production loss for all cases was valued using average weekly total earnings for males and females combined of $678.03 per week. Our method of calculating production loss embraces both market and nonmarket activities. Intangible costs of disability were evaluated at $2 million and the consequences to quality of a statistical life. For consistency we excluded GST from this estimate.

### Results

The total cost (direct, indirect and intangible) of the estimated 119 320 episodes of foodborne infectious disease was $55.1 million, at a cost per case of $462. The total cost consists of direct medical costs of $2.1 million (3.8% of total), direct non-medical costs of $0.2 million (0.3%), indirect cost of lost productivity of $48.1 million (87.4%) and the intangible cost of loss of life $4.7 million (8.5%) (Table 1).

When the total costs of the individual infectious diseases were analysed (Table 2) it was found that campylobacteriosis was responsible for 72.9% of the total costs. The long term illnesses associated with campylobacteriosis account for approximately half of its total hospital costs. Infection with small round structured viruses (SRSV) had the second largest number of episodes of the diseases studied but the short duration and less severe nature of this disease means that both the direct medical costs and production loss were low when compared with campylobacteriosis.

As the cost of days lost to campylobacteriosis was the largest component of total costs we used sensitivity analysis to consider the effect of both reducing and increasing the number of days lost for cases who self treat or who were treated in the community by a GP. Decreasing or increasing the days lost by two from the base case of five days, changed the total costs by $14.5 million.

A cost estimate was also generated for the number of cases of potentially foodborne infectious disease, that is, the total number of cases for the ten disease categories.

These 198 648 cases were estimated to cost $88.8 million, of which campylobacteriosis cases generate $61.7 million ($40.1 million divided by 0.65 = $61.7 million), (Table 2).

Costs were also calculated for the estimated number of infectious intestinal disease cases caused by non-foodborne pathogens (an additional 111 882 self treating community cases and 26 212 cases visiting a GP) and cases for which no pathogen was identified (431 845 self treating community cases and 54 560 cases visiting a GP). It was assumed that infection with these agents would generally produce illness of similar severity to infection with SRSV. If these cases each experienced an average of two days lost productivity, the additional costs would be $28.6 million for non-foodborne infectious intestinal disease cases, and $98.3 million for the cases in which no pathogen was identified. These additional categories generated an upper bound cost estimate for all infectious intestinal disease of $215.7 million ($88.8 + 28.6 + 98.3).

### Discussion

Infectious intestinal disease caused by foodborne pathogens does not incur high direct medical costs, but the loss of production is substantial and was the largest cost category. The incidence of campylobacteriosis and the time off work with this disease were the major cost drivers for the range of diseases considered.

Our estimate of the cost of foodborne infectious disease is conservative, as a proportion of the other infectious intestinal disease cases could be due to foodborne pathogens, particularly those cases for which no specific pathogen is identified.

Excluding the intangible costs associated with death made little difference to the overall results. We have not attempted to provide a cost for loss of quality of life associated with days lost to infectious intestinal disease or long term illness. A crude estimate of quality of life adjusted years (QALYs) lost could be made by converting total days lost as a result of illness to years, and multiplying by a weighting factor that reflects the reduction in quality of life. However, if any QALY estimate is used in conjunction with the reported cost estimates productivity loss must be excluded to avoid double counting.

Neither the public health costs of surveillance and control activities were included, nor was the cost to the food industry of preventive activity. These costs were considered unrelated to the number of disease cases. However, it could be argued that some of these costs, for example those associated with outbreak investigations and recalls, would be reduced if the incidence of foodborne infectious disease was lowered.

We used the average weekly total earnings for males and females combined for all ages, as a proxy for the value of lost
production (paid and unpaid) and leisure time activities. This approach ensured that our costs were gender, age, and employment status neutral. Some of the diseases (for example, SRSV) result in only a short time off work and it could be argued in such instances other workers will do the work or that the work will be set aside to be done when the absent worker returns.14

In the absence of specific data on prescriptions for foodborne infectious disease we chose to account for these costs by using the fluid replacement product most likely to be prescribed or to be purchased OTC. However, as some patients may also purchase an anti-diarrhoeal medicine or may be prescribed an antispasmodic, an anti-emetic, or even a broad spectrum antibiotic, our estimates could be regarded as conservative.

The study is conservative in the estimation of some costs, particularly long term illness where the cost was estimated for only one year. Some of these patients will incur costs beyond the first year but these ongoing costs were unable to be assessed because of inadequate data. Costing for long term illness was based on the length of hospital stay. This gives a higher value than costs assessed using the associated DRG from NZHIS data but we considered that it more closely reflects actual cost. This argument is supported by an earlier study of the cost of campylobacteriosis.4

Previous estimates1,2 used a ratio (0.08%) of the cost of foodborne illness to GDP from overseas studies to derive a cost for New Zealand. Comparisons of health care costs calculated as percentages of GDP may be inappropriate. There may be differences country by country by between: health care reporting

### Table 1. Estimated economic cost to New Zealand of foodborne infectious disease.

<table>
<thead>
<tr>
<th>Resource item/cost</th>
<th>Incidence (episodes)</th>
<th>Unit cost</th>
<th>Total resource utilisation</th>
<th>Total cost of illness</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk population1</td>
<td>3,681,546</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence rate1 per 100,000</td>
<td>3,241</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence2 (Episodes)</td>
<td>119,320</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct medical costs</td>
<td>$</td>
<td>Units</td>
<td>$(000)</td>
<td></td>
</tr>
<tr>
<td>General practitioner consultations</td>
<td>31.40</td>
<td>19,420</td>
<td>610</td>
<td></td>
</tr>
<tr>
<td>Drugs: prescription courses</td>
<td>9.73</td>
<td>18,968</td>
<td>185</td>
<td></td>
</tr>
<tr>
<td>Drugs: over-the-counter</td>
<td>9.73</td>
<td>9992</td>
<td>97</td>
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<tr>
<td>Laboratory tests</td>
<td>15.30</td>
<td>18,968</td>
<td>290</td>
<td></td>
</tr>
<tr>
<td>Hospital: admissions 1st</td>
<td>1136*</td>
<td>429</td>
<td>573</td>
<td></td>
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<td>Hospital: admissions long term</td>
<td>16,051*</td>
<td>22</td>
<td>351</td>
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<tr>
<td>Hospital: admissions</td>
<td>2054</td>
<td>451</td>
<td>926</td>
<td></td>
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<tr>
<td>Sub total: direct medical costs</td>
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<td></td>
<td>23,088</td>
<td></td>
</tr>
<tr>
<td>Direct non medical costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport: private motor vehicle trips community</td>
<td>3.10</td>
<td>58,824</td>
<td>182</td>
<td></td>
</tr>
<tr>
<td>Transport: private motor vehicle trips hospital</td>
<td>6.20</td>
<td>903</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Sub total: direct non medical costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub total: direct costs</td>
<td></td>
<td></td>
<td></td>
<td>22,96</td>
</tr>
<tr>
<td>Indirect costs</td>
<td>Productivity: weeks</td>
<td>678.03</td>
<td>70,990</td>
<td>48,134</td>
</tr>
<tr>
<td>Total: direct and Indirect Cost</td>
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<td></td>
<td></td>
<td>50,430</td>
</tr>
<tr>
<td>Intangible costs</td>
<td>Death</td>
<td>2,000,000</td>
<td>2.3</td>
<td>46,582</td>
</tr>
<tr>
<td>Total: direct, indirect and intangible cost</td>
<td></td>
<td></td>
<td></td>
<td>53,088</td>
</tr>
</tbody>
</table>

*Hospital unit costs are a weighted average over all diseases in the study. Because of rounding, individual items may not add exactly to the totals shown.

