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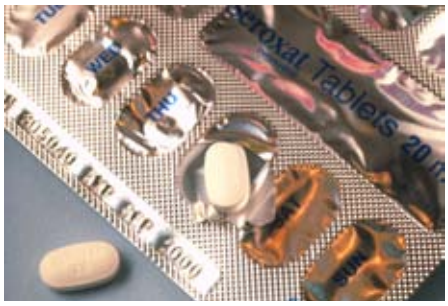
LETTERS

PAROXETINE DURING PREGNANCY

Paroxetine is associated with malformation during pregnancy



SPL

In their clinical review of the diagnosis and management of premenstrual disorders O'Brien and colleagues state[1]: "Obviously, some patients may become pregnant while taking SSRIs [selective serotonin reuptake inhibitors] and these drugs have not been shown to be teratogenic" with a reference to an article reviewing the adverse effects of SSRIs in pregnancy.[2] This is incorrect and is inconsistent not only with the reference provided but also with both the label (black box warning and the pregnancy category D labelling) and the wider literature. Tuccori *et al* in fact state:

"Paroxetine has been associated with significant risks of major malformation, particularly cardiac defects, when used during pregnancy.

"Significant associations between maternal exposure to SSRIs and both persistent pulmonary hypertension of the newborn and a self-limiting neonatal behavioral syndrome have been reported in a number of recent original studies and meta-analyses."[2]

They correctly conclude: "The available evidence suggests that SSRIs and other serotonergic/noradrenergic antidepressants should be used with caution during pregnancy, with careful follow-up of infants exposed to these agents in utero."

Evidence shows SSRIs to be teratogenic in early pregnancy.[3] Concerns about the effects on child development are emerging with a recent signal of a potential link with autistic spectrum disorder.[4 5] This is important information for clinicians and patients to be aware of when use is in women of reproductive age. Women need to be warned of these potential adverse events when these medicines are prescribed.

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Competing interests: DM and DH are expert witnesses for the plaintiff in cases involving Paxil and birth defects in the US. DM is also principal investigator in a New Zealand HRC funded randomised controlled trial of SSRI cessation in primary care. She is a member of the New Zealand Pharmaceutical and Therapeutic Products Advisory Committee.

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Cite this as: *BMJ* 2011;343:d5060

Authors' reply

It has been called to our attention that our statement that selective serotonin reuptake inhibitors (SSRIs) have not been shown to be teratogenic is in error.

Selective serotonin reuptake inhibitors cross the placenta and are found in breast milk.[1] Although the risk of major malformations is very low, the severity of the potential structural and behavioural risks for the infant associated with taking SSRIs and selective noradrenaline reuptake inhibitors (SNRIs) in the first trimester of pregnancy is real and must be weighed against the risks associated with severe depression and anxiety in pregnancy.[1] During late pregnancy the occurrence of postnatal SSRI related symptoms increases to 30% of exposed infants.[1] Paroxetine has been associated with right ventricular outflow tract defects, cleft lip or palate, and digestive system defects; luoxetine has been associated with an increased risk of isolated ventricular septal defects.[2 3] However, current data on the associated risks of SSRI use during the first trimester are limited and further well designed studies are required.[4 5] Even so, the small risk associated with SSRIs should be taken into consideration when discussing treatment plans with a patient.

Women with core premenstrual disorder who do not have a coexistent psychiatric disorder should be warned of the small but potentially severe fetal risks, provided with effective contraceptive methods, and stop taking the SSRI/SNRI as soon as they have an obviously delayed menstrual period or a positive pregnancy test. The requirement for SSRI/SNRI treatment should disappear once a woman with core premenstrual disorder becomes pregnant as the premenstrual symptoms improve. Those with coexisting psychiatric disorders, such as depression, should be managed jointly with a psychiatrist, and whether to continue such drug treatment in the event of conception should be decided when the drugs are first prescribed and then reassessed at frequent intervals.

