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Medication errors: pharmacovigilance centres in detection and prevention

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1. Detecting medication errors needs collaboration between various organizations, such as patient safety institutions, pharmacovigilance centres, and poison control centres. In order to evaluate the input of pharmacovigilance centres and poison control centres in detecting and evaluating medication errors a pilot project was initiated by the World Alliance for Patient Safety in collaboration with the Uppsala Monitoring Centre; the Moroccan pharmacovigilance centre acted as project coordinator. As part of this project, a questionnaire on detecting medication errors was circulated to pharmacovigilance centres and poison control centres around the world, in order to assess their ability to detect and analyse medication errors.
2. The results showed that through their databases pharmacovigilance centres can detect, identify, analyse, and classify medication errors and carry out root cause analysis, which is an important tool in preventing medication errors.
3. The duties of pharmacovigilance centres in preventing medication errors include informing health-care professionals about the importance of reporting such errors and creating a culture of patient safety. Pharmacovigilance centres aim to prevent medication errors in collaboration with poison control centres. Such collaboration allows improved detection and improved preventive strategies. In addition, collaboration with regulatory authorities is important in finalizing decisions.
4. Collaboration between pharmacovigilance centres and poison control centres should be strengthened and bridges need to be built linking pharmacovigilance centres, poison control centres, and organizations dedicated to patient safety, in order to avoid duplication of workload.

According to the World Health Organization definition, pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse reactions or any other drug-related problem [1].

Over the last 40 years, the activity of pharmacovigilance has grown and come to have a large impact, both nationally and internationally, providing data on adverse drug effects and the rational use of drugs, with implications for patient welfare and safety [2].

In 1999, the US Institute of Medicine's report 'To err is human' showed that there were more than one million preventable adverse drug reactions each year in the USA, of which 44 000–98 000 were fatal and 7000 were due to medication errors [3]. Although pharmacovigilance had always been concerned with minimizing the risks of adverse drug reactions and medication errors, in March 2007 the Erice Manifesto formulated a new vision, in which patient safety constitutes one of the main challenges to pharmacovigilance [4].

To this end, a pilot project was initiated by the World Alliance for Patient Safety in collaboration with the Uppsala Monitoring Centre, with the Moroccan Pharmacovigilance Centre as project coordinator. The aim of the project was to develop an extended role for national centres of pharmacovigilance, to include the collection of information on the incidence of adverse events related to medication errors, to enable international analysis of these data, and to disseminate the findings.

As part of the project a questionnaire on detecting medication errors was circulated to pharmacovigilance centres, in order to assess their ability to detect and analyse medication errors. All the countries involved received reports from healthcare professionals, but only 19% received reports from poison control centres and 40% from other organizations, such as pharmaceutical companies, drug information centres, traditional practitioners, and regional centres; 66% received reports from patients. Reports of adverse drug reactions were received by all routes of communication: 85% of the countries received spontaneous reports by mail, 76% by telephone, 62% by internet, and 28% by fax.

Some countries have started to work on improving patient safety, by improvements to the yellow card forms, the use of root cause analysis, the establishment of specific databases for medication errors, retrospective analysis of such errors, prospective studies, actions to prevent

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medication errors, and seminars on medication errors. Half of the countries surveyed were interested in organizing seminars on preventing medication errors, and four of the countries had already conducted a root cause analysis and taken preventive actions.

Given that pharmacovigilance centres can identify medication errors, some centres in different countries undertook retrospective analyses of their pharmacovigilance databases. In Morocco, a retrospective analysis of the database showed that 14% of all suspected adverse drug reactions were preventable. Medication errors associated with preventable adverse drug effects and related to the medication use system occurred most often at the stages of prescribing (36%) and administration (34%) [5].

Root cause analysis

Retrospective analysis of a pharmacovigilance database allows identification of the classes of medication that are most often involved in preventable suspected adverse reactions, the system classes most involved in preventable adverse reactions, the stage at which the error occurs during therapy, and the types of error involved. All these pieces of information can be used in root cause analysis, an important tool in preventing medication errors [6–8].

Root cause analysis is a systematic investigation technique that looks beyond the affected individual and seeks to understand the underlying causes and environmental context in which an incident related to a medication error occurred. It is usually applied to serious adverse events or critical incidents, which are also known as sentinel events. A sentinel event is an unexpected occurrence that involves death or serious physical or psychological injury, or a risk thereof [9, 10]. The phrase 'or a risk thereof' includes any process variation a recurrence of which would carry a significant chance of a serious adverse outcome. Such events are called sentinel events because they signal the need for immediate investigation and response, as the term 'signal' implies in pharmacovigilance [11].

There are several methods of conducting root cause analysis, such as the Canadian root cause analysis framework, the Ishikawa or Fishbone Diagram [12] and the Guidelines for Root Cause Analysis of the Massachusetts Medical Society [13], but they all have the same goals and the same concepts.

