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Management of chronic suppurative otitis media

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TO THE EDITOR: Chronic suppurative otitis media (CSOM) is a long-term problem which often has serious effects on hearing, speech and learning. Couzos and colleagues have shown that local treatment with ciprofloxacin (CIP) eardrops clears episodes of purulent discharge more efficiently than the commonly used framycetin, gramicidin and dexamethasone (FGD) eardrops.¹ This hardly ranks as a “cure” as suggested by the authors.

The natural history of CSOM is known²⁻⁴ (see Box). The disease commonly starts in infancy with painless perforation of the ear drum and purulent discharge. The perforation is usually central and often large. It remains for several years. During this time there are episodes of painless discharge of foul-smelling pus associated with a blocked ear canal and poor hearing. Between these episodes, the perforation remains, but the ear is usually dry and hearing can be normal or at least adequate. By mid-childhood the perforation often closes spontaneously. In some children this leaves a scarred retracted eardrum, but, in others, fluid collects behind the now intact drum, and this chronic serous otitis media decreases hearing. Eventually, this chronic serous otitis media clears, leaving a scarred, retracted eardrum. Hearing then improves and is often functionally normal. Cholesteatoma and other medical complications are uncommon, but the loss of hearing during childhood has severe social and educational effects on the child.

Attempts to hasten closure of the perforation and limit the episodes of purulent discharge have had incomplete success.^{5,6} Any treatment that hastens recovery is welcome, but we should ask:

■ Does local CIP treatment retain its effectiveness in repeated episodes of purulent discharge? (The most common organisms are *Pseudomonas spp* which rapidly develop resistance to antibiotics);

■ Does CIP treatment alter the interval between purulent episodes compared with other treatments?; and

■ Is there any evidence that local CIP treatment alters the natural history of the disease or lessens the hearing loss? (it is probably too early to detect this).

CSOM is a disease of poverty and overcrowding, but the mechanism leading from social disadvantage to ear disease is not clear. In Cherbourg Aboriginal Community where I work, social and living conditions have improved and CSOM is now much less common than reported by Stuart and co-workers more than 25 years ago.² I hope that treatment with local CIP eardrops will maintain its promise as a significant improvement in the management of this disease in children who have already acquired it, while we work towards eliminating the disease in the long term.

1. Couzos S, Lea T, Mueller R, et al. The effectiveness of otological antibiotics for chronic suppurative otitis media in Aboriginal children: a community-based, multi-centre, double-blind randomised controlled trial. *Med J Aust* 2003; 179: 185-190.
2. Stuart JE, Quayle CJ, Lewis AN. Follow-up studies of Aboriginal children with ear disease and hearing loss at Cherbourg. *Med J Aust* 1975; 1 (10 May Suppl): 38-40.
3. Dugdale AE, Cauty A, Lewis AN, Lovell S. The natural history of middle ear disease in Australian Aboriginals: a cross-sectional study. *Med J Aust* 1978; 1 (25 Mar Suppl): 6-9.
4. McCafferty GJ, Lewis AN, Coman WB, Mills C. A nine-year study of ear disease in Australian Aboriginal children. *J Laryngol Otol* 1985; 99: 117-125.
5. Leach AJ. Otitis media in Australian Aboriginal children: an overview. *Int J Otorhinolaryngol* 1999; 49 (Suppl 1): S173-S178.
6. Mak D, MacKendrick A, Weeks S, Plant AJ. Middle ear disease in remote Aboriginal Australia: a field assessment of surgical outcomes. *J Laryngol Otol* 2000; 114: 26-32. □

