Letters

Shipman proposals will alter general practice profoundly

See also p 274

EDITOR—The proposals for developing a new system for death certification in the discussion paper that has arisen from the Shipman inquiry, will require any death that was not expected in advance to be reported to the medical coroner immediately.[1] In our experience of auditing deaths in a small group over 11 years, at least 75% of deaths should then be reported.[2] If most deaths are going to be handled by the medical coroner, why not all? This would dispel increased suspicion that deaths may have been unlawful or due to medical error.

We estimated that some action by general practitioners may have contributed to 5% of deaths. We did not, however, find any cases where errors caused the death, a crucial distinction that the inquiry seems to have overlooked.

General practitioners are faced each day with the possibility that a patient they are treating will die unexpectedly in the near future. Handling this uncertainty humanely and efficiently is part of our skill. If we as general practitioners are going to face regular medical coroner's investigations, looking for the all encompassing "incidents of medical error," our practice will change profoundly. We would be much more willing to offer further investigation or referral, even when the chances of benefit to the patient seem slim. We would also insist on long (probably 20 minutes) consultations to minimise the possibility of any medical error and to make very detailed records.

Every general practitioner will come to ask, "What will happen if this patient dies soon? Have I shared the uncertainties fully, so the patient and his or her family appreciate these symptoms may be the start of major illness?" This will help end both medical paternalism and the deeply ingrained habit of offering hope in adversity. The implications for NHS spending are also stark.

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1 Shipman Inquiry. Developing a new system for death certification. Available at: www.the-shipman-inquiry.org.uk/mediainfo.asp?from=w&ID=58 (accessed 23 Jan 2003).
2 Holden J, O'Donnell S, Brindley J, Miles L. Analysis of 1263 deaths in four general practices. *Br J Gen Pract* 1998;48:1409-12.

Volume of procedures and outcome of treatment

NHS needs to understand relation more effectively

EDITOR—For procedures relying primarily on individual doctors or surgeons, evidence shows that patients have better outcomes treated by providers with high versus low volumes.[1] Where care is shared over a group, evidence of a relation between volume and outcome is less strong. Current theories for such relations are "practice makes perfect" and "selective referral." Halm criticises these theories as lacking robust empirical support and providing little explanation of how high volume may relate to better outcomes.[2] One explanation of the relation may be the greater uptake of effective interventions in high compared with low volume hospitals.[3] It is important to examine how the timing of the introduction of new therapies impacts on relations between volume and outcome. Often trials of new interventions are conducted in specialist hospitals with high volumes. If effective, patients receiving the intervention will have benefited, and those high volume hospitals will seem to have better outcomes. Eventually, the new intervention will become adopted in all hospitals, removing that differential in the relation between volume and outcome.

For example, in neonatal intensive care in the United Kingdom in 1988-90 a volume-outcome relation seemed to exist.[4] Concurrently the positive effects of treatment with surfactants and maternal steroids were both being realised with greater uptake in high versus low volume hospitals.[5] By 1998-9 both treatments were routinely administered in all hospitals and the relation between volume and outcome had disappeared.[4] If a major factor impacting on the volume-outcome relation is the uptake of effective treatments, there is little surprise that a relation between volume and outcome existed in 1988-90 but not in 1998-9.

In developing policies to improve NHS performance it is important to consider the effect different uptakes of new therapies have on relations between volume and outcome.

All factors affecting the relations between volume and outcome must be identified and quantified to more fully inform policymakers considering issues of access to local (smaller) hospitals and more distant (larger) hospitals in a centralised service.

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1 Soljak M. Volume of procedures and outcome of treatment: The NHS needs to harness the relation more effectively. *BMJ* 2002;325:787-8. (12 October.)
2 Halm EA, Lee C, Chassin MR. *How is volume related to quality in health care? A systematic review of the research literature.* Washington, DC: Institute of Medicine, 2000
3 Thiemann DR, Coresh J, Oetgen WJ, Powe NR. The association between hospital volume and survival after acute myocardial infarction in elderly patients. *N Eng J Med* 1999;340:1640-8
4 UK Neonatal Staffing Study Collaborative Group. A prospective evaluation of patient volume, staffing and workload in relation to risk-adjusted outcomes in a random, stratified sample of all UK neonatal intensive care units. *Lancet* 2002; 359:99-107
5 Scottish Neonatal Consultants' Collaborative Study Group, International Neonatal Network. Trends and variations in use of antenatal corticosteroids to prevent neonatal respiratory distress syndrome: recommendations for national and international comparative audit. *Br J Obstet Gynaecol* 1996; 103:534-540

Danish study found no association between hospital and surgeon volume

EDITOR—The outcome of some surgical procedures is related to the surgeon's experience or the hospital's volume of procedures.[1] This relation must be studied separately for each procedure or diagnosis in question.[2]

In a study of colon surgery in the region of Copenhagen in Denmark in 1999 we found that colon surgery was performed by a large number of surgeons in many hospitals. One hundred and two senior surgeons operated on 674 patients, but only five surgeons performed more than 14 operations in 1999. More than 50% of the surgical procedures were carried out by surgeons who performed fewer than 10 colon operations in 1999. Most of the low volume surgeons' operations were performed during calls.[3]

It is not clear whether there is a positive relation in colon surgery between surgeon's experience and outcome,[1] but if this is true the number of surgeons performing colon surgery in our area should be limited in order to enable a suitable number of surgeons to achieve and maintain the necessary level of experience indicated by the evidence.

