All medicines have the potential to cause adverse drug reactions, which can be defined as harmful and unintended responses to a medicine or vaccine. To minimise the harm caused by ADRs, the Medicines and Healthcare products Regulatory Authority monitors the safety profile of all medicines in the UK, ensuring their overall balance of benefits and risks is positive. This process, known as pharmacovigilance, involves collecting information about suspected ADRs through the Yellow Card scheme, assessing any new suspected ADRs, and issuing information or taking regulatory action to minimise risks when necessary.

The Yellow Card Scheme relies on suspected ADRs being reported to the MHRA even if they are already recognised.

**ADVERSE DRUG REACTIONS: THE YELLOW CARD REPORTING SCHEME**

This learning unit is free to all users thanks to a development grant from the Medicines and Healthcare regulatory Agency at nursingtimes.net/drug-reaction. After studying this unit, you will be able to:

1. Explain the importance of reporting suspected adverse drug reactions
2. Describe the Yellow Card scheme and what happens to Yellow Cards
3. Define who can complete a Yellow Card and the situations that should trigger their completion
4. Specify the information needed for filling out a Yellow Card
5. List up-to-date sources of information on adverse drug reactions
6. Answer patients’ questions about ADRs and explain how they can fill out a Yellow Card themselves

**Effects of adverse drug reactions**

Adverse drug reactions can range from minor discomfort to serious harm, and a minority result in fatal complications. Many are identified after medicines have been launched; one reason for this is that patients seen in routine practice may be taking a combination of medicines that results in an interaction causing an ADR.

Many ADRs can be predicted from knowledge about how a medicine works. The effects are usually dose related, so increasing the dose may make the ADR more obvious and intense. However, a few ADRs cannot be reliably predicted and are not related to the pharmacological action of the drug; these occur far less frequently.

ADRs can have important consequences for patients and have a major impact on public health. They are among the leading causes of death in many countries (World Health Organization, 2008), and may account for more than 5% of hospital admissions (Rogers et al, 2009); they are also costly – in 2004, researchers calculated that ADRs probably cost the NHS £466m a year (Pirmohamed et al, 2004).

**The need to monitor medicines**

It is imperative that information about a medicine’s clinical properties and ADRs is gathered continually even after its release for routine clinical use because:

- Patients in pre-approval clinical trials may not be representative of those who go on to receive the medicine;
- Limitations on the number of people participating and the duration of trials may not permit identification of rare, unpredictable and long-term ADRs.

**The Yellow Card scheme**

The Yellow Card scheme, run by the MHRA, is the UK system that collects information on spontaneous suspected ADRs to medicines. The scheme is not exclusive to health professionals – anyone can complete a card if they suspect that a medicine or combination of medicines has caused an ADR.

Information from Yellow Card reports is assessed by a team of medicine safety experts, who study the benefits and risks. Information is considered in the context of overall ADR profile, and how this compares with that of other medicines used to treat the same condition. The MHRA takes action, whenever necessary, to ensure medicines are used in a way that minimises risk while maximising benefits to patients.

**Analysing and acting on the data**

The MHRA assesses Yellow Card reports as well as ADR data from all possible sources to assess whether a medicine might be responsible for the reported ADR. Regulators also try to establish the size of the problem in terms of the proportion of people likely to be affected and severity.

The Yellow Card scheme thus enables the detection of problems; the data may also be rich enough to identify risk factors such as age, predisposing conditions, use of other medicines and treatment duration.

If the information shows there is a causal link between a medicine and suspected ADR, the MHRA can act to minimise harm. At one extreme, the medicine’s marketing authorisation might be withdrawn, but this is rarely necessary. More commonly, the medicine’s summary of product characteristics (SPC) is adjusted to accommodate information on the identified effect. If a causal link cannot be established easily, the MHRA may request studies from the company holding the marketing authorisation.

