

Yellow card reporting scheme: what to report and where to?

In the UK spontaneous reports of adverse drug reactions are collected via the yellow card scheme. Anthony Cox explains what should be reported and why

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At any one time the equivalent of seven 800-bed hospitals may be occupied by patients admitted with adverse drug reactions (ADRs), and once you are registered you will inevitably contribute to this burden.

The last thing you will want to do when you arrive at work is cause harm to patients. However, even if you are 100 per cent accurate in your work, and as knowledgeable as you can be about preventing ADRs, some will occur despite your best efforts.

Pharmacists need to recognise the equally important duty of care they have towards the public as a whole, as well as the duty of care they have in ensuring the safe use of drugs in individual patients.

In the UK spontaneous reports of ADRs are collected via the yellow card scheme, which is administered by two Government agencies: the Medicines and Healthcare products Regulatory Agency (MHRA) and the Committee on Safety of Medicines (CSM). The yellow card scheme came into existence after the

thalidomide tragedy in 1964, and was initially restricted to doctors. Over the years the scheme has been expanded to include pharmacists, nurses, dentists and coroners, and is even starting to be piloted for patients.

The key reason spontaneous reporting schemes are required is to detect reactions to new drugs and new reactions to established drugs. Every year important safety signals are noted about drugs, safety warnings are issued, summaries of product characteristics are updated and occasionally drugs will be withdrawn from the market.

Even though millions of pounds are spent on the production of a new drug and companies have to prove efficacy to have a licence granted, safety is always provisional at the time of marketing. New drugs may only have been used in 2,500 patients by the time they are marketed, and of those only 100 or so will have taken the drug for more than a year.

Clinical trials cannot define uncommon, but important, adverse effects of medicines. It can be calculated that if you treat n patients with a medicine, and none suffer a particular adverse effect, then the incidence of that adverse reaction will be between $0/n$ and $3/n$. In a trial with 1,500 patients, a reaction not found could occur in as many as 1 in 500 patients. Given the potentially large numbers of patients taking a newly launched drug, spontaneous reporting of ADRs by vigilant health professionals is of vital importance. So what should you report?

Established drugs

For established drugs, that have been on the market for a number of years, only serious or unusual adverse effects need be reported. So what is serious? Serious reactions are fatal, life-threatening, disabling, incapacitating, or reactions which result in or prolong hospitalisation. Reactions such as hallucinations, epileptic fits or anaphylaxis are quite obviously serious, yet what if it is less clear to you? Suspected drug interactions can also be reported to the yellow card scheme.

Here professional judgement is required, and if you are in any doubt as to



In Confidence

SUSPECTED ADVERSE DRUG REACTIONS

COMMITTEE ON SAFETY OF MEDICINES

If you are suspicious that an adverse reaction may be related to a drug or combination of drugs please complete this Yellow Card. Please report all adverse reactions for black triangle (▼) drugs and only serious adverse reactions for established drugs. Suspect ADRs can also be reported electronically via www.yellowcard.gov.uk. For additional reporting advice please see page 10 of the BNF or the MHRA website <http://medicines.mhra.gov.uk/>. Do not be put off reporting because some details are not known.

PATIENT DETAILS		Patient Initials: _____	Sex: M / F	Weight if known (kg): _____
Age (at time of reaction): _____		Identification (Your Practice / Hospital Ref.): _____		
SUSPECTED DRUG(S)				
Give brand name of drug and batch Number if known				
Route	Dosage	Date started	Date stopped	Prescribed for
_____	_____	_____	_____	_____
SUSPECTED REACTION(S)				Outcome
Please describe the reaction(s) and any treatment given:				Recovered <input type="checkbox"/>
Date reaction(s) started: _____ Date reaction(s) stopped: _____				Recovering <input type="checkbox"/>
Do you consider the reaction to be serious? Yes / No				Continuing <input type="checkbox"/>
If yes, please indicate why the reaction is considered to be serious (please tick all that apply):				Other <input type="checkbox"/>
Patient died due to reaction <input type="checkbox"/>	Involved or prolonged inpatient hospitalisation <input type="checkbox"/>			
Life threatening <input type="checkbox"/>	Involved persistent or significant disability or incapacity <input type="checkbox"/>			
Congenital abnormality <input type="checkbox"/>	Medically significant; please give details: _____			

* This is to enable you to identify the patient in any future correspondence concerning this report

whether a reaction is serious, then err on the side of caution and report it. Research shows that many reactions are thought of as non-serious by reporters, yet meet the criteria of a serious reaction used by regulatory authorities. In ADR reporting the problem is under-reporting, not over-reporting.

Even though you may think a reaction is well-known, the report adds valuable information to the CSM's database and may allow comparison of ADRs between drugs of a similar class.

Paediatrics

Children are a particularly poorly served group in terms of medicines, and any reports of adverse reactions to drugs (whether licensed or not) is potentially of use. Any reaction should be reported, no matter how trivial.

Herbal products

Rarely does a week pass without some new fashionable herbal treatment being discussed in the newspapers. As in paediatrics, data on adverse drug reactions and interactions with herbal products is limited. Any reports, no matter how trivial, are welcomed.

Black triangle drugs

The final group to which any reaction, no matter how trivial, should be reported are the "black triangle" drugs. As noted before the yellow card scheme

is particularly suited to discovering adverse drug reactions to new drugs, and the CSM puts these drugs under intensive surveillance. They are indicated by an inverted black triangle in the British National Formulary.

The black triangle can also be applied to drugs given new indications which may alter the established risks of the drug. For example, bisoprolol is a black triangle drug when used in heart failure but when used in hypertension, where it is an established drug, it is not.

Where to report

Yellow cards are available in the BNF, and from the MHRA and local regional centres. For those of you more at home with the internet, you can report via the yellow card scheme's own website at www.yellowcard.gov.uk.

Top tips on reporting

- Be confident, you only need a suspicion that drug caused a reaction, not a cast iron certainty.
- Do not think that your report is unimportant. Under-reporting is the biggest barrier to improved drug safety. Every report counts.
- If in doubt, write one out. ✍

Useful contact points

- Medicines and Healthcare products Regulatory Agency**
 CSM
 Freepost
 London
 SW8 5BR
 Tel: 0800 731 6789
- CSM Mersey**
 Freepost
 Liverpool
 L3 3AB
 Tel: 0151 794 8206
- CSM Wales**
 Freepost
 Cardiff
 CF4 1ZZ
 Tel: 029 2074 4181 (direct line)
- CSM Northern & Yorkshire**
 Freepost 1085
 Newcastle upon Tyne
 NE1 1BR
 Tel: 0191 232 1525 (direct line)
- CSM West Midlands**
 Freepost SW2991
 Birmingham
 B18 7BR
 Tel: 0121 507 5672
- CSM Scotland**
 CARDS
 Freepost NAT3271
 Edinburgh
 EH16 4BR
 Tel: 0131 242 2919