

Preference is given to letters commenting on contributions published recently in the *JRSM*. They should not exceed 300 words and should be typed double spaced

The surgeon's job

Professor Rowley (August 2004 *JRSM*¹) correctly identifies *Skills for the New Millennium: Report of the Societal Needs Working Group CanMEDS 2000* as an influential document identifying necessary elements in the area of professionalism. However, he errs in indicating it was a product of the Canadian Medical Association. It was authored by a working group of the Royal College of Physicians and Surgeons of Canada (RCPSC). The CanMEDS framework was developed and validated from 1993 to 1996. It was incorporated into Canadian specialty postgraduate education during the next six years along with enhanced material for faculty development. The CanMEDS framework of competencies that began as an initiative of forward-thinking Fellows of the RCPSC has become a popular standard for medical education around the world, including Australia, the Netherlands, Denmark and the UK.

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Achilles tendinopathy

The juxtaposition of articles on statins and Achilles tendinopathy in the October 2004 *JRSM* reminded me of a case relevant to the article by Maffulli and colleagues.¹ A young man was referred to me with a raised cholesterol (LDL approximately 7 mmol/L) and a family history of premature coronary heart disease. On history-taking it emerged that the patient had recently developed unilateral tendinitis, for which he had received peritendinous injections of corticosteroids. On examination he had bilateral corneal arcus and Achilles tendon xanthomata. Heterozygous familial hypercholesterolaemia was diagnosed and he was started on a statin.

The association between familial hypercholesterolaemia and Achilles tendinitis is well known.^{2,3} Treatment of the hypercholesterolaemia will probably lead to resolution of the tendinitis⁴ but, more importantly, it may prevent a premature death. I advise looking at the eyes as well as the legs.

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Textbook of Tropical Surgery

Imre Loeffler (September 2004 *JRSM*¹) compares the new *Textbook of Tropical Surgery* unfavourably with *Principles of Medicine in Africa*. However, the latter is in its third edition whereas, as he acknowledged, the editors of the surgical textbook had 'embarked on a task never undertaken before'. I write as one of the 265 contributors from thirty-nine countries. Some of Mr Loeffler's points require attention and we are grateful for the critique; others stem from the editors' aim to bridge the gap between developed and developing countries. This mammoth surgical work has no rivals, and doubtless when the time comes for second and third editions it will withstand better comparison with the medical book.

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The sickly Stuarts

Neither in Milo Keynes' review of Professor Holmes' book *The Sickly Stuarts—the Medical Downfall of a Dynasty* (June 2004 *JRSM*¹) nor in Graham Brack's comments on the review (August 2004 *JRSM*²) is mention made of Holmes' view of the hypothesis that James VI/I suffered from familial porphyria. Having described the renal findings at the necropsy of James VI/I, Holmes writes 'this finding negates and lays to rest the presumption of Dr Ida Macalpine and her colleagues that James and his mother had acute intermittent porphyria . . . unfortunately this idea has had a life of its own . . .' Having cited publications opposing the porphyria hypothesis, Holmes concludes 'James did not have porphyria. Nor, for that matter, did any of the Stuarts or Hanoverians'. In the subsequent paragraph, he states 'The clinical description of de Mayerne and the autopsy report of Walton provide a clear description of chronic kidney stone disease'.³

Although Macalpine and Hunter⁴ are supported by Rohl, Warren and Hunt,⁵ Holmes' contrary view needs to be made known to a wider readership than those who have read his book.

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Coxibs and serious adverse cardiovascular events: a class-effect?

Selective cyclo-oxygenase-2 (COX-2) inhibitors, sometimes referred to as 'coxibs', are widely prescribed by hospital doctors and general practitioners for arthritic pain. Their gastrointestinal tolerability is believed to be superior to that of 'non-selective' non-steroidal anti-inflammatory drugs (NSAIDs) such as naproxen and diclofenac. Since the US Food and Drug Administration (FDA) approved the use of rofecoxib (Vioxx) in May 1999, 83 million prescriptions have been issued worldwide. However, on 30 September 2004, rofecoxib was voluntarily withdrawn by Merck Sharp & Dohme because of an increased relative risk of serious cardiovascular events seen after 18 months' use in the APPROVe (Adenomatous Polyp Prevention On Vioxx) trial. The APPROVe trial was initiated because of two previous studies^{1,2} indicating that daily aspirin had protective effects against colorectal adenomas.

The finding of increased risk of cardiovascular events in relation to rofecoxib did not come as a complete surprise. Such an effect was evident in the Vioxx Gastrointestinal Outcomes Research (VIGOR)³ study, the results of which were reported almost 4 years ago. Results for the first 6 months from a similarly large trial of another selective COX-2 inhibitor, the Celecoxib Long-term Arthritis Safety Study (CLASS),⁴ suggested that celecoxib had a better gastrointestinal toxicity profile than diclofenac or ibuprofen but results for the 12 month period, made available on the FDA website,⁵ do not entirely support this conclusion. The discrepancy generated criticism of the way the CLASS data were initially reported.⁶ Moreover, although celecoxib was not associated with a higher risk of serious cardiac sequelae than diclofenac or ibuprofen over the whole duration of the

trial, the data do not exclude the possibility of lesser effects related to cardiac ischaemia.

