



## Is drug regulation failing?

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deprivation or large ethnic minorities are less likely to have their diabetes care recorded thoroughly. Hippisley-Cox and colleagues (p 1267) surveyed 237 UK general practices and examined records of 54 180 diabetic patients among a population of 1.8 million patients. Of 17 recorded

quality indicators for care (such as body mass index, smoking status, HbA<sub>1c</sub> concentration, blood pressure, and having flu vaccination or treatment with angiotensin converting enzyme inhibitors), 10 were inversely associated with deprivation, nine with ethnic origin, and eight with being female.

## POEM\*

### Steroid is effective for vestibular neuritis, valacyclovir is not

**Question** Which is more effective for vestibular neuritis, valacyclovir or methylprednisolone?

**Synopsis** Vestibular neuritis is characterised by sustained rotatory vertigo, positive Romberg's sign falling toward the affected ear, horizontal nystagmus toward the unaffected ear, and nausea. Because vestibular neuritis is thought to be a virally triggered inflammatory condition, it makes sense that antiviral drugs or steroids may be helpful. These authors identified 141 adults presenting to two German emergency departments with vestibular neuritis diagnosed after a detailed clinical examination. They then randomised the patients (allocation concealed) to one of four groups: placebo only, methylprednisolone (MP), valacyclovir, or both. MP was initially given in a dose of 100 mg each morning for three days and then tapered slowly to 10 mg over three weeks. Valacyclovir was given as 100 mg three times a day for one week. All patients were also given 150 mg pirenzepine to reduce gastric acid secretion, and antiemetics as needed, and were admitted to the hospital for at least one day. The groups were similar at baseline, with a mean age between 46 and 52 years. Patients were followed up for 12 months. Outcomes were evaluated by assessors blinded to treatment assignment, but analysis was done not seem to have been by intention to treat. A total of 114 patients completed the study. Six to eight patients dropped out or were lost to follow up in each group. The primary outcome was the degree of nystagmus provoked by caloric irrigation. This is relatively easy to quantify, and it's unfortunate that the researchers did not report any more global symptom measures. They found that treatment with MP was more effective than placebo, but valacyclovir was not. Complete or nearly complete recovery of vestibular function occurred in 8 of 30 patients in the placebo group, 10 of 27 in the valacyclovir group, 22 of 29 in the MP group, and 22 of 28 in the group receiving both drugs (27% for placebo *v* 76% for MP;  $P < 0.001$ , number needed to treat = 2). One patient in the MP group had a bleeding gastric ulcer and several others had mood swings or dyspepsia.

**Bottom line** Methylprednisolone, starting at 100 mg per day and tapering to 10 mg over three weeks, is an effective treatment for vestibular neuritis. Valacyclovir is not effective.

**Level of evidence** 1b (see [www.infoPOEMs.com/levels.html](http://www.infoPOEMs.com/levels.html)). Individual randomised controlled trials (with narrow confidence interval).

Strupp M, Zingler VC, Arbusow V, et al. Methylprednisolone, valacyclovir, or the combination for vestibular neuritis. *N Engl J Med* 2004;351:354-61.

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\* Patient-Oriented Evidence that Matters. See editorial (*BMJ* 2002;325:983)

## Editor's choice

### Is drug regulation failing?

Something is rotten at the heart of the FDA. The United States Food and Drug Administration, mired in controversy over the last 12 months, now faces an extraordinary charge of attempting to discredit a whistleblower. As this week's issue reveals, David Graham, the FDA's associate director of drug safety, was so bothered about the difficulties of presenting his data on rofecoxib (Vioxx) in the *Lancet* that he took his case to the Government Accountability Group, a public interest group that protects whistleblowers. What was extraordinary, reports Jeanne Lenzer on p 1255, was that an FDA manager then called the accountability group to rubbish Graham's account and accuse him of scientific misconduct. In a quandary, the accountability group checked both sides of the story, and found that Graham's version was perfectly credible, while the FDA agent's version failed every test of credibility. It says something of the turmoil within the FDA that when Graham returned to work after giving his damning testimony at Senate hearings—he described the approval of rofecoxib as the “single greatest drug safety catastrophe in the history of the world”—he received a standing ovation from his colleagues (p 1253).

His testimony raises serious questions about the ability of the FDA to fulfil its role as regulator. The dangers of rofecoxib were apparent eight years ago and not acted upon, the harms suppressed. What has now unfolded may be the most serious example of regulatory failings about drug related harm since the thalidomide scandal, suggests Graham. Apart from questions around scientific credibility and accusations of being too close to industry (*BMJ* 2004;329:189), the FDA has spent much of the year defending itself against allegations that its decision not to offer over the counter emergency contraception—imaginatively named plan B—was politically motivated (*BMJ* 2004;328:1219). Ray Moynihan offers another example that will test the FDA's decision making, this time around indication creep, with its fast track review of testosterone patches for hypoactive sexual disorder (p 1255, p 1294). The patches increase sexual activity by one “episode”—or less—per month.

Not that UK regulators need be smug. This year's paroxetine saga has tarred the Medicines and Healthcare products Regulatory Agency with the brush of industry bias (*BMJ* 2004;329:865), and I was surprised to discover the extent to which senior policy makers at a meeting to discuss futures for the NHS saw the drug industry as an essential financier of research and development with barely an acknowledgement of issues of transparency, competing interests, and disentangling the relationship between drug companies and drug regulators. The FDA and MRHA are two of the world's leading drug regulators and their reputations have taken a battering. When will they show that their primary role is to protect the public and not to protect industry?

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