REVIEW ARTICLE

Consumer reporting of adverse drug reactions: A current perspective

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Abstract

Adverse drug reactions (ADRs) have been identified as one of the leading causes of hospitalization leading to morbidity and mortality worldwide. Reporting of ADRs to national databases is thus necessary. To strengthen this system, consumers apart from health-care professionals have also been empowered to report any ADRs directly to the regulatory agencies. Direct and spontaneous patient or consumer reporting offers various benefits beyond pharmacovigilance (PV). Consumer reporting of ADRs has existed in several countries for decades, but in India, the role of consumers as a source of information on ADRs has not been fully accepted until recently. In Europe, The Netherlands and Sweden were among the first countries to implement consumer reporting well before it was mandated by law throughout the European Union. The World Health Organization is promoting the role of the consumer in spontaneous ADR reporting as an adjunct to existing PV strategies. Indian Pharmacopoeia Commission has launched the ambitious medicines adverse effect reporting form for consumers along with a patient centric helpline number for the general public to enable reporting of ADRs directly. Consumer reporting is an integral part of the spontaneous reporting systems with yearly numbers of reports constantly increasing.

Key words: Adverse drug reactions, consumer adverse drug reaction reporting, Indian Pharmacopoeia Commission, pharmacovigilance, Pharmacovigilance Programme of India

INTRODUCTION

In the past few decades, with an exponential growth in the global human population, improved patient care and better medicines to treat various diseases have played a substantial role in protracting human lifespan thereby reducing morbidity and mortality to a great extent. 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 leading to morbidity and mortality.[1] This leads to pain or suffering among recipients, also increasing the economic burden. The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem."[2] According to the WHO, an adverse reaction can be defined as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function."[3] Spontaneous and voluntary reporting of suspected ADRs generates signals about rare, delayed and unexpected drug reactions that are undetected in the initial phases of drug development. ADRs are considered the most limiting factor that compromises patient compliance and adherence.[4] Moreover, ADRs become a concern and public health problem particularly in developing nations as adequate drug toxicity monitoring and reporting schemes barely existed.

Reporting of ADRs to national databases has traditionally been the sole responsibility of health-care professionals. To strengthen the systems in some countries, consumers have also been empowered to report any ADRs directly to

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the regulatory agencies.[5] Direct and spontaneous patient reporting offers added value for PV in that it can speed up the acquisition of knowledge about adverse effects. Patient reports are more direct and often more detailed and explicit than indirect reports through health professionals. Unlike reports from clinicians, they often describe how the adverse effects affect people's lives. Consumers can provide first-hand information about their experience with medicines and their adverse effect affecting people's lives, thereby constituting a valuable information source. Studies have established the significant contribution of consumer reporting to ADR signal detection. Combining all reports regardless of reporter type is recommended since it yields the largest critical mass of reports for signal detection. The WHO is promoting the role of the consumer in spontaneous ADR reporting as an adjunct to existing PV strategies and has developed guidance for establishing effective consumer reporting systems.[6] This interest in consumer ADR reporting comes at a time of relative decline in reporting by health-care professionals. Poor reporting by health-care professionals has been a perennial problem, and multiple reasons are assumed globally for this decline in ADR reporting by professionals.[7] While medical specialty has been identified as a key influence on underreporting of ADRs by physicians, other influencing factors may include ignorance about what should be reported; diffidence (fear of appearing ridiculous for reporting suspected ADRs); lethargy (procrastination and lack of interest or time to report); indifference (a belief that reporting would make little contribution to medical knowledge); insecurity (lack of certainty of the drug causing the ADR). The low rate of ADR reporting undermines efforts to identify and estimate the magnitude of drug risks, confirmation of actionable issues and possible regulatory action.[8]