### Table 2. Estimated economic cost to New Zealand of foodborne infectious disease.

<table>
<thead>
<tr>
<th>Resource item/cost</th>
<th>Incidence (episodes)</th>
<th>Unit cost</th>
<th>Total resource utilisation</th>
<th>Total cost of illness</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk population5</td>
<td>3,681,546</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence rate5 per 100,000</td>
<td>3,241</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of cases5</td>
<td>7,345</td>
<td>8481</td>
<td>257</td>
<td>22,888</td>
</tr>
<tr>
<td>Resource item/cost</td>
<td>$(000)</td>
<td>$(000)</td>
<td>$(000)</td>
<td>$(000)</td>
</tr>
<tr>
<td>Direct medical costs</td>
<td>$11,87</td>
<td>227</td>
<td>10</td>
<td>37</td>
</tr>
<tr>
<td>Direct non medical costs</td>
<td>$100</td>
<td>18</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Total: direct costs</td>
<td>12,888</td>
<td>245</td>
<td>11</td>
<td>41</td>
</tr>
<tr>
<td>Indirect costs</td>
<td>36,639</td>
<td>2929</td>
<td>54</td>
<td>1,997</td>
</tr>
<tr>
<td>Total: direct and indirect cost</td>
<td>37,926</td>
<td>3,175</td>
<td>65</td>
<td>2,037</td>
</tr>
<tr>
<td>Intangible costs</td>
<td>2210</td>
<td>1,288</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total: direct, indirect and intangible cost</td>
<td>40,136</td>
<td>4,465</td>
<td>65</td>
<td>2,037</td>
</tr>
<tr>
<td>Percentage of total cost</td>
<td>72.9%</td>
<td>8.1%</td>
<td>0.1%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Cost per case</td>
<td>$533</td>
<td>$526</td>
<td>$253</td>
<td>$891</td>
</tr>
</tbody>
</table>

*Illness caused by toxins produced by *Clostridium perfringens*, *Bacillus* spp., or *Staphylococcus aureus*, as well as unspecified food poisoning. VTEC = verotoxigenic *Escherichia coli*, SRSV = infection with small round structured viruses. Because of rounding, individual items may not add exactly to the totals shown.
and treatment systems, relative costs within the health sector and between the health sector and the rest of the economy, the composition of GDP, and the mix of market and non-market activities. Nevertheless, (excluding intangible costs because they do not involve resource opportunity costs) we found that the direct and indirect cost of foodborne infectious disease as a ratio to GDP was 0.1% ($50 million plus 12.5% GST divided by $98734 million) using GDP for the year ending March 1999.14

Further research is required to more accurately define the incidence of campylobacteriosis and the aetiology of infectious intestinal disease cases for which no pathogen is identified. It would also be useful to clarify, for all of the infectious intestinal diseases, the proportion of cases which are foodborne versus other modes of transmission and the actual productive time lost for each.

Our findings imply that resources of $55 million could be allotted for the prevention and control of foodborne infectious disease. Priority should be given to reducing the incidence of campylobacteriosis.

Acknowledgements. We are grateful to Brian Easton for his valuable comments on the draft of this paper. Funding for this work was provided by the Health Research Council of New Zealand.

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TREATING INFECTIONS

Acute otitis media: antimicrobial therapy in an era of resistant bacteria and sceptical meta-analysts

David W Teele, Professor, Department of Paediatrics, Christchurch School of Medicine, University of Otago and the Christchurch Hospital, Christchurch.

Prefatory thoughts by others:

“The greatest evil is physical pain.”

St. Augustine (4th century)

“Infants do not cry without some legitimate cause.”

Ferrarius (16th century)

“Those that do not feel pain seldom think that it is felt”

Samuel Johnson (18th century)

Acute otitis media is the most common treatable bacterial illness diagnosed in children. In developed countries it is invariably in the short list of most common indications for antimicrobial therapy. Recent and sometimes explosive development of penicillin resistant pneumococci in all parts of the world raises many questions about appropriate therapy for acute otitis media. Additionally, investigators in both Europe and North America have questioned routine antimicrobial therapy for apparently uncomplicated acute otitis media. This review will examine each of the issues faced by the thoughtful practitioner.

Accurate diagnosis

All ill children deserve careful examination of their ears. Acute otitis media and otitis media with effusion may be found in up to 30% of such children during the first five years of life.1

Accurate diagnosis requires the appropriate equipment, ie a sealed otoscope with pneumatic attachment and halogen light source. Failure to use such equipment results in a diagnostic accuracy that is little better than a coin toss.

Otitis media with effusion, that is a middle ear effusion unrelated to the child’s illness, does not require prompt antimicrobial therapy.2 By contrast, the weight of evidence supports the benefits of antimicrobial therapy for children with acute otitis media. Simply improving practitioners’ skills would reduce unnecessary usage of antimicrobial therapy.

An algorithm to assist with accurate diagnosis prepared by the US Public Health Service/Centers for Disease Control (CDC) appears in Figure 1, which may be downloaded in colour from the web-site (www.cdc.gov).

Increasing prevalence of resistant bacteria responsible for acute otitis media

Results of more than 10 000 tympanocenteses show that acute otitis media is usually caused by a selected few bacteria. In some cases, viral agents can be found in mixed culture with common bacterial agents. These are, in usual order of importance, Streptococcus pneumoniae, non-typable Haemophilus influenzae and Moraxella catarrhalis. In some studies, usually from Scandinavia, up to 10% of children may have illness due to Streptococcus pyogenes. Data obtained during outbreaks of influenza and respiratory syncytial virus (RSV) show that many children have acute otitis media that appears to be caused solely by one of these two agents. These data are the exceptions to prove the rule of bacterial causation.

The prevalence of resistance to commonly used antimicrobial agents has increased among all pathogens isolated from children with acute otitis media. Until recently in New Zealand, the
prevalence of resistance among isolates of *S. pneumoniae* was low. Unfortunately, there has been a worldwide change, and now in some countries a majority of isolates of pneumococci are resistant to penicillin. When the CDC surveyed children just outside its own front doors in Atlanta in 1994, they recovered penicillin resistant pneumococci from more than 40% of white children aged less than six years. A 1998 analysis of clinical isolates of pneumococci in the USA revealed that more 50% were no longer fully susceptible to penicillin. Further, questions are increasingly being asked about the personal benefit of a patient versus the well being of the larger population. In other words, is it acceptable for a patient to suffer so that the larger population may benefit from reduced rates of antibiotic utilisation or antimicrobial resistance?

### Possible end points for treatment trials

#### Microbiologic End Points

Investigators have often selected a time that would coincide with the end of traditional treatment with antimicrobial therapy. Sufficient data exist to show that children infected with *H. influenzae* should experience a high rate of self-cure. Data for the pneumococcus suggest that the rate of self-cure is much lower. Data for group A streptococci suggest that the rate of self-cure is negligible. Little is known about the rate of self-cure for *M. catarrhalis*.

Recently a number of analyses of the literature have appeared; most, but not all, question routine antimicrobial therapy. Usually such analyses ignore the short term outcome of the clinical illness. Most recently, a working group convened by the CDC concluded, after wide consultation with other experts, that therapy is indicated. They also concluded that treatment should be directed primarily at the pneumococcus, the organism with a low rate of self-cure and the ability to gain access to the bloodstream (due to its capsule). Finally, the pneumococcus is most likely to be associated with severe pain in the ear.

#### Clinical endpoints

**Pain and suffering at two weeks.** The outcome of the illness that we call acute otitis media is an issue of intense interest to our patients (even if they are too young to speak) and the patients’ parents. Data from studies with bacteriology of the middle ear fluid and either placebo or ineffective antimicrobial therapy are few. They do, however, provide doctor and patient with the best answers.

Virtually all investigations, whether they be drug trials (many) or trials with a non-treatment arm (few) report a high rate of clinical cure at ten to fourteen days after diagnosis, perhaps 95% with antimicrobial therapy and 80% without. This phenomenon was first discussed by Marchant who coined the phrase: “the Pollyanna phenomenon.”

