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# LETTERS



## OBESITY

### Stop all further research—and act

How many studies into obesity does it take to build one cycle path for children to get to school on? I believe we have now reached saturation point as to how many studies and articles it takes to convince us that we are too fat as a nation.<sup>1,2</sup> What good does it do to advise people that they need to walk/cycle/swim when the infrastructure is doing its best to prevent exactly this?

Given all the suggested health assessments, dietitians' advice, government guidelines, and supermarket labels there is something missing: action to force planners, developers, councils and local authorities to end totally unsustainable, fat-making practices. These practices include building roads without cycle lanes (or trying to get away with painting a thin white line on a 70 mph road and declaring it a cycle path) and putting up a nice little "walk to health" road sign beside a traffic jammed road heavy with exhaust fumes.

Councils have "cycle to work days"—knowing that the best that cyclists can hope for on most roads is that they have a decent, soft ditch to fall into. The worst is to run out of cycle path and find yourself between a bus lane and two lanes of heavy traffic.

I suggest that all research stops now, all advice stops now, and all infuriatingly patronising labelling stops now. The money must now be spent on buying land from private owners, farmers, developers—and on building cycle paths. The only way we will be able to tie our laces in the future and not need cardiopulmonary resuscitation at the age of 35 is to demand and build a functioning, cyclist and pedestrian centred,

integrated, reliable public transport network. Having witnessed the government's transport policies in the last decades, I would say: fat chance.

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Competing interests: None declared.

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## ORLISTAT OVER THE COUNTER

### People should be free to spend their money as they wish

Williams's analysis "at first glance" is correct—orlistat works and is safe, and people should be free to spend their money as they wish.<sup>1</sup> His subsequent caveats have no merit.

It is true that users may see less benefit than the hoped for loss of 10% of their weight, that they may abandon the drug altogether, or avoid it when about to eat fish and chips. That is their choice and their problem. The medical profession doesn't have a monopoly of knowledge about the input-output logic of weight control—most people, even we fat people, can read, and we are all bombarded on a daily basis with messages about exercise and other forms of "lifestyle modification."

Removing 100 kcal per day from the equation is not irrelevant. Many people become overweight, not because they binge on six hamburgers a day and eat ice cream in the middle of the night, but because over a period of years they steadily ingest every day a few calories more than they use up. A drug that tips that balance, even marginally, has the potential to provide more encouragement for accompanying dietary control and exercise than any amount of medical supervision.

This medical supervision that is supposed to save foolish patients from their unrealistic expectations is in fact something that many overweight people will do a great deal to avoid, having, in past encounters, been met with thinly-veiled disgust and no effective help. The medical profession doesn't have a great record of success in this matter and should not be restricting access to

a safe drug that may help people to help themselves.

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- 1 Williams G. Orlistat over the counter. *BMJ* 2007;335:1163-4. (8 December.)

## Is it worth it?

Stung by recent criticism that general practitioners were failing, among other things, to contribute to the thinning of the nation by not prescribing enough orlistat,<sup>1</sup> I carried out a brief audit of the patients for whom we had, in our practice, prescribed this drug over the previous three and a half years.

Fifty two patients lost 172 kg between them. Totalling up the cost of their prescriptions this worked out at a price of £74.34 per kilogram lost. Some of them actually put on weight while they were taking orlistat, and at least 12 put on substantial amounts of weight when they came off it. It is acknowledged that this audit was small and had many limitations, but it confirmed our gut feeling that merely prescribing medication is not the answer to the obesity epidemic, as Gareth Williams says in his editorial.<sup>1</sup> Most of these patients needed to lose at least 10 kg—for £740 they could have had a treadmill or several years' subscription to a commercial weight reduction company or even a gym, and this would have benefited their general health much more.

It is a curious world that demands that we prescribe ineffective medication for people to lose weight and then in the next post asks us to prescribe sip-feeds to fatten up others.

And all this when we have been watching the news from Darfur the night before.

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- 1 Williams G. Orlistat over the counter. *BMJ* 2007;335:1163-4. (8 December.)

## TIBOLONE

### Still waiting and searching for answers

Clinicians working in the subject area of menopausal problems are still waiting for answers from trials designed to give

results on relevant topics in the treatment of climacteric complaints.

Two important trials were planned (and registered) to define the efficacy and safety of tibolone versus placebo in preventing osteoporotic fractures (LIFT)<sup>1</sup> and managing menopausal symptoms in women after treatment for breast malignancy (LIBERATE).<sup>2</sup> The start of the two studies received great attention from the media; repeated attention was sparked by every favourable report of the study data and safety monitoring boards (DSMBs).