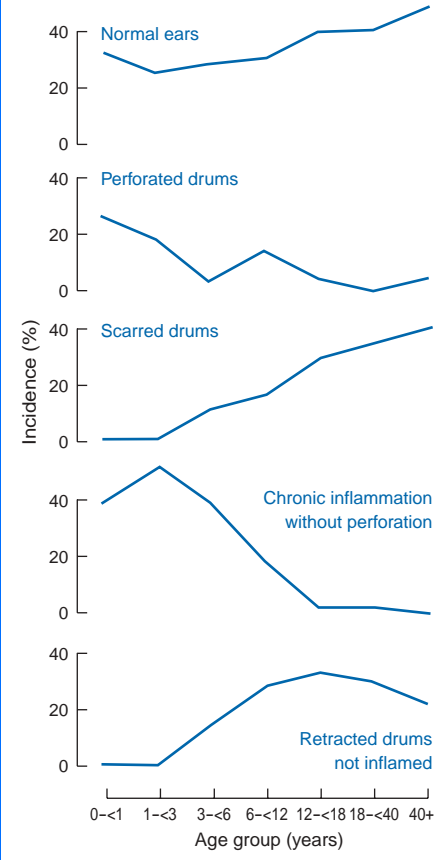
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TO THE EDITOR: Although the study by Couzos et al¹ is important, I have serious concerns about (i) the lack of “intention-to-treat” analysis and (ii) the implication that the use of otological aminoglycosides is unethical and could lead to litigation.

The CONSORT statement indicates that analysis by intention-to-treat (ITT) is a key measure of methodological quality in reporting of randomised trials.^{2,3} Of 147 children randomly allocated to the two treatments in this trial, the primary outcome (resolution of otorrhoea) is only reported for 111 chil-

Changes in the incidence of ear disease with age in an Aboriginal community (from Dugdale et al³)



dren (75.5%), and the secondary outcomes of healed tympanic membrane perforation in 64 (43.5%), and of improved hearing in 49 (33.3%). In addition, although the difference in cure rates is indeed 24.6% if drop-outs are ignored, the authors report incorrect 95% confidence intervals (15.8%–33.4%, instead of 7.3%–41.8%).

Analysis by intention-to-treat means that the 36 children lost to follow-up are assumed to still have ear discharge, so 33 of 75 in the ciprofloxacin group and 43 of 72 in the combined framycetin, gramicidin and dexamethasone group would not have “clinical cure”. This reduces the absolute difference to 15.7% (95% CI, 0–32%; $P=0.07$), which is no longer a significant difference.

It is also unlikely that the clinical cure rates of 50%–70% in the study can be replicated in the real world of remote Top End Aboriginal communities with a high prevalence of chronic suppurative

tive otitis media (CSOM). Cleaning ears twice a day with gentle syringing with 0.5% povidone-iodine, followed by ototopical ciprofloxacin for 10–14 days is not a feasible intervention among the competing priorities in most Aboriginal communities in the Northern Territory. The really important clinical outcomes for CSOM are the two secondary outcomes of healed perforations and improved hearing, but these outcomes were not significantly improved by ciprofloxacin compared with combined framycetin, gramicidin and dexamethasone.

Couzos and colleagues conclude that the use of aminoglycosides in CSOM is unethical and could lead to litigation on the basis of potential ototoxicity. Were this true, it would make this trial unethical. This misuse of ethics and law in the medical literature must be denounced. Nearly all drugs have potential side effects which have to be measured against their potential benefits. The potential ototoxicity of ototopical aminoglycosides (and other antibiotics) is not an absolute contraindication to their use, and has not been documented in any of the randomised controlled trials that have measured hearing before and after use of topical aminoglycosides.⁴

Couzos and colleagues misinterpret the strength of evidence for changing to ototopical ciprofloxacin. Although it is probably true that ciprofloxacin is superior to combined framycetin, gramicidin and dexamethasone in eradicating *Pseudomonas aeruginosa*, and for the short-term resolution of ear discharge, it is still unclear whether this transient benefit will be maintained in the long term, or whether resistant organisms will emerge in the middle ear, mitigating any benefit from the new drug. Haphazard use of ototopical ciprofloxacin in Top End Aboriginal communities is likely to result in resistance (indeed there is already anecdotal and unpublished evidence of this), so I believe that its use should currently be restricted to studies and programs whose outcomes are healed perforations and improved hearing (rather than only transient resolution of ear discharge).

children: a community-based, multicentre, double-blind randomised controlled trial. *Med J Aust* 2003; 179: 185–190.