Thus, if one selects an endpoint of ten to fourteen days one could reasonably conclude that only one child in six requires treatment. A few caveats are in order. First, nobody has yet been able to identify the child who does require treatment at the time of diagnosis. Second, many trials that withheld treatment have excluded children in the first two years of life, the very period of highest risk for complications.

Klein has reviewed these data and their implications in a thoughtful publication. His conclusion was “...in *vivo* sensitivity tests are uniform in demonstrating that a drug that is effective in eradicating the bacterial pathogen almost always leads to early resolution of clinical signs, and that drugs that fail to eradicate the pathogen have lower rates of clinical success.”

**Pain and suffering during acute otitis media.** Only a few investigators have considered how the child feels a few days into treatment. A few caveats are in order. First, nobody has yet been able to identify the child who does require treatment at the time of diagnosis. Second, many trials that withheld treatment have excluded children in the first two years of life, the very period of highest risk for complications.

Klein has reviewed these data and their implications in a thoughtful publication. His conclusion was “...in *vivo* sensitivity tests are uniform in demonstrating that a drug that is effective in eradicating the bacterial pathogen almost always leads to early resolution of clinical signs, and that drugs that fail to eradicate the pathogen have lower rates of clinical success.”

**Pain and suffering during acute otitis media.** Only a few investigators have considered how the child feels a few days into treatment, as compared to children receiving placebo. Appropriate clinical trials of the outcome of acute otitis media require tympanocentesis at entry, to determine the aetiology, and a second tympanocentesis later, even if the child appears to have recovered, to demonstrate sterilisation of the middle ear.

In 1991, Carlin et al, using data from published studies examined the correlation between eradication of bacterial pathogens and early therapeutic response. They concluded “that failure to eliminate bacteria from the middle ear is often associated with persistent signs and symptoms”. It is worth noting that such failures were most common in children younger than two years old.

Recently Dagan et al analysed their own data from a number of trials of antimicrobial therapy for acute otitis media. Their data show convincingly that treatment that sterilises the infected...
middle ear is associated with a statistically and clinically improved outcome. The more severe the illness, the greater is the effect. They also noted an important rate of clinical improvement, even when drugs had not yet sterilised the middle ear.

Pyogenic complications. Historically, one of the chief reasons to treat children with acute otitis media was to reduce the risk for life-threatening complications, such as acute mastoiditis. There is no doubt about the reduction in such illnesses that has occurred since antimicrobial therapy for acute otitis media became routine. What is in doubt is the proportion of this reduction that has been caused by such treatment and the proportion that would have occurred anyway. Virtually all common infectious diseases of childhood are now either less severe and/or less frequent. This, then, is the challenge to those who advocate routine non-treatment: what will happen to rates of life threatening complications should their suggestions be followed?

Answers to such a challenge may be a long time coming. The rate of complications with treatment is low, the rate of self-cure is not inconsiderable, and very large numbers of children (many thousands) will have to be enrolled in any study. Children at highest risk will have to be included, and they have been specifically excluded from a number of studies concluding treatment should be withheld. Such data are eagerly awaited.

Data may also come from comparing different countries with different policies. Recently, there has been a disquieting report from Germany, where therapy is often withheld, showing an important rise in the rates of hospitalisation for acute mastoiditis. It would be safe to conclude that ‘the jury is still out’ on the extent to which antimicrobial therapy prevents severe and possibly fatal complications of acute otitis media.

Selection of antimicrobial therapy

For the reasons listed in the earlier section, the chief target of therapy is the pneumococcus. For this reason, the agent selected should possess these characteristics: excellent activity against pneumococci, good penetration into infected middle ear effusions, good serum levels to reduce the risk of pneumococcal infection outside of the middle ear, limited side effects, established record of safety and efficacy, ease of dosing and safety of dosing at higher than standard levels.

In January 1999, the report of the “Drug-resistant Streptococcus pneumoniae Therapeutic Working Group” appeared in print. Before publication, this Group presented their conclusions at a consensus meeting attended by an international selection of authorities in the field. Their recommendations were:

1. Amoxicillin remains the drug of choice, but the standard dose should be increased to 80-90 mg/kg per day. This dose achieves levels of amoxicillin in the middle ear sufficient to kill many strains of pneumococci with reduced susceptibility to penicillin. This dose has also been shown to be well tolerated in children.

2. For clinical failure after three days of treatment, acceptable alternatives include: amoxicillin-clavulanate, cefuroxime-axetil, and intramuscular ceftriaxone.

3. Other oral agents now licensed lack sufficient evidence of efficacy for resistant pneumococci.

Duration of treatment

A number of investigators have attempted to determine the optimal duration of treatment. This issue remains unresolved, but several points bear mention. First, for children over the age of two years, five to seven days appears to be comparable to longer treatment. Second, single dose oral treatment appears to be unacceptable. Third, single dose treatment with intramuscular ceftriaxone is as effective as a usual ten day oral course. Fourth, for children with otitis media accompanying acute otitis media, shorter oral courses may be ineffective.

Other treatment

Analgesic therapy (paracetamol) is often forgotten, particularly for a child too young to explain the severity of their pain. From time to time, more potent analgesics may be required, usually in older patients. Abundant data exist to show no benefit for decongestants and/or antihistamines.

Cautionary note.

Although acute otitis media occurs primarily in children and especially in young children, outside of the neonatal period the microbiology does not change with age. The responsible bacteria are the same in a 22 year old as they are in a 22 month old.

Recommendations for follow-up

Considerable variation in opinion exists with regard to the need for and timing of follow-up visits. It would be fair to note however, that there is consensus on the need to reassess a child with acute otitis media who remains ill after about 48 hours. Such follow-up is prudent whether an antimicrobial has been offered or omitted.

Assuming an apparently uneventful clinical recovery, the next issue is need for any later follow-up. Two things seem clear. First, no matter what treatment is given initially, there is a high rate of relapse within the next month. Second, most children with acute otitis media experience several weeks to several months of middle ear effusion (otitis media with effusion). Concern for these effusions (and attendant hearing loss) is inversely proportional to the child’s age. It seems prudent to arrange follow-up six to eight weeks after diagnosis, especially for children in the first three years of life.

Correspondence. Professor David W Teele, 413 McDonnell Rd, RD1, Queenstown.

17. Seikel K, Sholton S, McCracken GH Jr. Middle ear fluid concentrations of amoxicillin after several weeks to several months of middle ear effusion (otitis media with effusion). Concern for these effusions (and attendant hearing loss) is inversely proportional to the child’s age. It seems prudent to arrange follow-up six to eight weeks after diagnosis, especially for children in the first three years of life.
The use of antibiotics to treat infection can be miraculously beneficial or foolish and wasteful. Antibiotics save lives when used to treat endocarditis, meningitis and pneumonia, and restore health and prevent complications in many other infections (Figure 1). However, antibiotics provide no benefit for the common cold and in some other common respiratory tract infections their risk of adverse effects, cost, and contribution to the selection of resistant organisms outweigh their relatively trivial health benefits. Colds, upper respiratory tract infections and bronchitis are among the most common reasons to visit a doctor. Despite a widespread appreciation that viruses are the overwhelmingly predominant causes of these illnesses, antibiotics are prescribed surprisingly frequently. Any reduction in the use of antibiotics for these illnesses is therefore likely to make a major contribution to reducing the overall use of antibiotics in our community without placing patients at risk of adverse health outcomes.

**Colds - no benefit from antibiotic treatment**

The cold is among the most common of human ailments. On average, children suffer six to eight episodes and adults two to four episodes per year. The usual duration is one week but symptoms including cough and nasal discharge can persist for as long as two weeks. Contrary to common perception, involvement of the para-nasal sinuses is the rule rather than the exception. Consequently, the common cold should be thought of as an episode of viral rhinosinusitis. Another widely believed fallacy is that clear nasal discharge indicates viral infection while mucopurulent discharge is due to a bacterial super-infection. In fact, the change to a thick, coloured nasal discharge which commonly occurs after one to three days of illness is due to the presence of increased numbers of desquamated epithelial cells and neutrophils.

