LETTERS

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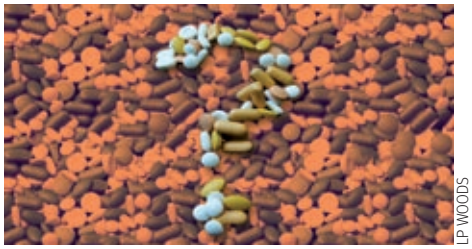

LP WOODS

CANDOUR ON UNFUNDED TREATMENTS

Ignorance is a public health issue

Marcus indicates the importance of candour in outlining the choices available to individuals.[1] However, there is also the effect on wider issues of public health and the availability of treatment options from which patients can choose.

Unacceptable radiotherapy waiting times have been highlighted by the Royal College of Radiologists for over a decade.[2] They have now started to improve, but the last audit in September 2005 still showed that over half our patients wait longer than one month for curative treatment. What is probably not made clear to patients is the impact that this can have on their prognosis. A systematic review has shown that for breast cancer a wait of longer than eight weeks carries a 60% increase in the risk of local recurrence over five years.[3] For postoperative radiotherapy of head and neck cancer, a delay of six weeks increases the risk of local recurrence 2.6-fold.[3]

Worse than this, delay may render patients untreatable. An audit of waiting times in lung cancer patients showed that 20% progressed so that they were unsuitable for radical radiotherapy while on a waiting list.[4] An update in 2007 showed no change.[5]

These are serious risks to patients. Our failure to communicate them or to bring them into the public arena has contributed to the current lamentable state of our radiotherapy services. The report of the National Radiotherapy Advisory Group, which is currently with ministers, proposes a plan to tackle these issues.

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Competing interests: MVW holds a joint lymphoma clinic with Dr Marcus.

1 Marcus R. Should you tell patients about beneficial treatments that they cannot have? Yes. *BMJ* 2007;334:826. (21 April.)
2 Dodwell D, Crellin A. Waiting for radiotherapy. *BMJ* 2006;332:107-9.
3 Huang J, Barbera L, Brouwers M, Browman G, Mackillop WJ. Does delay in starting treatment affect the outcomes of radiotherapy? A systematic review. *J Clin Oncol* 2003;21:555-63.
4 O'Rourke N, Edwards R. Lung cancer treatment waiting times and tumour growth. *Clin Oncol* 2000;12:141-4.
5 Muirhead R, O'Rourke N. Waiting times for radical radiotherapy in NSCLC. *Clin Oncol* 2007;19: S41.

Patients do not live in an information vacuum

Firth has done his best with a very short straw and moved the debate from the general question to a very specific patient.[1]

Mr Brown is that rarity in today's society: a person disinterested in his medical condition and bereft of sources of information or indeed of friends, relatives, or campaigners who will give him information he may not want.

My concern would be that when (not if) he receives the information, and then appreciates that the doctor failed to inform him, his trust in that doctor and the profession in general will be undermined.

People with ill health have to face many uncomfortable and distressing changes in their lives, and, although doctors have a duty to comfort, this cannot mean protecting patients from information that is both empowering and uncomfortable. Doctors cannot know what resources their patients may have or be able to rally.

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Competing interests: None declared.

1 Firth J. Should you tell patients about beneficial treatments that they cannot have? No. *BMJ* 2007;334:827. (21 April.)

All that is needed is for good men to say nothing

I am sure Firth is a committed, caring, and competent doctor, but on this occasion he has failed his patient, Mr Brown.[1] His actions are supporting the political lies and administrative sleight of hand which deny patients life enhancing treatments.

He should read the General Medical Council's guidance further; after telling his employer of inadequate resources, he should seek independent advice on how best to put matters right.

A primary care trust that refuses to fund treatments recommended by the National Institute for Health and Clinical Excellence should be reported to the secretary of state for health, with a copy to the press.

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Competing interests: Remuneration from pharmaceutical industry for advice and lectures on ethical and legal aspects of off-label treatments for macular degeneration.

1 Firth J. Should you tell patients about beneficial treatments that they cannot have? No. *BMJ* 2007;334:827. (21 April.)

ROYAL COLLEGES AND MMC/MTAS

We are alive and kicking and have upped our game

Hawkes focuses on the role of the royal colleges in Modernising Medical Careers (MMC) and the Medical Training Application Service (MTAS).[1] On MTAS, the royal colleges were permitted very little influence on its development.

