Medicines: safety of medicines – adverse drug reactions

Fact sheet N°293
Updated October 2008

Key facts

• Unintended, harmful reactions to medicines (known as adverse drug reactions) are among the leading causes of death in many countries.
• The majority of adverse drug reactions (ADR) are preventable.
• People in every country of the world are affected by ADRs.
• In some countries ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications.
• No medicine is risk free. Vigilant assessment of the risks and benefits of medicines promotes patient safety.

The safety of medicines is an essential part of patient safety. Global drug safety depends on strong national systems that monitor the development and quality of medicines, report their harmful effects, and provide accurate information for their safe use.

Harmful, unintended reactions to medicines that occur at doses normally used for treatment are called adverse drug reactions (ADRs). ADRs are among the leading causes of death in many countries.

Preventing and detecting adverse effects from medicines is termed pharmacovigilance. Vigilant assessment of the risks and benefits of medicines applies throughout the life cycle of a medicine - from the pre-approval stage to use by patients.

Global information-sharing on adverse effects strengthens drug safety in countries, and can translate into timely policy decisions that safeguard patient safety when problems emerge.

Related links

– WHO International Drug Monitoring Programme
– The Importance of Pharmacovigilance: safety monitoring of medicinal products [pdf 117kb]
  Key document
– Publications list
– Uppsala Monitoring Centre (UMC)
Examples of ADRs include:

<table>
<thead>
<tr>
<th>Medicines</th>
<th>Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amidopyrine (for inflammation)</td>
<td>white blood cell disorder</td>
</tr>
<tr>
<td>Clioquinol (for skin infections)</td>
<td>visual impairment</td>
</tr>
<tr>
<td>Erythromycin estolate (antibacterial)</td>
<td>hepatitis (liver disorder)</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>thromboembolism (blood clots)</td>
</tr>
<tr>
<td>Statins (for controlling cholesterol)</td>
<td>muscle degeneration</td>
</tr>
<tr>
<td>Thalidomide (for managing morning sickness)</td>
<td>phocomelia (disfigured infants)</td>
</tr>
</tbody>
</table>

**Risks**

No drug is without risk and all medicines have side effects, some of which can be fatal. People in every country of the world are affected by ADRs. In some countries ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications. At least 60% of ADRs are preventable, and can be due to:

- wrong diagnosis of the patient’s condition;
- prescription of the wrong drug or wrong dosage of the right drug;
- an undetected medical, genetic or allergic condition that might cause a patient reaction;
- self-medication with prescription medicines;
- not following the instructions for taking the medication;
- reactions with other drugs (including traditional medicines) and certain foods;
- use of a sub-standard medication whose composition and ingredients do not meet the correct scientific requirements, and can be ineffective and often dangerous;
- use of counterfeit medicines with no active ingredients or the wrong ingredients, which can be dangerous or fatal.

Even when the above situations are avoided, all medicines have side effects and some can be damaging. The effects of any treatment with a medicine cannot be predicted with absolute certainty. All medicines have both benefits and the potential for harm. The risk of harm can be minimized by ensuring that prescribed medicines are of good quality, safe, effective and used by the right patient in the right dose at the right time.

**Safety measures**

Pharmaceutical companies, or drug-makers, are required by law in all countries to test their drugs on healthy and patient volunteers before making them widely available. These clinical trials show how well a drug works for a defined disease and what potential harm it can cause. However they provide no information for larger, untested populations with different characteristics from the trial group, such as age, gender, state of health, and ethnic origin. For many medicines, and particularly complex products,
safety monitoring does not stop at the manufacturing stage. Medicine safety must be followed by careful patient monitoring and further scientific data collection. This aspect of drug monitoring is called post-marketing surveillance. The effectiveness of national post-marketing surveillance is directly dependent on the active participation of health professionals.

Health professionals (physicians, pharmacists, nurses, dentists and others) are in the best position to report suspected ADRs as part of their daily patient care. Health professionals should report ADRs even if they are doubtful about the precise relationship between the given medicine and reaction.

WHO Response

WHO promotes global drug safety through its International Drug Monitoring Programme, which began in the 1960s. Through the cooperative effort, Member States and WHO work together to identify possible relationships between the use of a drug and adverse effects. Nearly 100 countries now have national systems in place to report ADRs to the database managed by the WHO Collaborating Centre, the Uppsala Monitoring Centre. When signals of drug safety problems emerge, WHO shares the results with all Member Countries.

In addition, WHO:

• facilitates regular information exchanges among Member States on the safety and effectiveness of medicines, involving a network of national information officers;
• promptly informs national health authorities about new information on serious adverse effects of pharmaceutical products;
• provides guidelines to help countries set up national drug monitoring centres;
• assists countries as they work to strengthen drug regulatory authorities and reporting systems;
• trains health professionals on safety monitoring for new and complex medicines (e.g. antiretrovirals to treat HIV);
• draws together regulatory authorities, police, customs officials and others to combat counterfeit medicines worldwide.

For more information contact:
Liz Finney
Telephone: +41 22 791 1866
E-mail: finneye@who.int

WHO Media centre
Telephone: +41 22 791 2222
E-mail: mediacentre@who.int