When an unexpected drug effect is observed, whether adverse or beneficial, the possibility of a 'class-effect' has to be considered. So, might adverse cardiovascular effects be expected with COX-2 agents other than rofecoxib? This question will need to be addressed with complete transparency in future studies of COX-2 inhibitors—especially with the advent of agents such as valdecoxib (Bextra), the successor drug of celecoxib, and etoricoxib (Arcoxia), planned successor of the withdrawn rofecoxib. Meanwhile, for the purposes of alleviating arthritic pain at least, COX-2 inhibitors have lost some of their attraction compared with the older NSAIDs such as diclofenac in combination with a proton pump inhibitor (omeprazole).⁷

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Adult bone-marrow stem cells

In their paper about the therapeutic potential of adult bone-marrow stem cells (October 2004 *JRSM*¹) Professor Hassan and Dr El-Sheemy refer to ethical controversies over use of embryonic stem cells. Apart from the ethical objections, cell replacement therapy from embryos and fetal tissue is complicated by difficulties with standardizing the procedure, ensuring viability of tissue and obtaining tissue at optimal time points. By induction of fate-specific cells from an *in-vitro*-expanded population of isolated progenitor/stem cells, bone marrow stem cells may be more readily exploited. Differentiation of expanded cells can be induced

by mitogen withdrawal or by exposure to cytokines, hormones or vitamins that cause lineage restriction.

Cytokines involved in the clonal expansion and lineage restriction of stem/progenitor cells in the haematopoietic system may play an important analogous role in the developing nervous system. For example, interleukin-1 can induce expression of the dopaminergic marker tyrosine hydroxylase. Furthermore, in a study by Carpenter *et al.*² leukaemia inhibitory factor, a member of the interleukin-6 cytokine family, when combined with other mitogens was shown to enhance proliferation of human forebrain neural stem cells. Importantly, we need to consider the possibility that bone marrow stem cells are able to redifferentiate. Already there is evidence that neural stem cells can become bone-marrow-like: they were shown capable of reconstituting the haematopoietic systems of mice that had undergone marrow ablation.³ These studies suggest that the lineage path taken by multipotent cells is influenced by the environments to which they are exposed.

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Diathermy and tonsillectomy: criticism of NICE

Earlier this year the National Institute for Clinical Excellence (NICE) issued guidelines for use of diathermy in tonsillectomy, based on a nationwide audit that is still continuing. A letter issued by Mr Andrew Dillon, Chief Executive, and Professor Bruce Campbell, C Chair of the Interventional Procedures Committee, advised that 'all surgeons should consider how best to minimize their use of diathermy during the tonsillectomy' [www.nice.org.uk/page.aspx?o=203699]. As the surgeon who does most of the adult tonsillectomies in my hospital, I have found this advice both puzzling and disruptive. An immediate consequence was that the 'risk management' section of our trust expressed grave concern that diathermy (bipolar in our case) was being used in our department. Within a fortnight a departmental policy was created stating that diathermy may be made available only if all attempts at controlling bleeding with ligatures have failed. When does that point arrive? If one tries hard enough and keeps on

ligating every red object in the tonsillar bed, all bleeds eventually stop. The surgeon now feels guilty even about mentioning diathermy.

Having looked at the 'evidence', I wonder why NICE was in such a hurry to release this interim guideline before reaching definitive conclusions. Take the chart providing figures for 'cold steel dissection with diathermy haemostasis' (the method I use). No distinction is made between monopolar and bipolar types even though the audit form differentiates between the two. We are told that patients operated in this way are 0.7% more likely to return to theatre with postoperative bleeding than those in whom ligatures only are used. Since the document later states that the monopolar type is twice as harmful as the bipolar type, we might reasonably assume that in patients receiving bipolar diathermy for haemostasis the excess risk of returning to theatre will be even less than 0.7%. Should we really change our practice on the basis of this very small difference and lose the advantages that bipolar haemostasis has to offer—notably, a much quicker operation and less preoperative blood loss (both matters on which the 'interim guidance' is silent)? The practical advantages of bipolar dissection have been well discussed by Silveira *et al.*¹ In presenting its haemorrhage figures, NICE states that patients operated upon by trainees are roughly twice as likely to bleed as those operated on by non-training grades and consultants. Unfortunately, this difference is not allowed for in discussion of individual methods. If, for example, cold steel tonsillectomy with ligature haemostasis is done mainly by experienced surgeons while the younger generation favour diathermy, that might explain the apparent advantages of the former. Many aspects of the interim guidance are in conflict with recent studies. Both Belloso *et al.*² and Timms³ have reported lower rates of postoperative bleeding with coblation than with cold-steel dissection and bipolar haemostasis. Moreover, in a review of the published work, Leinbach *et al.*⁴ showed no significant difference in postoperative bleeding between monopolar dissection and cold steel dissection.