As to upping our game, the colleges have over recent years developed new roles and responsibilities, have modernised their organisations, and have instigated new initiatives to advance medical practice in line with the continued development of healthcare reform. Such work has transformed the agenda of the colleges into one of proactive engagement with policy makers, of innovation, and of providing patient focused healthcare delivery.

The Academy of Royal Colleges, well placed to bring a unified medical professional view of issues that should be addressed, is developing a broad agenda that reflects continuing change in the nature and delivery of better health and health care, both generally in the UK and abroad, and in the context of the reformed NHS. The colleges, either working individually or together through the academy, are already influencing 21st century medicine, in a variety of alliances with other bodies—independent and statutory—that have interests and responsibilities in health. Examples are the highly acclaimed work on medical professionalism by the Royal

College of Physicians, the development of accreditation of radiological services currently being piloted by the Royal College of Radiologists, and the work currently being undertaken by the academy on reconfiguration of acute services. Finally, the academy and the individual colleges welcome their new and central role in helping implement a robust system of recertification or "revalidation" of doctors.

Such new roles and initiatives demonstrate that colleges are championing change and helping to direct modern trends in the development of health care. Representing a living and very important profession, the colleges are very much alive.

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Competing interests: None declared.

1 Hawkes N. The royal colleges must up their game—or die. *BMJ* 2007;334:724. (7 April.)

IT AND PATIENT SAFETY

Software must be robust

De Wildt et al concentrate on the shortcomings of Excel but ignore other inadequacies.[1] Using Excel or other spreadsheets for dose checking (with or without the locking facility) is inappropriate. The problem is not just data going in the wrong place—it is essential that the concepts of strength and dose are not confused, which seems to have occurred in this case, and that every entry is clear, follows accepted standards, and its purpose is clear.

Writing robust software for handling dose calculations is straightforward, but this is not a job just for the computer programmer. The first requirement is to assemble the knowledge domain of the application—in this case, all drug products (and all their details in standardised format) that would ever be needed in paediatrics and the medical information domain for their use (indications, contraindications, side effects, interactions, dosage, and so on). Next the knowledge concepts and related terminology need to be organised, preferably into some form of hierarchical thesaurus and put into a database. Now the algorithm to do the dose checking can be written and checked. Finally the programmer can write the program. This program makes calls to the knowledge domain database on the basis of the strictly controlled entries of the user. The drugs required are selected from the database, ensuring that real products are chosen by the user, as are the weight, age, and medical conditions. The knowledge database must contain all the drugs and other treatments including strengths, formulations, dose per kg body weight, dose for specific indications, and routes and rates of administration.

The whole job could be done by a team of one doctor or pharmacist with the necessary knowledge, one database expert, and one programmer—in one year or in standardised units three man years.

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Competing interests: RW is the managing director of SafeScript Ltd and co-author of its product: the World Standard Drug Database.

1 De Wildt SN, Verzijden R, van den Anker JN, de Hoog M. Information technology cannot guarantee patient safety. *BMJ* 2007;334:851-2. (21 April.)

NEW CARE AFTER SURGERY

How new is new?

I was very excited when I read the headline "New approach to surgical care aims to improve recovery."[1] Like many surgeons I have been interested in improving recovery of patients after elective surgery for quite a while. However, the only thing new I was able to find in this "new approach" was a new acronym (enhanced surgical treatment and recovery programme, ESTREP).

Surgeons, anaesthetists, and other doctors interested in enhancing postoperative recovery have known the multimodal approach allegedly developed at University College London Hospitals NHS Foundation Trust for more than a decade under the acronym ERAS (enhanced recovery after surgery) or "fast track." Except for intraoperative oesophageal Doppler guided fluid management (in some hospitals already a part of fast track surgery), the "new approach" does not seem to offer anything new.

The *BMJ* did publish a clinical review on this topic more than five years ago,[2] while the first series of fast track rehabilitation for elective colonic resection by Henrik Kehlet and coworkers from Hvidovre Hospital in Copenhagen, Denmark is as old as 12 years.[3] Not only is the "new approach" not really new, but also the potential of fast track or ERAS or ESTREP is underestimated in this article—to reduce the average stay in hospital for patients undergoing complex colorectal surgery from 12 days to eight days. In the Copenhagen group postoperative hospital stay was decreased to two to three days after elective colectomy, postoperative hospital stay was five days in a recent international study,[4] and postoperative hospital stay decreased from 12 to five days after introduction of fast track rehabilitation in my hospital.

