

## Open letter to Annette King, Minister of Health, New Zealand

EDITOR—We learn with great concern that Medsafe [the New Zealand Medicines and Medical Devices Safety Authority], a part of your ministry, intends to stop funding the intensive medicines monitoring programme (IMMP) next year.

In its 27 years' work the IMMP has contributed very valuably to the safety of medicines in New Zealand and worldwide. Drug regulatory agencies in other countries and professionals working on the safety of medicines have admired and envied it because it has so successfully identified previously unrecognised adverse reactions, measured risks, and identified risk factors. For example, it enabled New Zealand to lead the world in taking regulatory action over agranulocytosis due to mianserin and liver toxicity due to nefazodone.<sup>1 2</sup>

Many drug disasters have shown that it is unsafe to rely only on spontaneous reporting of suspected adverse drug reactions. Such systems are essential, but the data they provide mostly suffer from gross under-reporting and other biases and are usually hard to interpret. There is a great need to support and develop techniques such as computerised drug safety monitoring (the GP research database in the United Kingdom), prescription event monitoring in the United Kingdom, and IMMP in New Zealand. The loss of IMMP would substantially damage pharmacovigilance internationally.

Patients and the public want to see more, not less, attention paid to monitoring the safety of medicines. We believe that the cost of the programme is a small price to pay for the safety of your citizens. Its achievements are considerable, although for most of its life it has employed only one half-time medical researcher. Adverse reactions to medicines result in an enormous cost to health and social services budgets and to patients and their families, as numerous studies across the world have shown. A report from the United States put deaths from adverse reactions among the top six

causes of death there.<sup>3-5</sup> It has been estimated that 15-20% of the health budget goes to the management of adverse drug reactions. The IMMP should be seen as a cost-effective investment in the welfare of your people.

We are also concerned for the wellbeing of the 800 000 or so Maori and Pacific Island people in whom specific genetic variants affect drug metabolic pathways. The IMMP is the only drug monitoring system in place to protect these people. Its closure would, we believe, put these groups at added disadvantage and would be a medical, social, and political oversight.

We see the proposed closing down of the IMMP as a serious blow to pharmacovigilance in New Zealand and internationally and we hope that you will avoid this. The IMMP has been very productive and has helped make the New Zealand Pharmacovigilance Centre one of the most effective in the world. It should be not only allowed to continue but strengthened so that it can reach its full potential and contribute even more to the safe use of medicines.

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This letter is signed by 34 others given in alphabetical order by country: Australia: Peter R Mansfield; Belgium: Marc Bogaert; Canada: Joel Lexchin, Giulia Muraca, Nancy Olivieri, Barbara Mintzes, Thomas L Perry, James M Wright; Croatia: Bozidar Vrhovac; France: Nicholas Moore; Germany: Heiner Berthold, Bruno Mueller-Oerlinghausen, Peter Schönhofer; India: Nilima Kshirsagar; Italy: Silvio Garattini; Japan: Hirokumi Beppu, Rokuro Hama; Netherlands: Leo Offerhaus, Kees van Grootheest; Norway: Graham Dukes; South Africa: Karen Barnes; Spain: Joan-Ramon Laporte; Sri Lanka: Krisantha Weerasuriya; United Kingdom: David Healy, Robin Ferner, Nick Freemantle, Martin Kendall, Alain Li Wan Po, Joe Collier, Stephen Evans, Jeffrey Aronson, Saad Shakir; United States: Peter Lurie, Sidney Wolfe.

Competing interests: AH—none declared. See bmj.com for co-authors.

- 1 Coulter DM, Edwards IR. Mianserin and agranulocytosis in New Zealand. *Lancet* 1990;336:785-7.
- 2 Nefazodone. *WHO Pharmaceuticals Newsletter* 2003 No 1. [www.who.int/medicines/library/pnewslet/news2003.pdf](http://www.who.int/medicines/library/pnewslet/news2003.pdf)
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**P+** *Affiliations and competing interests are available on bmj.com. Also a response is expected from the minister and will be posted on bmj.com as soon as possible.*

## Postmarketing surveillance is needed

EDITOR—The drug point by Harrison-Woolrych and Clark on nose bleeds associated with risperidone highlights a real need for effective communication in the medical fraternity.<sup>1</sup>

The problem with doctors is that they are quite enthusiastic in prescribing new drugs. Unfortunately the mechanism for reporting adverse or unexpected side effects of drugs is not uniform across countries. Only some of the strikingly bad or unusual side effects will be published in a journal. I do not know whether there is a central body keeping track of such information.

