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## Sex, drugs, & dental pain

Dhikav, V. et al. *Pharmacoepidemiology and Drug Safety* 2008;17: 211-212

A 28-year-old patient took celecoxib 100 mg for short-term treatment of dental pain, and noted a failure to maintain an erection. There was no prior history of erectile dysfunction, and the patient had no risk factors for erectile dysfunction such as psychological stressors, trauma, substance abuse, alcohol use, smoking, or other medication use. There was no family or personal history of diabetes, hypertension or coronary artery disease.

Following the withdrawal of celecoxib, his sexual function returned to normal. Two months later, a further bout of dental pain led to use of celecoxib and an associated repetition of erectile dysfunction.

Erectile dysfunction is age-related, reaching a prevalence of 50% in those over 50 years of age. Up to 25% of erectile dysfunction is drug-induced. This may be difficult to diagnose because of concomitant diseases which act as confounders, and because of understandable patient reluctance to draw attention to their sexual dysfunction. Implicated drugs include antipsychotics, antiepileptics, antidepressants, and antihypertensives.

Reports of suspected drug-induced sexual dysfunction, particularly to recently marketed “black triangle” ▼ drugs, are welcomed by the Yellow Card scheme.

## Dropping into depression

Schweitzer I et al. *Med J Aus* 2008; 189: 406-407

Drugs administered topically to the eye have the potential to cause adverse drug reactions. Schweitzer et al. report the case of an elderly man, with worsening glaucoma, where treatment was switched from lantanoprost to travoprost/timolol eyedrops. Within 2–3 days the patient reported symptoms of depression, including poor concentration, tiredness and sleep disturbance,

anorexia and loss of libido. Eleven years previously he had developed depression at the time of starting treatment with betaxolol eyedrops. His symptoms improved after treatment with venlafaxine, and a switch to a combination of travoprost, brimonidine and brinzolamide to control his glaucoma.

Suspected systemic adverse effects due to ocular treatment can be reported to the Yellow Card scheme, as can suspected ocular effects of systemic treatments.

## A prod about jabs

Letourneau, M. et al. *Vaccine* 2008; 26: 1185-1194

Despite the unarguable benefits of vaccination, no vaccine is perfectly safe. As the risk of disease declines after successful vaccination programmes, awareness of the serious consequences of disease can fade. The adverse events of vaccines may then become more prominent in the public mind. As many vaccines are administered to young and healthy individuals, optimising vaccine safety surveillance systems is important in maintaining public confidence in vaccines and to discover any new potential safety concerns.

A recent review of the World Health Organisation’s (WHO) Adverse Reactions Database has focused on such vaccine-related reports. Seventy-six countries participated in the WHO international drug monitoring programme at the time of the review.

Analysis of adverse events after immunisation showed that 82% of such reports were contributed by just three countries; the United Kingdom, Canada, and the United States. The average number of adverse effects to vaccines reported per 10,000 population (<5 years of age) varied considerably, with Canada, New Zealand, and Sweden having the highest reporting rate. The most commonly reported adverse effects included fever, injection site reactions, rash, and convulsions.

That a relatively high proportion of reports submitted to WHO are sourced from the UK is indicative of a relatively good reporting culture in comparison to other countries. However, even with the UK's relative success in obtaining vaccine safety data, under-reporting is a known deficiency of reporting systems that are dependent on the good will and vigilance of healthcare professionals. Although the Yellow Card scheme can find new signals of vaccine safety concerns without the reporting of every suspected reaction, improvements in the numbers of reports would be welcomed.

Hinrichsen et al (*Journal of the American Medical Informatics Association* 2007; 14: 731-735) report on the development and assessment of an automated vaccine adverse event surveillance system in the US, designed to stimulate vaccine reports in primary care. When a doctor entered a diagnosis into a surgery's computer system within 14 days of a vaccination, a prompt asks the clinician if the diagnosis might be associated with the use of a vaccine. If so, then an automated system would populate an adverse event form for submission to the US Vaccine Adverse Event Reporting System (VAERS).

To reduce the number of false positive alerts, and reduce the chances of doctor "fatigue", relatively common events (such as asthma, otitis media, conjunctivitis) and very unlikely events (such as injuries and routine check-ups) were excluded.

Their system generated reports two weeks earlier than those normally reported to the FDA, and reports were also more complete. In addition, they produced a six-fold increase in the rate of reporting vaccine-related events to the VAERS database.

Good reporting of adverse event suspected to be caused by vaccines improves the knowledge of the safety of vaccines, and increases public confidence in vaccine safety surveillance systems.

In adults, only serious reactions to established vaccines are required. However, for children, any reaction, no matter how trivial, may be reported to the Yellow Card scheme.

*"If in doubt write one out."*

### Sharing our expertise

If you require a speaker for a lunchtime meeting or continuing professional development programme, why not contact us?

Our centre is keen to promote the Yellow Card scheme, and can provide training on adverse drug reactions and the Yellow Card scheme.

If you would like to discuss this with us, please ring 0121 507 5672 or email [yccwm@swbh.nhs.uk](mailto:yccwm@swbh.nhs.uk).

## The Yellow Card Centre West Midlands

**We encourage the reporting of Yellow Card reports for all suspected adverse reactions to new (▼) drugs, vaccines and unlicensed herbal remedies, all suspected reactions to all drugs in children, and all serious or unusual reactions to well-established drugs. You do not have to be certain that a drug caused a reaction in order to report.**

Please send reports to: MHRA, CHM, Freepost, London, SW8 5BR. Or Use <http://www.yellowcard.gov.uk>

No stamp is needed. If you would like a supply of pre-addressed and reply-paid yellow cards, please contact us:

**Phone:** 0121 5075672 **Email:** [yccwm@swbh.nhs.uk](mailto:yccwm@swbh.nhs.uk)

**Address:** Yellow Card Centre West Midlands, City Hospital, Dudley Road, Birmingham, B18 7QH.

### SOME ADDITIONS TO THE LIST OF INTENSIVELY MONITORED DRUGS

Approved name	Trade name	Indication
Doripenem	▼ Doribax <sup>®</sup>	Nosocomial pneumonia
Rivaroxaban	▼ Xarelto <sup>®</sup>	Prevention of venous thromboembolism
Temsirolimus	▼ Torisel <sup>®</sup>	Renal cell carcinoma

Please send any comments to:

Prof R E Ferner at West Midlands Centre for Adverse Drug Reaction Reporting, email: [r.e.ferner@bham.ac.uk](mailto:r.e.ferner@bham.ac.uk)