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adverse drug reactions

Reporting Adverse Drug Reactions: Patients to be involved or not?

Dr.Shirley Samson Varughese M.Pharm, PhD

Senior Pharmacologist, Directorate of Pharmaceutical Affairs & Drug Control, Ministry Of Health, Muscat, Oman

Medicines are designed to prevent or treat illnesses, or relieve symptoms. Any medicine can cause adverse reactions. These reactions may not be discovered until many people have used the medicine over a period of time. They can occasionally appear after a person has stopped taking a medicine as well. Patients are no longer passive recipients of drug therapy instigated by medical professionals.

There is increasing patient involvement in individual decisions about their own drug therapy especially with increasing access to over the counter drugs. It is there fore politically unacceptable to exclude patients from reporting of spontaneous *adverse drug reactions* (ADR). International experience of patient reporting is summarized in Table given below[1].

Healthcare systems rely mainly on the detection and reporting of suspected ADRs to identify new reactions, record the frequency with which they are reported, evaluate factors that may increase risk and provide information to prescribers with a view to preventing future ADRs. Patient reporting of suspected ADRs has the potential to increase knowledge about the possible harm of medicines. Patient reporting mean 'users of drugs (or their parents or carers) reporting suspected ADRs directly to a monitoring center[2]. Positive and negative effects of patient reporting can be viewed from a number of different perspectives.

Concerns:

Concerns about patient reporting have always existed. Recently a Lancet editorial argued that patient reporting could "risk being seen as politically rather than scientifically driven" and despite the increasing interest in patient reporting, the scientific evidence for its utility has been equivocal. However, recent examinations of regulator's experiences of patient reporting may remove this concern. The Netherlands has examined patient reports received from 2004 to 2007 and compared them with the healthcare professional reports.

For correspondence: shirley.varugheese@gmail.com
 2229 3590, 0975 6221

Patient reports made up 19percent of all reports during the period. Patients and health professionals reported ADRs to similar drugs, and overall seriousness of the reports was not significantly different. However, patients reported a higher number of "life threatening" ADRs (5.2% vs 2.7%)and cases of "significant disability" (2.3%vs 0.4%). Patients were more likely to report outcomes of the ADR, as well as non recovery from the ADR, since the constant reminder from the ADR would prompt a report.

Interestingly patients were more likely to report symptoms related to more delicate matters, such as sexual dysfunction associated with drugs, directly rather than to healthcare professionals. Patients reported differing ADRs such as weight gain, decreased libido and fatigue, which the authors suspect is because of the impact the reactions have on patients' quality of life. Examples of the contribution of patients reporting to new drug safety messages , inflammatory bowel disease associated with isotretinoin, hyperparathyroidism with lithium, etc.,.

Evidence: Evidence for patient reporting from Denmark, Sweden, Australia and the US was presented at the ISOP annual conference. The Danish medicinal agency received more reports from women. In comparison with health professionals, patients reported relatively higher numbers of ear and labrynth disorders, infections and infestations, nervous system, psychiatric, reproductive and breast disorders, but lower numbers of blood, lymphatic, and hepatobiliary disorders. Psychoactive drugs were reported in far higher proportions by patients and ADRs related to nervous system made up the majority of patient ADRs. Another review showed withdrawal reactions, dependency, suicidal behavior and "electric shocks" were reported by patients but no comparable reports were received from professionals.

The Australian experience highlighted some limitations of patient reporting: reports consisted of symptoms rather than diagnoses and sometimes were non specific and vague. However the overall experience was that patients could contribute novel and serious ADRs to reporting systems, and provide additional post marketing surveillance on the OTC products and complementary and Alternative medicines.

Patient reporting is a relatively new development in Europe, but the US FDA has been having it since the 1960s either directly or via manufacturers. One of the studies by Syed Ahmed of the FDA showed that patients are largest contributor to the Adverse Event Reporting System of the FDA. The proportion of patient reports has risen from 22 percent of all reports in 1998 to 46 percent of all reports in 2008. Differences in the type of drugs reported were evident, the top 3 drugs from 2003-2007 were paroxetine, sertraline and levofloxacin, compared with warfarin, lisinopril and simvastatin from professionals.

Two examples were given of cases where patient reports had played a major role in triggering FDA regulatory action. First of severe heart failure in a mitoxanthrone treated multiple sclerosis patient, made review of the database and as a result , revised warnings and an educational program to inform prescribers of the risk of heart failure were issued. In the second a patient report of liver failure with tolcapone was a pivotal report in a series of cases submitted to the FDA, and led to the addition of liver failure in the product literature.

The FDA believes reports from patients and professionals complement each other, and have experience that suggests that even a single report from a patient could trigger major reviews and labeling changes[3].

The review found that there is lack of published research to evaluate spontaneous reporting of suspected ADRs by patients. However, there is now substantial experience from several countries in which patient reporting is established, that patients have identified possible new ADRs.

Therefore introduction of patient reporting should now be considered by other countries, together with a good evaluation process and outcomes.

Country	Direct or Indirect reporting to regulators	Reporting methods	System commenced
Australia	Indirect	Telephone, Pharmacists	2003
Denmark	Direct	Hard copy and eform. Same reporting form used by doctors	2003
The Netherlands	Direct Indirect via DGV consumer group scheme	Electronic	2003 2004
Sweden	Indirect via KILEN	Electronic, telephone, email, hard copy	1978
USA	Direct	Electronic, paper based, telephone	1993
Canada	Direct	Telephone	2003

DGV, KILEN are patient reporting system run by a consumer group

Table 1: International experience of patient reporting

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