Advances in Pharmacoepidemiology & Drug Safety

Kalaiselvan et al., Adv Pharmacoepidemiol Drug Saf 2015, 4:3
DOI: 10.4172/2167-1052.1000184

Research Article Open Access

Direct Consumer Reporting of ADRs to PvPI, a Position Paper of Indian Pharmacopoeia Commission

Kalaivani M[1], Kalaiselvan V[2*], Dabhi K[3] and Singh GN[4]

[1]*Scientific Assistant, NCC-PvPI, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare (Govt. of India), Ghaziabad, India*
[2]*Principal Scientific Officer, NCC-PvPI, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare (Govt. of India), Ghaziabad, India*
[3]*Technical Associate, NCC-PvPI, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare (Govt. of India), Ghaziabad, India*
[4]*Drugs Controller General of India (DCGI), Central Drugs Standard Control Organisation (CDSCO), New Delhi and Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare (Govt. of India), Ghaziabad, India*

Abstract

Patients/consumers are end user of medicines and should play important role in reporting the Adverse Drug Reactions (ADRs) to pharmacovigilance system. Consumers can provide detailed first-hand in formation about their experiences with medicines and how these medicines have affected their life. Direct consumer reporting leads to earlier identification and accumulation of signals and may provide neglected details related to psychiatric feelings and quality of life. Consumers may report ADRs due to "over the counter" (OTC) medicines, herbal medicines, and ADRs related to excipients and potential interactions. Direct patient/ consumer reporting will also rectify the under-reporting by patients to physician and will change the attitude related to importance of patient's experience. NCC-PvPI (National Coordination Centre-Pharmacovigilance Programme of India), IPC (Indian Pharmacopoeia Commission) had launched "Medicines Side Effect Reporting form for Consumer" (blue form) at the National level conference on "Participation of patient/consumer organization in PvPI" on 1st August, 2014, which encourages patient or his/her representative (relative) to report ADRs directly either by submitting the form to the NCC-PvPI or to the nearest AMC (Adverse Drug Reaction Monitoring Centres) under PvPI. Consumers can also reports through toll free helpline number: 1800-180-3024 or email id: pvpi.compat@gmail.com to NCC-PvPI.

Keywords: ADR; Consumer reporting; NCC-PvPI; Pharmacovigilance

Introduction

The primary aim of pharmacovigilance is to identify new signals and to alert the health system regarding the same; in turn it enhances the quality of medical therapy and promotes the rational use of medicines for patients [1]. Adverse drug reactions (ADRs) are a major cause of morbidity and mortality worldwide [2,3]. About 0.3% to 11% patients hospitalized were due to ADRs [4,5]. Traditionally ADRs are reported to national pharmacovigilance system by healthcare professionals (HCPs) only but patients are the end users of the medicines, who have fundamental rights and equity to report the adverse or side effect they experience due to drug therapy.

Patients will provide unique experience and their perception of drug use, which may become a signal. To make use of patients experience during drug treatment various countries in the world encourages the consumer reporting system through forms, online data submission or telephone and included the same in spontaneous reporting system of the country [6]. Since 1964, Australia being whistle blower for including consumer/patients in spontaneous reporting system, almost 11 countries included patients in their system of pharmacovigilance and their experiences are favorable and significant. A well-documented data showed that only small proportion of HCPs contribute to the pharmacovigilance of the country as compared to the patients [7]. A report from UK also states the data received from patients/consumers directly were for long term, provides first line in formation on suspected ADRs and suspected Drugs as compared to Healthcare professionals (HCPs) [8,9]. World Health Organization (WHO) also developed a guideline for reporting of ADR by consumers/ patients directly [10].

Pharmacovigilance programme of India-IPC

Monitoring of ADRs are of great concern to the Indian healthcare system since 1998 and has become an official member of WHO Programme for International Drug Monitoring. Pharmacovigilance programme of India (PvPI) is launched in year 2010 to monitor the safety of medicines in the country. From the year 2011, Indian Pharmacopoeia Commission (IPC), an autonomous body under Ministry of Health and Family Welfare, Government of India is functioning as a National Coordination Centre (NCC) for PvPI. At present 150 adverse drug reactions monitoring centres (AMCs) are functioning and reporting the ADRs to the NCC by spontaneous reporting system through Vigiflow (a web-based system developed by WHO-UMC) [11].