A variety of viruses (rhinoviruses, corona viruses, respiratory syncytial virus, adenoviruses etc) may be responsible for the common cold. In a minority of patients, bacterial respiratory pathogens (ie Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis) can be cultured from swabs of nasal mucus but these patients cannot be distinguished on clinical grounds. A recent meta-analysis of seven placebo-controlled studies involving 2056 patients aged over six months found no benefit in terms of cure or improvement from antibiotic treatment of the common cold. A significantly increased incidence in side effects (usually gastrointestinal) was found in the patients treated with antibiotics. Another reason sometimes given for the prescription of an antibiotic for an illness acknowledged to be viral in origin is to prevent the progression to secondary bacterial infection. There is however, no evidence to support such prescribing. A meta-analysis which reviewed five randomised controlled trials involving a total of 2520 children found no evidence that antibiotic therapy of upper respiratory tract infections (URTIs) prevented the subsequent development of pneumonia.

**Acute bronchitis - trivial, brief benefit from antibiotics**

The diagnosis of bronchitis is usually made in patients with an acute cough (or an exacerbation of a pre-existing cough) and scattered abnormal chest sounds such as wheeze and coarse or moist sounds. The illness may be difficult to differentiate from the common cold in which cough may also be a prominent feature. Acute bronchitis occurs most frequently in children aged less than four years and in the elderly. It is almost always preceded by symptoms of a cold and there is significant overlap between the viral causes of these two syndromes. In a minority of patients bronchitis is caused by bacterial pathogens such as Mycoplasma pneumoniae, Chlamydia pneumoniae and Bordetella pertussis. Cough frequently persists for two weeks, although production of sputum usually resolves within one week.

The effects of antibiotic therapy for acute bronchitis or cough have been studied in four recent systematic reviews of randomised placebo-controlled trials. Antibiotic treatment tended to provide modest beneficial effects which reached statistical significance for some of the variables evaluated eg. ‘congestion’, ‘feeling unwell’, ‘number of patients taking cough or cold medications’. In those studies which found a benefit from antibiotic treatment, the effects were greatest between four and eight days after starting treatment and were no longer apparent at ten days. The overall benefit of antibiotic treatment, in terms of days of purulent sputum,
days of cough or time off work was never more than half a day. This clinical benefit was offset by a 6% risk of adverse events of which the most common were nausea and vomiting. The authors of these reviews concluded that “the benefit from antibiotics, where present, was modest" and “may be outweighed by the side-effects of treatment”.

Chronic bronchitis - modest benefit from antibiotics may be useful in sickest patients

Chronic obstructive pulmonary disease (COPD), or chronic bronchitis, affects approximately 10% of the adult population. The relationship between infection of the large airways and clinical symptoms is difficult to unravel. In approximately 50% of patients oropharyngeal flora, S.pneumoniae and H.influenzae persistently colonise the bronchi. Acute exacerbations of COPD are characterised by increased cough, sputum volume, sputum purulence and breathlessness. While increased numbers of bacteria (especially H.influenzae, S.pneumoniae and M.catarrhalis) and neutrophils are present in sputum during acute exacerbations of COPD, the role of infection in the causation of these exacerbations remains unclear and treatment of infection appears to provide only modest benefit.

A recent meta-analysis of nine randomised placebo controlled trials conducted between 1957-1992 found that antibiotic treatment provided a small but statistically significant benefit. The average improvement in peak expiratory flow rate attributable to antibiotic therapy was 11 L/min (95% CI 5-17 L/min). The beneficial effect of antibiotic therapy in outpatients was approximately half of that seen in hospitalised patients. In the best designed study, the mean peak flow on day six was approximately 212 L/min for antibiotic treated patients and 200 L/min for placebo treated patients. At the other times when peak flow was measured (days three, nine, twelve and fifteen), the mean difference in peak flow between patients treated with an antibiotic or placebo was always less than 7 L/min. The mean duration of each exacerbation of COPD was 14.1 ± 6.3 days for antibiotic treated patients and 15.5 ± 6.1 days for placebo treated patients. These short-lived modest benefits of antibiotic therapy may be clinically beneficial in the most frail patients, such as those who are over 60 years or in patients with poor underlying lung function (FEV1<50% predicted) and/or significant concurrent medical illnesses. However, there is little evidence that antibiotic treatment of patients with less severe disease provides any significant clinical benefit.

Sinusitis - modest benefit from antibiotics

Sinusitis is a common reason to consult a doctor and is widely regarded by doctors and patients as an illness requiring antibiotic therapy. However, as the sinuses are involved in most episodes of the common cold, it is likely that most episodes of sinusitis are viral in origin. Acute bacterial sinusitis complicates approximately 2% of episodes of the common cold and is usually caused by S.pneumoniae, H.influenzae or M.catarrhalis. Differentiation of viral rhinosinusitis from bacterial sinusitis is difficult but predominantly unilateral facial pain, unilateral purulent rhinorrhoa, poor response to decongestants, and maxillary toothache have all been found to be associated with bacterial infection. Demonstration of an air-fluid level, complete opacification or mucosal thickening on sinus X-rays or CT scanning will confirm the presence of sinus disease but cannot be taken as proof of a bacterial aetiology.

There have been conflicting results from placebo controlled trials of antibiotic therapy in acute sinusitis. Some studies have failed to find a significant benefit from antibiotic therapy, while others have shown a modest but significant benefit. Taken together, the studies show that the proportion of patients who are improved or cured by day ten is approximately 60-80% for placebo treated patients and 80-90% for those treated with an antibiotic. Overall it seems likely that antibiotics offer a small benefit to those patients most likely to have bacterial infection i.e those with symptoms present for more than ten days (and who have radiological evidence of sinus disease). While concern has been expressed that the increasing prevalence of beta-lactamase producing organisms (especially H.influenzae and M.catarrhalis) may render older regimens less effective, there is no evidence that newer agents provide any improvement in clinical outcome compared with amoxycillin. Treatment is traditionally given for ten to fourteen days but shorter treatment courses, eg three days, may provide similar efficacy.

Adverse consequences of antibiotic therapy for URTI

The evidence suggests that antibiotic treatment provides no benefit in patients with colds, trivial benefit in patients with acute bronchitis, trivial benefit in all but a minority of patients with acute exacerbations of COPD and modest benefit in patients with sinusitis. These conclusions will not be surprising for most doctors or their patients, and yet antibiotics are commonly prescribed for these conditions. Studies of the prescribing patterns of doctors in New Zealand and abroad show that antibiotics are prescribed for the majority of patients who present with an upper respiratory tract infection. The consequences of this continued overuse of antibiotics include rapidly increasing antimicrobial resistance, which will inevitably lead to failures of antimicrobial therapy in the future. For example following recent antibiotic therapy, children have an increased (two to five times) prevalence of nasopharyngeal carriage of S.pneumoniae with reduced penicillin susceptibility and a similar increase (two to nine times) in the risk that otitis media, pneumonia, bacteraemia or meningitis is caused by infection with these non-susceptible strains of S.pneumoniae. Unfortunately, the genes for penicillin resistance in S.pneumoniae are frequently associated with genes for resistance to other unrelated antibiotics such as erythromycin, cotrimoxazole and tetracycline. The effects of this linkage are firstly, that treatment with any one of a wide range of antibiotics can select for penicillin resistant S.pneumoniae and secondly, that a limited range of agents is available to treat the infections due to these multi-resistant organisms. It is for this reason that a recent British working party has suggested we should adopt new habits of antibiotic therapy.