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Competing interests: None declared.

1 Mayor S. New approach to surgical care aims to improve recovery and reduce length of hospital stay. *BMJ* 2007;334:816-7. (21 April.)
2 Wilmore DW, Kehlet H. Management of patients in fast track surgery. *BMJ* 2001;322:473-6.
3 Bardram L, Funch-Jensen P, Jensen P, Crawford ME, Kehlet H. Recovery after laparoscopic colonic surgery with epidural analgesia, and early oral nutrition and mobilisation. *Lancet* 1995;345:763-4.
4 Maessen J, Dejong CH, Hausel J, Nygren J, Lassen K, Andersen J, et al. A protocol is not enough to implement an enhanced recovery programme for colorectal resection. *Br J Surg* 2007;94:224-31.

STUART CLARK/REX

ASYLUM SEEKERS

Detained asylum seekers may be being re-traumatised

Bisson's review does not mention torture, a common cause of post-traumatic stress disorder (PTSD), or the risk of re-traumatisation in such patients. UK doctors are most likely to encounter these problems among asylum seekers, especially those who have been detained in removal centres after being "failed" by the Home Office and immigration judges.[1] The number of such cases probably exceeds 5000 per year.

It was accepted in the drafting of the detention centre rules[2] and underlying statutory instruments that detention of torture survivors was unduly likely to cause severe psychological harm and should occur only under "exceptional circumstances."

Doctors working in detention centres are required to report to the Immigration and Nationality Department (IND) about anyone whose health is likely to be harmed by detention, which can be of indefinite duration, exceeding one year without any conviction in some cases. Sadly, receipt of such reports (when sent) has resulted in inaction and significant misrepresentation by the department.

In a report on Harmondsworth Detention

Centre, Her Majesty's Chief Inspector of Prisons identified 57 such "torture reports" sent to the immigration department over the first half of 2006.[3] Not one of these is known to have resulted in any action by the department to investigate the accuracy of such reports.

In the past 18 months, colleagues in the Medical Justice Network and I have seen at least 25 detained asylum seekers with strong physical evidence of torture (including cigarette burn scars and stigmata of falaka (beating of the feet)) as well as fulfilling all necessary criteria for a diagnosis of post traumatic stress disorder. In some cases, we have been able to provide medicolegal reports that have helped their release by judicial decision. This has usually been resisted by the Home Office.

Doctors, especially general practitioners, whose asylum seeking patients have evidence they were tortured before coming to the United Kingdom, who have PTSD as a result and who are at risk of detention, may wish to supply them with a letter (or full medicolegal report) outlining evidence that detention would be unduly harmful. This would go some way to reducing the very substantial numbers who suffer re-traumatisation while seeking refuge.

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Competing interests: FWA helped to found the Medical Justice Network (www.medicaljustice.org.uk). For helping detained hunger strikers to obtain adequate medical care, he was reported to the GMC by the management of a detention centre, against the wishes of the patients concerned. He is occasionally paid, under legal aid, for medicolegal reports.

1 Bisson JI. Post-traumatic stress disorder. *BMJ* 2007;334:789-93. (14 April.)
2 Detention Centre Rules 2001 (item 35). www.aviddetention.org.uk/aviddefault.htm
3 HM Chief Inspector of Prisons. Report on an unannounced inspection of Harmondsworth Immigration Removal Centre 17–21 July 2006. http://inspectorates.homeoffice.gov.uk/hmiprisons/inspect_reports/irc- inspections.html/

Highest attainable standard of health is a human right

Since my editorial explaining how the denial of failed asylum seekers' access to free hospital care violates their fundamental human rights was published, there has been a deafening silence from the BMA.[1] Yet the BMA has a proud record of promoting human rights—its website claims that "Action by medical associations ... to ensure that resources [reach] the most vulnerable populations, have played an important role in supporting the realisation of the right to health."[2] Not for over 400 000 failed asylum seekers living in the UK, it hasn't.