The Moroccan Pharmacovigilance Centre has taken action to prevent medication errors after root cause analysis, using the Massachusetts Medical Society's method in 30 cases of local reactions to intravenous flucloxacillin, with tissue necrosis leading to amputation in two cases. This method has four steps: describing the event, identifying the proximate cause(s) that led to the effect(s), identifying the contributing factors (or latent errors) that led to the proximate cause(s), and creating an action plan. Root cause analysis identified the proximate cause and the contributory factors: failure to follow the recommendations of the Summary of Product Characteristics (SPC) and the absence of water for intravenous injection in the drug box [14]. Preventive actions were taken: information was disseminated to paediatricians and the manufacturers were advised to modify the SPC in order to mention the risk of local necrolysis if the drug is not diluted as recommended.

Prevention

The duties of pharmacovigilance centres in preventing adverse drug reactions and medication errors include alerting healthcare professionals to the importance of reporting such errors, making them aware of the factors that cause them, encouraging them to develop a safety culture that leads to enhanced awareness, and stressing the need for commitment among healthcare professionals in preventing medication errors and improving patient care.

Pharmacovigilance centres aim to prevent medication errors by disclosing information regarding the most frequent drug-related problems, through monthly information bulletins to healthcare professionals. Examples are given in Table 1.

In a study conducted in the Moroccan Poison Control Centre, 11% of poison cases were due to medication errors. Thus, the experience gained in poison control centres is an important source of human toxicological data, and collaboration of poison control centres with pharmacovigilance centres in preventing medication errors is very important. Such collaboration will allow improved detection of medication errors and improved quality of data collected. Some success stories emphasize the importance of poison control centres as a valuable source of information on patient safety and as models for public health surveillance. Drawing on its observations and experience, a poison control centre can contribute to preventing poisoning by encouraging manufacturers to use less toxic formulations, to restrict pack sizes (e.g. paracetamol) [15], and to improve the packaging and labelling of their products (e.g. avoiding look-alike or sound-alike drug names) [16], and by encouraging manufacturers and regulatory authorities to withdraw drugs when indicated (e.g. co-proxamol in the UK) [17]. Close collaboration between pharmacovigilance centres and poison control centres allows greater input and harmonization of adverse events datasets in order to ascertain those events that are related to medication errors and to develop preventive strategies.

In some countries the two functions of pharmacovigilance and drug regulation reside in the same organization (for example, the Medicines and Healthcare products Regulatory Agency in the UK). Elsewhere, collaboration between pharmacovigilance centres and regulatory agencies is important. For example, after receiving, detecting,

Table 1

Examples of actions taking after detection of medication errors by the Moroccan Pharmacovigilance Centre during 2002–2005

Product	Type of error	Details	Action
BCG vaccine	Route of administration and dose	Intramuscular instead of intradermal administration; 10 times the recommenced dose given, because BCG vaccine contains 10 doses in one bottle	Letter to physicians
Methyl-ergometrine	Wrong patient	Drug prescribed for the mother but given to the neonate because of the use of one prescription sheet for the mother and the neonate	Letter from the Ministry of Health to all gynaecologists and all maternity hospitals in the country
Corticosteroid	Wrong indication	Drug given for weight gain	Letter to the pharmacist
Cypro-heptadine	Wrong indication	Drug given as an appetite stimulant	Letter to the pharmacist
Dontomycin	Erroneous publicity	Described as an analgesic instead of an antibiotic	Letter to the manufacturer
Rinomycin	Lack of specific warning	No warning for people with hypertension due to phenylephrine	Modification of the SPC
Indomethacin calcium pentahydrate	Erroneous publicity	Described as a coxib instead of an NSAID	Letter to the manufacturer
Flucloxacillin Injectable	Wrong dilution	Lack of information on dilution in the SPC; sterile water for injection not included in the drug package	Modification of the SPC

SPC, Summary of Product Characteristics; BCG, bacille Calmette–Guérin; NSAID, nonsteroidal anti-inflammatory drug.

and analysing notifications of suspected adverse drug reactions, the Moroccan Pharmacovigilance Centre submits these results to the Moroccan Drug Regulatory Directorate [18], which can submit the findings and proposed solutions to the national commission of pharmacovigilance, which submits the outcome to the Minister of Health for a final decision.

Conclusion

Pharmacovigilance centres can contribute to the detection and prevention of medication errors. Collaboration between poison control centres and pharmacovigilance centres needs to be strengthened, in order to improve the quality of data collected, enhancing patient safety, and bridges need to be built linking pharmacovigilance centres, poison control centres, and organizations dedicated to patient safety, in order to avoid duplication of workload.

Competing interests

None to declare.

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