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Competing interests: The full statement is available at www.bmj.com/content/342/bmj.d2994.full

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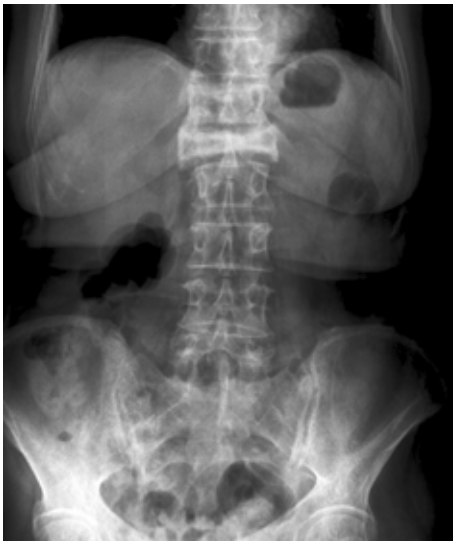
Cite this as: *BMJ* 2011;343:d5079

A correction is published on p 368

VERTEBRAL FRACTURE TREATMENT

No role for vertebroplasty

Current evidence does not support a role for vertebroplasty in vertebral fracture.[1] Combined data from the two most methodologically sound trials to date found that vertebroplasty conferred no benefit over a sham procedure; this result was consistent across subgroups, including people with symptoms for longer than



ZEPHYR/SPL

six weeks.[2] Most, if not all, published controlled trials of vertebroplasty for osteoporotic vertebral fractures have included participants who have had inadequate pain relief with standard medical treatment so they have already failed first line therapy. In weighing up the relative merits of vertebroplasty, Wilson also failed to point out its potential harms.

We are also concerned by Wilson's advice to administer local anaesthetic and perhaps glucocorticoid injections in the region of pain as first line treatment in light of the risk of fracture with systemic glucocorticoids and lack of any high level evidence of the benefit of these approaches. Although his own case series reported positive results with facet joint injections for people with vertebral fractures of various cause, these results need to be confirmed in appropriately controlled randomised trials, particularly as this treatment has not been shown to be effective for back pain.[3] Open and uncontrolled studies predictably overestimate treatment benefit for a variety of reasons, including the favourable natural course of the condition and failure to take performance, detection, and expectation bias into account.

Because of doubts about the role of vertebroplasty for osteoporotic vertebral fracture, additional randomised trials are needed with "more tightly controlled patient selection" and blind treatment allocation (participants and investigators), which will necessitate the use of a sham or placebo control.

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Competing interests: RB was an author of one of the placebo controlled trials of vertebroplasty for osteoporotic vertebral fracture and an author on the individual patient data meta-analysis that appeared in the same issue of the *BMJ*.

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Cite this as: *BMJ* 2011;343:d5043

Treat underlying osteoporosis

Wilson asks how clinicians should treat vertebral fractures in the light of current evidence.[1]

A vertebral compression fracture signals a patient at high risk of subsequent fractures who should be managed appropriately.[2] Vertebral fractures have debilitating consequences and even increase the risk of death. Coordinated, multidisciplinary, and systematic systems of care are being implemented worldwide, which capture fracture patients and accompany them through diagnosis, treatment, and follow-up. These systems are cost effective and can help prevent recurrent fractures.[3] A key objective of this approach is the treatment of the underlying cause of vertebral fracture, which is usually osteoporosis.

Treatments do not prevent all fractures, but large scale clinical trials have shown that treatment for osteoporosis can reduce vertebral fracture rates by 30-70%.[4] However, patients are still being missed and left undiagnosed and untreated. In elderly patients in hospital who had a lateral chest radiograph, fewer than 50% of vertebral fractures identified later by radiography were reported in the radiological reports and even fewer in the medical records.[5] Less than a fifth of patients identified as having vertebral fractures received appropriate treatment for osteoporosis within a year of the fracture.[6]

We thus urge all doctors to narrow this gap in care.

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Competing interests: None declared.

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Cite this as: *BMJ* 2011;343:d5040

DIARRHOEA AFTER ANTIMICROBIALS

Over-diagnosis of *Clostridium difficile*

Settle and Kerr highlight the potential risks of late diagnosis of *Clostridium difficile* infection because of false negative toxin results.[1] Clinicians need also to be aware of the implications of false positive results.

We recently reviewed all adult cases of presumed *C difficile* infection (defined as clinical suspicion of infection plus a positive toxin result) in a 1500 bed trust over three months.[2] Of 47 patients with presumed infection, 18 had ongoing diarrhoea at two weeks despite treatment with oral vancomycin. Duration of diarrhoea was independent of clinical and laboratory markers of severity. When we cross-referenced our cases with stool culture results from a larger study, we found that stool culture gave negative results in five of the 18 patients with persisting diarrhoea, suggesting a false positive toxin result.

Persisting diarrhoea after *C difficile* infection is poorly understood but seems common in clinical practice.[3] Diarrhoea may persist in some patients because of the infection, as for other gastrointestinal pathogens such as *Campylobacter*.[4] Given the difficulties in diagnosing *C difficile* infection, however, alternative causes of diarrhoea may be important.