CHRONICLE OF CONSUMER ADR REPORTING

Only few studies have analyzed consumer reports submitted to ADR databases, but over the last years studies analyzing ADRs reported to national PV databases have been published. Medawar and Herxheimer investigated ADR reports on the risk of dependence and suicidal behavior from paroxetine from UK consumers and health-care professionals, respectively. Medawar found individual patient reports much richer in their descriptions of behavioral phenomena and feelings compared to those submitted by professionals in the UK. He concluded that though individually such reports may be deficient or exaggerated and sometimes wrong, collectively they reflect good common sense.[9] In 2011, McLernon *et al*. published a study investigating the characteristics of consumer ADRs reported in the UK from 2008 to 2009.[10] In Sweden, it has been possible for consumers to ADR report directly to the non-profit organization KILEN since 1978, and research conducted on these data has been published in several papers and reports.[11] Experience with consumer reporting (2004-2007) in the Netherlands was recently published showing differences in the categories of seriousness and outcome of the reported ADRs between patients and health-care professionals.[12] A study from Denmark analyzing differences in ADR reporting patterns between consumers and health-care professionals (2004-2006) showed that consumers reported ADRs for the nervous systems medications and that patients report rather unspecific symptoms, as they use lay terms to describe reactions.[13] The patients also reported several ADRs, which prescribers may not consider serious but may be troublesome to patients, and therefore, patients find worthy of reporting. O'Brien and Yearwood found the information on ADRs to be analytical.[14] Jarernsiripornkul observed that patient perceptions of potential ADRs provides useful information but GPs do not report all the symptoms told to them by patients, and thus, recommended that they should be an integral part of any pain management strategy.[15] Blenkinsopp observed that reports by patients identified possible new ADRs that had previously not reported by health-care professionals.[16]

INDIAN PHARMACOPOEIA COMMISSION (IPC) AND PV PROGRAMME OF INDIA (PVPI)

The Central Drugs Standard Control Organization, New Delhi, under the aegis of Ministry of Health and Family Welfare, Government of India has initiated a nationwide PvPI in July, 2010, with the All India Institute of Medical Sciences, New Delhi as the National Coordinating Centre (NCC) for monitoring ADR in the country to safeguard public health by ensuring that the benefit of use of medicine outweighs the risks associated with its use. The purpose of this PV programme is to collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to health-care professionals and the public. The broadened patient safety scope of PV includes the detection of medicines of substandard quality as well as prescribing, dispensing and administration errors.

PV in public health programmes has been a recognized strategy toward medicine safety. In India, a host of national disease control programs is in operation, and they share a common agenda of safety monitoring of medicines recommended for use under the programs. With the PvPI in place, it was worthwhile to consider integration of such safety monitoring activities with PvPI. During the index period, aligned with this objective, the NCC-PvPI has collaborated with three key national health programs - AEFI, NACO and Revised National TB Control program.

MEDICINES ADVERSE EFFECT REPORTING BY PATIENTS IN INDIA

In a strategic move that involves direct participation of patients in the PvPI, the IPC has launched the ambitious medicines adverse effect reporting form for consumers, i.e., the patients at the national level conference on "participation of patient/consumer organization in PvPI, which was held on 1 August, 2014.[17]

IPC has inked a pact with the department of consumer affairs to establish a patient-centric helpline number for the general public to enable reporting of ADRs directly. The general public may report ADRs, either directly to the National Coordination Centre (NCC) - PvPI via helpline number, i.e., 1800-180-3024 or via a dedicated email, i.e., pvpi.compat@gmail.com or to their nearest ADR Monitoring Centre (AMC) under PvPI. Since its inception on 11 October, 2013, 3826 calls have been received through the Helpline, mostly from Uttar Pradesh (19.31%), Madhya Pradesh (13.54%), and Maharashtra (10.47%). Interestingly, the queries in the Helpline are not limited to suspected ADRs and ADR reporting, but the facility sometimes has also been used also for general drug information.