These adverse consequences of antibiotic prescribing, need to be explained to our patients so that they are our partners in reducing antimicrobial use. However, it is reasonable to expect the medical profession to lead the community in this movement. For patients in whom antibiotic therapy can be expected to have only a net negative effect, maybe the admonition applied to another drug taking context, “Just say no”, is applicable. In those patients for whom antibiotics might provide some benefit, the use of a delayed (contingent) prescription can allow reduced antibiotic use without a significant increase in patient morbidity. For example, patients with sinusitis might be given a prescription for amoxil (or an equivalent agent) and advised to only dispense if they had not experienced spontaneous improvement within two to three days of the consultation. A UK study which examined the use of delayed prescription for patients with sore throats found that this approach reduced the proportion of prescriptions which were dispensed from 99% to
A committee of The National Heart Foundation of New Zealand last reviewed recommendations for prophylaxis against bacterial endocarditis in 1992.1 The American Heart Association (AHA) reviewed and simplified their recommendations in 1997.2 They have more clearly delineated cardiac conditions into high, moderate and negligible risk categories. Surprisingly, however, they have not commented on the important issue of decreasing susceptibilities of viridans streptococci to penicillin and cephalosporins reported in the last few years.3 As part of their simplifying process, the AHA has now opted for a single pre-treatment dose of antibiotic in almost all situations, including for dental, respiratory and oesophageal procedures at a reduced dose of 2.0 g of amoxicillin. While this is the initial dose we have always recommended in New Zealand, the data on decreased susceptibilities have played a pivotal role in our decision to generally stay with our previous two dose regimens.

Our Committee re-emphasises that special care is necessary for patients for whom bacterial endocarditis is a particular threat (eg those with prosthetic valves) and that it is not possible to make recommendations for all clinical situations. For example, practitioners will need to exercise their own clinical judgment about continuing antibiotics after the prophylactic dose(s) when established infection is present. Endocarditis may occur despite technically appropriate antibiotic prophylaxis. A high index of suspicion must be maintained regarding events clinically suggestive of endocarditis after an at-risk procedure. It should be noted that, at most, only about 15% of patients with infective endocarditis will have had a defined at-risk procedure: optimal regular dental care is thus a critical component of the care of those with at-risk cardiac defects.

Recently,4 attention has again been drawn to the relatively weak epidemiological evidence of a significant association between dental procedures and subsequent endocarditis, further questioning the need for prophylaxis in some situations. We acknowledge these data and the international debate, but do not think that a major change in policy is warranted at present.

**Microbiological issues**

Prophylaxis for dental, respiratory and oesophageal procedures is directed against viridans streptococci. While these are not the only organisms which cause bacteraemia following these procedures, they are the organisms most likely to cause endocarditis. In contrast, for gut, genitourinary, obstetric and gynaecological procedures, Enterococcus spp. (eg *Enterococcus faecalis*) are the important organisms.

In the last few years there have been many reports of streptococci with reduced susceptibility to penicillin.3 In Auckland, for example, only 50% of isolates remain fully susceptible and many are only inhibited rather than killed by penicillin.5 These strains are typically less

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susceptible to cephalosporins also, especially the oral first generation cephalosporins presently available in New Zealand (eg cephradine, cephalexin, cefaclor). Because viridans streptococci remain more susceptible to the oral second generation cephalosporins, we have recommended one of them, cefuroxime axetil, as an option. ¹

The principles of prophylaxis have been established in animal models. Most of the available data for these principles are for viridans streptococci. This is appropriate given their pre-eminent role in potentially preventable endocarditis. We generally extrapolate from these principles for other organisms.

Successful prophylaxis is not necessarily, nor simply dependent, on the prevention of bacteraemia. Prolonged antibacterial activity over many hours is the common background requirement for maximal efficacy with most agents. The most effective single dose prophylactic regimens against viridans streptococcal experimental endocarditis are synergistic killing regimens (eg a penicillin or cephalosporin plus an aminoglycoside, or vancomycin used alone). However, bacteriostatic or sub-lethal (non-killing) regimens are also very effective, if continued for long enough. For example, either clindamycin or clarithromycin provides effective prophylaxis against viridans streptococcal endocarditis, if given for a prolonged duration. These drugs replace erythromycin in our current recommendations because of their greater efficacy in experimental animals, ⁶ their more predictable pharmacokinetics and fewer gastrointestinal side effects. Clarithromycin is the only oral agent recommended as a single dose because of its extremely long half-life of about twelve hours.

Prophylaxis must begin just before the procedure. If it is begun hours or days beforehand, it may select strains of decreased susceptibility so that if endocarditis occurs it is more difficult to treat.

**Patients at risk (Table 1)**

Some cardiac conditions are especially associated with endocarditis and the consequences may be particularly threatening. Examples are listed in the ‘High-risk category’ in Table 1. Other cardiac anomalies, with a lesser but significant risk of endocarditis are listed in the ‘Moderate-risk category’ in Table 1. Conditions with no special risk of endocarditis are listed in the ‘Endocarditis prophylaxis not recommended’ section of Table 1.

**Procedures**

1. **Dental (Table 2).** The incidence and magnitude of bacteraemia of oral origin is directly proportional to the degree of oral and gingival inflammation and infection. It is of great importance that at-risk patients remain free of dental disease. Treatments to achieve this goal include:
   - Removal of impacted teeth and unerupted teeth with, or likely to develop communication with, oral bacteria
   - Treatment of all teeth with periapical disease by endodontic debridement and root filling or apical surgery or extraction
   - Removal of all carious teeth which cannot be restored
   - Treatment of other abnormalities such as cysts or intra-bony lesions associated with the dentition and related structures
   - Treatment of oral ulcers including those caused by ill-fitting or irritating dental appliances
   - Treatment of inflammatory periodontal disease

2. **Oral hygiene instructions for the patient to ensure maintenance of ideal oral health**

Patients need to be persuaded to comply with a continuing oral care regimen. Optimal oral health is maintained through regular professional care and the use of appropriate products, such as manual and powered toothbrushes, floss and other plaque control devices including antibacterial mouthwashes.

### Table 1. Cardiac conditions and endocarditis prophylaxis.

<table>
<thead>
<tr>
<th>Endocarditis Prophylaxis Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High-risk category</strong></td>
</tr>
<tr>
<td>- All patients with a previous episode of endocarditis*</td>
</tr>
<tr>
<td>- Prosthetic cardiac valves, including bioprosthetic and homograft valves†</td>
</tr>
<tr>
<td>- Complex cyanotic congenital heart disease (eg tetralogy of Fallot, truncus arteriosus, complex anomalies with functional single ventricle or transposition of the great arteries)</td>
</tr>
<tr>
<td>- All major left sided valve anomalies</td>
</tr>
<tr>
<td>- Surgically constructed systemic-pulmonary shunts, or conduits from the heart to the great arteries‡</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endocarditis Prophylaxis Not Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Isolated secundum atrial septal defect</td>
</tr>
<tr>
<td>- Complete surgical or device closure of atrial septal defect, ventricular septal defect or patent ductus arteriosus (beyond six months after repair)</td>
</tr>
<tr>
<td>- Previous coronary artery bypass graft surgery</td>
</tr>
<tr>
<td>- Mitral valve prolapse without valvular regurgitation or thickened leaflets and dysplastic myxomatous valves</td>
</tr>
<tr>
<td>- Major congenital right-sided lesions, eg Ebstein’s anomaly of the tricuspid valve and significant pulmonary stenosis</td>
</tr>
</tbody>
</table>

* Even if the underlying lesion is minor, a previous attack of endocarditis demonstrates risk.
† The risk of endocarditis remains high after replacement of the native valve with any prosthesis.
‡ All surgical conduits carry a high risk, particularly as the wall becomes irregular and thickened.
§ A degree of mitral valve prolapse is very common. Dysplastic, myxomatous mitral valves are associated with connective tissue anomalies such as Marfan’s syndrome, and with increasing age. Sometimes both these types of valves can leak with exercise, but an increased risk of endocarditis has not been seen unless valvular regurgitation is present at rest, or valve structure is very distorted.
¶ Six months allows scaling of minute leaks around the periphery of the closure, and endothelialisation of surfaces. The same period is advised for these lesions treated by percutaneous placement of a mechanical device. In the small number of patients with a residual leak, long term prophylaxis may be recommended.