False positive toxin test results have obvious implications, including unnecessary use of antibiotics, pressure on infection control resources, and prolonged inpatient stay. Careful consideration should be given to alternative diagnoses in patients treated for *C difficile* infection, particularly when the condition fails to improve with treatment.

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Competing interests: None declared.

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NHS HEALTH CHECK

Risk stratification could reduce costs

England is rolling out a major primary prevention programme for cardiovascular disease, the NHS Health Check.[1 2] Only patients at high risk of diabetes need a blood glucose test, not all need serum creatinine tests, but all must have lipids assessed. We investigated, using data from 73 853 medical records in NHS Ealing,[3] the need to measure lipids in low risk patients.

We applied the QRISK2 algorithm[4] in patients aged 40-74, firstly replacing lipid data with age and sex estimates from the Health Survey for England, and secondly using complete data. Using survey data, 27 682 (37.5%) (table) patients were estimated at ‹5% risk, and none was at high risk of cardiovascular disease when complete patient data were substituted. Another 13 170 (17.8%) were at 5-10% risk, and only 11 became ›20% risk. Around 15 million people are eligible for the programme.[5] Given our estimates and a cost of £4.20 (€4.8; $7) per lipid test,[4] £24m will be spent every five years on lipid tests in patients at the lowest (‹5%) risk.

We question the usefulness of universal lipid testing during a health check. Many already have lipids recorded.[3] For patients at the lowest risk, lipid values add limited information to risk profiles, with risk scores unable to discriminate between low levels of risk. Familial hyperlipidaemia is an important mediator of cardiovascular risk, but family history of coronary heart disease should be the important driver in diagnosis, not population screening. The premise of lipid testing as a "hook" to promote attendance has no supporting evidence. With increased strain on NHS spending, risk stratification within the programme could reduce costs.

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Competing interests: None declared.

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Cardiovascular disease risk scores using lipid data or estimated lipid data

CVD risk score using lipid data	CVD risk score using estimated lipid data					
	‹5%	5-10%	10-15%	15-20%	›20%	Total
‹10%	27 682	13 170	1528	0	0	42 380
10-20%	3	1626	8219	6144	1666	17 658
›20%	0	11	136	1292	12 376	13 815
Total	27 685	14 807	9883	7436	14 042	73 853

INDIVIDUAL HEALTHCARE RATIONING

Experience of lay member of IFR panel

Many of the questions raised by Russell and colleagues about whether IFR (individual funding request) panels should have lay representation[1] have been addressed by other parts of the public sector for 50 years or more, so why hasn't the NHS learnt from these experiences? Generally there is antipathy to lay participation in NHS policy or it is limited to "informing" rather than "involving." However, productive participation means that both professionals and public have to move, with professionals ceding some power and status, which they are often reluctant to do. Unfortunately, increasing risk aversion and the spurious certainty of evidence based policy may serve to justify their reluctance.

"Complexity" is a defence for all professions, but the onus should not only be on lay members to get up to speed with polysyllabic biochemistry: professionals also need to communicate clearly. As IFR panels deal with exceptional cases, the problems or solutions are frequently unknown to both clinicians and lay members so have to be explained in a way that everyone can understand. The robustness or fairness of a decision depends on process and detail. With clear explanation, lay members can contribute to both.

I sometimes wonder whom I represent, but neither I nor any configuration of panel could represent all constituencies. I see myself as outside rather than inside, trying to ensure that the technical doesn't become technocratic and possibly adding accountability.

Compared with being on the boards of various organisations, I have found that being on an IFR panel entails a greater and more complex workload; seems to require attendance during the working day; and seems to carry more responsibility because of the life and death issues and the great deal of public money concerned. These are not the types of obligations that every member of the public would be willing or able to accept.

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Competing interests: None declared.

1 Russell J, Greenhalgh T, Burnett A, Montgomery J. "No decisions about us without us"? Individual healthcare rationing in a fiscal ice age. *BMJ* 2011;342:d3279. (13 June.)

Cite this as: *BMJ* 2011;343:d4914

SHARED DECISION MAKING

Obstacles to shared decision making in France

Although Marshall and Bibby state that a recent systematic review has demonstrated the advantages of shared decision making,[1] our results indicate that in France it is not yet common practice or generally considered to be necessary in cancer treatment.

In 2008, the French National Cancer Institute commissioned us to design and construct a shared decision making tool in breast cancer adjuvant chemotherapy. We were to research existing decision making aides, opinions, and practices from multicentre field observations of 50 patient-cancer specialist consultations and 50 clinician and patient interviews. Over two years, we had observed only 32 consultations because of a shortage of such consultations. In the 41 interviews, a reluctance to engage in shared decision making was expressed for various reasons, related to patients, practitioners, and processes.