2. Huwiler-Muntener K, Juni P, Junker C, Egger M. Quality of reporting of randomized trials as a measure of methodologic quality. *JAMA* 2002; 287: 2801–2804.
3. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ* 1999; 319: 670–674.
4. Acuin J, Smith A, Mackenzie I. Interventions for chronic suppurative otitis media (Cochrane Review). CD000473. In: The Cochrane Library, Issue 3, 2003. Oxford: Update Software. □

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IN REPLY: Dugdale correctly refers to the natural history of chronic suppurative otitis media (CSOM), and the spectrum of endpoints. The primary endpoint chosen in our trial after ototopical treatment was a dry ear¹ (commonly referred to as a “clinical cure” by other trials²), an outcome to be expected after short-term follow-up. Surgical closure of the tympanic membrane (TM) has also been defined as “curing” CSOM. Attaining a dry ear is essential to TM healing, and is therefore a functionally important outcome.

Brewster seems to confuse intention-to-treat (ITT) analysis with sensitivity analysis. Patients for whom there is no data after random allocation to study groups fall into the “missing” category, and may be included as “failures” in a sensitivity analysis. This may reveal additional information if missing data occurred differentially (ie, in some way associated with the treatments). However, in an ITT analysis, patients (with recorded data) are analysed in the group to which they were randomly allocated, irrespective of the actual treatment they received.³ Our analysis followed this principle and included all children, irrespective of the completeness of their treatment regimen.¹ A sensitivity analysis revealed no new information, which was not surprising as the missing data were lost for (ascertained) reasons exclusively unrelated to the treatment,

and double-blinding excluded any differential follow-up efforts by the healthcare workers. Consequently, the missing values occurred randomly and our analysis not only follows the ITT principle but is also unbiased (ie, valid with respect to “missing” patients).

We are surprised that our treatment regimen is not feasible in the Northern Territory given that it has been used for years in remote Aboriginal communities in Western Australia. We also confirmed the effectiveness of *twice-daily* use of ototopical medications, which is simpler than current four-times daily schedules.

In 1996, the World Health Organization recommended that topical aminoglycosides (AG) *not be used* for CSOM because of ototoxicity.⁴ Such use is also contraindicated by manufacturers.¹ Given the availability of a safer alternative, healthcare professionals face potential medicolegal challenges if they choose ototopical AG to treat CSOM.

The relative superiority of ototopical fluoroquinolones (FQ) over AGs in effecting a dry ear is likely to persist with repeated treatments, as the risk of bacterial resistance generated in CSOM pathogens appears to be very small,⁵ and is far outweighed by the risks of resistance found with oral or parenteral FQs. In our trial, bacterial resistance to ciprofloxacin in ear isolates was not demonstrated in the short term. Systemic absorption of FQ through ototopical use is also negligible.⁵ In Japan, ototopical ofloxacin has been used as treatment for CSOM since 1992. Based on repeated nationwide surveys from 1995, increased FQ resistance attributed to ototopical use has not been seen in chronic otitis media isolates (Professor K Suzuki, Department of Otolaryngology, The Second Hospital, Fujita Health University School of Medicine, personal communication).⁶

Whether antibiotics can affect the interval between purulent episodes of CSOM is predicated on host and environmental factors, as well as the duration of effective drug therapy.

A multifaceted approach to the problem of CSOM, requiring the political will to improve the living conditions of Aboriginal families, access to appropriate primary healthcare, ototopical FQs, and surgery will see a reduction in the rate of this disabling disease.

