

**Case Report****Problems and challenges faced in consumer reporting of adverse drug reactions in developing countries – A case study of Yemen, Nepal and Malaysia**

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ABSTRACT

Background: Pharmacovigilance is the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems”. The most commonly used adverse drug reaction (ADR) reporting system worldwide is spontaneous and voluntary reporting, which forms the backbone of reporting systems. **Aims:** To explore the current status of consumer involvement in the pharmacovigilance program in three developing countries, Yemen, Nepal and Malaysia. **Method:** An analysis was carried out for these three countries based on the current status of pharmacovigilance and involvement of consumers in their pharmacovigilance programs.

Results: Malaysia has a good system for involving consumers in their national pharmacovigilance system, whereas Yemen still lacks the well-formed national drug policy. Lack of legislation and regulation which govern the import and distribution of drugs in Yemen is a limiting factor for development of consumer pharmacovigilance. Despite establishment of a pharmacovigilance centre, no reports have been released by the centre. The status of pharmacovigilance in Nepal is still in infancy. The regulatory body is assigned to be a national pharmacovigilance center, and coordinates with seven regional centers for pharmacovigilance activities. Nepal also lacks the involvement of consumers in the national pharmacovigilance program. **Conclusion:** Consumer reporting may be important for developing countries to implement a proper and effective pharmacovigilance program that can reduce morbidity and mortality rates, as well as reducing the economic burden of ADRs.

Introduction

In the past few decades, there has been an exponential growth in the global human population. Improved patient care and better medicines to treat diseases have played a pivotal role in extending human lifespan and reducing morbidity. However, medicines could also be potentially hazardous. Recipients of prescribed drugs or medicines may expose themselves to Adverse Drug Reactions (ADRs) which have been identified as one of the leading cause of hospitalization and may lead to morbidity and mortality. This leads to pain or suffering among recipients and also causes economic burden.[1]

One of the earliest definitions for Adverse Drug Reaction was established by the World Health Organization which reads as: “.....any response to a drug which is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis or therapy of disease or modification of physiological function.”[2]

Quite recently, addressing the absence of the patient’s perspective found in the previous definition, Edwards and Aronson propose the following definition: “.....an appreciably harmful or unpleasant reaction resulting from the use of a medicinal product, which predicts hazard for future administration and warrants prevention or specific treatment, alteration of the dosage regimen or withdrawal of the product.”[3]

The field of drug safety or pharmacovigilance has attracted serious attention and focus especially during the last ten years. This is evident from the increased number of publications addressing post-marketing drug-related events in scientific journals globally. Originally, 10 countries contributed information to the international system for monitoring ADRs. At present, the number of contributing countries has reached 113; Malaysia and Nepal are members of the WHO drug monitoring program.

The most commonly used ADR reporting system worldwide is spontaneous and voluntary reporting. However, significant under-reporting of ADRs by healthcare professionals has been identified as a serious drawback of the voluntary reporting system and is prevalent in various countries.[4] There are many previous studies which underline the importance of ADR reporting. The motivation behind the establishment of the ADR reporting system is the fact that ADRs are common, yet preventable causes of illness and disability. ADRs are ranked as the top 10 causes of mortality in the United States of America (USA), United Kingdom (UK) and Europe. For instance, 6.5% of all hospital admissions in the UK were caused by ADRs. In terms of the economic burden, this is equivalent to £466 million annually. [5] Hence, establishing a well-organized and efficient pharmacovigilance system to evaluate and monitor the safety of medicines in clinical use is crucial.

The current system of reporting depends on spontaneous reports submitted by doctors and pharmacists. Involvement of consumers in ADR reporting can reinforce their rights and ensure the safer use of medicines in future. Consumers' experiences and views can provide additional information about ADRs. ADR reporting by consumers has been possible for almost 15 years in developed countries. However, only a few countries currently accept patient reports. Countries like Sweden started consumer reporting for ADRs in 1978 and the USA followed in 1993. Denmark started consumer reporting in 2003, Canada and Australia started in 2003 the Netherlands in 2004, and the UK in 2005. [1]

In Europe and the United States there is now over two decades of experience regarding consumer ADR reporting. A study done to investigate the relative contribution of patient reporting to signal detection in the UK showed that patient reporting may provide a positive complementary contribution to the reports received from health care practitioners (HCPs). [5] Similarly, another study indicated that free text comments often contained in case reports directly submitted by patients can be of value in pharmacovigilance and provide important information on how a drug may affect the person using it and the influence it may have on his or her personal life. [6]

An 11 country survey of the methods of patient reporting of ADRs revealed the importance of giving the public the opportunity to report ADRs and the additional value of patient reports. Most countries have three different ways for patients to report ADRs - a paper form, an electronic form on a website or by telephone. The route of handling of patients' and HCPs' ADR reports is the same for most countries. The Netherlands and the UK are actively evaluating their patient reporting systems.