Oncologists indicated that application of clinical practice guidelines and mandatory multidisciplinary committee meetings dominate patient input into treatment decisions. This is set within a culture of risk management in France where the main priority—documented in different domains across medicine, anthropology, and sociology[2]—is to remove risk via reference to objectified guidelines. This has been referred to as the "French social idea of zero risk."[3] Our experience indicates that the paternalistic approach to oncology care dominates in France and involvement of patients in decision making is not considered essential by health professionals or patients. This contrasts with recent US results on more than 10 000 cancer patient decisions, where only 17.5% were "physician controlled."[4] In France, medical practices are clearly different from those in other countries, especially the US and UK, and these practices are based on cultural models that go beyond the realm of medicine.

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Competing interests: None declared.

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BMJ COVER

False colour diagnostic images have no place in the *BMJ*

The use of a false colour computed tomography image on the front cover of the *BMJ* is disappointing. Hepatic steatosis can be demonstrated elegantly with ultrasound, computed tomography, or magnetic resonance imaging, but the image used not only fails to show this condition but also suggests that a colour scale may be used to diagnose and grade hepatic steatosis. Worse, the use of colour may actually be obscuring the subtle alteration of density of the hepatic parenchyma that is seen with steatosis.[1]

The *BMJ* has a history of producing such false colour images, which are presumably created for supposed visual impact rather than veracity. Unfortunately, they invariably turn out as poor and visually unappealing substitutes for the powerful images that diagnostic imaging is capable of producing.

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Competing interests: None declared.

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Cite this as: *BMJ* 2011;343:d5047

RESPONSE

Charlotte Paterson and colleagues respond to Margaret McCartney

The CACTUS Study is a randomised pragmatic trial with a nested qualitative study comparing traditional acupuncture with usual care in people who consult frequently with medically unexplained symptoms.[1 2] Margaret McCartney has based her Observations article about it on several inaccuracies (quotations from her article in italics below).[3]

(1) *The "wellbeing score" was better in the control group than in the acupuncture group*. This statement is untrue: an adjusted mean difference in favour of acupuncture was seen with wellbeing (wellbeing questionnaire, W-BQ12: 4.4 (1.6 to 7.2); P=0.002). This difference remained significant after missing values were imputed (3.4 (0.5 to 6.3); P=0.02).

(2) *The graphical information behind the paywall showed the difference between the scores in the two groups over time. These were almost identical*. The table of scores at baseline and 26 weeks includes 95% confidence intervals and shows a statistical difference for the primary outcome (Measure Yourself Medical Outcome Profile) in favour of acupuncture (adjusted mean difference: acupuncture *v* control −0.6 (−1.1 to 0); P=0.05) and for the wellbeing score, as described in point 1. The scores cannot therefore be said to be "almost identical."

(3) *The "measure yourself medical outcome profile," is a self administered questionnaire used mainly in alternative medicine . . . There were no blinded functional assessments*. The Measure Yourself Medical Outcome Profile has been validated in several studies that have included patients in conventional general practice (www.pcmd.ac.uk/mymop). It is an individualised outcome questionnaire and is therefore particularly suited to study populations with various chronic symptoms—such as these patients with medically unexplained symptoms. Functional assessments are not an appropriate method of measuring symptoms such as chronic pain.

(4) *There was no sham acupuncture group, which is a big problem*. A pragmatic design, comparing the intervention with usual care instead of a placebo or sham intervention, is an accepted method of investigating complex non-pharmaceutical interventions; it is the appropriate design to "measure effectiveness—the benefit the treatment produces in routine clinical practice."[4] Sham acupuncture trials distort normal practice, thus producing results that are difficult to interpret.[5] We used a waiting list design so that all patients were offered acupuncture.

(5) *The energy is the main thing I have noticed. You know, yeah, it's marvellous!* This was indeed said by one of the patients: it is a published quotation from one of the patient interviews. The qualitative analysis indicated that many patients who were treated with five element acupuncture not only perceived a range of positive effects but also seemed to take on a more active role in consultations and self care.[2]

In our paper we acknowledged the limitations of a pragmatic design and of blinding the statistician but not the patients. We did this with reference to scholarly peer reviewed papers rather than McCartney's approach of referring readers to blog sites with names such as the Quackometer.[3] We believe that the statistical findings of the randomised trial, together with the qualitative analysis of the patients' perspectives, provide doctors and patients with robust and useful information for treatment decision making as well as providing a firm basis for a future cost effectiveness study.

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Competing interests: None declared.

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