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

This bulletin and other items of news about the Centre are available on the internet at http://www.chtpharm.demon.co.uk/csmwm.htm

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, MIMS, the ABPI Compendium of Data Sheets, OTC Directory and in FP10 prescription pads. Further supplies can be obtained from CSM West Midlands.

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 CLOSELY MONITORED DRUGS include

Approved name	Trade name	Indication
− amisulpiride	Solian®	acute and chronic schizophrenia
− balsalazide	Colazide®	mild to moderate ulcerative colitis
− irbesartan	Aprovel®	hypertension
− tazarotene	Zorac®	mild to moderate plaque psoriasis
− tolcapone	Tasmar®	Parkinson's disease, especially patients with end-of-dose phenomena
− verapamil & trandolapril	Tarka®	hypertension

We are keen to receive reports of all suspected reactions to all closely monitored drugs and unlicensed herbal preparations.

RECENT REPORTS

Increased risk of ADRs in Critical care (Current Opinion in Critical Care 1997; 3: 262)

A recent article warns of the increased risk of adverse drug reactions in patients on intensive care units. It suggests that no drug should be given to a critical care patient without weighing the potential benefit against the risk of possible ADRs or interactions. The authors report that many ADRs go unreported in critically ill patients, as symptoms may be masked by or confused with the patient=s underlying illness; and the patients are unable to communicate their symptoms. There may also be a number of doctors concerned in the care of any particular patient. Even if an ADR is suspected, there is confusion as to which particular drug is responsible as many drugs are used simultaneously.

Two reports from ITUs have recently been sent to us. In one, a 3-year old child in ITU after cardiac surgery developed low white cell and platelet counts after fluconazole treatment for a suspected but unproven fungal infection. Concomitant drugs were nystatin, aspirin, imipenem, ranitidine and sucralfate. The second case concerned a 63-year old woman in ITU after CABG who developed acute hypotension after treatment with amiodarone. Other drugs were cefuroxime, flucloxacillin, noradrenaline, alfentanil, dopamine and frusemide.

Doctors and pharmacists responsible for patients in intensive care units should be on the lookout for ADRs and interactions in critically ill patients and consider sending a Yellow Card report in such patients even if the ADR has

not been previously described. We welcome Yellow Card reports of suspected ADRs from doctors and pharmacists responsible for patients in intensive care units; a suspicion is enough, and there is no need to prove a causal link between a particular drug and a reaction. The most useful reports are those concerning severe or unusual reactions and reactions to new drugs.

Gastrointestinal reactions with alendronic acid (BMJ 1997; 315: 1235)

Debate continues over the risks and benefits of treatments for osteoporosis. A recent study of 77 women who were treated with alendronic acid detailed reports of upper GI reactions. Twenty-two of the women experienced such reactions. These included dyspesia (16 patients), heartburn (14), retrosternal pain (9), dysphagia (5), nausea (8), vomiting (3) and oesophageal stricture (1). Twenty of the women discontinued treatment with alendronic acid because of the severity of the symptoms. All the patients reported that they had been given instructions on posture when the tablets were prescribed, and only 7 of the patients who developed symptoms had disregarded these instructions.

In the West Midlands we have had 5 recent reports of upper GI reactions with alendronic acid, one, oesophagitis and stricture, was serious. We welcome **any** reports of reactions to alendronic acid (□).

Reporting of reactions to vaccines (Canadian Family Physician 1997; 43:1551-60)

Results of a study in Canada showed that the reporting rate for adverse reactions to vaccines is very low and that there was a low level of perceived awareness and knowledge of reporting such events.

We are keen to receive all reports of **any** reactions to black triangle (□**)** vaccines, and all reports of **serious** reactions to any other vaccines. Reports completed by practice nurses should be countersigned by the GP. It would be useful to have the batch number on all vaccine reports.

The current □ vaccines are DTP and HIB conjugate vaccine (Trivax-HIB[7] and Act-HIB[7] DTP dc), hepatitis A vaccine (Avaxim[7]), and hepatitis A and rDNA hepatitis B vaccine (Twinrix[7] Adult and Twinrix[7] Paediatric).

Hepatic reactions to isoflurane (Anaesthesia 1997; 52: 892-5, American J. Gastro. 1996; 91: 2406-9)

The spectres of Ahalothane jaundice@ and its predecessor Achloroform jaundice@ persist. Two recent articles describe hepatitis after anaesthesia with isoflurane. In one case a 67-year old man was found to have elevated liver enzyme levels on admission; he had recently started treatment with phenytoin. Two weeks later, after an operation where anaesthesia was performed using isoflurane his transaminase levels had increased 20- to 30-fold. A liver biopsy was consistent with an idiosyncratic response to isoflurane. In this case it was thought that the phenytoin, which is capable of inducing the cytochrome P-450 system, played a role.

In the second case, a 36-year old woman admitted for a hysterectomy suffered fatal hepatic necrosis after she underwent anaesthesia with isoflurane. Symptoms developed on the second day after the operation and her condition deteriorated over the next 3 days. She died 5 days later after an emergency liver transplant. Prior to this, she had previously undergone anaesthesia with enflurane, which may have led to sensitisation.

We have recently received one report of jaundice in a man who had undergone anaesthesia with isoflurane. He was not exposed to other drugs, and his symptoms started 5 days after the operation. His ALT rose above 4,000 iu/L. The eventual outcome is unknown.

We welcome reports of serious reactions to established drugs even where the reaction is well documented previously.

Our next ADR study day for doctors and pharmacists will be held on Wednesday, 29th April at the Postgraduate Centre, City Hospital, Birmingham. Details will be available in the new year from Christopher Anton.
Email: chrisa@chtpharm.demon.co.uk
or fax: 0121-507 5585

Please send any comments, questions or suggestions to:

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