BMJ

BMJ 2012;344:e4269 doi: 10.1136/bmj.e4269 (Published 21 June 2012)

EDITOR'S CHOICE

More marketing than science

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The lessons from this week's Patient Journey are a bit old fashioned, says Mark Weatherall, the neurologist who managed Joyce Dobson's care when she developed facial palsy, double vision, and unsteadiness in her late 70s. "Cast your differential diagnosis wide," he writes, "don't dismiss results that don't fit your diagnosis; many brains are better than one (even a neurologist); and the answer, more often than not, lies in the history." The answer in this case was Lyme neuroborreliosis, contracted while the patient was on holiday in southern France (doi:10.1136/bmj.e3250).

Despite alarming symptoms and some continuing troubling sequelae, the outcome for this patient was largely good. And so it is for most people who develop symptoms after tick bites, according to Christopher Duncan and colleagues (doi:10.1136/bmj.e3124). They advise against testing or giving prophylaxis to asymptomatic patients, and the figures they quote should help to reassure those who do develop erythema migrans. Neurological involvement is rare, especially if the disease is contracted from tick bites in the UK.

Explaining the risks relating to symptoms, tests, and treatments is perhaps one of the most difficult parts of being a doctor, especially where the data are uncertain, says this week's clinical review (doi:10.1136/bmj.e3996). One uncertainty at least seems now to be resolved—the link between bladder cancer and pioglitazone. The study by Laurent Azoulay and colleagues clearly confirms an increased risk (doi:10.1136/bmj.e3645), which the linked editorial says could have been predicted earlier (doi:10.1136/bmj.e3500). Post-marketing studies found a link, but other clues were not picked up or acted on.

Post-marketing studies are crucial to our understanding of how safe and effective new drugs are in the real world. But as currently done they are a cause for serious concern. As Edwin Gale observes, they are often of low scientific value, with no control group and no clear question, and they are poorly regulated especially outside the United States (doi:10.1136/bmj.e3974). The overall impression is that they are more marketing than science. A common hallmark is that they are "extravagantly powered." In the case of recent studies of new insulins, Gale reports that large numbers of patients were recruited and switched to the new treatment, well beyond the numbers required to detect common adverse events such as hypoglycaemia. The benefits to the manufacturer are clear: doctors' prescribing habits have been changed, new patients are started on the new drug, and the costs of the trial and the ongoing treatment are borne by the patient or the health system. The benefits to patients are harder to detect, not least because most of the results remain unpublished. And since, as John Yudkin reports (doi:10.1136/bmj.e3987), most such studies are now happening in low income countries, the effect can be "catastrophic health expenditure."

Gale calls for much tighter regulation to ensure a proper balance between the commercial and clinical functions of such studies. Perhaps most crucially, a company should be bound by the regulatory and legal framework of the country in which it is based, rather than by the far less well regulated, low resource environment in which such studies often take place.

Cite this as: *BMJ* 2012;344:e4269

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