Less than 3% of reports added to the WHO database in the year 2000 originated from developing countries, although around 80% of the global population lives in the developing world. Developing countries have an urgent need to improve their pharmacovigilance systems. Hence, consumer reporting is highly acceptable and should be encouraged from the developing countries. [8,9]

Pharmacovigilance in Yemen

In Yemen health services particularly hospitals and private health facilities are concentrated in major cities. Primary health units and centres as well as polyclinics are scattered throughout the country. The local pharmaceutical industry is growing at a slow rate and most of the country's needs are catered to by imports. ADR reporting systems do not cover the whole country and there is lack of a systematic plan to monitor drug reactions and related problems. A pharmacovigilance center was established in 2011 by the Supreme Board of Drugs and Medical Appliances(SBDMA). However, there are no official data or reports released by the SBDMA on the number of ADRs being reported and how they are being processed [10]. There is no provision for collecting and disseminating information about ADRs. The centre is located in the capital city and has no systematic contact with other governorates. Neither health care providers nor medicine consumers are aware about the centre. Therefore it can be concluded that there is little involvement of both health professionals and the public in the national pharmacovigilance program.

Pharmacovigilance in Nepal

The Ministry of Health and Population, Department of Drug Administration (DDA) was established in Nepal as per the Drug Act 1978. It is responsible for the manufacture, import/export, sales, distribution and storage of drugs in Nepal. DDA is also the National Center for Pharmacovigilance. Pharmacovigilance was initiated in Nepal in 2004 and the country became a member of the International Pharmacovigilance Program in 2007.[11] The national pharmacovigilance center coordinates with seven regional centers in Nepal among which five are situated in the capital of the country while two are located in the eastern and western region of Nepal. These centers collect ADR reports from health care professionals and forward them to the Department of Drug Administration (DDA) from where the reports are sent to the Uppsala Monitoring Centre in Sweden, a centre for international service and scientific research towards patient safety. [12]

A national ADR reporting form is available through the DDA's website, and other regional centers have developed their own forms. But, many of the stakeholders within as well as outside the regional pharmacovigilance centers are not yet aware of the form and its intended use as a reporting mechanism for suspected ADRs. The collected ADRs are reported to the national center through a database system known as 'Vigibase'. There are very few ADRs which have been reported to the national center till date. There is a lack of a system for disseminating information

about the types of reactions reported to the DDA and no provisions for reporting by consumers in the pharmacovigilance program in Nepal. The whole program is still in the developing stage and is only 10 years old in Nepal.

Pharmacovigilance in Malaysia

In Malaysia, spontaneous, voluntary ADR reporting is the most commonly used method, and the program is monitored by the National Adverse Drug Monitoring Center. The ADR reporting system covers the entire country and some major hospitals and pharmaceutical companies have been running ADR monitoring systems.[1] Even though the monitoring system has been running for more than 20 years, the quantity of reports, especially from the community of pharmacists remains low, compared to other countries.[13]

Malaysia has a well established national centre of pharmacovigilance, namely the National Adverse Drug Reaction Monitoring Centre. Some major hospitals and pharmaceutical companies also operate ADR monitoring systems under the national centre. ADRs can be reported either directly to the national center or through hospitals and pharmaceutical companies that run pharmacovigilance programs. Reports are then consolidated at the national center. Reports from doctors, pharmacists and dentists are made on a voluntary basis but reports from pharmaceutical industry are mandatory. The centre monitors drugs for human use, vaccines, biological and herbal remedies, using prepaid postage report forms or report cards. It also records ADRs manually, and has a local database. The national centre has an advisory committee that assesses the causality of the reported ADRs.[1] The Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) was established under the Drug Control

Authority (DCA) to monitor the safety profiles of drugs registered for use in Malaysia. MADRAC provides DCA with information pertaining to drug safety issues occurring locally and internationally. The National Drug Safety Monitoring Centre, which is the secretariat of MADRAC, was accepted as the 30th member of the WHO Safety Monitoring Program in 1990. Under this program, all ADR reports that have been received and screened by MADRAC are submitted to the Uppsala Monitoring Centre in Sweden for inclusion in the WHO database.