Until recently ADR reporting under the PvPI was limited to health-care professionals. One achievement during the index period has been the recognition of the role of consumers in reporting suspected ADRs. A milestone step in this respect was releasing the "Medicines adverse effect reporting form for consumers/patients" (available in seven vernaculars); thus consumers/patients can now directly report suspected ADRs. Consumers are also encouraged to use the helpline for ADR reporting. The medicines side effect reporting form for consumers is available on the website: http://www.ipc.gov.in.

Data or the information collected through them will be directly sent to the researchers and scientist designated for the same from the relevant field for further details. Once the required investigation is done and if the complaint is found to be of serious nature required steps will be immediately taken by the Drug Controller Generals office. This strategic pro-patient initiative is one of the many steps that the IPC has been taking in the recent time to further boost and strengthens the PvPI. Through this initiative, IPC hopes to ensure timely reporting of ADRs from the patients across the country by providing them a platform that will directly involve them in the PvPI. This initiative acts as a foundation stone in empowering the patients with the right to report on any issues related to the medicines. It focuses on sensitizing the public on the need for timely reporting on the ADRs for the benefit of the patients at large. It provides a window of reporting to each and every patients of this country, so that they can directly get in touch with the regulators on their problems and issues relating to the drugs which will cut short the time taken by the regulators to take the required steps to safeguard the interest of the public ensuring a better and effective ADRs.[18] This consumer ADR reporting form was launched to sensitize the patients about the ADRs and the immense importance in participating in PvPI programme directly to achieve grand success of this programme. As of now, there are two forms available in reporting of ADRs; first one is red form for health-care professionals and another one is blue form for consumers to report adverse events due to medicinal and health products administration. PvPI encourages direct patient reporting. To empower patient participation in PvPI, NCC introduced ADR reporting form in Hindi and another regional language such as Bengali, Gujarati, Kannada, Tamil, Malayalam and Oriya. Patients are advised to use this ADR reporting form in case of any adverse events on your medication (annexure I - consumer side effect reporting form).[19]

WORLDWIDE SITUATION OF CONSUMER ADR REPORTING

Consumer reporting of ADRs has existed in several countries for decades, but throughout Europe, the role of consumers as a source of information on ADRs has not been fully accepted until recently. In Europe, The Netherlands and Sweden were among the first countries to implement consumer reporting well before it was mandated by law throughout the European Union.[20] Patients, in the US, were the first to get an opportunity to report ADRs directly to the Food and Drug Administration in the 1960s. In April 2003, Dutch patients began to report possible ADRs to LAREB, a foundation separate from the country's national drug regulatory authority. Denmark allowed patients or relatives to report ADRs from June 2003. In Italy, patients have been able to download a special form to report ADRs to the AIFA (Italian Drug Regulatory Agency) since 2004. A consumer organization established in Belgium accepted reports from patients and transfer them to the Federal Agency for Medicines and Health Products. Medicines and Health Related Products Regulatory Agency in the UK made substantial efforts in February 2008 to raise awareness so as to increase the number of reports from patients.[21]

Widespread use of electronic medical record databases has enhanced patient safety through automation of signal detections for ADRs, thereby improving healthcare service delivery. Introduced in Australia in 19 October, 2003, the Adverse Medicine Events Line is a telephone reporting service that allowed consumers to report suspected ADRs to the Therapeutic Goods Administration and receive advice about side effects, which is funded by the Australian Council for Safety and Quality in Health Care. The adverse medicine events line allows consumers to report their ADRs, and medication errors and near misses.[22]

Analysis of the use of this service demonstrated that consumers can identify potential medication risk, report novel adverse reactions to prescription and complementary medicines, and identify serious reactions and drug-induced hospitalizations not earlier reported by health care professionals. The website of Swedish Medical Products Agency added an interactive section to enable patients and consumers to report ADRs in June 2008. Norwegian Medicines Agency started accepting electronic reports directly from patients since March 2010.[23]

Patients and consumers have the right to be involved as well as health professionals and have to report their experiences and their suffering as a result of these adverse effects, which threaten their health and their lives.[24]

Experience in The Netherlands obtained over 3 years showed that patient reporting can be a good source of information for drug safety monitoring and has qualitative and quantitative value. An evaluation of the first 6 months of patient reporting via the yellow card scheme in the United Kingdom showed that there were no differences in the proportion of serious ADRs reported, compared with reports made by health professionals.[25]

Fernandopulle and Weerasuriya[26] from Sri Lanka suggested that consumer reporting is the best method for developing countries to overcome under-reporting and may complement the existing system of reporting based on physicians and pharmacists.