**Nurses and pharmacovigilance**

Nurses have a vital role in pharmacovigilance because the system relies on the vigilance of nurses and other health professionals to identify and report suspected ADRs (Hall et al, 1995). Nurses make excellent ADR reporters (Ranganathan et al, 2003) and an increasing number are doing this (Hawcutt et al, 2012).
Nurses have a good opportunity to identify ADRs when carrying out observations or administering medicines, and can use formal checklists to monitor patients for suspected ADRs (Jordan et al, 2004). Since they are the health professionals with the most contact with patients, specific enquiries on, for example, discomfort, aches and pains, and bowel habit may reveal new suspected ADRs, as well as other undesirable treatment-related changes.

**Reporting adverse drug reactions**

When there is any suspicion that a medicine or vaccine has caused an ADR, it should be reported on a Yellow Card. You do not need to be certain of this – if there is any uncertainty about whether to report an ADR, it should be reported.

The quickest and easiest way to complete a Yellow Card is to do it online at yellowcard.mhra.gov.uk. You can also report on paper Yellow Card forms, found at the back of the British National Formulary, the BNF for Children, or the Nurse Prescribers’ Formulary. You should complete a Yellow Card if the suspected ADR is:

- Serious;
- In a child (regardless of seriousness).

All suspected ADRs that may have resulted from a medicine on the additional monitoring list should also be reported. A reaction is considered serious if it:

- Is fatal or life-threatening;
- Is incapacitating or disabling;
- Results in a new hospital admission or prolongs hospital stay;
- Is associated with congenital abnormalities in a child;
- Is otherwise medically significant.

**The Black Triangle scheme**

Some medicines (mainly new ones) are subject to additional monitoring to gather new suspected ADRs, as well as other undesirable treatment-related changes. Other drug information sources, such as the BNF, will show the triangle symbol against these medicines.

**What medicines can I report?**

You can use the Yellow Card to report suspected ADRs that may have resulted from:

- Any conventional medicine, whether prescribed or purchased;
- Vaccines;
- Complementary remedies such as herbals and homoeopathic medicines.

You should report ADRs even if the medicine has not been used as recommended. Report all suspected reactions that occur after:

- Therapeutic use of a medicine (in line with the SPC);
- Medication error (including incorrect prescribing, dispensing or administration);
- Off-label use – use of a medicine in a way that is not covered by its SPC (for example use in a child when it is only authorised for use in adults);
- Drug abuse – use of a medicine for a purpose other than that for which it is intended;
- Drug misuse – use of a medicine with a therapeutic intent, but not as authorised.

**References**


**TEST YOUR KNOWLEDGE**

Can you answer these questions? To check whether you are correct, go to our learning unit at nursingtimes.net/drug-reactions.

1 Which of the following pieces of information is essential to include on a Yellow Card?

A. Reporter’s name and contact details
B. The patient’s NHS number
C. Batch number of the medicine
D. The patient’s height and weight
E. The responsible doctor’s signature

2 Which of the following provides information on important emerging adverse effects?

A. British National Formulary
B. Drug Safety Update
C. NHS Choices
D. Patient information leaflets accompanying medicines
E. Summary of product characteristics

3 Which of the following does NOT call for a Yellow Card?

A. Cholestatic jaundice developing after three weeks on flucoxacinil
B. Cough and pharyngitis after intravitreal injection of a new ophthalmic medicine
C. Liver injury after treatment with a herbal remedy
D. Pulmonary embolism after off-label use of tranexamic acid
E. Fainting in a child about to receive a vaccination

4 Which of the following explain why adverse drug reactions may remain undiscovered when a medicine is approved for market?

A. Clinical trials may exclude children or people with long-term conditions
B. Medicines are only tested on animals and human volunteers before receiving approval
C. Many pre-approval clinical trials are conducted overseas
D. The chance of discovering adverse effects increases as more people take the medicine
E. Clinical trials conducted for licensing focus on proving the medicine works and are not concerned with adverse drug reactions