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. It also provides information to doctors, pharmacists and other healthcare professionals on ADRs and participates in the WHO ADR monitoring program. A total of 7079 reports were received in the year 2010 which is in tune with the increasing trend every year. This figure is a 21% increase from the year 2009. Of the 7079 reports received, 5976 reports (84.4%) were sent in by healthcare professionals from the government sector. This is an increase from the previous year's 4698 reports from the government sector. The year 2010 also showed an increase (72.2%) in the number of ADR reports from private healthcare professionals (248 reports) compared to 2009 (144 reports). However, reports from Marketing Authorisation Holders (MAH) saw a decreasing trend since the year 2008. There was also an increase in the number of reports from the 'Others' category of reporters due to the higher number of reports submitted by nurses (338 reports) in accordance with the Human Papillomavirus (HPV) national immunisation programme. Only 7 reports were submitted by consumers.[14] Table 1 compares different facts and figures for the three countries, Yemen, Nepal and Malaysia.

Table1: Characteristics of Malaysian, Nepali and Yemeni health care systems

Key figures	Malaysia*	Nepal**	Yemen***
Population	29.7 million	30.5 million	25 million
GDP	USD 9,977.32 per capita	USD 619 per capita	USD 659 per capita
Health Expenditure (%GDP)	4.9	6.33	5.3
Practicing physicians	36,607	14,059	7,629
Practicing dentists	4,253	950	329
Practicing pharmacists	8,632	1311	1,024
Year when pharmacovigilance activities were started	1983	2004	2011
No. of total ADRs reports in 2010	7079	523	No data
Year when consumer reporting was initiated	2007	Not yet started	2011

Source: *Malaysian Health Fact 2012. : http://www.moh.gov.my/images/gallery/stats/health_fact/health_fact_2012_page_by_page.pdf

**Ministry of Public Health & Population of the Republic of Yemen, in collaboration with the World Health Organization. (2012). Yemen Pharmaceutical Country Profile.

***Department of Health Services: Annual report F/Y 2009/10. Government of Nepal, Kathmandu; 2011.

Benefits of incorporating consumers in ADR reporting systems

Most ADR reporting systems in the world have focused heavily on spontaneous and voluntary reporting. National pharmacovigilance initiatives in most countries have suffered from under-reporting.[15] Self-medication is common in most developing countries. Inappropriate use of medicines and ADRs could have originated from commercial advertising which promotes self-medication. Consumers/patients could well be an important source of ADR reporting since in principle, they have a vested interest in reporting ADRs.

One of the first countries that allowed ADR reporting by consumers was the United States. The initiative started as early as the 1960s and consumers had the opportunity to report ADRs directly to the Food and Drug Administration (FDA). Since 2003, consumers in the Netherlands have the opportunity to report possible ADRs to a foundation, separate from the country's national drug regulatory authority known as LAREB. In the same year, patients in Denmark were offered a similar opportunity, followed by Italy in 2004, the UK and Sweden in 2008 and Norway in 2013. In a survey conducted in three states of India involving 566 households, the author concluded that there was an increasing trend of involving consumers in the process of health care. Advantages of consumer reporting include better quality of ADR reports, increase in number of ADRs being reported, newer ADRs being reported, early detection of ADRs and allowing establishment of a strategy to prevent medication errors. [16]. In another article which analyzed previous literature on ADR reporting by patients, the authors concluded that patient reporting of suspected ADRs has more potential benefits than drawbacks. [17]

In a report by WHO in 2000 entitled "Consumer reporting of adverse drug reactions" it is revealed that the benefits of incorporating consumers in ADRs reporting include the promotion of consumer rights and equity. Involving consumers could serve as a means of acknowledging that they have unique perspectives and experiences. As a result, healthcare organizations would in turn benefit from consumers' involvement. In return, consumers will be driven by the motivation to benefit other medicine users. A study conducted by Medawar which attempted to compare the ADR reports from professionals and consumers related to the risk of dependence and suicidal behavior with paroxetine concluded that individual patient reports were much richer in their behavioral phenomena and feeling descriptions compared to the Yellow Card reports submitted by HCPs in the UK.[17] Potharaju asserts that ADR reports have the potential to be a quantitative indicator of quality and safety based on a research conducted by Agoritsas and co-workers in 2005 on patients being hospitalized [16].