This situation acts in favour of the drug companies as there is no effective dissemination of data on drug related problems. But, as we all know, the drug companies are very efficient in "educating" doctors about new drugs, especially the data that they want doctors to believe. Hence the system is bound to result in medical disasters.

The only way is to have a central body that scrutinises drug side effects and communicates effectively to all doctors, not just those in the developed world. We are all aware of drugs that are frowned on in the advanced nations being sold in their millions in poorer countries.

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Competing interests: None declared.

<sup>1</sup> Harrison-Woolrych M, Clark DWJ. Nose bleeds associated with use of risperidone. *BMJ* 2004;328:1416. (12 June.)

## Electronic incident reporting and professional monitoring transforms culture

EDITOR—We report how incident reporting and personal professional monitoring has been achieved using programmed handheld computing devices (personal digital assistants (PDAs)). Data and performance information have been collected and critical incidents reported for accredited trainees of

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the Australian and New Zealand College of Anaesthetists (ANZCA) in Geelong.<sup>1,2</sup> This work favourably transforms the culture of the users, which has been our goal for some time.<sup>3,4</sup>

The programmed PDA has allowed a denominator figure to be supplied for cases undertaken by the trainees, as well as an assessment of the impact on patient outcome. Thus incidents reported by trainees occurred in 1.5% of anaesthetics, but half of the incidents reported had no impact or a minor impact on patient outcomes.<sup>1</sup> This may well be the “near miss” incident data that are the “holy grail” of healthcare safety experts. Our most recent (unpublished) study has found that 98% of all incidents occurring in the practice of ANZCA accredited trainees are reported using this programmed PDA technology.

All incidents are routinely emailed to the quality coordinator for the Division of Perioperative Medicine, Anaesthesia, and Pain Management for analysis and system improvement when possible. Critical incidents in which the outcome for the patient was judged severe or causing death are automatically emailed to the quality manager for Geelong Hospital. We are planning research to assess the effect of these automated critical incident alerts on critical incident rates over time.

The information in the database is collected under an approved quality assurance programme and therefore in the State of Victoria is protected from legal disclosure. The Victorian privacy legislation may allow patients to access data on their particular case but would not allow open disclosure of all the information in the database.

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Competing interests: SB, AP, and MC designed and developed the PDA programme described.

- 1 Bent PD, Bolsin SN, Creati BJ, Patrick AJ, Colson ME Professional monitoring and critical incident reporting using personal digital assistants. *Med J Aust* 2002;177: 496-9.
- 2 Bolsin SN, Colson M. Making the case for personal professional monitoring in health care. *International Journal for Quality in Health Care* 2003;15:1-2.
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## North-south divide in social inequalities in Great Britain

### Divide in social class inequalities may exist but is small

EDITOR—Doran et al conclude that a northwest-southeast divide in social class inequalities existed in Great Britain at the start of the 21st century.<sup>1</sup> They present tables and summary statistics but no analysis to support this statement. Inspection of their tables shows that the differences between

the socioeconomic groups are very consistent between the regions.

Using their data for both men and women, for socioeconomic groups 1 to 7, I found that socioeconomic class was the best predictor of rating health as “not good,” accounting for 74.7% of the variation in rate of reporting poor health, followed by region, which accounted for 18.5%. The extent to which there is regional variation in social class inequalities, as measured by the interaction between socioeconomic class and region, accounted for only 2.5% of the variation (though this was significant,  $P < 0.0001$ , the sample being very large). Sex and its interactions accounted for 3.9% of the variability, leaving only 0.4% unaccounted for. Hence we should conclude that socioeconomic class is a far better predictor of reported health than is region and that the differences between socioeconomic classes do not vary much between regions.

In addition, this is reported, not actual, health and a fairly crude indicator. Also, association does not necessarily imply causation. Ill health may lead to a slide down the socioeconomic ladder and prevent migration to more affluent areas.

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- 1 Doran T, Drever F, Whitehead M. Is there a north-south divide in social class inequalities in health in Great Britain? Cross sectional study using data from the 2001 census. *BMJ* 2004;328:1043-5. (1 May)

### Self perceived health is affected by anxiety and self esteem

EDITOR—Doran et al clearly believe that the term “poor health” is synonymous with “self reported poor health.”<sup>1</sup> A precise definition of “health” is beyond crisp definition, but we should at least agree the difference between health (measured objectively) and health (reported subjectively). This work begs this question.