In contrast, the parliamentary Joint Committee on Human Rights recently recommended that free secondary health care be provided "to comply with the laws of common humanity and the UK's international human rights obligations," and an innovative Department of Health policy document that requires health professionals to respect human rights acknowledges the government's responsibility to comply with international treaties.[3 4] The BMA's reticence, given its influence and reputation on human rights, means that it has become part of the problem

In 1984 the BMA withdrew from the World Medical Association (WMA) in protest at the reinstatement of a white dominated Medical Association of South Africa that supported apartheid. The protest was prompted by a representative organisation following government policy which violated international human rights law—a practice the BMA now seems to be emulating. In an ironic twist, the current South African government's deliberate obfuscation of the cause of AIDS violates the same international covenant and may ultimately be responsible for more suffering and death than apartheid.[5] Now human rights are to be engaged as best practice,[4] doctors will have to understand that international human rights law is there to be respected not cherry picked.

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Competing interests: PH played a part in developing the General Comment 14 of the International Covenant on Economic, Social and Cultural Rights.

1 Hall, P. Failed asylum seekers and health care. *BMJ* 2006;333:109-10.
2 BMA. An introduction to the right to health. BMA website www.bma.org.uk/ap.nsf/Content/righttohealthintro?OpenDocument&Highlight=2,health,rights
3 Joint Committee on Human Rights. *The treatment of asylum seekers.* London: Stationery Office, 2007:5.
4 Equality and Human Rights Group. *Human rights in health—a framework for local action*. Sn 1.3a. London: Department of Health, 2007.
5 United Nations. *The right to the highest attainable standard of health*. Geneva: UN, 2000. Para 36. (General comment No 14.)

BMA's response

The plight of failed asylum seekers in the United Kingdom is a matter of serious humanitarian concern. The BMA's medical ethics department receives regular inquiries about the rights of extremely ill individuals to vital health services where legal entitlement is in doubt. We did not respond immediately to Hall's thoughtful comments (previous letter), but this is not the same as silence. The BMA is a membership organisation, and its overall policy is decided at its annual representative meeting (ARM). This year, for example, we understand a motion is being taken to the ARM calling on the BMA to lobby the government to ensure the provision of appropriate health services for failed asylum seekers. If the motion is passed then we have a mandate to lobby directly. In the absence of such a mandate, our job is to interpret so far as possible existing policy and apply it to emergent circumstances.

Hall is right, the BMA does have a record of promoting human rights in health, and it is out of this background that we have shaped our policy. The medical ethics department has, for example, published guidance on rights of access to health care.[1] Largely as a result of Hall's vigilance, we have clarified that general practitioners have the discretion to register failed asylum seekers for routine primary care, although they are not obliged to do so.

In secondary care failed asylum seekers, who are not "ordinarily resident" in the UK, are entitled to free care only when it is "immediately necessary." Despite these legal restrictions, the BMA has met with representatives of the Department of Health and the Home Office and established that what constitutes "immediately necessary" is a matter of medical judgment and, therefore, medical discretion. The government also undertook to set up a working party, with BMA representation, to look at broader questions of access to health care among migrants without entitlement, but despite our efforts, the group has yet to convene.

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Competing interests: JS is the BMA's lead on health and human rights.

1 BMA. Access to health care for asylum seekers. January 2001. www.bma.org.uk/ap.nsf/Content/asylumhealthcare.

DEPENDENCE ON OTC DRUGS

Over the counter drugs can be highly addictive

The development of dependency on over the counter (OTC) drugs is often forgotten.[1] In the past three months we have seen three patients with addictions to Nurofen plus (ibuprofen and codeine phosphate). All three had started using the product for

its approved indications, but their use had escalated as they became tolerant to the codeine element. Each patient presented with side effects related to ibuprofen.

Codeine phosphate is now only available on prescription but has been available over the counter in combination with aspirin, paracetamol, or ibuprofen for many years.

A Medline search found no research into addiction to OTC drug dependence in the UK. Numerous websites are, however, documenting cases of addiction and offering support to those people trying to withdraw from these drugs. Websites such as over-count.org.uk and codeinefree.me.uk tell many personal stories, often remarkably similar and usually starting with appropriate use of analgesia for pain such as back injury or menstrual cramps. Postings on the over-count website illustrate the most common addiction is to Solpadeine (paracetamol and codeine) and suggest more than 4000 people registered there currently have this problem.

There are no official statistics documenting the extent of dependence on legal non-prescription drugs. We need large scale research to assess and monitor the extent of the problem.

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Competing interests: None declared.

1 Zarocostas J. Misuse of prescription drugs could soon exceed that of illicit narcotics, UN panel warns. *BMJ* 2007;334:444. (3 March.)

COMSTOCK COMPLETE

MASKING OR BLINDING?