We found no association between hospital volume and surgeon volume, indicating that referral of a patient to a high volume hospital instead of a low volume hospital may not improve the probability of a positive outcome. These data suggest the need for an explicit division of tasks between the surgeons in each department to ensure that surgeons achieve and maintain the necessary level of experience.

Presumably these findings from colon surgery are applicable to other surgical procedures, but the opportunities for concentration of a surgical procedure on few surgeons will probably be inversely related to the amount of the surgery performed on acute patients.

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2 Teisberg P, Hansen FH, Hotvedt R, Ingebrigtsen T, Kvalvik AG, Lund E, et al. Hospital volume and quality of health outcome. Oslo: The Norwegian Center for Health Technology Assessment, 2001. www.oslo.sintef.no/smm/Publications/Engsmdrag/volume.htm (accessed 6 Nov 2002).
3 Birk HO, Joenler M, Jensen LP, Knudsen JL, Moesgaard F, Frimodt-Moeller C. Surgeons' experience in colon surgery in eleven hospitals in the Copenhagen region in 1999. *Ugeskr Laeger* 2002;164:4537-9. www.dadlnet.dk/ufl/0239/VP-html/VP38833.htm [Danish]

Electronic tagging of people with dementia

Devices may be preferable to locked doors

Editor—Having spent several years in a leadership position in a progressive, culture changing nursing facility, I have seen the devices mentioned by Hughes and Louw in their editorial in use.[1] I have seen that they allowed for the closing of the so called dementia unit and granted opportunity for confused residents to have freedom of the building instead of being contained and restrained. Of course, a stigma was attached to the bracelet, and people with mild dementia at times objected as they understood this stigma intuitively. On balance, however, the usage allowed more freedom of movement and more personhood than the alternatives of specialised and restrictive units.

Hughes and Louw's call for supervision by governments is off the mark.[1] The answer does not lie in increased government supervision, which by its nature appeals to the lowest common denominator and assures loss of liberty. The answer lies in adequate funding of services to the population with dementia across the myriad of living situations. If home care were supported properly the use of these devices could be lessened. If nursing homes were at all adequately staffed and funded perhaps they could be eliminated all together. No one wants to be tethered to an electric bracelet, but it is preferable by far to locked doors and restraints.

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Tagging should be reserved for babies, convicted criminals, and animals

Editor—In some hospitals in the Republic of Ireland newborn babies are electronically tagged to prevent kidnapping. The use of such devices is well established for convicted criminals in some jurisdictions. Animals are also often tracked by means of electronic tags. Therefore, consideration to extend this technology to people with dementia, as mentioned in the editorial by Hughes and Louw, evokes unfortunate metaphors for our attitudes to people with dementia: infantilisation, custody, and a subhuman existence.[1]

To those who might see this interpretation as unduly melodramatic, it is important to be aware of movements in bioethics which seek to diminish or deny personhood in dementia. A typical example is the Royal Dutch Medical Association's use of the word *ontluistering* (removal of the light) for this condition, suggesting a lower level of being.[2] One prominent ethicist, Daniel Callahan, has stated a viewpoint that the presence of dementia should be considered as a basis for the rationing of health care.[3] Another has likened people with severe dementia to dogs, since they supposedly lack capacities for hopes and fears, dreads, and longings for their futures.[4]

Fortunately, an ethical countercurrent exists which is actively promoting the concept of personhood in dementia. One eloquent defender of the preserved humanity of people with dementia has spoken of the challenge of asserting this position in a hypercognitive society where people are valued for what they produce rather than for what they are.[5] In this book, Post urges us to convert the dictum "I think, therefore I am" to "I will, feel, and relate while disconnected by forgetfulness from my former self, but still, I am."

This position challenges us to reflect carefully and study in depth the causes of behavioural and psychological symptoms in dementia. Wandering may be triggered or exacerbated by external factors such as inappropriate environments, inadequate staffing, and failure to provide for the specialised emotional and social needs of a vulnerable group of people.

Although Hughes and Louw are to be applauded for opting for a predominantly libertarian approach to electronic tagging, they seem to imply that in certain circumstances its use should be considered.[1] This is disappointing: our focus should be not only on understanding the basis of wandering in dementia but also on addressing support for people with dementia and their carers at home as well as deficits in the design and staffing of our institutions.