India's existing system for monitoring ADRs relies on voluntary reporting by health care professionals as its main source of in formation and are encouraged to report by submitting 'Suspected Adverse Drug Reaction Reporting form for Healthcare Professionals' (red form) available from official websites of IPC and CDSCO such as www.ipc.gov.in and www.cdsco.nic.in, respectively [11,12]. Traditionally, physicians have been the major source of spontaneous reports of ADRs but currently PvPI encourages other HCPs and pharmaceutical industries also to submit ADR reports to NCC.

***Corresponding author:** Kalaiselvan V, Principal Scientific Officer, NCC-PvPI, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare (Govt. of India), Ghaziabad, India, Tel: 0120-2783400; Fax: 0120-2783311; E-mail: vivekarts@rediffmail.com

Received April 29, 2015; **Accepted** May 20, 2015; **Published** May 23, 2015

Citation: Kalaivani M, Kalaiselvan V, Dabhi K and Singh GN (2015) Direct Consumer Reporting of ADRs to PvPI, a Position Paper of Indian Pharmacopoeia Commission. Adv Pharmacoepidemiol Drug Saf 4: 184. doi:10.4172/2167-1052.1000184

Consumer reporting to PvPI

A report states that developing countries report contributes only for 3% of report as compared to developed countries, this problem of underreporting could be reduced by promoting direct consumer reporting [13,14]. Developed countries (e.g. Australia, Canada, Denmark, Netherlands, Sweden, United Kingdom, and United States) consumers are being encouraged to report adverse reactions to medicines through spontaneous reporting system [15]. In order to strengthen the patient safety and direct participation of consumer/patient in pharmacovigilance programme, NCC-PvPI has recently launched "Medicines Side Effect Reporting form for Consumer" (blue form) at the National level conference on "Participation of patient/consumer organisation in PvPI" at IPC on August 1, 2014. Patient or his/her representative (relative) are encouraged to report ADRs either directly to the NCC - PvPI through toll free helpline number: 1800-180-3024 or email id: pvpi.compat@gmail.com or to their nearest AMC under PvPI by submitting 'Medicines Side Effect Reporting form for Consumers' (blue form) which can be downloaded from the official website of IPC www.ipc.gov.in (Figure 1) [11].

Promoting direct ADR reporting by patients/consumers is initiated on pilot scale basis across all the 150 AMC under PvPI to gauge the impact it creates among the patients and on whether the patients/consumers are comfortable with the module and form. On successful analysis of this pilot scale reports NCC-PvPI plans to promote it across

Version 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

1. Patient Details

Patient Initials: ☐☐ | Gender (√): Male ☐ Female ☐ Other ☐ | Age (Year or Month) :

2. Health Information

a. Reason(s) for taking medicine(s)(Disease/Symptoms):

b. Medicines Advised by (√): Doctor ☐ Pharmacist ☐ Friends/Relatives ☐ Self (Past disease experienced/No past disease experienced) ☐

3. Details of Person Reporting the Side Effect

Name (Optional):

Address:

Telephone No: | Email:

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form (√) : Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐ If Others (Please Specify.....)