Blinding is better than masking

We agree with Morris et al that "blinding" terminology is probably inappropriate in ophthalmological settings.[1] However, we disagree that these settings should ordain terminology for all randomised trials. They describe "masking" done in 1784 and provide dictionary definitions of masking and blinding to buttress their argument for using masking terminology. The techniques used in 1784, however, were not termed masking, and regular dictionaries do not adequately define methodological terms for clinical trials.

Blinding in clinical research enjoys a splendid history spanning over two centuries.[2] Over the years it became entrenched in the tenets of medical research, and most researchers and readers grasp its meaning, although they have more difficulty understanding the different types of blinding.[3] Evidently, "blinding" terminology surfaced when Antoine Lavoisier and Benjamin Franklin actually blindfolded (not masked) participants to shelter them from knowledge in their evaluations of the therapeutic claims made for mesmerism.[4] The visual imagery of blindfolding, a complete covering of the eyes, conveys stronger bias avoidance than masking, where eye openings allow extensive viewing.[5] Moreover, the International Conference on Harmonization (ICH) guidance primarily uses "blinding" terminology.[4] The long history, pervasive general understanding, strong visual imagery, and adoption by the ICH lead us to suggest that "blinding" should remain the predominant terminology.

However, we encourage authors to be more descriptive when describing the blinding used in the conduct of their randomised trial. For example, reporting that "participants and care providers were blinded" is more informative than simply stating "double blinding was used." Moreover, with global electronic access to articles, if authors use "masking" they jeopardise communication. Medical researchers in Africa and Asia, for example, have little familiarity with masking terminology. Totally discarding blinding terminology seems imprudent.

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Competing interests: None declared.

1 Morris D, Fraser S, Wormald R. Masking is better than blinding. *BMJ* 2007;334:799. (14 April.)
2 Kaptchuk TJ. Intentional ignorance: a history of blind assessment and placebo controls in medicine. *Bull Hist Med* 1998;72:389-433.
3 Devereaux PJ, Manns BJ, Ghali WA, Quan H, Lacchetti C, Montori VM, et al. **Physician interpretations and textbook** definitions of blinding terminology in randomized controlled trials. *JAMA* 2001;285(15):2000-3.
4 Franklin B, Bailly JS, Lavoisier A. Rapport des commissaires chargés par le roi, de l'examen du magnetisme animal. ed. **A Nice: Chez Gabriel Floteron;** 1785.
5 Schulz KF, Grimes DA. Blinding in randomised trials: hiding who got what. *Lancet* 2002;359(9307):696-700.

TRANSPARENCY OF NICE

NICE was explicit in constructing guideline

Fahey questions the transparency of the model used in the 2006 update of the NICE (National Institute for Health and Clinical Excellence) hypertension guideline and of the process of stakeholder consultation.[1] The 2006 NICE hypertension guideline brought together NICE and the British Hypertension Society in developing a single guideline, using robust methods to consider both clinical and cost effectiveness.[2]

The fact that Fahey was able to contribute detailed, constructive criticism of the guideline model's assumptions illustrates the transparency with which the model was laid bare for public consultation. His comments on behalf of the Royal College of General Practitioners were considered by the guideline development group, along with many others, and influenced the final model and recommendations. For example, many stakeholders asked for heart failure to be given more prominence as an adverse outcome in the model, and this was done. All comments from registered stakeholders are available, together with the developers' responses, in a 126 page document available on NICE's website (http://guidance.nice.org.uk/page.aspx?o=394279). We are unclear why Fahey should contrast NICE with SIGN's (Scottish Intercollegiate Guidelines Network) methods, as SIGN does not routinely undertake economic modelling.

Fahey's criticisms of the transparency of arrangements for stakeholder involvement is in contrast to the view expressed by the World Health Organization when it reviewed NICE's clinical guidelines programme in 2006. Its independent report says that collaboration with stakeholders in the development of the guidelines through the consultation and feedback mechanisms available was in general very effective.[3]

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Competing interests: None declared.

1 Fahey T. Transparency in NICE: Construction and assumptions of models should be explicit. *BMJ* 2007;334:814. (21 April.)
2 National Institute for Health and Clinical Excellence. *The guidelines manual*. London: NICE, 2007.
3 World Health Organization. *The clinical guideline programme of the National Institute for Health and Clinical Excellence (NICE): a review by the World Health Organization May 2006*. Copenhagen: WHO, 2007. (EUR/05/5063284).