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2 Berghmans RL. Ethics of end-of-life decisions in cases of dementia: views of the Royal Dutch Medical Association with some critical comments. *Alzheimer Dis Assoc Disord* 1999;13:91-5.
3 Callahan D. *Setting limits: medical goals in an aging society.* New York: Simon and Schuster, 1987.
4 Brock DW. *Life and death: philosophical essays in biomedical ethics.* New York: Cambridge University Press, 1993:372.
5 Post SG. *The moral challenge of Alzheimer disease.* Baltimore: Johns Hopkins University Press, 1995.

Technologies may be enabling

Editor—Hughes and O'Neill have contributed to the debate about the ethics of electronic tagging in dementia.[1] Although technology has a role in promoting independence and improving quality of life in people with dementia, products that infringe on human rights, strip the individual of personhood, and relegate him or her to the status of an animal are totally unacceptable.

A European funded research project entitled ENABLE is currently investigating the role that assistive technology has in tackling the practical difficulties people with dementia and their principal caregivers experience in negotiating the home environment. Products undergoing trials in Norway, Ireland, Finland, and the United Kingdom have been carefully selected to ensure that no monitoring device or item with a surveillance component is included. Products have also been sensitively and creatively designed and adapted to blend in with the user's natural environment.

For example, a cooker switch off device contains knobs that look no different from those seen on a normal cooker. Similarly, a night lamp, which is linked to sensors attached to bed legs and fades on to enable the user to reach the toilet at night, has been designed to promote the dignity of the person with dementia while enabling him or her at all times. The study looks at outcome measures including quality of life, and people with dementia are themselves invited to comment on this aspect of their lives by using a standardised assessment scale. In Ireland all but one of the 15 people with a cognitive impairment interviewed to date have been able to complete the assessment tool.

The ethics of undertaking a cross national longitudinal study of this sort with people who have dementia has been at the centre of every major decision undertaken by ENABLE. Norway's principal investigator, Inger Hagen, is herself a former family caregiver.

In dementia we need to move beyond quick fix practical solutions such as electronic tagging, which so often serve the needs of formal caregivers while eroding the rights of those with a cognitive impairment. For people with dementia wandering may well be pottering with a purpose—a desire to use up excess energy, to check out an unusual aspect of the local environment, or simply to seek fresh air. Let us not stigmatise and dehumanise this vulnerable group any further; rather, let us rise to the challenge of attempting to understand the meaning behind these behaviours and develop person centred and creative ways of addressing the issue.

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Squamous cell carcinomas of the head and neck

Oral care for patients with cancer needs more than lip service

Editor—I had hoped to see a mention of the need for oral care for patients with cancer in the review article by Sanderson et al on squamous cell carcinomas of the head and neck, but I was again disappointed.[1] Patients with head and neck cancers must receive a dental assessment and oral care before and after their treatment to ensure minimisation of oral complications for an improved quality of life. The clinical guidelines published by the Royal College of Surgeons of England in 2000 state that a clear pathway of care is necessary to prevent or minimise oral complications.[2]

However, many patients with cancer still receive no proper dental assessment or preventive treatment to minimise or avert the known and common oral complications of radiation treatment. This may be due, in part, to the lack of resources and recognised local standards of dental care for such patients, as well as to lack of information and apathy.

The Restorative Dentistry Oncology website (www.rdoc.org.uk) was created to increase awareness of the oral complications of cancer treatments and to help patients, dentists, and doctors to find free information on oral cancer easily. The website includes first hand accounts of patients' experiences. A discussion forum offers patients, carers, and interested members of the public the opportunity to ask questions, help others, share ideas and opinions, and learn about other people's experiences in dealing with head and neck cancers. The guides for patients and professionals link to other websites dealing with basic aspects of oral cancer such as treatment and complications. Links cover other concerns that doctors rarely address but that are just as important, such as the financial implications of cancer, financial planning and support, and personal care and support.

A section on tobacco risks includes links on the connection between chewing Gutkha or paan and developing mouth cancer. Although this is mainly a problem on the Indian subcontinent, the United Kingdom has a sizeable immigrant population that continues with these habits. Other sections cover treatment, complications, and spiritual help. A daily dental cartoon helps to bring humour.

I hope that doctors will find the website useful and recommend it to patients and their carers should they ask for information. Oral care for patients with cancer needs more than lip service.

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2 Faculty of Dental Surgery, Royal College of Surgeons of England. Clinical guidelines: the oral management of oncology patients requiring radiotherapy, chemotherapy or bone marrow transplantation. Available at: www.rcseng.ac.uk/dental/fds/clinical_guidelines/ (accessed 24 Jan 2003).