**Recommendations for which dental procedures require prophylaxis against endocarditis are given in Table 2.** 2. **Other (Table 3).** In particular, this section refers to genito-urinary or gastro-intestinal procedures. In contrast to bacteraemia following dental and respiratory tract procedures,
bacteraemia following genito-urinary or gastro-intestinal tract procedures is likely to be due to enteric Gram-negative bacilli such as *Escherichia coli*, or to *Enterococcus* spp. While enteric Gram-negative bacilli almost never cause endocarditis, *Enterococcus* spp. are an important, difficult to treat, rare cause of endocarditis and are the species against which prophylaxis is directed for genito-urinary or gastro-intestinal tract procedures.

### Table 2. Dental procedures and endocarditis prophylaxis.

**Endocarditis Prophylaxis Recommended**

- In general, any procedure which causes bleeding from the gingiva, mucosa or bone
- Periodontal procedures including probing, scaling, root planing and surgery
- Endodontic instrumentation or surgery **beyond** the apex
- Application of matrix bands **below** the gingival margin
- **Sublingual** placement of gingival retraction cord/straps
- Placement of orthodontic bands but not brackets
- **Intraligamentary** local anaesthetic injections
- Reimplantation of avulsed teeth and repositioning of teeth after trauma
- Oral surgical procedures including biopsy procedures and raising of mucosal flaps
- Surgical drainage of dental abscesses
- Extraction of teeth

**Endocarditis Prophylaxis Not Recommended**

- Natural shedding of primary deciduous teeth
- Dental examination, **unless** periodontal probing
- Radiographic examination
- Local anaesthetic injections, **unless** intraligamentary
- Restorative dentistry where the procedure is above the gingiva
- Impressions, construction and placement of removable prosthodontic/orthodontic appliances
- Adjustment of orthodontic appliances
- Placement of rubber dam, **unless** sublingual manipulation
- Post-operative suture removal

### Table 3. Other procedures and endocarditis prophylaxis.

<table>
<thead>
<tr>
<th><strong>Respiratory tract</strong></th>
<th><strong>Endocarditis Prophylaxis Recommended</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonsillectomy and/or adenoidectomy</td>
<td></td>
</tr>
<tr>
<td>Surgical operations that involve the respiratory mucosa</td>
<td></td>
</tr>
<tr>
<td>Bronchoscopy with a rigid bronchoscope (with or without biopsy)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Genito-urinary tract</strong></th>
<th><strong>Endocarditis Prophylaxis Recommended</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostatic surgery, transrectal prostatic biopsy, cystoscopy or urethral dilatation (even in the absence of infection)</td>
<td></td>
</tr>
<tr>
<td>Surgical procedures in the presence of infection eg urethral catheterisation, ureteral dilatation and curettage, therapeutic abortion, sterilisation procedures, insertion and removal of intra uterine devices, circumcision</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Gastro-intestinal tract</strong></th>
<th><strong>Endocarditis Prophylaxis Recommended</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sclerotherapy for oesophageal varices or oesophageal stricture dilatation</td>
<td></td>
</tr>
<tr>
<td>Endoscopic retrograde cholangiography and biliary tract surgery</td>
<td></td>
</tr>
<tr>
<td>Surgical operations involving the intestinal mucosa (other than endoscopic biopsy and percutaneous endoscopic gastrostomy)</td>
<td></td>
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</tbody>
</table>

**Other sites**

- Incision and drainage of focal sepsis eg subcutaneous abscess. (Note that prophylaxis here will often necessarily be part of more prolonged antibacterial treatment.)

### Table 4. Antibacterial recommendations for dental, oral, respiratory tract or oesophageal procedures.

<table>
<thead>
<tr>
<th>Cardiac risk*</th>
<th><strong>Moderate</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Penicillin allergy †‡</strong></td>
<td>Oral amoxicillin 2.0 g one hour before procedure and oral amoxicillin 1.0 g six hours later.</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td>Oral IV amoxicillin 2.0 g plus IV/IM gentamicin (2.0 mg/kg, not &gt;120 mg) within 30 min of procedure. No subsequent dose recommended.</td>
</tr>
</tbody>
</table>

**Penicillin allergy †‡**

- Oral cefuroxime axetil 1.0 g one hour before procedure and oral cefuroxime axetil 1.0 g six hours later.§
- Oral clindamycin 300 mg one hour before procedure and oral clindamycin 150 mg six hours later.§
- Oral clarithromycin 500 mg one hour before procedure. No subsequent dose recommended.§

**IV cefuroxime 750 mg + IV/IM gentamicin (2.0 mg/kg, not > 120 mg) within 30 min of procedure. No subsequent dose recommended.**

| **IV clindamycin 100 mg within 30 min of procedure and IV/oral clindamycin 150 mg six hours later** |

*Some international recommendations now have the same recommended regimen for those with high and moderate cardiac risks. The options for high risk here are those with theoretically maximal preventative activity.

‡Those who have received a beta-lactam (either a penicillin or cephalosporin) within two weeks of the procedure, or are on long term penicillin prophylaxis for rheumatic fever, need a clindamycin or clarithromycin regimen from the moderate risk category or any of the high risk-category options. In some of the latter, the synergistic killing of the combined beta-lactam plus aminoglycoside overrides the possible reduced beta-lactam susceptibility from prior beta-lactam treatment.

‡The oral cefuroxime axetil and IV cefuroxime/gentamicin regimens are options for patients whose penicillin allergy was not anaphylaxis or rapid onset skin reaction.

§Prescriptions for these drugs need to be endorsed 'for endocarditis prophylaxis'.

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Table 5. Antibacterial recommendations for genito-urinary and gastro-intestinal (excluding oesophageal) procedures.

<table>
<thead>
<tr>
<th>Cardiac risk</th>
<th>Moderate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard *</td>
<td>• Oral amoxycillin 2.0 g one hour before procedure and oral amoxycillin 1.0 g six hours later.</td>
</tr>
<tr>
<td>Penicillin allergy*†</td>
<td>• IV vancomycin 1.0 g infused over 1.0-1.5 hours ending within 30 min of procedure. No subsequent dose recommended.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>High</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• IV amoxycillin 2.0 g + IV/IM gentamicin 2.0 mg/kg within 30 min of procedure plus oral/IV amoxycillin 1.0 g six hours later.</td>
</tr>
<tr>
<td></td>
<td>• IV vancomycin 1.0 g infused over 1.0-1.5 hours ending within 30 min of procedure plus IV/IM gentamicin (2.0 mg/kg, not &gt;120 mg). No subsequent dose recommended.</td>
</tr>
</tbody>
</table>

* Prior or continuing penicillin treatment does not affect these regimens. † No oral option for those with penicillin allergy.

**Drug doses for children**

Drug doses must be adjusted appropriately for children. For the oral regimens listed, children aged five to ten years receive half the adult dose and children aged under five, one-quarter the adult dose. Appropriate intravenous dosages are: amoxycillin 50 mg/kg, vancomycin 20 mg/kg, gentamicin 2.0 mg/kg, clindamycin 10 mg/kg, cefuroxime 50 mg/kg. The maximum dose must not exceed the total adult dose.

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Having prepared this article in a personal capacity I wish to make it clear from the outset that I have not discussed its contents with senior officers or councils of organisations with which I have been associated over recent years. The following comments are therefore based on my perspective. I hold quite strongly to the viewpoint that an extremely serious issue has been raised by the situation described in the Editorial pages of the Journal under the heading - “The missing paragraph - freedom of open, scientific debate and legal threats.”

