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

This bulletin (complete with an index of all past issues) and other items of news about the Centre are available on the internet at http://www.chtpharm.demon.co.uk/csmwm.htm

RECENT REPORTS

Meningitis C (Meningitec®) vaccinations

Meningitec® is an intensively monitored (▼) drug and the CSM invites reports of any suspected reaction to it, even if not clinically severe. Reports of adverse reactions to Meningitec® completed by school and practice nurses are very welcome, but the GP's or hospital doctor's details are required.

We had received over 130 reports of reactions to Meningitec® in the first few weeks of the immunization campaign. Most of these reactions were minor. Headache and fainting predominate. Given the wide usage, these data were reassuring.

Other ▼ vaccines are

Infanrix (Diphtheria Tetanus & Pertussis)
Hepatyrix (Hepatitis A and Salmonella Typhi)
Twinrix (Hepatitis A (inactivated) and rDNA Hepatitis B)
Priorix (Measles, mumps and Rubella virus)

and we welcome reports of any suspected adverse reactions to all these vaccines, as well as suspected serious reactions to established vaccines.

Under the counter... illicit Viagra® use (*BMJ* 1999; **318**: 669)

We have recently received a report from a GP of a 30-year-old man who had been obtaining supplies of sildenafil illicitly and who suffered a widespread urticarial rash after ingesting one tablet. He made a complete recovery. A recent report found that 3% of those (33% women) surveyed in a nightclub (n = 519) had used illicitly obtained sildenafil in the previous three months.

Additionally we have this year received a further 21 reports of adverse reactions to sildenafil - three of these reports had a fatal outcome: a 69-year-old man had a myocardial infarction after 2 weeks' use of sildenafil; a 72 year old man suffered a sub arachnoid haemorrhage after recently starting sildenafil; in the third a 77-year-old man had a ruptured aortic aneurysm after 3 months' treatment with sildenafil. Eight further reports were also of serious reactions; two of these were ocular reactions: a 49-year-old man developed corneal ulceration after 4 weeks' use of sildenafil - it remains unclear whether the sildenafil was responsible; in the other a 67-year-old-man suffered one episode of transient loss of vision lasting about 3 minutes after 4 weeks' use of sildenafil. Most of these reports of cardiovascular events occurred in men with pre-existing cardiovascular risk factors. Sexual activity is known to increase the risk of myocardial infarction, especially in men with underlying cardiovascular disease. Currently, it is not clear whether these events are related directly to sildenafil, to sexual activity or to underlying undiagnosed cardiovascular disease.

We welcome further reports of reactions to sildenafil even if the patients did not obtain the drugs through the usual channels.

Methylprednisolone and anaphylaxis

(*Am. J. Emerg. Med.* 1999;**15**: 583-5, *J. Rheumatol.* 1997; **24**: 1191-4)

We have recently received a report of anaphylaxis with methylprednisolone and lignocaine used intra-articularly in a 59-year-old woman with no known allergic history who collapsed 5 minutes after injection. In another case, a 66-year-old woman who was being treated with an IV infusion of methylprednisolone mixed with normal saline suffered an acute allergic reaction of urticaria, maculopapular rash, fever and flushing. She recovered after treatment with IV chlorpheniramine. Again there was no known allergic history. The reporters commented that the reaction was probably due to the methylprednisolone or one of the diluents, and we agree.

A recent case history reports a 17 year old asthmatic man who suffered an anaphylactic reaction on being treated with a bolus injection of methylprednisolone 125mg over 15 to 30 seconds. He was intubated and treated on ITU and made a successful recovery.

Lignocaine has also been implicated in anaphylactic reactions in 14 reports of anaphylaxis to the CSM.

We welcome reports of serious or unusual reactions to medicines even if it is not possible to positively identify a single drug as having caused the reaction.

St John's worst?... Drug interactions with hypericum (*Clin. Pharmacol. Therap.* 1999; **66**: 338-45)

A recent slingle-blind pharmacokinetic study in 25 healthy volunteers in Germany has shown that multiple doses of hypericum extract significantly reduces the bioavailability of digoxin. The volunteers received dried hypericum extract 300mg 3 times daily or placebo concomitantly with digoxin for 10 days. The authors comment that hypericum may interact with other drugs that are P-glycoprotein substrates.

We have received very few reports of reactions to herbal preparations since they were added to the reporting scheme in 1997. Community pharmacists may be well placed to spot problems with herbal preparations.
We are keen to receive all reports of reactions involving herbal preparations or other "alternative" medicines, especially if the herbal preparations is suspected of interacting with a licensed product. In cases of serious reactions a sample of the herbal remedy should be retained for testing in our Quality Control Lab.

Bleeding with SSRIs (*BMJ* 1999; **319**: 1106-9)

A recent population-based study has reported an increased risk of SSRIs causing upper GI bleeding. At therapeutic doses SSRIs are thought to block the reuptake by platelets and it is possible that these drugs impair haemostatic function and increase the risk of bleeding.

At CSM West Midlands we have had no recent reports of NSAID-induced GI bleeding but we have had a report of a 47-year-old man who suffered gum bleeding and haematospermia 1 day after changing treatment from paroxetine 20mg od to reboxetine 4mg bd. He recovered after 4 days and cessation of reboxetine treatment.

We welcome any similar reports.

REPORTING TO CSM West Midlands

We welcome Yellow Card reports on all adverse reactions to new (▼) drugs including vaccines and unlicensed herbal remedies, and on all serious or unusual reactions to well-established drugs.

Yellow Cards can be found in the BNF, occasional MIMS, and the ABPI Compendium of Data Sheets, OTC Directory. Further supplies can be obtained from CSM West Midlands. Alternatively you may **download a yellow card in Adobe PDF format** from our website.

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.

ADDITIONS TO INTENSIVELY MONITORED DRUGS include

Approved name	Trade name	Indication
infliximab	▼ Remicade®	severe active Cohn's disease
leflunomide	▼ Arava®	active rheumatoid arthritis
lomefloxacin	▼ Okacyn®	acute bacterial conjunctivitis
meningococcal group C conjugate vaccine	▼ Meningitec®	active immunisation against type C meningitis
rimexolone	▼ Vexol®	post operative ocular inflammation and anterior uveitis

There are around 220 drugs on the intensively monitored list. An up-to-date list can be obtained from the centre or on our website: http://www.chtpharm.demon.co.uk/csmwm.htm. Please report **all** adverse reactions you suspect are due to intensively monitored drugs.

Please send any comments, questions or suggestions to:

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