Precancerous lesions in oral cavity of Indian schoolchildren may hint at epidemic

Editor—Sanderson et al's review of squamous cell carcinomas of the head and neck prompts me to describe an unprecedented phenomenon facing India.[1] Consumption of smokeless tobacco, especially Gutkha (a mixture of areca, catechu, betel nut, lime, tobacco, and mint), is rising among school children in rural India.[2] It is considered to be a harmless mouth freshener, and children therefore consume in large amounts and keep it in the mouth for a long time.[2]

A survey of school children in a coastal village in the state of Kerala showed a 29% prevalence of tobacco chewing, and another survey in Mizoram showed a rate of 56.5%. The age for initiation for Gutkha in India has been reported as 8-14 years. A survey of 986 school children in a rural part of central India showed leukoplakia in 32, erythroplakia in six, and submucous fibrosis in 18.[2] Some 50-60% of patients with submucous fibrosis will develop invasive cancers. In 1991, 11 premalignant lesions were found in 200 college students who used tobacco.[2]

The evidence of early onset of the smokeless tobacco habit and reports of increases in oral precancers among children raise serious concerns of an impending epidemic of oral cancer in this population.[3] The age at onset of oral cancer in India is falling and is significantly lower than reported in the rest of the world.[3]

Smokeless tobacco is becoming popular among children and adolescents in Canada, the United States, Scandinavia, and the United Kingdom.[4 5] In the United States the use of smokeless tobacco has increased among adolescent boys and young men in recent years.[4 5] National data indicate that 10-12 million Americans use some form of smokeless tobacco.

Tobacco in its various forms has killed more people than al-Qaeda, yet we still lack an international coalition against "tobaccoism." Let the tobacco companies not poison our future generations.

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1 Sanderson RJ, Ironside JAD. Squamous cell carcinomas of the head and neck [with commentary by WI Wei]. *BMJ* 2002;325:822-7. (12 October.)
2 Chaturvedi P, Chaturvedi U. Prevalence of tobacco consumption in school children in rural India—an epidemic of tobaccogenic cancers looming ahead in the third world. *J Cancer Educ* 2002;17:6.
3 Gupta PC. Mouth cancer in India: a new epidemic? *J Indian Med Assoc* 1999;97:370-3.
4 Schaefer SD, Henderson AH, Glover ED, Christen AG. Patterns of use and incidence of smokeless tobacco consumption in school-age children. *Arch Otolaryngol* 1985;111:639-42.
5 Bruerd B. Smokeless tobacco use among native American school children. *Public Health Rep*1990;105:196-201.

On teething symptoms

Editor—One of the messages of the short report by Wake and Hesketh is that healthcare professionals should be wary of attributing symptoms such as fever and irritability to teething because of the risk of missing significant illness.[1] Another seems to be that teething rarely causes any symptoms and that healthcare professionals who believe that it does are misinformed. I think this misrepresents the facts.

At least three or four retrospective studies and three good prospective studies show the association of symptoms with teething. The prospective studies vary in size (Wake et al, 21 infants and 90 eruptions; Jaber et al, 46 infants and 46 tooth eruptions; and Macknin et al, 125 infants and 475 eruptions).[2–4] All show significant associations between teething and at least one of the symptoms that were monitored.

The biggest study, with the greatest power, showed associations with biting behaviour, drooling, gum rubbing, irritability, sucking, wakefulness, reduced appetite, and temperature more than one standard deviation above normal. All associations were significant (P=0.01 or less) and for fever above 38.3°C (P=0.001). Altogether 35% of infants had one or more of these symptoms in the period around tooth eruption in comparison with background rates for symptoms on non-teething days in the range of 6-20%.

Parents clearly associate certain symptoms with teething, as is borne out by several studies, including one by Wake et al.[5] In my experience, these views are prevalent in Australia, Canada, the United Kingdom, and South Africa. Maybe these parents are misinformed by a global old wives' tale or by an international confidence trick played by teething gel manufacturers, or maybe observations of their own children lead them to these conclusions.

I plump for the last explanation: paediatricians have a long tradition of listening carefully to, and believing, the mothers (and fathers) of their patients. I agree that if a healthcare professional sees an irritable and febrile baby, he or she should be cautious in attributing the symptoms to teething because no specific pattern can reliably differentiate teething symptoms from symptoms of early serious infection.

Given that teething does cause some symptoms, are healthcare professionals wrong if they recommend drug treatment with the intention of alleviating them, as implied by Wake et al? I am unaware of any scientific evidence that guides either way. When evidence is lacking, recommend no treatment or only treatments with a minimal risk of adverse effects.