Unfortunately, the facts didn't match clinicians' and patients' expectations. In October 2005 a letter published in the *BMJ* reported the first unfavourable result for LIFT.<sup>3</sup> Women treated with tibolone 1.25 mg showed an increased risk of stroke compared with women treated with placebo.<sup>3</sup> (4.26 cases/1000 woman years versus 1.64 cases/1000 woman years, respectively; relative risk 2.59, P=0.01). In March 2006, this increased risk was confirmed (hazard ratio 2.3, P=0.02); a second letter in the *BMJ* announced that the DSMB decided to stop the trial.<sup>4</sup> The letter ended with the declared purpose "to publish a more detailed report," but no further publication has become available since.

What about LIBERATE? We found some minimal communications on the premature stop of the trial by searching Google (no trace on this trial was found on PubMed). The news appeared on May 2007 on Drug Information Online (drugs.com) and on the Organon website. But after similarly sparse communications about the early halt of the study (because of an excess rate of recurrent breast cancer in patients taking tibolone compared with placebo), no more detailed publication has followed.

The official clinical trial registers do not contain any more information either. According to the WHO and US NIH websites the LIBERATE trial is ongoing (search performed on 28 November 2007).

We need to know the complete data on the safety profile of tibolone as found in the LIFT and LIBERATE trials. Many years after tibolone marketing, data from long term clinical trials on the incidence of relevant outcomes—such as deep venous thrombosis, myocardial infarction, or the risk of breast cancer—are still lacking. The only results from a randomised controlled trial come from the THEBES study,<sup>5</sup> in which the incidence of adverse events after two years was strikingly lower than that observed after the two years in other randomised controlled trials on hormone replacement therapy.

We need prompt, fully transparent access to potentially relevant information about drugs' unfavourable results. Maybe less emphasis should be placed on ongoing studies, interpreted under the optimism bias, which transforms uncertainty into expectations or even positive results, far before the studies' completion.

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## COMMERCIAL CT SCANS

### VOMIT—victim of medical investigative technology

Kmietowicz did not go far enough in highlighting the consumerist nature of commercial body CT scanning.<sup>1</sup> Well, asymptomatic young and middle aged patients have a low pretest probability and wouldn't benefit from a screening test. Furthermore, non-symptom led, non-focused investigations are rife for misinterpretation and error.<sup>2</sup> The initial scanning centres in the United States targeted educated, affluent, health conscious neighbourhoods where there was a preoccupation with wellness and immortality and advertisers fed into these insecurities.<sup>3</sup> This reflects the ethos of big corporations' intent on making profits rather than promoting health. We would do

well to heed the lesson from America where there has been a decline in the number of patient funded scans following dissuasion from professional societies.

Leaving aside the issue of stochastic effect of the radiation, there is the issue of administering contrast—a double edged sword in scanning terms.<sup>4</sup> Without contrast—the most common scenario in CT screening—the merit of the study is questionable, with again a gamut of future medicolegal connotations with missed diagnoses. With contrast, nephrotoxicity remains a notable cause of renal impairment, not to mention life threatening complications such as anaphylaxis. In a normal, physician referred scan, because of the altered risk benefit balance, the use of contrast to show potential abnormalities becomes justified, indeed almost mandatory. In self referred studies, with inherent low sensitivity, the use of contrast becomes more ethically contentious.

Further evidence may be available on screening at least for lung carcinoma in the at risk population with the National Lung Screening Trial in America, which has enrolled 50 000 subjects though won't be ready to publish its findings for a number of years. Until then, the tongue in cheek medical acronym VOMIT sums up the argument against consumer-led CT screening succinctly—victim of medical investigative technology.

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## HEALTH CARE AND MARKETS

### We need to be more pragmatic

I worked for two years as an attending physician at the University of California, San Francisco, and the past 12 years as a consultant in the NHS. Rampant commercialism in health care doesn't work well,<sup>1 2</sup> but nor does health care by slavish social dogma, as in the United Kingdom.

In my experience in the United States,

university medicine was of a high calibre; knowledge and procedural skill levels were the best I have encountered, and patients were treated as individuals and routinely attended by a specialist every day, something that is unheard of in the NHS. Politics of a parliamentary or hospital kind were subservient to care.