By presenting its confusing interim guidance NICE breached a basic principle of audit that changes are effected only after the data collection phase of the audit is over; otherwise the final assessment is falsified. For example, whereas before the guidelines nearly all the tonsillectomies at our hospital involved diathermy, the procedure is now almost extinct - yet the data collection phase is yet not over. As it happens, the number of post-tonsillectomy bleeds has slightly increased, though (as with some of the differences in the NICE document) this may be due to chance.

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Reply from NICE

The interim guidance [www.nice.org.uk/interimtonsillectomyguidance] was issued in response to a request from the Chief Medical Officers of England, Scotland and Northern Ireland to review urgently the use of diathermy tonsillectomy, and followed an interim analysis of the results of the National Prospective Tonsillectomy Audit which was carried out in England and Wales. The results¹ suggested that there was a higher risk of secondary haemorrhage requiring readmission to hospital and return to theatre after tonsillectomy using diathermy techniques or coblation compared with techniques which use no diathermy either for dissection or haemostasis.

This advice was issued in conjunction with an accompanying letter from Professor Richard Ramsden, Chairman of the Audit Steering Group, in which he summarized the results [www.nice.org.uk/pdf/diathermytonsillectomyletterichardramsden.pdf]. The interim guidance advised that all surgeons should consider how best to minimize their use of diathermy during tonsillectomy, particularly when diathermy is being used for both dissection and haemostasis. It highlighted that the risk may be particularly high for monopolar diathermy and surgeons should consider discontinuing this method. The risk may also be higher with currently available disposable diathermy equipment for tonsillectomy and again surgeons should consider discontinuing use of such equipment. In addition the Institute advised that the National Prospective Tonsillectomy Audit should continue and that all patients having tonsillectomy should be included.

In advising the Institute on this matter, the Interventional Procedures Advisory Committee were aware of the methodological challenges of assessing interim data, some of which have been raised by Mr Shahzad. The Institute will issue full guidance when a systematic review of the literature together with a more detailed analysis of the audit data is available.

In view of the concerns raised by the British Association of Otorhinolaryngologists, Head and Neck Surgeons' audit we consider that the Institute has taken a measured and appropriate approach to ensuring patient safety.

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Referral criteria in early rheumatoid arthritis

Dr Suresh (September 2004 *JRSM*¹) highlights the importance of early referral in a patient with suspected rheumatoid arthritis or RA-like polyarthritis. As he indicates, the diagnosis is a clinical one and absence of rheumatoid factor (RF) is not informative. Unfortunately, there is reason to think some general practitioners delay referral when the serology is negative. Sinclair and Hull,² looked at the reasons general practitioners request RF assays and the effect of the result on their subsequent action. The requests were generally backed by appropriate clinical signs of RA; however, 32% of responders believed that a negative RF excluded RA, even in a patient who fulfilled the American Rheumatism Association⁴ classification criteria. Referrals were made to a consultant rheumatologist in 52% of patients with a positive RF, but 66% of patients with a negative RF would not be referred. In only 1.2–2.5% of instances were patients referred for specialist review on clinical grounds alone. Seronegative RA should account for about 25% of total cases. With 60% of cases seronegative at presentation,⁵ the above data suggest that a sizeable number of RA patients are being missed. Should RF be removed from the decision-making process? If general practitioners relied wholly on clinical criteria and the RF test was restricted to rheumatologists only, we could expect a large increase in consultant referrals.

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Compulsory helmets for cyclists

Professor Sheikh and colleagues (June 2004 *JRSM*¹) favoured legislation that would compel cyclists to wear helmets. They conceded that the ethical argument was somewhat stronger for children than for adults. Subsequent correspondents questioned the evidence on helmet efficacy and argued that legislation would have negative effects by discouraging the healthful activity of bicycling. When analysing the cost–benefit ratio of legislation we should factor in the full effects which flow from traumatic brain injury, not only to the patient but also to the patient's family and carers.^{2,3} These involve many levels ranging from the formally quantifiable health costs, through changes in quality and quantity of life, to the less measurable personal, family and social losses. Wearing seat belts in motor vehicles now seems common sense and has reduced the neurological burden imposed by accidents. Wearing helmets by all cyclists should also seem common sense. Combined with public health campaigns on the long-term benefits of exercise, any potential negative impact of

mandatory helmet-wearing should disappear. We have already accepted the impositions on our freedom of movement (e.g. airports and elsewhere) brought about by the global terrorist threat. In many countries the risk of traumatic brain injury following a cycle accident may be much greater than a terrorist threat.

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