1. Couzos S, Lea T, Mueller R, et al. Effectiveness of ototopical antibiotics for chronic suppurative otitis media in Aboriginal

1. Couzos S, Lea T, Mueller R, et al. Effectiveness of otological antibiotics for chronic suppurative otitis media in Aboriginal children: a community-based, multicentre, double-blind randomised controlled trial. *Med J Aust* 2003; 179: 185-190.
2. Acuin J, Smith A, Mackenzie I. Interventions for chronic suppurative otitis media (Cochrane Review). CD000473. In: The Cochrane Library, Issue 3, 2003. Oxford: Update Software.
3. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. Guidance for industry. E9 Statistical principles for clinical trials. Rockville, Md. 1998. Available at: www.fda.gov/cder/guidance/ICH_Eq-fnl.PDF (accessed Dec 2003).
4. Prevention of hearing impairment from chronic otitis media. Report of a WHO/CIBA Foundation Workshop held at the CIBA Foundation, London, UK, 19-21 Nov 1996. Geneva: World Health Organization, 1998. (WHO/PDH/98.4). Available at: www.who.int/pbd/pdh/Docs/COM-Cover-sum.html (accessed Jan 2003).
5. Simpson KL, Markham A. Ofloxacin otic solution: a review of its use in the management of ear infections. *Drugs* 1999; 58: 509-531.
6. Suzuki K, Nishimura T, Baba S. Current status of bacterial resistance in the otolaryngology field: results from the Second Nationwide Survey in Japan. *Infect Chemother* 2003; 9: 46-52. □

Overweight and obesity in Australia: an underestimate of the true prevalence?

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TO THE EDITOR: While the rates of overweight and obesity among Australian adults, as determined by the Australian Diabetes, Obesity and Lifestyle Study (AusDiab),⁴ may be alarming to some, they may in fact be underestimates of the true prevalence of overweight and obesity.

The AusDiab study design⁵ and its low response rates indicate that the results will need to be interpreted with caution.

Firstly, the AusDiab study design excluded rural and predominantly Indigenous census collection districts (CDs). In Queensland, all CDs selected were capital city or other major urban centres (Rural and Remote Areas Classification, categories 1 and 2);³ thus, people living in major rural centres (such as Rockhampton or Bundaberg) or major remote centres (such as Mt Isa) were excluded (ie, in Queensland, about 20% of the population were excluded).

Secondly, another potential bias may have been introduced by the Socio-Economic Indexes for Areas (SEIFA) scores of the CDs sampled in the AusDiab study. For example, the overall SEIFA score for the CDs included in Queensland was 1035 (73rd percentile), well above the state average.

Finally, the response rates in the AusDiab study were low: only 29% of those estimated to be eligible, and only 52% of those invited, actually completed the study.

Our analysis of risk factors of Queensland-AusDiab participants suggests that these participants may have been more health conscious than the general Queensland population. Rates of smoking reported for men and women were considerably lower in the Qld-AusDiab cohort compared with those in the Queensland phase of the 2001 National Health Survey⁴ (17.3% and 14.5% v 28.4% and 19.8%, respectively).

Compared with results of a Queensland Omnibus telephone survey⁵ conducted at about the same time, higher proportions of Qld-AusDiab participants reported greater intakes of vegetables (≥ 4 serves/day: 27.4% Qld-AusDiab v 16.4% Omnibus) and fruit (≥ 2 serves/day: 28.9% v 24.3%), and less frequent consumption of fast foods (> 1 day/week: 37.3% v 49.5%).

Given the low response rate and possible selection bias in the AusDiab study, we suggest that the overweight and obesity data should be interpreted with caution. Several indicators suggest that these data could be underestimates of the true prevalence of overweight and obesity, and that the AusDiab population may have been of higher socioeconomic status, more health conscious (lower rates of smoking, better dietary intake), and more willing to participate in a lengthy examination than the general Australian population. These factors may all be associated with lower rates of overweight and obesity, and therefore future national surveys will need to take these factors into consideration to obtain more accurate estimates of important determinants of health.

1. Cameron AJ, Welborn TA, Zimmet PZ, et al. Overweight and obesity in Australia: the 1999-2000 Australian Diabetes, Obesity and Lifestyle Study (AusDiab). *Med J Aust* 2003; 178: 427-432.

2. Dunstan D, Cameron A, deCourten M, et al. The Australian Diabetes, Obesity and Lifestyle Study (AusDiab). Data

report: Queensland. Melbourne: International Diabetes Institute, 2001.