My own perspective is that self perceived health is affected by individual anxiety and self esteem. As Alain de Botton recently argued,<sup>2</sup> we now have no excuses for our failure to achieve other than our own personal inadequacy (50 years ago I might have put my lowly general practitioner (not university professor) status down to absence of social connections. Nowadays, I can only point to my mediocre ambition and intelligence).

The juxtaposition of social status to self reported health status in the census questionnaire is likely to introduce bias. Self reported ill health represents an admissible explanation for having a low status job. Absence of intelligence or ambition, how-

ever, is viewed as a personal failing. Not admitting to poor health begs the question of why I am a social failure.

I would hypothesise that social status, actual ill health, and subjective ill health are all features that are independently associated with genetic characteristics such as intelligence and ambition, and environmental exposures such as good enough upbringing and access to inherited wealth. They are also likely to be influenced by the prevalence of rainfall and grim urban environment, increasing in the United Kingdom the further northwest one goes. Subjective and actual ill health may correlate, but this study is not gospel that they do.



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- 1 Doran T, Drever F, Whitehead M. Is there a north-south divide in social class inequalities in health in Great Britain? Cross sectional study using data from the 2001 census. *BMJ* 2004;328:1043-5. (1 May)

- 2 de Botton A. *Status anxiety*. London: Penguin, 2004.

### Health inequalities in Wirral: a living Black report?

EDITOR—Having read the paper by Doran et al on the north-south divide in social class inequalities in health in Great Britain, I am prompted to write about our local health divide.<sup>1</sup> Wirral, across the Mersey from Liverpool, is demographically divided by the M53 motorway into two: a healthy, educated west sector and a less prosperous east. They show different rates of deprivation, smoking, childhood accidents, teenage pregnancy, and coronary heart disease. The healthier west sector, with a lower standardised mortality ratio for coronary heart disease, has a higher rate of referral for coronary angiography, coronary angioplasty, and bypass surgery—and vice versa.

Private referrals from the affluent sector do not explain this divide. I suspect that belief systems underpin some of it. Affluent patients are more likely to request referral for angiography while poorer patients present only in crisis. They accept their lot. They are shackled by powerful belief systems—for example, patients with angina being told by family or friends: “Don’t take any exercise, you’ll give yourself a heart attack.”

General practitioners also hear such questionable beliefs as “β blockers are bad in heart failure,” etc. Such concepts have a crucial role in receiving or providing health care.

Attempts at redressing the balance led four years ago to the development of the Wallasey Heart Centre. This locally accessible service, led by general practitioners with a special interest, has brought improvements in coronary heart disease standardised mor-

tality ratio, general practitioner prescribing, and knowledge of patients and carers.

Are services driven by general practitioners with a special interest across a primary care trust, the way to reduce UK health inequalities?

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### Authors' reply

**EDITOR**—The message we hoped readers would take from our paper is that the United Kingdom has large health inequalities in terms of social class, geography, and geography within the social class inequalities. We therefore concur with Bland's analysis, as his figures confirm this point. The differences between regions within each social class, although smaller than the differences between the social classes, are substantial.

Bland and Croft criticise the subjective nature of the self rated health measure. Several studies have shown that even very simple self rated health scales are powerful and reliable predictors of subsequent mortality across all social groups.<sup>1,2</sup> Self rated health is not simply a crude and pragmatic proxy for more objective measures, however: it is a direct way of capturing people's perceptions of their own health, by using their own criteria. Our findings for different social groups are therefore likely to be the result of a combination of factors: prevalence of disease, definitions and expectations of health, demands of everyday life, quality of available medical care, and acknowledgement and recall of symptoms.<sup>3</sup>

The issue of over-reporting of "actual" poor health has been addressed elsewhere. People in manual classes are less likely than those in non-manual classes to report their health as poor despite having signs of disease on examination.<sup>4</sup> This certainly seems to have been Cummins's experience in Wirral. With respect to the regions, further research is required. Our findings are consistent with previous findings based on mortality data,<sup>5</sup> with the possible exceptions of Scotland, where self rated health was better than might have been expected, and Wales, where it was worse.

Our study gave an overview of social inequalities in self rated health regionally. Even greater inequalities are likely to emerge when considering self rated health locally.

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1 Idler E, Benyamini Y. Self-rated health and mortality: a review of twenty-seven community studies. *J Health Soc Behaviour* 1997;38:21-37.

2 Burström B, Fredlund P. Self-rated health: is it a good predictor of subsequent mortality among adults in lower as in higher social classes? *J Epidemiol Community Health* 2001;55:836-40.