Before I went to the US, the NHS was lean and efficient and served the sickest patients in greatest need first, with an exceptional standard at reasonable cost, albeit with long waiting times for elective care. In the 12 years since I got back, the NHS has become overrun by managers, average waiting times have been cut at very high cost by targeting hips and cataracts, and the experience of sick patients in need has deteriorated. Spending has skyrocketed, but we have little to show for it, and bigger salaries don't seem to have made medical professionals happier. The big money has ruined a cherished institution.

Many of the 47 million Americans without insurance chose not to purchase it, although they are able to afford it, because they are young and well. US critics of their own system, such as Woolhandler and Himmelstein,<sup>2</sup> and Michael Moore, never write about the systems that the Organisation for Economic Cooperation and Development (OECD) ranks highly—such as those of Australia, France, Belgium, and Austria—because they all involve a large dollop of realism and pragmatism and avoid the extremes of commercialism and socialism.

However, more than any of these, the future of successful health care lies in the Kaiser Permanente model. This integrates primary, secondary, and tertiary care in a single managed “wedge,” with a single budget linked to clinicians' remuneration, with formulas for discouraging overuse. Kaiser can't function in a socialised setting such as the NHS, and needs competition between similar “wedges” to thrive.

It is not beyond our wit to create such a system of healthy competition and incentives, care before politics, and cost control, without rampant commercialism, but I don't see sense prevailing in my working lifetime.

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Competing interests: None declared.

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## ELECTRONIC HEALTH RECORDS

### Time for an NHS smart card?

Recent correspondence on electronic patient records, including the editorial by McGilchrist and colleagues,<sup>1</sup> seems to avoid facing up to a major philosophical difference in approach.

The Department of Health (abetted by the medical establishment) favours securing data centrally for logistic and research purposes. The issue of capacity (or otherwise) of individual people to give consent for this has been neglected. Furthermore, cost and safety concerns remain, along with the risk of system breakdown.

The alternative approach would be for individuals to carry (and be responsible for) their own medical information. An NHS smart card (ideally chip and PIN based) could facilitate this, with the person allowing access to selected staff by using the PIN. Similarly, only staff with an appropriate password can add to the person's record with PIN based consent.

An NHS card (ideally backed up by facilities to avoid identity fraud) could provide individuals with a wide ranging choice between NHS approved providers—as a referral could be “carried” on the card to a clinic or hospital selected by the patient or carer. Furthermore, the card could also be used for direct payments or an electronic voucher system.

I believe an NHS card would be attractive to a sizeable proportion of patients who have bought into autonomy and self management as regards their health care. Worth a pilot, perhaps?

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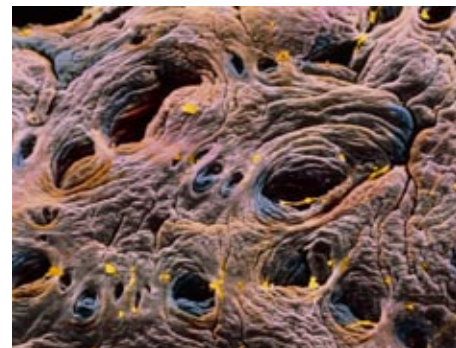
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## SCREENING FOR COELIAC DISEASE

### But where does it take us?

With reference to the study reported by Korponay-Szabó et al,<sup>1</sup> we do not know the natural history of screen detected patients with coeliac disease.<sup>2</sup> Although the investigation process for population screening and case finding may be the same, there is an important ethical difference between them, largely to do with who identifies the patient as ill.

We recently performed a primary



care based cross sectional study using serological markers (endomysial and gliadin antibodies) to initially recognise coeliac disease.<sup>3</sup> We recruited 1200 adult volunteers from January 1999 to June 2001 from five general practices in south Yorkshire, United Kingdom. Any participant with a positive serological result was offered a small bowel biopsy to confirm the diagnosis of coeliac disease. Twelve new cases of coeliac disease were diagnosed from 1200 samples. The prevalence of coeliac disease in this primary care population sample is 1% (95% confidence interval 0.4% to 1.3%).<sup>1</sup> In this screening study, 9/12 diagnosed cases of coeliac disease ultimately had subtle symptoms that could be attributed to coeliac disease (for example, anaemia or subtle gastrointestinal symptoms). Five years later, 5/12 screen detected patients are no longer complying with the gluten free diet.

We, and others, have shown a delay in the diagnosis of coeliac disease—surely the important change in our clinical practice (both in primary and secondary care) is to have a low threshold for case finding. Now that point of care testing is here we must be cautious about how we advocate its use—if this test is available over the counter the risk is that individuals will test and treat themselves without ever seeking healthcare professionals' advice or even a duodenal biopsy. With excellent technology comes the burden of increased responsibility.

