JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH

How to cite this article:
AHMED A M, IZHAM IM, SUBISH P. IMPORTANCE OF CONSUMER PHARMACOVIGILANCE SYSTEM IN DEVELOPING COUNTRIES: A CASE OF MALAYSIA. Journal of Clinical and Diagnostic Research [serial online] 2010 August [cited: 2010 Aug 31]; 4:2929-2935.

Available from
http://www.jcdr.in/article_fulltext.asp?issn=0973-709x&year=2010&volume=&issue=&page=&issn=0973-709x&id=868

ORIGINAL ARTICLE

The Importance of the Consumer Pharmacovigilance System in Developing Countries: A Case of Malaysia

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ABSTRACT

Adverse drug reactions (ADRs) are a major cause for morbidity and mortality. The existing system for monitoring ADRs in Malaysia depends on spontaneous reporting from health professionals as a main source of information. We present here, an overview on the need for consumer reporting in Malaysia and on the advantages, disadvantages and international experiences on consumer reporting. We discuss here, how to start consumer reporting in Malaysia and its significant contribution to the existing system of drug monitoring in Malaysia. We conclude that consumer reporting should be introduced to overcome underreporting, to promote consumer rights and to increase the knowledge about the risks of medications.

Keywords: Adverse drug reactions, Consumer reporting, Drug safety, Malaysia, Pharmacovigilance.

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Introduction

Adverse drug reactions (ADRs) can cause short-term and long-term hospitalization and mortality.[1] Despite all their benefits, evidence continues to mount that ADRs are common, but yet are often a preventable cause of illness, disability and even death. ADRs are responsible for a significant number of hospital admissions ranging from 0.3% to 11%.[2] It has been estimated that over 770,000 people are injured or die each year from adverse drug events.[3] A commonly quoted meta analysis performed in the United States indicated that ADRs were between the 4 th and 6 th most common cause of death in 1997.[4] The World Health Organization (WHO) defines an ADR as 'any response to a drug that is noxious and unintended, and that occurs at doses which are used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose'.[5]

There are a few studies on the incidence rate of ADRs in developing countries. A prospective observational study from Iran identified that 11.8% of the patients had experienced at least one ADR.[6] In another study from Iran, it was reported that approximately 16.8% of the patients had at least one ADR and that 2.9% of the ADRs were identified as lethal.[7] Another study from South India reported the overall incidence of ADRs as 9.8%. This included 3.4% ADR related admissions and 3.7% ADRs occurring during the hospital stay.[8] A retrospective study from Riyadh, Saudi Arabia, reported 54% of the ADRs to be preventable. The prevalence per year ranged from 0.07% in 1993 to 0.003% in 1999.[9] In Nepal, the prevalence of ADR was found to be 0.86%, the male to female ratio was found to be 0.85 and 10.81% of the ADRs were considered to be severe.[10]

Pharmacovigilance is defined by the WHO as 'the science and activities related to the detection, understanding, assessment and prevention of adverse drug reactions and any other problems which are related to drugs'.[11] This science began 40 years ago, at the time of the disaster caused by thalidomide, which resulted in embryonic malformations in thousands of children, whose mothers used the drug during pregnancy in Europe in the early sixties; where the concerns of the world rapidly evolved, topics were discussed and the interest in the safety of medicine emerged.

The WHO began its global monitoring of drugs on an international scale in the sixties. Therefore, there is a need for pharmacovigilance because the medical information which is gathered before marketing the drug is incomplete [12]. Therefore, using animals to test the effects of the medicine cannot be an evidence to use it for human beings, as these tests are done with only a small number of human beings. Therefore, the effects of the medicine could only be noticed when the drug was widely used, as there were differences between countries in the incidence of drug-related problems such as genetic and ethnic problems, the food, traditions and the materials used in the local production of medicines and the use of traditional medicines.[12]

Right to the highest standard of health

The right to the highest standard of health is one of the human rights emanating from the Declaration of Alma Ata and that does not mean only that the health system must be available to all according to their needs and that it does not depend on the results, but also during the course of this process, for example, transparency and participation, equality and fairness.[13] Access to health services and information and the right to the highest attainable standard of health and health information to enhance the health of individuals and communities can achieve a degree of transparency which ensures that all key partners including the patients and the states and public and private sectors, international organizations and civil society organizations. Also, to ensure the participation of all people in issues that affect and impact on human health is the right of such participation, including participation in defining strategies, development and policy-making, implementation and accountability have been noted in the Declaration of Alma Ata. Fairness and equality are among the most basic elements of the international human rights law.[13]