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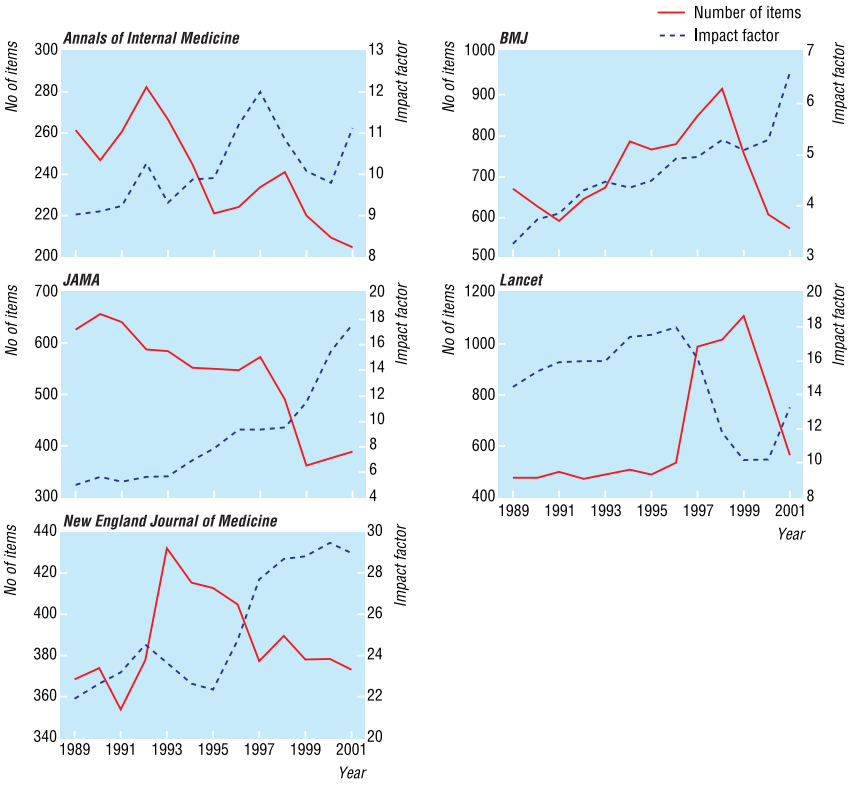
2 Wake M, Hesketh K, Lucas J. Teething and tooth eruption in infants: a cohort study. *Pediatrics* 2000;106:1374-9.
3 Jaber L, Cohen IJ, Mor A. Fever associated with teething. *Arch Dis Child* 1992;67:233-4.
4 Macknin ML, Piedmonte M, Jacobs J, Skibinski C. Symptoms associated with infant teething: a prospective study. *Pediatrics* 2000;105:747-52.
5 Wake M, Hesketh K, Allen M. Parent beliefs about infant teething: a survey of Australian parents. *J Paediatr Child Health* 1999;35:446-9.

Quality of impact factors of general medical journals

Editor—Citations are deemed the currency of science, and their utility in measuring the quality and impact of scientific articles and journals is generally accepted.[1–3] Citation based impact factors and rankings of leading general medical journals have changed substantially in recent years, and this seems to have been associated—unexpectedly—with simultaneous changes in publication volume.[4]

JAMA's impact factor increased from 4.8 in 1989 to 17.6 in 2001, while publication volume declined steadily, from a high of 656 substantive items published in 1990 to 389 in 2001. Publication volume at the *Lancet* increased from 469 substantive items in 1989 to 1108 in 1999. Meanwhile, the *Lancet's* impact factor increased from 14.4 in 1989 to 17.9 in 1996 then dropped sharply to 10.2 in 1999 (figure). Among the five leading journals in the fields of general and internal medicine, the number of substantive items published in the previous two years was inversely related to impact factor ($r = -0.45$, $P<0.001$; mean difference in impact factor −0.68 per 100 additional substantive items, 95% confidence interval −0.24 to −1.11, P=0.002).

The increase in publication volume of the *Lancet* in 1997 was associated with the creation of a large section given to research letters and the consequent decline in impact factor was predicted.[5]



Numbers of substantive items published annually and impact factors for five leading journals in general and internal medicine, 1989-2001. Impact factors are number of citations in a given year to any article published in the journal in the previous two years divided by number of substantive items published by the journal in the previous two years

A hand count of the number of substantive items published by *JAMA* for the years 1989 and 1990 showed that, whereas *JAMA* published 376 and 397 substantive items in 1989 and 1990, respectively, *Journal Citation Reports* (*JCR*)[4] identified *JAMA* as having published 627 and 656 items, respectively. In fact, "*JAMA* has not significantly changed the number of citable items for at least 20 years" (C DeAngelis, personal communication). *JAMA*'s corrected impact factor for 1991 is 8.6, compared with 5.2 published by *JCR*. A similar error, concerning the labelling of news articles as substantive items, was identified by the *Canadian Medical Association Journal* and led to a significant change in its impact factor.[5]

Assessing the quality and impact of scientific work through the use of citation based measures is a lofty concept which underscores the altruistic nature of the scientific enterprise.[1] Impact factors and other citation based indices remain the best measure of a journal's scientific performance. However, studies on the potential relation between publication volume and journal impact among general medical journals will have to await improvements in data quality for previous years.

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2 Cronin B, Atkins HB, eds. *The web of knowledge. A festschrift in honor of Eugene Garfield.* Medford, NJ: Information Today, 2000. (ASIS monograph series.)
3 Garfield E. Journal impact factor: a brief review. *CMAJ* 1999;16:979-80.
4 Institute for Scientific Information. *Journal citation reports 1989-2001. Science citation index.* Philadelphia: ISI, 1990-2002.
5 Joseph KS, Hoey J. CMAJ's impact factor: room for recalculation. *CMAJ* 1999;161:977-8.