All over the world, there is an increasing trend of involving consumers in the process of health care. Consumer reporting has several advantages like qualitative details; increase in ADRs reported, newer ADRs being reported, early detection of ADRs and also as a strategy to prevent medication errors. Patient reports contain data on personal and social consequences. Moreover allowing patients to report demonstrates a necessary attitudinal change toward showing greater respect to those experiencing illness and taking medicines. None of the countries with patient reporting systems has reported poor quality of patient reports to be an issue.

WHO HANDBOOK ON DIRECT PATIENT REPORTING

A 26-page handbook or new guidance document on reporting systems for medicine-related problems for the general public is now available from the WHO. In an increasing number of countries, consumers are being encouraged to report adverse reactions to medicines to a spontaneous reporting system, and WHO acknowledges the role of the consumer in spontaneous reporting.[27]

CONCERNS OF SPONTANEOUS ADR REPORTING

Under-reporting is a major concern in national PV programmes, especially those dependent on spontaneous reporting. Patients/consumers have vested interest in reporting ADRs. The motivations and attitudes of health-care professionals toward ADR reporting to a PV centre have been studied extensively. In contrast, the reasons why patients report ADRs are less well known. As Aagaard *et al*.[13] noted consumers' experiences with and perspectives on ADRs should be further studied. A qualitative study involving guided interviews with 21 patients in the Netherlands was performed to gain insight into the motivations of patients who report ADRs to a PV centre.[28] Most patients expressed altruistic motives, but also the severity of the ADR and the need for extra information about the ADR were mentioned as motives for reporting. Raising public awareness of ADR reporting is important, but time and resource-consuming. The minimum effort taken should be to passively inform consumers, e.g., via stakeholders' homepages and via drug product information leaflets. Another possibility of reaching out to this target group could be through cooperation with other (non-government) organizations. Information from consumer reports may give a new perspective on ADRs via the consumers' unfiltered experiences. Consumers' views may change the way the benefit-harm balance of drugs is perceived and assessed today, and, being the ultimate users of drugs, consumers could have a relevant influence in the regulatory decision-making processes for drugs. All stakeholders in PV should embrace this new valuable source of information.

BENEFITS OF DIRECT CONSUMER ADR REPORTING

Direct patient/consumer reporting has important benefits beyond PV:

1. The patient becomes an active participant instead of a largely passive recipient of treatment, and in the process learns how to manage her or his medicines and to communicate more effectively with health professionals
2. Faster accumulation of knowledge of ADRs than can be achieved with reports from only health professionals in the population
3. Directness, as it comes delivered straight from the person who has experienced the effects, with no intermediary
4. Reports are in non-technical language which makes it easier to use them in information for patients
5. They give more detail information
6. The effect on the person's life and his family or caregivers is often explicit

7. Direct patient/consumer reports describe the burden of ADRs for individuals, a major component of health that is missing from public health estimates of disease burden in populations[23,20]
8. With consumer reporting, ADRs are detected earlier and therefore, more ADRs are reported, e.g., (over-the-counter) medicines
9. Consumer reporting will promote consumer rights.