3. Department of Human Services and Health. Rural and remote areas classification. Canberra: AGPS, 1994.

4. Australian Bureau of Statistics. National Health Survey 2001. Canberra: ABS, 2002. Available at: www.abs.gov.au/Ausstats/abs@nslf/0/cac1a34167e36be3ca2568a900139364?OpenDocument (accessed Dec 2003).

5. Epidemiology Services Unit. Omnibus 2001 survey: questionnaire and primary results. Brisbane: Health Information Centre, Queensland Health, July 2001. □

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IN REPLY: Coyne suggests that, based on comparisons within Queensland, the national prevalence of obesity in our article¹ is an underestimate. It should be noted that the Australian Diabetes, Obesity and Lifestyle Study (AusDiab) was designed primarily to produce national, not state-specific, data. Forty-two census collection districts (CDs) were selected Australia-wide, with only six CDs selected within each state. The primary objective of this sample selection was to obtain a nationally representative population, not necessarily one representative of each state.

Coyne states that none of the Queensland CDs were in major provincial centres. Of the six Queensland CDs, four were outside Brisbane. From the national sample, 17 of 42 CDs (40.5%) were outside capital cities. As a comparison, 36% of the Australian population lives outside capital cities.²

Regarding selection of CDs, we excluded only those in Statistical Local Areas defined as 100% rural, and those where the Indigenous population made up 10% or more of the overall population.³ This excluded only 5.8% of the total eligible population. If the prevalence of obesity among this group was double the overall prevalence, this would not significantly alter the national rate.

While the smoking rates in AusDiab were lower than reported elsewhere, the prevalence of obesity, hypercholesterolaemia and hypertension were in line with trends in a series of surveys over the past 20 years.⁴ In an extensive analysis of food consumption between AusDiab and the 1995 National Nutrition Survey, the rates of fruit and vegetable

consumption were within 4% between the surveys for those most commonly eaten.

Since our conclusion was that obesity has increased, the possibility of an underestimate only reinforces our message.

1. Cameron AJ, Welborn TA, Zimmet PZ, et al. Overweight and obesity in Australia: the 1999–2000 Australian Diabetes, Obesity and Lifestyle Study (AusDiab). *Med J Aust* 2003; 178: 427–432.
2. Australian Bureau of Statistics. Australian social trends. Population — Population distribution: population characteristics and remoteness 2003. Available at: www.abs.gov.au/Ausstats/abs%40.nsf/94713ad445ff1425ca25682000192af2/d7495af81c170735ca256d39001bc334!OpenDocument (accessed Dec 2003).
3. Dunstan D, Zimmet P, Welborn T, et al, on behalf of the AusDiab Steering Committee. The Australian Diabetes, Obesity and Lifestyle Study (AusDiab) — methods and response rates. *Diabetes Res Clin Pract* 2002; 57: 119–129.
4. Australian Institute of Health and Welfare. Heart, stroke and vascular diseases — Australian facts 2001. Canberra: AIHW, National Heart Foundation of Australia, National Stroke Foundation of Australia, 2001. (AIHW Cat. No. CVD 13; Cardiovascular Disease Series No. 14.) □

Aspirin for cardiovascular disease prevention

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TO THE EDITOR: We read with interest the article by Hung on aspirin for cardiovascular disease prevention,¹ and would like to alert readers to the fact that, from the same studies Hung discussed, it is clear aspirin fails to prevent 80% of recurrent serious vascular events, and that one in eight high-risk patients will suffer from another “event” in the next 2 years while taking aspirin.²

Recent studies have triggered discussion about the concept of aspirin resistance and competitive binding issues as possible causes for the observed failure of aspirin, or indeed the increased risk of all-cause mortality when aspirin is used in combination with ibuprofen.^{3,4} Although it may still be premature to recommend routine testing for aspirin resistance, the possibility that testing might lead to improved strategies for reducing the risk of thrombotic complications means that it should be considered. Another point for consideration is whether primary prophylaxis with aspirin might induce aspirin resistance, thereby nullifying the effect of taking it in the first place.