Efficacy should drive atypical antipsychotic treatment

Editor—Koro et al say that olanzapine is associated with a clinically important and significant increased risk of diabetes.[1] To date five other pharmacoepidemiological papers have been published about the possible increase in risk for diabetes in patients receiving atypical antipsychotics.[2–6]

All use a variety of methods and have come up with a variety of conclusions: clozapine poses a higher risk for diabetes for patients younger than 40,[2] clozapine, risperidone, olanzapine, and quetiapine are associated with higher rates of diabetes among patients aged 20-34,[3] neither clozapine nor risperidone pose a higher risk,[4] atypical antipsychotics may pose a higher risk,[5] and risperidone poses no additional significant risk as opposed to clozapine and olanzapine.[6]

Of these six studies, two have been funded and coauthored by a pharmaceutical manufacturer.[1 6] Two have used the same database.[1 5]

Missing from these analyses are important risk factors such as ethnic group,[1 2 5 6] body mass index,[1–4 6] family history of diabetes,[1–6] and level of activity.[1–6] These risk factors may overshadow the attributable risk posed by specific atypical antipsychotic exposure itself.

Concerns about efficacy ought to have the dominant role in selecting treatment. Whether a patient will develop diabetes based only on exposure to specific antipsychotic drugs is not easily predictable, but the consequences of poor control of the symptoms of schizophrenia are obvious.

Managing risk by routine monitoring of fasting plasma glucose and other measures ought to be done for all patients taking any antipsychotic drug, especially if risk factors are present.

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Competing interests: LC has received honoraria, research support, and consulting fees from Abbott, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, and Pfizer.

1 Koro CE, Fedder DO, L'Italien GJ, Weiss SS, Magder LS, Kreyenbuhl J, et al. Assessment of independent effect of olanzapine and risperidone on risk of diabetes among patients with schizophrenia: population based nested case-control study. *BMJ* 2002;325:243-7. (3 August.)
2 Lund BC, Perry PJ, Brooks JM, Arndt S. Clozapine use in patients with schizophrenia and the risk of diabetes, hyperlipidemia, and hypertension. *Arch Gen Psychiatry* 2001;58:1172-6.
3 Sernyak MJ, Leslie DL, Alarcon RD, Losonczy MF, Rosenheck R. Association of diabetes mellitus with use of atypical neuroleptics in the treatment of schizophrenia. *Am J Psychiatry* 2002;159:561-6.
4 Wang PS, Glynn RJ, Ganz DA, Schneeweiss S, Levin R, Avorn J. Clozapine use and risk of diabetes mellitus. *J Clin Psychopharmacol* 2002;22:236-3.
5 Kornegay CJ, Vasilakis-Scaramozza C, Jick H. Incident diabetes associated with antipsychotic use in the United Kingdom General Practice Research Database. *J Clin Psychiatry* 2002;63:758-62.
6 Gianfrancesco FD, Grogg AL, Mahmoud RA, Wang RH, Nasrallah HA. Differential effects of risperidone, olanzapine, clozapine, and conventional antipsychotics on type 2 diabetes: findings from a large health plan database. *J Clin Psychiatry* 2002;63:920-30.

Screening for aortic aneurysm

Human cost should not be dismissed

Editor—Greenhalgh and Powell's editorial assesses the economic evaluation of the multicentre aneurysm screening study (MASS), but it masks with numbers a human tragedy at the core of the story: this is a screening study that killed people.[1 2]

The authors mention in passing a mortality of 6% among the 322 men who had surgery as a result of the invitation to screening. This figure represents 19 men, comparatively young at retirement age, who before receiving the invitation would have been living their lives unfettered by the knowledge that they had an aneurysm. Now they are dead.

Obviously some of these men might have died anyway from a sudden rupture, but a clear distinction needs to be made between dying naturally and at the instigation of doctors. It could be considered ethically acceptable if the study showed a convincing overall survival benefit in the screened population, but the all cause mortality at the end of the study was the same in both groups, 11%.[2]

Greenhalgh and Powell confidently announce that the data support a national screening programme. They do not. The National Screening Committee's criteria are not fulfilled, as there is no evidence from randomised controlled trials of overall survival benefit and no evidence that benefit outweighs the physical and psychological harm of screening.

The results of the MASS study are surprisingly similar to a recent study comparing watchful waiting with radical surgery for early prostate cancer.[3] The group allocated to radical treatment had a halving of deaths related to prostate cancer, but overall no survival advantage was noted in comparison with the group who were watched.

Supporters of screening put a positive spin on these results,[4] but the result justified the United Kingdom's decision not to roll out a national screening programme for prostate cancer. Likewise, the results of the MASS study do not justify screening for aortic aneurysm.