5. About the Side Effect

When did the side effect start? dd/mm/yy | Side Effect is still Continuing (Yes/No): ☐

When did the side effect stop? dd/mm/yy

6. How bad was the Side Effect? (Please √ the boxes that Apply)

☐ Did not affect daily activities | ☐ Affect daily activities

☐ Admitted to hospital | ☐ Death

☐ Others

7. Describe the Side Effect (What did you do to manage the side effect?)

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

Please turn the page to read the instructions

Figure 1: MEDICINES SIDE EFFECT REPORTING form (For Consumers)

In formations	Medicines side effect reporting form (For consumers) (blue form)	Suspected Adverse Drug Reaction Reporting form for Healthcare Professionals (Red form)
Height of patient	×	√
Relevant tests / laboratory data	×	√
Other relevant history	×	√
Manufacture details of drugs	×	√
Dosage form of the drug	√	×
Concomitant drug in formation	×	√
Seriousness of the ADR	√ (Affect/not affect daily activities, admitted to hospital, death, others)	√ (Death (dd/mm/yyyy),life threatening, hospitalization-initial or prolonged, disability, congenital anomaly, required intervention to prevent permanent impairment / damage, other)
Dechallange and rechallange in formation	×	√
Outcomes	×	√
Causality Assessment	×	√

Table:1 Differences between the 'Medicines Side effect reporting form for Consumer' and 'Suspected Adverse Drug reaction Reporting form For Health Care Professional'.

the country on an active manner for the benefit of patients/consumer, a sole user of medicines.

As of now, there are two forms available for reporting of ADRs; one is red form 'Suspected adverse drug reaction reporting form for healthcare professionals' and another is blue form 'Medicines side effect reporting form (For consumers)' is for consumers/ patients to report adverse events due to medicinal and health products administration. Language used in the consumer reporting form is very simple and understandable by the amateur and can report ADR in non-technical words and is less descriptive as compared with suspected adverse drug reaction form for health care professionals (Table 1) [11]. NCC will be revising or amending the form periodically as per the suggestions or comments received from the stakeholders, to make it better acceptable. After the release of consumer reporting form in English, NCC–PvPI released first version of "Medicines Side Effect Reporting form for Consumer" in different regional languages (Hindi, Bengali, Tamil, Gujarati, Kannada, Oriya and Malayalam). The objective is to encourage the important role of consumers/patients as a key partner to enhance the ADRs reporting without the issue of any language barrier [11].

Consumers while calling to NCC-PvPI through the PvPI helpline number, the designated person at NCC-PvPI will collect reporter's in formation such as name, type of reporter, address and contact details, age, sex and the reaction as it is described by reporter to make the report more authentic and will be helpful further during data analysis. These in formations were collected in Suspected ADR reporting form and will be mailed to nearest AMC for further follow up and validation of the report [11]. After that ICSR data can be entered manually into VigiFlow with support from latest version of terminologies such as WHO-Drug Dictionary for coding of drugs and WHO-Adverse Drug Reaction Terminology, used for coding of Adverse Drug reaction. Once the data regarding ADR reporting is entered into the VigiFlow, the first version of ICSRs is generated and it will automatically saved in Vigibase (WHO Global ICSRs Database). Vigibase is updated with incoming ICSRs on continuous basis. It is easy to retrieve the reports for amend the content or add follow-up in formation [11]. The in formation available in Vigibase is now also accessible by the general public by using "VigiAccess" i.e, database that allows viewing the data on suspected side effect from various medicines and vaccines.

Significance of consumer reporting

HCPs may usually report ADRs from hospitalized patients but consumers will report the effects that they experience in their day-to-day activities. Also it may not be possible for HCPs to capture the ADRs due to self medication, OTC products, herbal medicines, excipients or their potential interactions [8-10]. Direct consumer reporting leads to earlier identification and accumulation of signals [16], provide first line and new in formation, safety in formations unfiltered through the view of HCPs, may provide different details particularly nervous system related [17], psychiatric feelings and quality of life (emotional, social impact etc.) which are important and often neglected. It will also be helpful in identifying how the medicines are actually used and can also highlight issues around lack of adherence (compliance). Direct patient/consumer reporting will also rectify the under-reporting by patients to physician and will change the attitude related to importance of patient's experience [18]. Consumers are active players in drug safety and key stakeholders in relation to pharmacovigilance and can actively contribute through an integrated and efficient reporting system. Direct reporting is an essential tool to empower consumers and to improve their involvement in the management of their own health.