Apart from that, consumer ADR reporting also helps to discover possible new ADRs that had not previously been reported by health professionals. This has been described in a review paper published by Blenkinsopp and co-workers in 2007. The authors analyzed a total of eight published papers. They found that patients' reports which are unfiltered by professional interpretation can bring new understanding about ADRs. This is because reports from users and their relatives regarding behavioral effects were far richer than that from professional reporters [18]. Commenting on the same paper published by Blenkinsopp in 2007, Alshakkain 2013 highlighted some important benefits of incorporating consumers in ADR reporting programs which can be listed as follows:

- a) provides regulatory authorities and clinical practice a new source of information
- b) discloses the drugs' previously unknown effects
- c) earlier detection of ADRs due to direct reporting by consumers or patients
- d) alleviates the problem of under-reporting by increasing the number of reports
- e) provides details and information on patient's quality of life
- f) alleviates the problem of lacking serious adverse effects in the reports written by health professionals
- g) provides useful information on ADRs as those provided by health professional, even though in a different style or expression
- h) encourages reports by the elderly people
- i) provides wider verities of reports on effects that have strong relationship with drugs.

Current situation of consumer reporting of ADRs in Yemen

Yemen lacks a proper pharmacovigilance program. Even though a regulatory body for drugs already exists (SBDMA), there have been no coordinated efforts among parties involved such as medical and pharmacy schools, pharmacovigilance centers and the pharmaceutical industry. The main reason for this is the lack of an active national drug policy. This might probably be the result of not having legislations and regulations which govern the importation and distribution of drugs. It is feared that the situation will worsen in the future if current stakeholders do not make efforts to rectify the problem [10].

The National Medicines Policy was established in 1998, sadly, it has not been implemented properly, where a formal implementation plan does not exist. There are no legal provisions in the Medicine Act that provide for pharmacovigilance activities as a part of Medicines Regulatory Authority mandate. Laws regarding the monitoring of ADRs do not exist. ADRs are not monitored systemically in any public health program.[7]

Current situation of consumer reporting of ADRs in Nepal

Currently, there is no provision for involving consumers in the existing pharmacovigilance program of Nepal. The drug act and the national drug policy of Nepal does not mention about pharmacovigilance, but the new national medicine policy which is under review will address pharmacovigilance. As mentioned by different authors, underreporting is still a major limitation hindering the success of the pharmacovigilance program in Nepal. Involving consumers in the program may be a good initiative for strengthening the existing system for pharmacovigilance. Currently, the program is focused on the reports collected from health care professionals. However the national drug regulatory authority, DDA is positive with regard to initiating consumer pharmacovigilance in the country as per verbal interactions of the author NJ with DDA officials.

Current situation of consumer reporting of ADRs in Malaysia

The history of ADR reporting by consumers or patients in Malaysia dates back to 2007. In the early years of its launch, the number of patients who submitted ADR reports was rather low, as indicated by the National Center. The reason for this is understandably similar as previously reported in research conducted in other countries, whereby pharmacists and other professionals tend to look at patients' reports with a skeptical eye as they regard the patients as having limited knowledge and low awareness.[1] However, a research conducted in 11 countries including Malaysia, concluded that the importance of giving the public the opportunity to report ADRs and the additional scientific value of the collected data is widely recognized by the countries who participated [19].

In a qualitative and quantitative study conducted at the Universiti Sains Malaysia, which attempted to compare the drug safety systems in Malaysia, Australia and Sweden, the author found that in terms of reporting requirements, report handling, resources spent and exchange of information in the environment were different. Australia and Sweden have a proper and more effective ADR reporting systems as well as consumer involvement compared to Malaysia.[1] The author also suggested that there is an urgent need for educational interventions among Health Care Practitioners (HCPs) in Malaysia due to their poor knowledge of pharmacovigilance. In addition, consumer knowledge about ADRs was also relatively low. For instance, out of the 500 general public surveyed, more than one-third did not know the definition of ADRs and more than half were unable to differentiate between side effects and ADRs. Almost 90% of both general public and HCPs agreed that consumer reporting would benefit the existing pharmacovigilance initiatives in Malaysia. The author has further concluded that in order to improve ADR reporting in Malaysia, the level of awareness of all stakeholders in the healthcare system needs to be improved. The consumers need

to be educated about their medications, writing and filing valid reports and sending it to the proper authorities[1].

Challenges faced by consumers in reporting ADRs in developing countries

In a research article entitled "Reporting Adverse Drug Reactions: Patients to be involved or not?" the author points out that there is a tendency for patient reporting to be viewed as politically driven rather than scientifically driven. Even though further examination based on data collected from patients' report compared to those from HCPs showed no significant difference between them, patients are found to reflect more on their concerns about life threatening and significant disability cases. For instance, they were more likely to report symptoms related to delicate matters such as sexual dysfunction directly to the authorities rather than HCPs. They also are more likely to report symptoms related to their quality of life. This shows that there is some bias involved in ADRs reporting by consumers or patients. It is feared that databases generated from reports submitted by patients might be overlooked and not treated in a fair manner.[20]