The importance of ADR reporting by consumers

The existing system of ADR monitoring in many countries rely upon the spontaneous reporting of health professionals as a mean source for information. Spontaneous reporting is the most widely used method for pharmacovigilance in many countries. Despite its inherent limitations, the system provides vital information of clinical importance. These limitations include difficulties with adverse events recognition, underreporting, biases, estimation of population exposure and report quality.[14] Patients and consumers have the right to be involved, as well as the health professionals and they have to report their experiences and their suffering as a result of these adverse effects which threaten their health and their lives.[15]

The spontaneous reporting programs make use of the information written by doctors and pharmacists and when consumers are involved in the process,this can reinforce their rights and achieve justice. The consumer's experiences and views can be used and these serve as good tools for information about ADRs.[[16],[17]] The reports of the consumers reporting about the possible harm effects of drugs were nearly over fifteen years. This report increases the amount of knowledge which reveals significant indicators of the damage done by medicines.

However, few countries currently accept patient reports; Sweden (1978), Denmark (2003), Netherlands (2004), USA (1993), Canada (2003), Australia (2003), UK (2005) and New Zealand.[[18],[19],[20]] The consumer can report directly to the medicine agencies or indirectly through consumer organizations. They are also able to submit electronic reports or paper and also telephoned reports.

The experience in the Netherlands, obtained during 3 years, showed that patient reporting can be a good source of information for drug safety monitoring and that it has qualitative and quantitative values.[15] The evaluation of the first 6 months of patient reporting of the yellow card scheme in the United Kingdom showed that there were no differences in the proportion of serious ADRs reported, as compared to the reports made by health professionals.[20]

Blenkinsopp *et al.* wrote a systemic review on patient reporting of suspected ADRs. The Medicines and Healthcare products Regulatory Agency (MHRA) team in the UK showed more evidences and advantages from international experience regarding patient reporting. They concluded that there was a lack of publication on the patient reporting of ADRs in the literature and

that most published studies were very small.[21] The qualitative examination of patient reporting has shown that the reports were rich in terms of their description of the nature, the severity and the significance of the reactions.[21]

Authors from Sri Lanka suggested that consumer reporting is the best method for developing countries to overcome underreporting and that it could complement the existing system of reporting based on physicians and pharmacists.[22]

The importance of the Consumer Reporting

Some of the significant roles of consumer reporting are mentioned below.

1. Consumers are active players in drug safety and key stakeholders with respect to pharmacovigilance and can actively contribute through an integrated and efficient reporting system.
2. Direct reporting is an essential tool to empower the consumers and to improve their involvement in the management of their own health.
3. With consumer reporting, ADRs will be detected earlier and more number of ADRs would be reported, especially with respect to the over-the-counter (OTC) medicines.
4. Consumer reporting can be a useful method to overcome underreporting which is a common limitation of the pharmacovigilance programs.
5. Consumer reporting can be a good solution for the limitation of the existing system based on the health professional's reports.
6. Consumer reporting will promote consumer rights.
7. Though consumer reporting cannot replace the existing system, it can complement and strengthen it.

The advantages of Involving Consumers in ADR Reporting

There are a number of benefits which are associated with the consumer reporting of ADRs. Some of them are listed below.

1. **A new source of information:** Consumer reporting is an important source of new information on the harmful effects of drugs that could benefit the regulatory authorities of the drugs and it is also an important source of information in clinical practice.[[21],[23]]
2. **Disclosure of the effects which previously unknown:** When consumer reporting started in Denmark in 2003 in the first year, there were 149 reports from the patients, which represented 7% of all the reports. One-third of these effects included unknown adverse reactions.[[17],[23]]
3. **Early reports than health professionals:** A study in the Netherlands suggested that patients recognize and report adverse effects more quickly and early than the health workers.[21-23]
4. **Increase of the number of reports:** The United States began consumer reporting in 1993. In 2004, the reports of the patients from the 24,553 reports were found to be 15%.
5. **Quality of Life**: After analysis of the data by the pharmacovigilance centre in Sweden, it was revealed that the style of the reports of the patients was different from that of the doctors, who provided more information on the impact of medicine on the quality of lives, more than those who worked in the health affairs.[21]
6. **The reporting of serious adverse effects:** The Center of Pharmacovigilance in the Netherlands noted that the reports of patients provided information on the serious adverse effects of drugs.
7. **Different style, but with the same quality**: The patients do not use the expressions which are used by the doctors and the pharmacists. Therefore, the authorities noted that it was difficult to assess the reports and that it required more time.[23] Also, there was no information about the time taken for the analysis of these data. Also, some authors raised concerns about the quality of the reports and their credibility. But, the Netherlands Pharmacovigilance Centre pointed out that the patient's reports had the same amount of information as provided by health workers.[19-23]
8. **Reports of elder people:** A group of Belgian authors compared between patients and health workers at the same period of time where the pharmacists asked 168 elderly patients. The authors asked the patients to explain the reasons for hospital admissions. The patients reported about 33 effects, while only 12 reports out of the 33 reports were provided. The