Generally, in a majority of Western countries, scientific debates whether held publicly or semi-privately at various seminars, conventions and so forth, by various forms of the professional and general media, progress within boundaries and rules set over several centuries. Scientists and technologists in New Zealand have been encouraged to adhere to an ethical code which has been promulgated by the Royal Society of New Zealand. In my opinion, the situation described in the Editorial Comment, does not conform to the dictates of that code. Over the last several hundred years, a prevailing view has evolved worldwide, that scientific activity is a ‘public good’. Historically, the sacrosanct nature of emerging scientific knowledge has been recognised even in wartime. For instance, during the Napoleonic wars, the Royal Society of London and the French Academy freely exchanged information which was protected in its transference by the warring parties! Particularly in relation to military applications of scientific knowledge arising within, eg nuclear physics; such purity of concept is no longer valid.

Developments within society generally have dictated alterations in conventions concerning what is and what is not acceptable in the scientific arena.

However, what is still sacrosanct is the capacity for scientists to voice their opinions, perspectives and criticisms of others, be they positive or negative, regarding their own work and that of colleagues. Only thus can other scientists and/or technologists, in any part of the world, repeat work and that of colleagues. Only thus can other scientists to voice their opinions, perspectives and criticisms of others, be they positive or negative, regarding their own work, or in their advocacy of a particular perspective, entered the scientific arena may be forcefully reminded that he need for their ideas to be tested by time proven methods. They cannot expect to apply one standard of practice of behaviour to themselves and another to those whose lives are devoted to science. Obviously, as scientific application moves into aspects of technology, any distinctions between non-scientific and, for example, commercial forms of behaviour and ethics, become quite blurred. Traditionally it is not held to be libellous for scientists and/or technologists to criticise the work of others, nor is it morally or ethically wrong for them to be quite forceful in rebuttal of criticisms of their own work, or in their advocacy of a particular perspective, provided they subscribe to the framework I have outlined above. Moreover, it is unethical within the scientific arena for any person to attempt to prevent another, who chooses to express a divergent opinion, from publishing or commenting upon the ideas, methods, results (if there are any) and interpretation relevant to a particular aspect of one's own work.

Historically, great periods in scientific history have been characterised by extremely intense debates and discussions. One of my teachers, Professor, later Sir John Eccles, commented on the golden days of the Physiological Society of Great Britain. “It was distinguished by the critical discussions that followed each paper. These criticisms were often severe, but it was an unwritten rule of the Society that all criticisms had to be accepted in a sporting manner. Under no account must it be taken personally.” Sir John was himself involved in a series of these controversies. He went on to win a Nobel Prize. Another antipodean scientist, Sir Macfarlane Burnett, had an enquiring nature and was a formidable opponent in any form of debate. He also went on to win a Nobel Prize. These men would be horrified by the situation described in the New Zealand Medical Journal.

There are good reasons, based on painful episodes in legal and scientific history, for this tradition for scientific disputes to be conducted outside the legal system. Moreover, scientific approaches to establishing evidence and its nature and validity contrast sharply with the concepts and precepts of the adversarial legal system. Recourse to the law involves enormous delays, colossal expenses at times, with no guarantee that judgment will be reached between those in dispute. I would hope that in New Zealand we can avoid rewriting history, so sadly demonstrated in such issues as debating whether or not the earth is flat, or whether the Book of Genesis is composed of mythology, allegory or accurate historical recording. The big debates which arise within the general community so far as they are reported, and their background, should always be available for checking by anybody who wishes to do so. Given that openness, it is libellous to attack a person’s integrity, and honesty. Equally, a particular person who has chosen to enter the scientific arena may be forcefully reminded that he or she must support their arguments with experimental evidence and logic which provides a reasonably substantial basis for construction of an hypothesis.

I have not read or had read to me the paragraph in question quoted in the New Zealand Medical Journal. I am thus raising a general issue, having been alerted by the Editorial Comment. It is my understanding that the
Advertising bans and cigars

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NZ Med J 2000; 113: 294-6

The recent furore over the Ministry of Health’s enforcement of the provisions of the Smoke-free Environments Act 1990 (the Act) raises important issues. The provisions, applied by the Ministry to cigars, ban tobacco product advertising and promotion. As a result of an apparent over-reaction to the Ministry’s enforcement of the legislation, it is important to review the health consequences of cigar smoking and the effectiveness of comprehensive bans on tobacco product advertising and promotion in reducing the prevalence of smoking of tobacco products.

In response to the Ministry’s investigation of whether certain cigar lifestyle magazines and columns constituted tobacco product advertisements within the meaning of the Act, the Ministry was accused of seizure of literature and book burning.1,2 The Ministry seized nothing, and burned nothing. These were actions taken by the publishers themselves, prior to the completion of the Ministry’s investigation, and in some instances after they had taken their own legal advice.

The prevention and cessation of tobacco use is one of the most important strategies to reduce death in New Zealand. 4700 deaths were attributed to tobacco smoking in 1996, accounting for 17% of all deaths.1 One in two New Zealand smokers die on average fourteen years early.4

Health consequences of cigar smoking

Tobacco is lethal no matter how it is packaged or used, and whether in cigarettes, cigars, pipes or chewed.1 The health consequences of cigar smoking are coming under increasing scientific scrutiny as evidenced by two important studies published last year. A recent European study indicates that tobacco smoked in cigars and pipes might exert a carcinogenic effect on the lung comparable to that of cigarettes.6 The three-country study included 5621 men with lung cancer, compared with 7255 men without lung cancer. Cigar and cigarillo smokers were nine times as likely to develop lung cancer and cigarette smokers nearly fifteen times as likely, compared with nonsmokers. A dose-response relationship between lung cancer risk and either duration of smoking or average and cumulative consumption was similar for cigar and cigarette smoking.

In the United States, a cohort of 1546 men who smoked cigars and 16 228 who did not, drawn from enrolments in the Kaiser Permanente health plan, were followed from...
Cigar smoking in New Zealand

Prevalence of regular cigar smoking in the New Zealand population is low, averaging just below 1% prevalence in both 1997 and 1998 in adults (males and females combined) in the AC Nielsen monitoring surveys purchased by the Ministry of Health. These national surveys are based on face-to-face interviews of approximately 3000 residents each quarter. They show prevalence may be increasing, from 0.69 percent in 1991 in adults (95% CI, 0.53 to 0.84) to 0.95% in 1998 (95% CI, 0.76 to 1.13). Apparent percentage increases are most marked amongst Maori, increasing from 0.48% in 1991 (95% CI, 0.16 to 1.04) to 1.15% in 1998 (95% CI, 0.60 to 2.15), and young adults aged fifteen to 24 years, increasing from 0.59% in 1991 (95% CI, 0.27 to 0.91) to 1.11% in 1998 (95% CI, 0.59 to 1.61).

The concern is that New Zealand may be following the US trends in cigar smoking prevalence where there has been an almost 50% increase since 1993. The National Cancer Institute report has associated the increased prevalence of cigar use in the US with increased promotional activity such as the publication of Cigar Aficionado, a cigar lifestyle magazine, and media coverage of the use of cigars by celebrities and social events featuring cigars. The Surgeon General has associated the increase in prevalence of cigar smoking in California with “...an unprecedented increase in promotional and product-placement advertisements for cigars in magazines, movies and music videos.”

Global bans on tobacco advertising and promotion

Dr Gro Harlem Brundtland, Director-General of the WHO, has emphasised that tobacco must not be advertised, subsidised or glamorised. It is useful to reflect on why the advertising and promotion of tobacco products is banned partially or completely by more than 22 countries. The number of countries taking action to ban tobacco advertising and promotion will increase significantly once the European Commission Directive is fully implemented resulting in tobacco advertising being banned in the European Union from 30 July 2002 and all sponsorship ending in the Union countries by 30 July 2006.