We agree with Hung that the current main alternative to aspirin is clopidogrel,

and that this agent could be used in cases in which there is any doubt about the efficacy of aspirin.

1. Hung J, for the Medical Issues Committee of the National Heart Foundation of Australia. Aspirin for cardiovascular disease prevention. *Med J Aust* 2003; 179: 147–152. www.mja.com.au/public/issues/179_03_040803/hun10816_fm.html
2. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. Antithrombotic Trialists' Collaboration. *BMJ* 2002; 324: 71–86.
3. Gum PA, Kottke-Marchant K, Welsh PA, et al. A prospective, blinded determination of the natural history of aspirin resistance among stable patients with cardiovascular disease. *J Am Coll Cardiol* 2003; 41: 961–965.
4. MacDonald TM, Wei L. Effect of ibuprofen on cardioprotective effect of aspirin. *Lancet* 2003; 361: 573–574. □

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IN REPLY: Janssen and Henshaw are correct to point out that aspirin fails to prevent 80% of recurrent serious vascular events among high-risk patients. However, to put this into perspective, simple treatment with aspirin produces about the same relative risk reduction as treatment with a statin or the angiotensin-converting enzyme inhibitor, ramipril, among patients at high risk of vascular events.^{1–3}

Janssen and Henshaw raise the concept of aspirin resistance and the role of a screening test. However, aspirin resistance is a poorly defined term, and could mean the clinical inability of aspirin to protect individuals from arterial thrombotic events, or laboratory measures indicating the failure of aspirin to inhibit platelet activity. There is currently no specific, accurate, and reproducible measure of the antiplatelet effects of aspirin, nor are there methods that can reliably predict the clinical efficacy of aspirin.⁴ For now, with high-risk patients, doctors should:

- ensure that patients comply with aspirin therapy along with other proven preventive treatments;
- avoid regular concomitant use of non-steroidal anti-inflammatory drugs with aspirin because of the potential for competitive inhibition;⁵ and
- consider the *addition* of clopidogrel to therapy with aspirin, so as to block other pathways of platelet activation not blocked by aspirin, particularly in

patients who experience thrombotic complications during aspirin therapy.¹

1. Hung J, for the Medical Issues Committee of the National Heart Foundation of Australia. Aspirin for cardiovascular disease prevention. *Med J Aust* 2003; 179: 147–152.
2. Genest J, Pedersen TR. Prevention of cardiovascular ischemic events: high-risk and secondary prevention. *Circulation* 2003; 107: 2059–2065.
3. The Heart Outcomes Prevention Evaluation Study Investigators. Effect of an angiotensin-converting-enzyme-inhibitor, ramipril, on cardiovascular events in high-risk patients. *N Engl J Med* 2000; 342: 145–153.
4. Eikelboom JW, Hankey GJ. Aspirin resistance: a new independent predictor of vascular events? *J Am Coll Cardiol* 2003; 41: 966–968.
5. Kurth T, Glynn RJ, Walker AM, et al. Inhibition of clinical benefits of aspirin on first myocardial infarction by non-steroidal antiinflammatory drugs. *Circulation* 2003; 108: 1191–1195. □

The impact of chronic illness: partnerships with other healthcare professionals

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TO THE EDITOR: The article by Brooks contains valuable forward-thinking for future healthcare management of the increasing burden of chronic illness. However, Brooks's suggestion that non-medical practitioners might perform cataract extraction shows his lack of knowledge of the complexity and potential complications of modern cataract surgery.

Modern cataract surgery is the most commonly performed major operation, and one of the most rewarding in lifestyle improvement. It is done under local anaesthetic with almost no discomfort, and recovery is rapid. Thus, the patient sees it as being simple. However, it is far from simple for the surgeon.

The small-incision, phacoemulsification technique has made the operation more demanding than ever before. The learning curve is both long and steep. Posterior capsule rupture during phacoemulsification is an ever-present threat, and if it occurs, the sight-threatening complications of cystoid macular oedema, retinal detachment and endophthalmitis all become more likely. The modern, highly technical procedure that Australians demand and deserve is comparable with coronary artery bypass and joint replacement surgery in terms of the skill required.