doctors reported serious adverse effects, while the patients reported some effects that forced them to stay in the hospital.[[21],[23]]

International Experiences on the Consumer Reporting of ADRs

Mainly, the western counties and Australia are successful in incorporating consumers in their ADR monitoring programs. A brief outline on the system in these countries is mentioned below.

1. **Sweden:** The Consumer Association for Medicines and Health (KILEN) started its activities on consumer reporting since 1978. The experience in KILEN showed that the patients can report different things in different ways and sometimes in far greater volumes than the professionals. For example, during 1984-1988, Kilen received 420 reports about lorazpam, while in the period between 19801988, the processional's reports totaled to only 18. A comparison of 327 consumer reports and 437 physician reports for straline showed that there were many side effects as reported in great numbers by the consumers.[[16-18],[21]]
2. **Netherlands:** The national pharmacovigilance centre received reports from consumers since 2003. After the first one year, it was found that the reports from the patients usually contained sufficient medical information and they referred more frequently to serious adverse drug reactions than that reported by the health professionals.[[16-18],[21]]
3. **United Kingdom:** The MHRA started a pilot study in 2003. The British yellow card scheme allowed patients to report directly to MAHRA in January 2005. Patients could submit the reporting form or electronic reports. The evaluation of the yellow card scheme in the first 6 months of patient reporting in the United Kingdom showed that there were no differences in the proportion of the serious ADRs reported, as compared with the reports of the health professionals.[20] After one year of online reporting by the consumers, more than 2,500 yellow cards were filled by the patients or their caretakers, bringing the total number of the patient reports to almost 9,000. The information collected over one year form online reporting has contributed to the advice of the agency on issues like Varenidine (Champix), adverse psychiatric reactions which are associated with Rimonabant (Acomplia) and the withdrawal of its license due to psychiatric risks.[24]
4. **Denmark:** The Danish Medicines Agency set up a patients' reporting system in July 2003, in part, as a response to pressure organised by the Danish Consumers Council after its own research on the anti-obesity drug, Letigen showed a greater level of adverse reactions than those reported by the professionals alone. As in the United Kingdom, efforts to promote to consumers the possibility to report are limited; a leaflet produced by the agency was not widely available. Again, like the United Kingdom, the form which patients had to fill, was an adaptation of that which was already used by the professionals and it employed medical terminology which was not clear to a lay reporter.[18]
5. **Belgium:** Test-Achats is a member of the European consumer's organization which was started in November 2006, which was an initiative on patients reporting in collaboration with the Belgian Agency of Medicines (FAGG). The Test-Achats experts' team (pharmacists and medical doctors) sends the report to the pharmacovigilance department of the medicines agency. Within a month, the agency sends the evaluation back to Test-Achats who provides a feedback to the consumer. From November 2006 to December 2007, 184 ADRs were reported. Test-Achats also registered 56 reports of other drug related problems and received 31 questions regarding the prices and the reimbursement of the medicines and 15 questions regarding the patient information leaflets.[25]
6. **Italy:** Altroconsumo, a member of the European consumers organization, launched in June 2006 on its web site, the initiative "Questa la racconto" (I tell you my story), to collect consumers' experiences of adverse reactions following the use of some specific medicines. In the beginning, they did it for two creams which were used to treat eczema and then they expanded it to coxib and to glitazones which were used to treat diabetes. In one year, they received 230 reports. The reports were sent to AIFA, the Italian medicines agency. This initiative showed that consumers' reports are essential, not only to know more about adverse

drug reactions, but also to know when the medicines are not used appropriately. For example, in the case of the two creams for eczema, Altroconsumo showed that they were prescribed for age not authorized, as first option treatment and not as second option treatment as required from the competent authorities and for longer period of time than suggested.[25]