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## Fighting obesity

### Physical activity has major role

**EDITOR**—Jain's editorial on fighting obesity, which focuses on the recent House of Commons Health Committee report on obesity, does not truly reflect the findings of that report.<sup>1</sup> The editorial's detailed comments focus almost exclusively on diet and energy intake. This seems to mirror much of the bias in the discussions in the public and health profession domains.

While I generally agree with the editorial that we must create the evidence because an evidence base is lacking, this does not give some imprimatur to ignore the potential for physical activity to make a major contribution to addressing the obesity and overweight problem (noting that people are overweight before they become obese and may find physical activity harder once obese). It is notable that the Health Committee says that if the government were to achieve its target of trebling cycling in the period 2000-10 (and there are very few signs that it will) that might achieve more in the fight against obesity than any individual measure recommended in this report.

Much is to be done in evaluating the benefits of environmental interventions in the promotion of physical activity, an area long ignored by many researchers into physical activity, but there is now some evidence from across the world that if people are given real choices for active travel many people will take them, and cite health and fitness reasons for doing so. To paraphrase from Professor Jerry Morris's work: physical activity is today's best buy in public health. It's not just about diet.

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1 Jain A. Fighting obesity. *BMJ* 2004;328:1327-8. (5 June.)

### Programme to fight obesity in primary care already exists

**EDITOR**—Jain cites the lack of existing data on the effectiveness of public health

initiatives in her editorial on the recent report on obesity issued by the UK House of Commons Health Committee.<sup>1</sup> She did not take note of the report's findings on the Counterweight Programme (paragraph 350, pp 90-1),<sup>2</sup> which has already proved to be effective in tackling obesity in general practice and provides more evidence of successful public health initiatives in primary care.

The Counterweight Programme, developed by seven obesity specialists and supported by the National Obesity Forum, is the largest worldwide primary care programme with 120 000 patients reviewed. Results show that the incidence of type 2 diabetes can be reduced by 50% as a result of appropriate weight management in the NHS.<sup>3</sup>

Counterweight is a dietetic trained nurse led intervention programme in 80 general practices in seven regions of the United Kingdom: Aberdeen, Bath, Birmingham, Glasgow, London, Leeds, and Luton. At each site a secondary care doctor in an obesity or diabetes centre works with a weight management adviser, a state registered dietitian, to facilitate local implementation of the programme. The primary end point of the programme is weight change, and secondary end points are changes in measures of obesity related comorbidities, including mean change in blood pressure, lipids and diabetes control, and drug use.

To date, the treatment of the United Kingdom's current obesity problem has been overlooked in favour of prevention, so we were delighted that the Health Select Committee has not ignored this issue and has highlighted the need for innovative treatments in the NHS such as the Counterweight Programme. The report will stand or fall, depending on the commitment of the government to take immediate action.

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1 Jain A. Fighting obesity. *BMJ* 2004;328:1327-8. (5 June.)

2 House of Commons Health Committee. *Obesity*. London: Stationery Office, 2004. (Third report of session 2003-04.) [www.publications.parliament.uk/pa/cm200304/cmselect/cmhealth/23/23.pdf](http://www.publications.parliament.uk/pa/cm200304/cmselect/cmhealth/23/23.pdf) (accessed 25 June 2004).

3 Diabetes Prevention Programme Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346:393-403.

### Clarification from World Health Organization

**EDITOR**—Jain's editorial calling for increased research into effective interventions against obesity contained some inaccuracies about the World Health Organization's role in this important global health issue.<sup>1</sup>



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The WHO global strategy on diet, physical activity, and health never "implicated" the marketing of junk foods, called for an immediate ban on the advertising of unhealthy foods to children, or was stalled. A first draft was presented to the executive board in January 2004 and revised in April after taking into account member states' comments. The second draft was endorsed without further change by all member states at the World Health Assembly in May, as was originally scheduled.

Although the strategy never called for bans, the first and final drafts both noted that food advertising should not exploit children's inexperience or credulity and emphasised the overall importance of the information environment. The strategy specifically calls for countries to discourage messages that promote unhealthy dietary practices and recommends that governments develop multi-stakeholder approaches to the marketing of foods to children, and to such issues as sponsorship, promotion, and advertising. The strategy also recommends that the private sector practises responsible marketing, which supports the strategy's goals.

Both drafts also recommended that the intake of free sugars should be limited, fat consumption should be shifted from saturated to unsaturated fats, and trans fatty acids should be eliminated, as well as calling for increased consumption of fruit, vegetables, legumes, whole grains, and nuts.