There are three reasons that non-ophthalmologists think cataract surgery is simple. First, it is simple from the patients' perspective. Secondly, cataract extraction can be done relatively cheaply in developing countries. However, the operation done in those countries is a different procedure, and comparisons are not valid. Thirdly, some unscrupulous ophthalmologists themselves have trivialised the procedure as a means of self-promotion.

Brooks and others would pay the operation much more respect if they took the trouble to view a few procedures in real life.

1. Brooks PM. The impact of chronic illness: partnerships with other healthcare professionals. *Med J Aust* 2003; 179: 260-262. □

Obstacles to research in complementary and alternative medicine

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TO THE EDITOR: Ernst raises the matter of obstacles to research in complementary and alternative medicine.

With respect to spinal manipulation therapy as an alternative medical approach to constitutional ailments, such as migraine, the key evidence is the recovery of vision, which occurs with spinal manipulation in appropriately ill patients. These data have not been acknowledged by this Journal because randomised controlled trials have not been performed.

Ernst says, "Randomisation is only ethical if there is substantial uncertainty about the best treatment for that patient."¹ Applied to the recovery of vision with spinal manipulation, this ethical principle prevents any randomised trials from being performed in studying that phenomenon.

In 1992, I sent 12 consecutive patients demonstrating constricted visual fields to four senior fellows of the then Royal Australian College of Ophthalmologists. The patients were examined by those consultant scrutineers, who agreed that the visual fields were constricted in all occasions. The patients were seen at independent locations, and I was present only on one

occasion. The patients were then treated by spinal manipulation under anaesthesia, with immediate recovery of the visual fields being noted on wakening from anaesthesia.² This recovery of vision merely reiterated many earlier anecdotal demonstrations.³⁻⁵ In every case, the scrutineers agreed that the vision had recovered when, at an independent location subsequent to the treatment, they saw the patients.

Further, when Stephens and his associates, including me, treated 17 patients by outpatient chiropractic spinal adjustments, that entire group showed immediate improvement in the visual fields, as measured by computerised static perimetry.⁶

Sletteberg and his associates found that 55% of patients with constricted visual fields of the type under discussion still had the visual disability on re-examination on a mean review period of 7 years after orthodox treatment.⁷ Kathol and his associates also found that 55% of these patients still had the visual disability at a mean review period of 4 years.⁸ When the 100 per cent improvement obtained by spinal manipulation is compared with results of orthodox medical treatment (45% improvement at mean review periods of 7 and 4 years), it is clear that spinal manipulation is more effective than orthodox medical treatment, so much so that to repeat the experiment would be unethical.

In my personal experience, the main obstacle to research of complementary medicine precepts has been the censorship of dissenting data from orthodox medical literature. The most blatant example of this is the studied neglect of the "tunnel vision information": the knowledge that vision improves in appropriately ill patients when the spine is manipulated.

1. British Medical Association. Medical ethics today, its practice and philosophy. London: BMA, 1993.
2. Gorman RF. The treatment of visual perception defect by spinal manipulation: a prospective peer-reviewed study of twelve consecutive patients. 24th Annual Scientific Congress of the Royal Australian College of Ophthalmologists. 1992 Nov 1-6; Sydney.
3. Langford-Wilson A. New view of tunnel vision. *The STAR* (Mt Isa) 1982; 14 Sep.
4. Howarth J. Claims of answer to vision scourge. *The NT News* (Darwin) 1982; 13 Nov: 17.
5. Morrison J. A dangerous twist. *60 Minutes*. TCN Channel 9, NSW, 22 Jun 1986.
6. Stephens D, Mealing D, Pollard H, et al. Treatment of visual field loss by spinal manipulation: a report on 17 patients. *J Neuromusculoskeletal Sys* 1998; 6: 53-66.
7. Sletteberg O, Bertelsen T, Hovding G. The prognosis of patients with hysterical visual impairment. *Acta Ophthal* 1989; 67: 159-163.
8. Kathol RG, Cox TA, Corbett JJ, Thompson ST. Functional visual loss — a follow-up of 42 cases. *Arch Ophthalmol* 1983; 101: 729-735. □