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1 Greenhalgh R, Powell J. Screening men for aortic aneurysm. *BMJ* 2002;325:1123. (16 November.)
2 Multicentre Aneurysm Screening Study Group. Multicentre aneurysm screening study (MASS): cost effectiveness analysis of screening for abdominal aortic aneurysms based on four year results from randomised controlled trial. *BMJ* 2002;315:1135-41. (16 November.)
3 Holmberg L, Bill-Axelson A, Helgesen F, Salo JO, Folmerz P, Häggman M. A randomized trial comparing radical prostatectomy with watchful waiting in early prostate cancer. *New Engl J Med* 2002;347:781.
4 Lenzer J. The operation was a success (but the patients died). *BMJ* 2002;325:664.

National screening programme is long overdue

Editor—It is a scandal that in the 21st century the United Kingdom has no national screening programme for the detection of abdominal aortic aneurysms in men, and this in spite of compelling evidence in favour of one.

In a randomised controlled trial Scott et al identified a 68% reduction in incidence of rupture at 5 years among those invited for screening compared with age matched controls and a 42% reduction in death from rupture.[1] The benefit persisted at 10 years, but no benefit was detected for women. In men only 4% of deaths from rupture occurred under the age of 65 years; no woman died below this age.

Screening of men aged 65 has been taking place in the English county of Gloucestershire since 1990. The total number of deaths related to aneurysm in this population decreased progressively year by year in the screened portion of the population ($P < 0.001$). No change was observed in the unscreened part of the population.[2]

Law has estimated that a national screening programme could save 2000 lives a year in men aged 60-79.[3] In addition, reducing modifiable risk factors, smoking, hypertension, coronary heart disease,[5] together with increasing awareness of unusual modes of presentation of ruptured abdominal aortic aneurysm, may save even more lives.

Finally, the multicentre aneurysm screening study (MASS) provides evidence of cost effectiveness of a national screening programme.[5]

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1 Scott RAP, Vardulaki KA, Walker NM, Day NE, Duffy SW, Ashton HA. The long-term benefits of a single scan for abdominal aortic aneurysm (AAA) at age 65. *Eur J Vasc Endovasc Surg* 2001;21:535-40.
2 Heather BP, Poskitt KR, Earnshaw JJ, Whyman M, Shaw E. Population screening reduces mortality rate from aortic aneurysm in men. *Br J Surg* 2000;87:750-3.
3 Law M. Screening for abdominal aortic aneurysms. *Br Med Bull* 1998;54:903-13.
4 Lederle FA, Johnson GR, Wilson SE, Littooy FN, Krupski WC, Bandyk D, et al. Yield of repeated screening for abdominal aortic aneurysm after a 4-year interval. Aneurysm Detection and Management Veterans Affairs Cooperative Study Investigators. *Arch Intern Med* 2000;160:1117-21.
5 Multicentre Aneurysm Screening Study Group. Multicentre aneurysm screening study (MASS): cost effectiveness analysis of screening for abdominal aortic aneurysms based on four year results from randomised controlled trial. *BMJ* 2002;315:1135-41. (16 November.)

Haemophilus influenzae type b epiglottitis

Occasional cases will present

Editor—Tanner et al describe *Haemophilus influenzae* type b as a cause of acute upper airways obstruction in children.[1] Such epiglottitis has indeed become much less common since the introduction of the Hib vaccine, and therefore doctors are not as experienced in managing this life threatening condition now as they were previously. The vaccine is not 100% effective; so occasional cases will present, and clinicians must be aware of the dangers and how to avoid them.

In the cases quoted, two of the three patients had been sent for a lateral neck *x* ray film before the airway was secured. This is contraindicated in patients suspected of having epiglottitis because at any time the patient may lose their airway, and a radiology department is not a safe environment to manage this problem.

Doctors also should not attempt to cannulate or obtain blood samples from a patient until the airway is secure. Taking

blood from a child is obviously distressing for them and may, once again, precipitate acute airway obstruction.

The most important point in managing a child with acute epiglottitis is to avoid acute airway obstruction, which can happen suddenly and lead to severe consequences. Involving an anaesthetist and otolaryngologist will allow safe airway management initially, which is then followed by appropriate treatment with antibiotics.

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1 Tanner K, Fitzsimmons G, Carrol ED, Flood TJ, Clark JE. Haemophilus influenzae type b epiglottitis as a cause of acute upper airways obstruction in children. *BMJ* 2002;325:1099-100. (9 November.)

Author's reply

Editor—We were asked to concentrate on epiglottitis as originally the *BMJ* was going to run an editorial alongside this article discussing epiglottitis and its management. I am not sure what happened to this. Space did not allow us to expand the clinical history of each patient. In fact both children who had lateral neck *x* ray films done had these from the emergency department of their local (different) district general hospitals before being referred to our tertiary service.

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Article gives timely lesson

Editor—Tanner et al highlight an increase in Hib epiglottitis cases in Newcastle.[1] Unfortunately, they are not alone.