Challenges

Various studies state that direct consumer reporting may result in reporting of unspecific symptoms like indisposition, dizziness and insomnia and consumers may use lay terminology for describing the symptoms, which may lead to data inappropriate for causality analysis [19]. To rectify these limitations NCC-PvPI encourages the consumers to report nearest AMCs and the reports received at NCC-PvPI directly from patients will be reverted to concern AMC for further follow up action to collect complete detail of the ADR and patient. Another challenge faced by consumers is poor knowledge regarding drugs and their reactions especially severe in India where lack of education and illiteracy are widespread. Medical mysticism is still dominant, characterized by a desire to maintain secrecy around medical facts and thinking. Good governance may be another hindering factor for proper development of such programs. Lack of funding to run, establish and ensure good atmosphere for pharmacovigilance centre and create safety culture among health professionals and public, lack of human resources dedicated for pharmacovigilance program is another major constraint.

Conclusion

Safety of medicines or patient safety cannot be addressed unless otherwise patients are not actively involved in pharmacovigilance,

therefore PvPI initiated to move with patients as key stakeholders through a separate side effect reporting form for consumers. To create awareness among public on reporting ADRs is the biggest challenge a head. NCC is intended to organize workshop/meetings in collaboration with professional bodies and NGOs/ consumer forum representatives and also through media and by other modes is need of an hour.

References

1. WHO (2002) Viewpoint Part 1: Issues, controversies and science in the search for safer and more rational use of medicines. Sweden, Europe.
2. Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR, et al. (2009) Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patient-episodes. PLoS One 4:e4439.
3. Davies EC, Green CF, Mottram DR, Pirmohamed M (2007) Adverse drug reactions in hospitals: a narrative review. Curr Drug Saf 2:79-87.
4. WHO (2002) The importance of pharmacovigilance - Safety Monitoring of Medicinal Products 146-157.
5. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP et al. (1997) Adverse Drug Events in Hospitalized Patients Excess Length of Stay, Extra Costs, and Attributable Mortality. JAMA 277:301-306.
6. Robertson J, Newby DA (2013) Low awareness of adverse drug reaction reporting systems: a consumer survey. Med J Aust 199: 684-686.
7. Necho W, Worku A (2014) Assessment of Knowledge, Attitude and Practice of Health Professionals towards Adverse Drug Reaction Reporting and Factors Associated with Reporting. J Pharmacovigilance 2:135.
8. McGuire T, Moses G. What do consumers contribute to pharmacovigilance? Lessons from the AME line. Conference Proceedings, National Medicines Symposium, National Convention Centre, Canberra 7–9 June 2006.
9. Blenkinsopp A, Wilkie P, Wang M, Routledge PA (2006) Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. Br J Clin Pharmacol 63:148-156.
10. WHO Drug In formation (2000) Consumer reporting of adverse drug reactions. General Policy Issues 14.
11. www.ipc.gov.in
12. www.cdsco.nic.in/ forms/
13. Fernandopulle RB, Weerasuriya K (2003) What can consumer adverse drug reaction reporting add to existing health professional-based systems? Focus on the developing world. Drug Saf 26:219-225.
14. http://www.lareb.nl/LarebCorporateWebsite/media/publicaties/kwb_2002_2_ssris.pdf.
15. van Hunsel F, Härmark L, Pal S, Olsson S, van Grootheest K (2012) Experiences with Adverse Drug Reaction Reporting by Patients An 11-Country Survey. Drug Saf 35: 45-60.
16. Aagaard L, Nielsen LH, Hansen EH (2009) Consumer reporting of adverse drug reactions: a retrospective analysis of the Danish adverse drug reaction database from 2004 to 2006. Drug Saf 32: 1067-1074.
17. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A et al. (2011) Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technol Assess 15: 1-234.
18. Hammond IW, Rich DS, Gibbs TG (2007) Effect of Consumer Reporting on Signal Detection: using disproportionality analysis. Expert Opin Drug Saf 6:705–712.
19. Aagaard L, Hansen EH (2010) Consumers' reports of suspected adverse drug reactions volunteered to a consumer magazine. Br J Clin Pharmacol 69: 317-318.