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IN REPLY: Gorman's story is characteristic of complementary/alternative medicine (CAM): someone makes an observation inconsistent with current medical teaching, and subsequently becomes convinced that therapy X is "100 per cent" effective. Yet clinical trials are never conducted and therapy X assumes somewhat of a cult status. Its proponents name various reasons why clinical trials are unavailable. In some instances (not in the case of spinal manipulation for recovery of vision), clinical trials do eventually emerge. These show that therapy X does not work. Proponents view this as a confirmation of their conspiracy theory. Eventually the cult status of therapy X becomes established.

This dangerous scenario would be avoidable if CAM proponents understood the role of science in testing emerging treatments. It is, of course, not unethical to conduct a randomised trial on spinal manipulation for recovery of vision. Sure, randomisation is only

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There should be no more than 5 references. The reference list should not include anything that has not been published or accepted for publication. Reference details must be complete, including: names and initials for up to 4 authors, or 3 authors et al if there are more than 4 (see [mja.com.au/public/information/uniform.html#refs](http://www.mja.com.au/public/information/uniform.html#refs) for how to cite references other than journal articles).

ethical if there is uncertainty, but to deny that uncertainty exists is unreasonable — as is the notion of “censorship of dissenting data from orthodox medical” journals. Gorman’s reference list shows that even CAM journals have resisted publishing the effects of spinal manipulation on vision recovery.

My conclusion is simple: science and medical publishing follow certain rules for good reasons. CAM should learn to follow them. □

The regulation of complementary health: sacrificing integrity?

Vivian Lin

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TO THE EDITOR: The Chinese Medicine Registration Board of Victoria would like to provide updated information relevant to the debate on the article by Parker.¹

All practitioners of acupuncture and Chinese herbal medicine in Victoria are now legally required to register. The *Chinese Medicine Registration Act 2000* (Vic) specifically includes transitional arrangements, and the Board has developed a “grandparenting policy” for assessing registration applications until 31 December 2004.

There are six key assessment areas for all applicants:

- adequacy of qualification (minimum requirements);
- recency of practice;
- competence;
- good character;
- fitness to practise; and
- having the required professional indemnity insurance, first aid and effective communication arrangements.

Details are available at www.cmrb.vic.gov.au. To date, 740 practitioners have become registered, and 11.5% of applicants have had a registration refusal or conditions imposed.

After the grandparenting period, new applicants will be required to complete an approved course or pass an examination set by the Board. The Board will consider advanced diploma courses for

approval up until December 2007, after which the minimum level will be a bachelor degree.

Complaints are handled according to the Act, which is modelled on the medical (and other health) practice Acts. The current Victorian model dictates that the Board include two non-practitioners, one legally qualified member and six practitioners with a minimum of 5 years practice experience. Very specific steps must be taken in dealing with complaints, and 28 complaints have already been investigated. The issues of concern include infection control, advertising, professional ethics and communication with patients.

Other boards (not medical practitioners) have asked us to assist with endorsement of their registrants, mainly for acupuncture. The Medical Practitioners Board of Victoria plans to ask medical practitioners seeking endorsement for Chinese herbal medicine to register directly with us.

We hope this information will help contribute to informed debate on the regulation of complementary and alternative medicine.


1. Parker MH. The regulation of complementary health: sacrificing integrity? *Med J Aust* 2003; 179: 316-318. □

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The Medical Journal of Australia (MJA) is published on the 1st and 3rd Monday of each month by the Australasian Medical Publishing Company Proprietary Limited, Level 2, 26-32 Pyrmont Bridge Rd, Pyrmont, NSW 2009. ABN 20 000 005 854. Telephone: (02) 9562 6666. Fax: (02) 9562 6699. E-mail: ampco@ampco.com.au. The Journal is printed by Offset Alpine Printing Ltd, 42 Boorea St, Lidcombe, NSW 2141.

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27,889 circulation as at

28 October, 2003

ISSN 0025-729X