These recommendations take into account member states' input to the strategy, developed over two years of consultations. WHO sees the strategy as a key instrument for addressing the global burden of mortality, morbidity, and disability caused by chronic non-communicable diseases. It is currently developing an implementation plan for the strategy at regional and country level, taking into account member states' differing needs and circumstances.

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1 Jain A. Fighting obesity. *BMJ* 2004;328:1327-8. (5 June.)

## Childhood obesity and consumption of fizzy drinks

### Diet is not that important in obesity

**EDITOR**—Managing risk is concerned with a hierarchy of control in which controlling a dangerous environment is the best strategy for limiting risk—for example, taking people off operating machinery by automating processes. The study by James et al on preventing childhood obesity by reducing the consumption of carbonated drinks seeks to limit the risk of obesity but its method,

using health promotion, is analogous to walking around a factory with a megaphone shouting: "Watch yourselves on those dangerous machines!"<sup>1</sup>

Life is not that complex despite our attempts in medicine to pretend that it is. My generation ate more junk food than this poor generation could ever dream of. In the 1970s we ate pork pies, scotch pies, Spam, corned beef, cake, biscuits washed down with dilute orange squash. I was, however, fit and slim. How can this be so?

Childhood obesity is not caused by diet but by a lack of exercise pure and simple. Some simple solutions are worthy of a randomised controlled trial. My intervention would have three core themes.

Firstly, create safe cycle paths and walking paths to schools and insist that parents walk their children to school in all weather conditions.

Secondly, have one hour of competitive mixed team sports a day from primary school onwards (not the absurd 2 minutes of arm waving each hour currently piloted in schools).

Lastly, give healthy free school dinners to all, which would mean that most children would take them. Cooking lessons for primary schoolchildren would be compulsory.

A trial for one year would undoubtedly have a dramatic impact on obesity, fitness, and conduct disorders. Society and the education system are obsessed with academic achievement and are producing an unhappy, fat, and drug dependent generation. Diabetes is a sideshow. In 10 years' time a new generation hooked on amphetamine from the age of 6 years seems possible. Doctors using megaphones only increase the sales of ear muffers.

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1 James J, Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. *BMJ* 2004;328:1237. (22 May.)

### Play outside to reduce childhood obesity

**EDITOR**—Preventing childhood obesity by reducing the consumption of carbonated drinks was studied by James et al.<sup>1</sup> The rise in childhood obesity is paralleled by the rise in parental fears of the risks to children of being unaccompanied outdoors. I find it strange that the simple solution, to let children play outside more, is dismissed as impossible in our modern society. Stranger-danger is largely a myth promoted by the mass media, yet there are few voices raised against it.

The big childhood obesity debate in January 2004 promoted by the *Observer* subsequently went unreported in the newspa-

per, and no wonder. It was a sad litany of "Big Sport," sensing a chance to climb onto a funding bandwagon while defending its rights to any corporate sponsorship, and the food industry desperate to escape blame, aided by a government minister's view that car ownership was a good thing and a great liberator of the working classes.

Much of the debate in the press surrounds schools, yet obesity is nothing to do with them—you sit down in school. Let them teach, and let childhood obesity be tackled in the community. Parents refusal to allow free play for their children is now becoming embedded in a system of parental peer pressure whereby parents are afraid to allow children out for fear of being labelled uncaring (or worse) by their peers.

I believe the answer is to adopt a children's rights approach. This debate must be joined by community regeneration specialists, urban planners, and sociologists, and not blamed on schools: they have enough to do.

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1 James J, Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. *BMJ* 2004;328:1237. (22 May.)

### Commercial interests have important role

**EDITOR**—The study by James et al on preventing childhood obesity by reducing the consumption of carbonated drinks underscores clinical intuition about why children are more obese these days.<sup>1</sup>

Wearing my hat of school governor, I have been trying to introduce a healthy eating policy to our local school. It was comparatively easy to change the catering contract to a company that guarantees to use fresh vegetables, low salt, less fat, etc, but it was much more difficult to influence the policy on soft drinks machines. The reason: the machines are a critical source of income for a cash strapped school that has seen its budget squeezed in real terms year on year. Sales from vending machines are now used to pay for books and equipment—and I suspect it won't be long before the school advertises for a "Coca Cola head of chemistry" or a "Fanta French teacher." Perhaps it's time the *BMJ* launched a new journal: *Sugar Control?*

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1 James J, Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. *BMJ* 2004;328:1237. (22 May.)



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