7. **United States:** MedWatch, the Food and Drug Administration (FDA)'s Safety Information and Adverse Event Reporting Program, offers patients some scope to directly report adverse drug reactions. However, the majority of reports originating from patients that actually reach the FDA are sent in by the pharmaceutical industry. This sector has the legal obligation to pass on all the reports that it receives. Thus, questions and complaints from patients concerning drugs which are addressed to the marketing authorisation holder are categorized as patient reports. A mere 9% of all the reports that the FDA receives have been directly submitted by physicians, pharmacists or health consumers. Approximately 40% of all the reports stem from patients. There are no publications yet, on the contribution of consumer reports to the FDA.
8. **Australia:** Since the early 1990s, Australia has been taking its first steps towards creating facilities to allow patients to report their complaints on drugs. The Australian Patient Safety Foundation runs and maintains the Australian Incident Monitoring System (AIMS). However, only 20% of the reports concern medication and only 4% of these are about adverse events. The national reporting system (ADRAC) receives about 10, 000 reports per year and this includes all appropriately documented patient reports. On an annual basis, the latter comprises fewer than 100 reports.

The current Pharmacovigilance Program in Malaysia

Malaysia has a national centre of Pharmacovigilance, namely, the 'National Adverse Drug Reaction Monitoring Centre', that covers the country overall. Some major hospitals and pharmaceutical companies also operate ADR monitoring systems, but all reports are consolidated by the national centre. The reports from doctors, pharmacists and dentists are collected on a voluntary basis, but the reports from marketing authorization holders are mandatory. They monitor drugs for human use, vaccines, biologicals and herbal remedies. The National ADR centre uses prepaid postage report forms or updated report cards every month. They still maintain records manually. They have a local database. The national centre has an advisory committee which makes the causality assessment of the reported ADRs. The Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) was established under the Drug Control Authority (DCA) to perform the function of monitoring the safety profiles of the drugs which were registered for use in Malaysia. MADRAC provides the DCA with the information pertaining to drug safety issues which occur locally and internationally. The National Drug Safety Monitoring Centre, which is the secretariat to MADRAC, was accepted as the 30th member of the WHO Safety Monitoring Program in 1990. Under the monitoring programme, all ADR reports which have been received and screened by MADRAC, are submitted to the Uppsala Monitoring Centre in Sweden for inclusion into the WHO database.[[26],[27]]

The MADRAC also promotes ADR reporting in Malaysia and provides information and advice to the DCA so that regulatory action can be taken, based on the ADRs received (local and foreign). It also provides information to doctors, pharmacists and other health care professionals on the ADRs and participates in the WHO ADR monitoring programme.

For the year 2007, the National Centre for Adverse Drug Reactions Monitoring received a total of 3068 spontaneous reports of suspected ADRs. This was an increase of 525 reports (20.6%) over the 2543 reports received for 2006. During the course of the year 2007, a combination of pharmacists and dentists submitted the most number of ADR reports, which was 41.8% of the total number of ADR reports which were received. It was an increase of 76.7% as compared to those received in the year 2006. However, the number of government doctors reporting ADRs decreased by 15.6% as compared to the year 2007. The ADR reports were mainly related to respiratory system disorders such as coughing/dry cough. The other suspected drugs among the top ten which contributed to the most number of ADR reports, were allopurinol, cloxacillin, diclofenac, metformin, aspirin,

ticlopidine, rifampicin, phenytoin and amoxycillin.[28]

The centre also makes recommendations to the drug control authority on the labeling changes, the restriction on the use and suspension or withdrawal of drugs from market, the assessment of the signals run by the manual screening for potential signals, the local data base, the WHO data base and medical literature which are examined and brought up for discussion with the advisory committee, which convenes six times a year and it is a subcommittee to the drug control authority in Malaysia.[[26],[27]]