Another challenge faced by consumers in reporting ADRs is poor knowledge about ADRs. Patients' knowledge about the definition of ADRs itself as well as how they report such cases and where they submit the cases may be poor. In a recent case study conducted in the state of Penang, Malaysia it was found that 65.6% of respondents reported that they were unaware about the existence of the ADR center established by the Ministry of Health. The author has pointed out that the result is in agreement with previous studies being conducted in the Philippines, Iran and Germany. In general the knowledge of general public, pharmacists as well as HCPs in university hospitals about ADRs is poor.[1]

Addressing the medium through which an ADR can be reported by consumers, a study in 11 countries including Australia, Canada, Denmark, Netherlands, New Zealand, Norway, Malaysia, Philippines, Sweden, UK and USA, found that only five countries offer the facility to file a report via phone, electronic forms and paper forms namely Australia, Canada, New Zealand, UK and USA. As for developing countries such as Malaysia and the Philippines, consumers would only be able to file their report either via telephone or paper forms. This restriction of methods through which a report can be filed might be the reason why consumer reporting of ADRs in these two countries is still relatively very low. In both countries, the percentage of consumer ADR reports is well below 10 percent [18].

In the same report, perhaps the answer to the question why the level of knowledge among general public, particularly in developing countries is still very low is the lack of funding for campaigns to make the public aware of the possibility that consumers can report ADRs as well as the reporting scheme. In Malaysia, the Ministry of Health remains the sole body

which provides funds to promote consumer reporting by putting it on a website, via posters that they put up in hospitals and flyers that they give to patients. These efforts are still insufficient to increase the level of awareness and knowledge among the general public on ADR reporting. It is hoped that other parties such as NGOs would work together to improve the pharmacovigilance initiatives in the country.[20]

In Yemen, the major problem faced by consumers is the poor pharmacovigilance system. Currently, Yemen is way behind other developing countries in terms of improving the effectiveness of the ADR reporting system. Another contributing factor is the lack of nationwide coverage of pharmacovigilance centers, as well as hospitals. This might probably originate from the lack of legislation and clear policy on pharmacovigilance. Studies have found that 60% of all imported medicines in Yemen originated through illegal channels. [10]. As a result, the occurrence of fake medicine and drugs is rampant which poses serious threat to the health of the public.

In addition, the lack of ADR monitoring in Yemen might lead consumers to believe that their reports may not be acted upon and this may eventually deter them from filing reports. This, added with the high illiteracy of the Yemeni population, might make it impossible to establish a proper and effective ADRs reporting system in the country [10]

Similarly, Nepal also being a developing country has many hurdles and obstacles for an effective pharmacovigilance program. Political instability and lack of good governance may be another hindering factor for proper development of such programs. Funding is another limitation. Till now, WHO has been helping financially with pharmacovigilance program in Nepal. Department of drug administration is the national center for pharmacovigilance and the seven regional centers are not having a nationwide coverage. Lack of human resources dedicated for pharmacovigilance program is another major constraint. Consumers are not yet involved in reporting ADRs till date. Pharmacovigilance program is still in its infancy in Nepal and there is a long way to go for a systematic and properly functioning system.

Conflict of interest statement

We declare that we have no conflict of interest.

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Realizing the potential benefits of consumer reporting as well as the motivation to establish a proper and effective pharmacovigilance program throughout the country, a pilot study has been carried out in Malaysia to test the viability of the newly formulated system. Now, more than 6 years after the first pilot study had commenced, a healthy increase of ADR reporting was observed. The number of ADRs being reported in the country in the year 2010 was 7079, a significant 21% increase compared to the previous year. Therefore, the future looks bright for consumer pharmacovigilance in Malaysia.

For Yemen and Nepal, however, much still needs to be done. The foremost is to have proper legislation backed by appropriate policies with proper implementation plans. The illiteracy rate needs to be addressed in a holistic and thorough manner. For this to be a success, all stakeholders, especially the government must work as a team and channel their energy and focus towards establishing a comprehensive pharmacovigilance program.

Conclusion

Having a proper and effective ADR reporting system is crucial for every country as it could reduce potential health hazards such as morbidity and mortality. The economic burden associated with these hazards can also be alleviated. Even though spontaneous and voluntary ADR reporting system has been the mainstay since its inception, the status quo is now changing due to increased awareness of all stakeholders on the need to incorporate consumers into the existing reporting system. This may partly alleviate the problem of under-reporting which has plagued the system.

Based on the facts presented above, it is clear that consumer reporting is the way forward to attain a proper and effective pharmacovigilance program that can address the very fundamental task of alleviating morbidity and mortality rates, as well as reducing the economic burden.

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