The evidence linking tobacco advertising and promotion with tobacco consumption and hence death and disease, has been reviewed by a number of authoritative bodies such as the US Surgeon General, the British Government, the WHO, and most recently the World Bank. The evidence is based largely on inter-country comparative studies and before and after studies within countries. Confounding factors such as the impact of changes to other tobacco control strategies, need to be taken into account in these studies, but nonetheless, the authoritative bodies are unanimous on the effectiveness of comprehensive bans on advertising and promotion, covering all media and all uses of brand names and logos, in reducing demand for tobacco products. The World Bank has estimated that comprehensive bans can reduce demand for tobacco products by about 7% in high-income countries. The Bank’s analysis has shown, however, that partial advertising bans have little or no effect on smoking. This is because the tobacco industry can substitute advertising in other media. The tobacco lobby and the New Zealand media consistently argue that advertising bans violate the principle of freedom of expression, but as Dr Nkosazana Zuma, South Africa’s health minister said in 1999, “Freedom of speech is not an unlimited right; there are limitations to every right and we strongly believe that this is an area where the limitation has to be applied.” Parliament can choose to place limits on the freedom of speech by overriding the New Zealand Bill of Rights Act 1990 when it considers that some legislative need (for example, the Smoke-free Environments Amendment Act 1997) is of greater importance.
consisting of education, cessation, taxation and legislation. The strategy has been successful. Smoking prevalence in adults (aged fifteen years and over) has declined so that overall between 1976 and 1998, the decline in prevalence was almost one-third. The decline has slowed in recent years, with a reduction in smoking prevalence in the adult population from 27% to 25% between 1994 and 1998. However, the amount of tobacco released for consumption in New Zealand fell to 1371 cigarette equivalents per adult aged fifteen years and over in 1998, a reduction of approximately 30% since 1990 (1971 equivalents).

New Zealand’s ban on the advertising and promotion of tobacco products

Part II of the Smoke-free Environments Act 1990 relates to tobacco products control and has as part of its purpose “to reduce the social approval of tobacco use, particularly among young people, by imposing controls on the marketing, advertising, or promotion of tobacco products and their association through sponsorship with other products and events...” (s 21). “Tobacco product” means “any product manufactured from tobacco and intended for use by smoking, inhalation, or mastication...” (s 2), and obviously this definition includes cigars.

Our legislators showed foresight. They defined a “Tobacco product advertisement” in the Act as meaning “any words, whether written, printed, or spoken, including on film, video recording, or other medium, broadcast or telecast, and any pictorial representation, design, or device, used to encourage the use or notify the availability or promote the sale of any tobacco product or to promote smoking behaviour...” (s 2). The Act does not include payment in the definition and thus does not distinguish between the printed word in a paid advertisement or in editorial.

The Act places responsibility for enforcement on the Director-General of Health (s 37). The implications of allocating responsibility for enforcement to the Director-General is that the ordinary citizen has been deprived of their right to initiate prosecution action which places an obligation on the Director-General to give consideration to whether or not prosecution action should be taken.

The enforcement of advertising bans is relatively straightforward. The complainant provides reasonable evidence of a breach of the law and information on the alleged offender. The regulator needs to confirm that a breach has indeed occurred. The Ministry followed this process when investigating alleged breaches of the Act relating to the promotion of cigars. Proof of fault does not rest on complex epidemiological studies or laboratory tests of arguable validity and reliability. There is not usually a long chain of evidence that has to be maintained. Once the Director-General has duly considered the matter, she then has discretion on whether or not to take prosecution action depending on the circumstances of the case. Enforcement of the Smoke-free Environments Act 1990 is considered important by the Ministry. The Ministry’s approach to enforcing the legislation is educational in the first instance, and prosecution action is only taken with recalcitrant advertisers or where there is disagreement on interpretation of the law and a test case would assist interpretation. As a result, only two prosecutions for unlawful advertising of tobacco products have been taken to date.

It is not possible to quantify the impact of the progressive ban on tobacco advertising in New Zealand during the 1990s due to a number of confounding factors. These factors include other tobacco control initiatives introduced during this period (for example, increase in tobacco taxation), and continuing, less direct, tobacco advertising (for example, smoking in movies and the expansion of point of sale advertising until further restricted in December 1999).

New Zealand’s comprehensive tobacco control strategy has contributed to the reduction in tobacco smoking in New Zealand in the 1990s. The ban on the advertising and promotion of tobacco products is pivotal in preventing the industry from encouraging young people to take up smoking and the undermining of the health sector’s efforts to discourage smoking and to promote cessation. In the face of declining sales, the tobacco industry is adept at finding new strategies to continue to encourage tobacco use. For example, the cigar is marketed as a symbol of a luxurious, successful and exciting lifestyle. Given the health effects of cigars described in this paper, and of other tobacco products, it is vital that effect is given to the ban on the promotion and advertising of tobacco products in the legislation.

Acknowledgements. We thank Drs Boyd Swinburn and Murray Laugesen for comments on an earlier draft of this paper. This paper is published with the permission of the Director-General of Health.

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2. Book-burning is no answer [editorial]. The Dominion 1999 April 14: 10 (col 1).
When do parents have the right to refuse medical treatment on behalf of their children?

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Following a couple of high profile cases, there has been media debate concerning the rights of parents to refuse treatment on behalf of their sick children. There are legal and ethical issues.

If a child is not competent to give consent to, or refuse, medical treatment, a parent or guardian of the child can act as a proxy and consent or refuse on the child’s behalf. In principle, the scope of the parent’s power as a proxy is relatively straightforward: to act in the child’s ‘best interests’.

If the parent’s refusal to provide consent is not in the child’s ‘best interests’, a medical practitioner can challenge the parent’s refusal by applying to the Court. The Court will hear all the evidence, medical and otherwise, and determine what treatment is in the ‘best interests’ of the child. The courts have shown that they are prepared to override the parent’s right to decide.

‘Best Interests’

What amounts to ‘best interests’ will substantially be resolved on an ad hoc basis, taking into account all the circumstances of the particular case. A number of principles provide assistance.

1. Inherent in the notion of ‘best interests’ is that the medical intervention must be therapeutic (ie, intended to benefit the particular individual).
2. Despite lack of competence, the child’s views of the proposed treatment should be ascertained as far as possible.
3. Regard may be paid to the religious views of a parent when the effect on the child is not significant, but the parent’s right to practice their religion cannot extend to imperil the life or health of the child. Jehovah’s Witness parents have had their refusal to allow a potentially life-saving blood transfusion overruled by the Court.
4. A doctor should not ordinarily be ordered to treat a child in a manner contrary to his or her clinical judgment.

The English Position

In the English case known as Re T, a mother refused to consent to a liver transplant on her three week old baby, as she was not willing to permit the child to suffer the pain and distress involved. Three paediatricians recommended the operation, noting that the child would be unlikely to live beyond two and a half years without it. If the operation succeeded, the evidence was that the child would be likely to have many years of normal life. The Court emphasised that the welfare of the child depended on the mother who would be expected to care for the child in the future. The Court considered that the mother’s views, combined with the possibility of failure, outweighed the medical evidence. The Court declined to override the mother’s refusal.

The English position is to be welcomed in that it recognises the need for considerations wider than just the medical interests to be taken into account in determining what amounts to a child’s ‘best interests’. However, in the specific facts of the case, the Court probably paid too little attention to the medical evidence in reaching its decision.

Alternative Treatments

Further complications arise when a parent wants his or her child to be treated in a manner other than that recommended by the medical advisers. Parents may, for example, elect treatment which has a lower chance of success but which has significantly less side-effects. This is substantially what happened in the case of Liam Williams-Holloway, where Liam’s parents refused chemotherapy treatment in favour of alternative treatment. The Court made an order that Liam be placed under the guardianship of the Court, and that Liam should be treated as approved by the paediatric oncologist.

Liam’s case can be contrasted to a United States case where parents refused chemotherapy as a treatment for their child’s leukaemia, preferring that the child be treated with laetrile, a natural substance derived from apricot pits. There was evidence that the nutritional treatment was controlling the condition. The Court refused to order chemotherapy, stating that it was unable to conclude that the parents had not taken reasonable efforts to ensure that acceptable medical treatment was being provided to their child.

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7. Re Hoffauer (1979) 393 NE ed 1109 (NY CA).