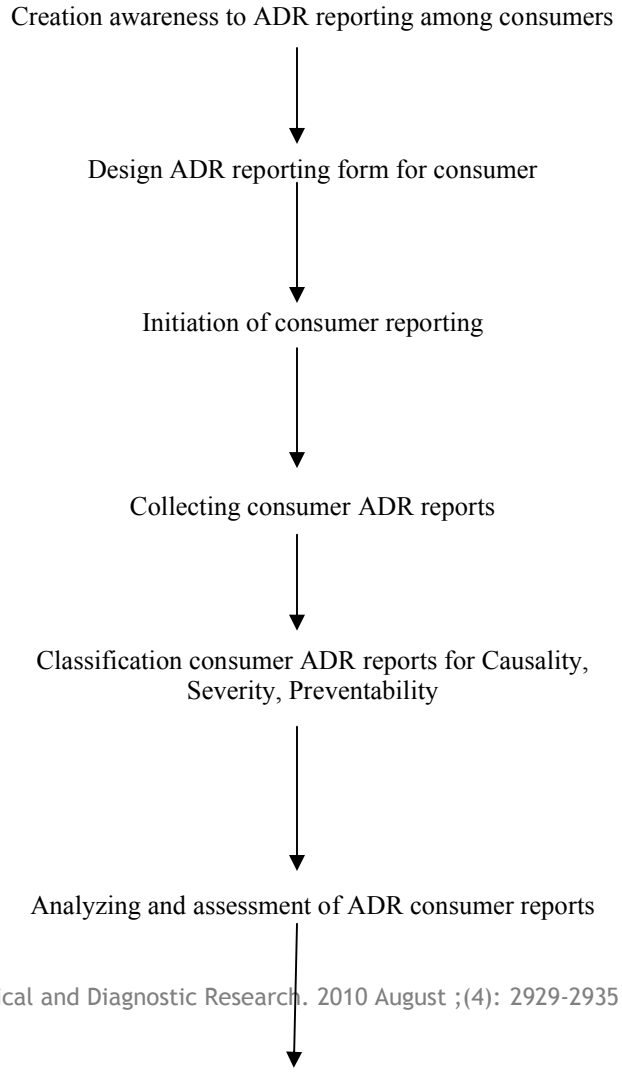
The need for a Consumer Reporting Program in Malaysia

Consumer reporting of ADRs can improve pharmacovigilance in Malaysia for these following reasons:

1. Greater amounts of information and awareness will raise and avoid pain and suffering and will prevent economic loss.
2. The numbers of reports given by the doctors, pharmacists and dentists is still small [25] and so, the consumer will be a rich source of useful information on the harmful effects of drugs and this program can lead to an increase in such reports.
3. Limitations of the existing reporting system: Worldwide, only a small number (less than 5%) of the doctors, pharmacists and dentists make reports. A number of doctors are reluctant to make such reports for fear of legal liability, or the indictment of bad practice.[27]
4. A study conducted in Malaysia to assess the causes of underreporting about ADRs revealed that 81.4% of the doctors suspected ADRs but did not report them, while 40% of the respondents were not aware that there was a system for monitoring the harmful effects of drugs in Malaysia and the lack of awareness and understanding of the functions and the purpose of this national program.[29]
5. There are a large number of people using traditional drugs without reference to the doctor, or the consequences of failing to report them, as well as a very small number of reports on the harmful effects of traditional medicines which are submitted to the national drug monitoring centre in Malaysia.
6. Consumer reporting can cover situations about which the physician is not informed and about which he therefore cannot report.
7. Consumer reporting can promote consumer rights and equity.[30]
8. Consumers can provide unique perspectives and experiences.[30]
9. Consumers can provide information and insight which are crucial to establish effective and safe drug use.

The medical establishment can profit from the discipline of consumer input. Consumers for this part, need a willing ear and channel through which they can make their experiences and feelings known, as they assume the risks and costs of the existing medicines. They are also exposed to the relationship between the benefits, harm and costs of drug use and can contribute to the knowledge of that relationship.[28]

[Table/Fig 1] An approach for starting a consumer reporting in Malaysia



Reporting to National Pharmacovigilance Centre

An Approach to Start a ConsumerReporting Program in Malaysia?

The establishment of a pharmacovigilance centre can start very quickly. This process needs time, vision, dedication, expertise and continuity.[31] The centre must have a strong relationship with drug regulation. It needs good collaboration, coordination, communication and public relations for its development. Any department under the health authority, in hospitals or in an academic environment can be a good host to establish such a centre.[31]

Contribution of Consumer Reporting to the Existing Pharmacovigilance Program

Consumer reporting cannot replace the existing pharmacovigilance program, but it can complement and strengthen it. Consumer reporting provides qualitative and quantitative contribution to the existing system which is available in the country. Consumer reporting as a new concept, will enhance the impact of the reporting system and can improve the knowledge about the ADRs of over –the-counter medicines, the off-label use of medications, traditional medicines and alternative medicines about whose risks doctors may be not familiar enough.

Conclusion

Evidence from developed countries has clearly revealed the benefit of involving consumers in pharmacovigilance programs. After 20 years of pharmacovigilance in Malaysia, there is a need of the consumer reporting of suspected ADRs to be introduced to improve the existing pharmacovigilance system. Consumer reporting of suspected ADRs can add many benefits to the available drug monitoring system, overcome under reporting, promote consumer rights, improve the public quality of life and can be an important information source for clinical practice.

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