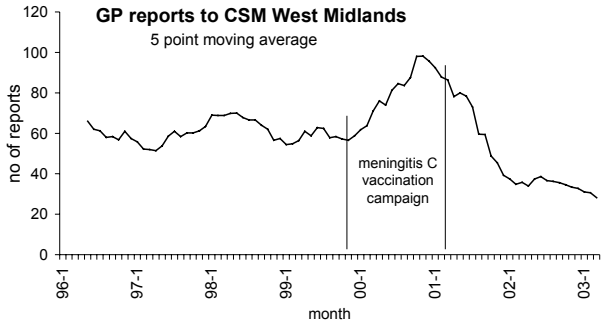
re:ACTION April 2003 No.27

An occasional bulletin from the West Midlands Centre for Adverse Drug Reaction Reporting

Please let us know if you would like to receive this bulletin by email: help@csmwm.org

RECENT REPORTS

GP reports plummet



GPs have been the mainstay of adverse drug reaction reporting ever since the Yellow Card Scheme was established in 1964. Until recently almost two thirds of our reports came from GPs. Last year just under half were. This year it is currently less than a third. We do not know why this is, though we appreciate how much busier general practice is becoming, we hope that GPs will continue to consider it important to report serious reactions and reactions to new drugs to us. One worry, with the advent of new classes of reporters, might be duplicate reports, but please do not let this put you off reporting as our software can detect duplicates, and under-reporting of reactions remains a big problem.

Sanguine or ex-sanguinating: SSRIs and GI bleeding. (*Archives of Internal Medicine 2003*: **163**:59-64)

A recent cohort study of selective serotonin reuptake inhibitors (SSRIs) provides more evidence for a potential risk of upper gastrointestinal tract bleeding.

Among 26,005 Danish users of antidepressants, those taking SSRIs were 3.6 times more likely than expected to have upper GI bleeding (95% confidence interval, 2.7-4.7); taking anti-inflammatory drugs or low-dose aspirin concomitantly increased the risk to 12.2 (95% confidence interval, 7.1-19.5).

We have received 30 reports of bleeding associated with SSRIs ranging from bruising to haematemesis and melaena. We are keen that serious ADRs associated with antidepressant use be reported to us.

COX-2 inhibitors are confusing too (*ADRAC Bulletin.* 2002; 22(1):3)

Non-steroidal anti-inflammatory drugs can cause psychiatric reactions. The Australian Adverse Drug Reactions Advisory Committee now reports that psychiatric reactions associated with rofecoxib and celecoxib.

The most common reports are related to somnolence, insomnia and confusion. Hallucinations were reported more often with rofecoxib.

We have received 18 similar reports:

	rofecoxib	celecoxib
depression	6 cases	1 case
confusion	2 cases	-
anxiety	2 cases	2 cases
aggression	1 case	-
hallucinations	1 case	1 case
agitation	1 case	-
panic	1 case	-
Total	14	4

Fundamental problem: nicorandil-induced anal ulceration (*Lancet* 2002; **360**:1979)

The Lancet reports 3 cases of severe anal ulceration following the use of nicorandil. In all three patients, the association was made post mortem and their ulcers failed to heal.

Ulceration is a known adverse effect of nicorandil. We have received 6 reports of mouth ulceration, 1 of tongue ulceration and 2 cases of oesophageal ulceration with nicorandil.

We encourage reporters to report severe ulceration with nicorandil.

I've got you, under my skin: clopidogrel-associated angioedema

(*Am. J. Med.* 2002; **114**: 78)

Fischer and colleagues report a case of angioedema with clopidogrel in a 71-year old man with chronic ischaemic heart disease. He developed angioedema and urticaria on a combination drug therapy. Double-blinded, placebo-controlled testing of the drugs led to severe angioedema 3 hours after taking clopidogrel.

We have received 3 reports of angioedema associated with clopidogrel. Please let us know of serious reactions to clopidogrel.

Uncomfortably numb? Hepatitis B vaccine and hypoaesthesia

We have received 5 reports of hypoaesthesia which reporters suspected were due to hepatitis B vaccine. The symptoms started immediately following administration, but not always after the first course of vaccine. It was mainly manifest as numbness in one or more limbs, and one patient had facial numbness.

Please report unusual reactions to vaccines via the Yellow Card scheme.

REPORTING TO CSM West Midlands

We welcome Yellow Card reports on all suspected adverse reactions to new (▼) drugs including vaccines and unlicensed herbal remedies and *all suspected reactions to all drugs used in children*, and on 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.

You can **download a copy of the redesigned yellow card in Adobe PDF format** from our website (http://csmwm.org).

Please send reports to: CSM West Midlands, Freepost SW2991, BIRMINGHAM, B18 7BR.
No stamp is needed. If you would like a supply of pre-addressed and reply-paid yellow cards, please contact the above address.

SOME ADDITIONS TO THE LIST OF INTENSIVELY MONITORED DRUGS

Approved name	Trade name	Indication
dutasteride	▼ Avodart®	moderate to severe benign prostatic hyperplasia
frovatriptan	▼ Migard®	acute migraine attacks
mometasone furoate	▼ Asmanex Twisthaler®	asthma
olopatadine	▼ Opatanol®	seasonal allergic conjunctivitis
risedronate sodium	▼ Actonel once-a-week®	post-menopausal osteoporosis
rosuvastatin	▼ Crestor®	primary hypercholesterolaemia
tadalafil	▼ Cialis®	erectile dysfunction
teriparatide	▼ Forsteo®	established osteoporosis in post-menopausal women
vardenafil	▼ Levitra®	erectile dysfunction

The entire list of about 220 intensively monitored drugs can be obtained from the centre or on our website: http://csmwm.org. Please report **all** adverse reactions you suspect are due to intensively monitored drugs. Please send any comments to: Dr R E Ferner at CSM West Midlands, or email: r.e.ferner@bham.ac.uk