Twenty nine cases of epiglottitis occurring in fully vaccinated children were reported to the Public Health Laboratory Service and Oxford Vaccine Group in 2001, and a further 16 to date this year. The overall incidence of invasive Hib infection in the United Kingdom last year was 2.96 per 100 000 children under 5 years of age, a figure well below the 23.8 described before the vaccine was introduced, but a worrying increase from the nadir of 0.66 in 1998 (www.phls.org.uk/publications/cdr/archive/immunisationarchive.html#surveillance).

The children experiencing Hib vaccine failure in Tanner's series are typical. Less than 10% of reported cases have an identifiable clinical risk factor predisposing to infection. Approximately one third have minor immunoglobulin abnormalities of uncertain clinical relevance.[2] Most mount a convalescent antibody response to disease of a magnitude consistent with priming in infancy, indicating that vaccine induced immunity has failed to protect.[3]

Hib antibody concentrations wane rapidly after the primary course of immunisation,[4] and in the absence of a fourth dose of vaccine British children are heavily dependent on B cell memory to prevent disease. For most this is apparently sufficient,[4] but it is only one component of host defence and is not infallible.[5] Much of the success of Hib vaccine in the UK population has been attributed to reduced carriage, thereby minimising exposure of susceptible individuals to the organism.[4]

Why is Hib incidence increasing? Seroepidemiology and carriage studies are being conducted to understand better the effect of Hib carriage on maintaining population immunity. Efficacy of the various Hib combination vaccines used in the United Kingdom is being investigated. A case-control study of socioeconomic risk factors will address the contribution of sociological changes. The importance of long term national surveillance to identify unexpected late effects of immunisation and find ways of addressing them is clear. In the meantime, paediatricians and general practitioners should remain aware of and consider all manifestations of invasive Hib disease in their differential diagnosis of serious illnesses of infancy and childhood.

We urge clinicians, public health doctors, and microbiologists to continue reporting to the Public Health Laboratory Service and Oxford Vaccine Group, as they have done over the past 10 years, and thank all those involved for their contributions to the long term surveillance of *H influenzae* infections.

Guidelines can be found at http://cphl.phls.org.uk/rsi/haemophilus_reference_unit.htm

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1 Tanner K, Fitzsimmons G, Carrol ED, Flood TJ, Clark JE. Haemophilus influenzae type b epiglottitis as a cause of acute upper airways obstruction in children. *BMJ* 2002;325:1099-100. (9 November.)
2 Heath PT, Booy R, Griffiths H, Clutterbuck E, Azzopardi HJ, Slack MP, et al. Clinical and immunological risk factors associated with Hib conjugate vaccine failure in childhood. *Clin Infect Dis* 2000;31:973-80.
3 McVernon J, Johnson PDR, Pollard AJ, Slack MPE, Moxon ER. Immunologic memory in Haemophilus influenzae type b conjugate vaccine failure. *Arch Dis Child* (in press).
4 Heath PT, Booy R, Azzopardi HJ, Slack MP, Bowen-Morris J, Griffiths H, et al. Antibody concentration and clinical protection after Hib conjugate vaccination in the United Kingdom. *JAMA* 2000;284:2334-40.
5 Lucas AH, Granoff DM. Imperfect memory and the development of Haemophilus influenzae type b disease. *Pediatr Infect Dis J* 2001;20:235-9.

EU reimporting drugs meant for Africa is only part of story

Editor—The proposed measures of the European Union to prevent reimportation of cheap drugs meant for Africa are welcome.[1] However, experience of drug access programmes suggests that relabelling will address only part of the problem of corrupt diversion of medicines.

The Diflucan donation programme, which offers fluconazole free to patients with HIV infection or AIDS, has already altered the presentation and labelling to reduce the risk of diversion. Despite these measures—effectively a pilot for the proposed European strategy—donated fluconazole has already been diverted.

A substantial proportion of the 290 000 tablets donated to Uganda have been diverted to private sale. Individual tablets are being sold in pharmacies without appropriate diagnosis or supervision. This represents not only a corrupt diversion for profit but also a serious risk of inappropriate or inadequate use. Inappropriate use risks harm to patients, whereas inadequate dosing may threaten the clinical value of fluconazole through selecting resistant pathogens.

Specific marking of products intended for Africa may reduce the risk of reimportation for profit into the Europen Union but, as shown by experience with fluconazole, it will do nothing to prevent corrupt diversion in Africa.

Prevention of the corrupt diversion of medicines for Africa requires far more than specific labelling. Characteristic marking must be accompanied by delivery through strategies proved to be secure. Such secure delivery is possible. Inter Care has lost less than 2% of donations over 30 years by delivering direct to prescribers and dispensers in six African countries. Routine commercial delivery strategies into Africa are too dependent on trust.

The generosity and goodwill of manufacturers must be complemented with experience of delivering into the disordered infrastructures of Africa. The proposal may reduce corrupt profits in the European Union, but it does little to deter corrupt diversion in Africa.

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1 Watson R. EU clamps down on reimportation of cheap drugs meant for Africa. *BMJ* 2002;325:1058. (9 November.)