Studies have shown that there is a significant contribution of consumer reporting to ADR signal detection. Examples of signals where consumer reports have been of crucial importance for signal detection are electric shock-like sensations associated with the use of duloxetine, and persistent sexual dysfunction after discontinuation of selective serotonin reuptake inhibitors. An example of consumer reporting significantly strengthening a detected signal is Pandemrix® (influenza H1N1 vaccine)-induced narcolepsy.[20]

DEMERITS OF DIRECT CONSUMER ADR REPORTING

The demerits of consumer ADR reports are the lack of medical confirmation, which might impede the interpretation of ADR causation. For consumers, it seems that lack of awareness of the reporting mechanisms is a major limiting factor. To facilitate and promote adverse event reporting by consumers, education is the first step which may include posters in pharmacies, education in schools and community organizations, media promotion, and encouragement from health professionals. Reporting methods also need to be easy to access and user-friendly. Possibilities include a smartphone application that is part of a medication management system.[23]

However, greater participation in ADR reporting by consumers presents challenges. Among various challenges, it becomes important for a regulatory agency to be adequately resourced to respond to a larger number of consumer reports, to interpret the information provided, and to provide feedback or acknowledgement to the reporter. There is limited evidence from other jurisdictions to establish the value of such systems. The PV systems must be restructured to enable direct patient reports to be appropriately handled. That will require more staff, new training, and time. To be able to analyze patient reports, PV staff needs to learn to analyze qualitative data. Physicians, pharmacists, nurses and other health professionals will need to improve their roles as "information intermediaries" with patients and the public. They should accept a greater role in teaching patients, careers, and consumers how to think about medicines and to use them well.[23]

SENSITIZATION OF CONSUMERS FOR REPORTING ADRS

Raising public awareness of ADR reporting is important, but time - and resource-consuming. The minimum effort taken should be to passively inform consumers, e.g., via stakeholders' homepages and via drug product information leaflets. IPC has circulated posters, consumer ADR reporting leaflets and toll-free number through various AMCs. Direct patient awareness program is yet to start. Another possibility of reaching out to this target group could be through cooperation with other non-governmental organizations. Because education and awareness level among consumers are very poor. Only a few percentages of people can have the excess of internet. Without doing direct awareness program for consumers through print media, social media, the goals of PvPI cannot be successfully achieved.

Starting an active awareness program for consumers by healthcare professionals to explain the importance, function and purposes of the ADR reporting by consumers in India is a need of the hour. The IPC should increase the role of AMC and dedicated health-care professionals in this program to sensitize consumers or patients. This will result in increased knowledge and awareness about the harmful effects of drugs currently used in the country among prospective consumers.

Information from consumer reports may give a new perspective on ADRs via the consumers' unfiltered experiences. Consumers' views may change the way the benefit-harm balance of drugs is perceived and assessed today, and being the ultimate users of drugs, consumers could have a relevant influence in the regulatory decision-making processes for drugs. All stakeholders in PV should embrace this new valuable source of information.[20]

Objectives of consumer organization training in consumer ADR reporting can be:

1. To increase the capacity of consumer organizations to undertake consumer reporting of ADRs
2. To increase the number of consumer reports forwarded to the WHO ICSR database.

CONCLUSION

Consumer reporting of ADRs has existed in several countries for decades. Consumer reporting is an integral part of the spontaneous reporting systems with yearly numbers of reports constantly increasing. Knowledge of the factors influencing patient reporting to PV systems on a day-to-day basis has been increasing in recent years. The patients are no longer the passive recipients of drug therapy instigated by medical professionals. There is increasing patient engagement in individual decisions about their own drug

therapy, public discussions about the provision of high-cost drugs and increasing access to over-the-counter drugs. Consumer reporting forms and handling procedures are essentially the same as for health-care professional reporting; the message in the reports, not the type of messenger, is what is of importance.

With consumer reporting, ADRs are detected earlier, and therefore, more ADRs are reported, e.g., (over-the-counter) medicines. It can be a useful method to overcome under-reporting. Consumer reporting can be a good solution to overcome the limitation of the existing system based on health professionals reports. Reporting of ADR by consumers will promote consumer rights. Consumer reporting cannot replace the existing system, but can complement and strengthen it.

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