re:ACTION September 1995 No.8

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

REPORTING TO CSM West Midlands

We welcome Yellow Card reports on all adverse reactions to new (–) drugs and on all serious or unusual reactions to well-established drugs.

Yellow Cards can be found in the BNF, MIMS, the ABPI Datasheet Compendium, 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. **This address has changed and will appear on future yellow cards.** The old address can continue to be used until March 1996.

ADDITIONS TO CLOSELY MONITORED DRUGS include

- citalopram (Cipramil®)
- triptorelin (De-Capeptyl® SR)
- alendronate (Fosamax®)
- amifostine (Ethyol®)
- cefpirome (Cefrom®)

We are keen to receive reports of **all** suspected reactions to all closely monitored drugs.

RECENT REPORTS

A hypertonic solution.... Neuroleptic malignant syndrome

This rare but serious reaction was the subject of a recent report of an elderly and confused man who was treated with haloperidol and then thioridazine. He became increasingly drowsy and confused, then immobile, unconscious, incontinent and feverish. He was admitted to hospital, where the diagnosis was made on the history, with physical findings of generalised rigidity and fever. In spite of treatment with dantrolene, this patient developed an aspiration pneumonia, and died.

Neuroleptic malignant syndrome can occur in patients of any age who are treated with antipsychotic drugs, and has occasionally been reported with other agents, such as lithium. It is characterised by a triad of mental clouding which progresses to coma, muscle rigidity and fever, which usually exceeds 40^{o}C. There is commonly autonomic disturbance, which can take the form of tachycardia, lability of the blood pressure, and urinary incontinence. The differential diagnosis includes drug-induced Parkinsonism complicated by infection.

Neuroleptic malignant syndrome, is a rare and potentially fatal condition. We welcome reports of serious reactions such as this, even if they are well recognised.

How safe is "safe"?

(*British Medical Journal* 1995, **311**:619)

Many patients, and some doctors, believe that all drugs should be proved to be safe before they are marketed. Unfortunately, we cannot be sure that a drug which has been used in only a small number of patients in a clinical trial will certainly be safe.

Recently, Eyspach and colleagues issued a timely reminder of an important statistical rule, in an article entitled *Probability of adverse events that have not yet occurred*. Briefly, if a drug has been tried in *n* subjects before it is marketed, and none of them has suffered a particular adverse effect then it is 95% certain that the true risk of that adverse effect is between 0 and 3/*n*. If a drug has already been used safely in, say 3000 patients, and none has developed bone marrow aplasia, then the highest likely risk of marrow aplasia with the drug is 1/1000.

The corollary is that many uncommon adverse reactions to new drugs are unknown at the time that they are marketed. The West Midlands Centre for Adverse Drug Reaction Reporting is keen to receive reports of **any** adverse reactions to new (▬) drugs.

Nurse knows best?

(*Br. J. Clin. Pharmacol.* 1995, **40**:173-175)

Professor J Feeley and colleagues in Dublin have reported a pilot study into the spontaneous reporting of adverse drug reactions by nurses in a 760 bed teaching hospital. Over 14 months 100 cards were received (compared with 28 cards from doctors). The doctors' cards were of a more substantial nature; however, nurses reported many life-threatening (17%) or moderately severe (76%) reactions. Nurses reported uncertainty in their role and deficiencies in education on drug therapy as major constraints in reporting.

ADVERSE DRUG REACTION STUDY DAY

Tuesday, 31st October 1995 from 9.30am to 4.30pm at the Postgraduate Centre
City Hospital, Dudley Road, Birmingham

Speakers include: Dr J Adu (the kidney), Dr N Bateman (sex), Mrs A Lee (was it an ADR?), Dr P McElhatton (teratogens), Dr I Morgan (the newborn), Dr J Neuberger (the liver), Dr G Rylance (children), Dr J Talbot (ADRs and industry).

Charge £60 to include coffee, buffet lunch and tea

Further details from: Debbie Eaton, Clinical Investigation Unit, Queen Elizabeth Hospital, Birmingham. Phone: 0121-414 6874 or Fax: 0121-414 1355

Please send any comments, questions or suggestions to: Dr R E Ferner, CSM West Midlands, City Hospital, Dudley Road, BIRMINGHAM B18 7BR