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Competing interests: None declared.

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## “BARE BELOW THE ELBOWS”

### Clinical value of a wristwatch

Trusts are about to implement a “bare below the elbows” dress code policy for doctors. This includes the banishing of wristwatches from “clinical areas.”<sup>1,2</sup> There is no evidence that wristwatches are carriers of infection. It has been proposed, but not shown, that watches may impair handwashing.<sup>1</sup> Little account has been made of the clinical benefits of a wristwatch. Most beds and examination couches in hospitals do not currently allow sight of a clock.

Twenty appropriately trained healthcare staff were assessed for their ability to carry out basic clinical observations without the use of a second hand, to assess the dependence placed on wristwatches. Nine senior medical students, six junior doctors, one consultant, and four trained nurses were asked to evaluate heart rate (pulse) and respiratory rate on the Laerdal Sim Man simulated patient. Each participant was assessed at regular pulse rates of 83, 36, and 168 beats per minute and respiratory rates of 14, 30, and 4 breaths per minute. Participants were given as much time as they wanted to make their estimate.

Every participant took longer than one minute to make each estimate. All participants would have failed an undergraduate objective structured clinical examination (OSCE) station, and only one participant gave values for each reading that would not have been potentially dangerous in a clinical setting. Estimates for a pulse rate of 83 ranged from 60 to 120, and estimates for a respiratory rate of 14 ranged from 10 to 28, which shows that it was often not possible for healthcare professionals even to distinguish normal from abnormal without the use of a second hand.

This study highlights the necessity for doctors to have sight of a second hand when assessing patients, especially in emergency situations where a clock might

not be present. A pilot study by the lead author of removing his own wristwatch had to be abandoned after one day because of consistent lateness.

Fob watches have been found to be impractical for some clinical procedures.<sup>3</sup> If trusts wish to persist with the banning of wristwatches, they will be obliged to provide each bedspace with its own clock with a second hand. The same department of health guidelines commend the wearing of soft soled shoes to avoid “disturbing patients’ rest.”<sup>1</sup> The sound of a thousand clocks ticking might be rather more than a little disturbing.

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## DISSEMINATING GUIDANCE

### You’ll find it on the intranet

I agree with Lewis about the vital importance of disseminating guidance adequately.<sup>1</sup> While working as a junior doctor on the wards, I have often thought to myself, “I’m sure there must be a hospital policy for this,” but I could never locate the relevant folder or navigate the depths of the intranet to find what I was looking for in the time available.

I recently completed an audit of a process that I felt wasn’t working well—only afterwards to be presented with a policy devised several years ago which had been dug up from the archives (and no, it wasn’t on the intranet) and consisted almost entirely of the changes I had recommended.

In contrast, one of the consultants at our accident and emergency department has produced a fantastic set of guidelines, providing a wealth of practical information for the staff. They are clear and concise, evidence based, accessible on every computer in the department, and so easy to use that anyone could work out from the Ottawa rules whether or not he needs his ankle injury x rayed.

So policy, guideline, protocol and pathway-writers take note: unless people can access your work easily and quickly,

and know it exists, you may as well have not written it at all.

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## TIME OF CHANGE IN ABORTION

### Abortion care in family medicine

I practise in a family medicine clinic in an urban setting. We offer early first trimester abortions as part of our general medical care. We started doing this after mifepristone became FDA approved, because it seemed a simple way to allow our female patients to make a decision about their accidental pregnancies without all the charge and drama involved in going to an abortion clinic, across a picket line. We thus allow our patients to work through their decisions in privacy, in consultation with us, much as they would other difficult decisions that have a medical aspect.

I suppose we could be worried about our reputations, status, and community respect, as Spence suggests,<sup>1</sup> but it seems more primary to worry about my patient’s ability to get good medical care in a private setting, with my support. In my practice group, we are quite open about our beliefs that women should be able to get abortion care from their primary physicians, and it has brought more patients to our offices rather than fewer. Our patients who find themselves with an unintended pregnancy are enormously relieved to find that they can get their care from us, and they tell their friends and relatives.

Maybe I feel strongly about allowing my patients to come to me for an abortion because I once found myself unintentionally pregnant as a young woman and did not have a private option. I had very few options, actually, because it was before abortion was legal in the United States. I obtained a safe abortion ultimately, but the whole process was very scary and quite traumatising.

Yes, it is a “time of change in abortion.” We can be part of this time of change by providing a needed service. To me, this is what being a physician is all about.

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