Review Article

Pharmacovigilance: Needs and Objectives

Ankur Rohilla*, Nishant Singh, Vipin Kumar, Mohit Kumar Sharma, Amarjeet Dahiya, Ashok Kushnoor

Department of Pharmaceutical Sciences, Shri Gopi Chand Group of Institutions, Baghpat-250609, UP, India

J. Adv. Pharm. Edu. & Res.

ABSTRACT

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, and prevention of adverse drug reactions in humans. Pharmacovigilance has been regarded as a type of continual monitoring of unwanted effects and other safety-related aspects of drugs, which are already placed in markets. The pharmacovigilance has been known to play an important role in rational use of drugs, by providing information about the adverse effects possessed by the drugs in general population. The present review presents in brief about the relevance, need, functioning, role, and importance of pharmacovigilance.

Key words: Pharmacovigilance, Adverse Drug Reactions

INTRODUCTION

The under-reporting of adverse drug reactions is the major setback worldwide which may be attributed to the lack of time and report forms. It has been known that world health organization (WHO) has initiated the program of reporting all adverse reactions possessed by the drugs. [1] The further awareness about the adverse drug reactions resulted in emergence of the practice and science of pharmacovigilance, which can be defined as the science of detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems. [2-3] It is widely accepted that a drug has to go through various phases of clinical trial to establish its safety and efficacy before it is marketed commercially. However, the clinical trials offer various limitations, like; strict criteria of inclusion and exclusion make it to be used in a very selective group of patients; special population groups like children, pregnant woman, and old age population are not studied during the trials; and other factors causing drug reactions such as genetic factors, environmental factors, and drug-drug interactions may not have been studied during the clinical trials. [4] Hence, need of pharmacovigilance has been demanded, which include the detection, assessment, and prevention of adverse drug reactions in humans. [5-6] Moreover, its concerns have been widened to include the herbal drug products; traditional and complementary medicines; blood products; biologicals; medical devices; and vaccines. In addition, pharmacovigilance possess various roles like, identification, quantification and documentation of drug-related problems which are responsible for drug-related injuries. [7-8] Further, national pharmacovigilance programmes have been introduced which occupies a prime role in increasing the public awareness about drug safety. [9-10] This review article discusses about the need and objectives of pharmacovigilance in day-to-day lives. Additionally, various adherents and followers of pharmacovigilance have been argued in the present review.

Address for correspondence

Ankur Rohilla, Senior Lecturer (Pharmacology), Dept. of Pharmaceutical Sciences,
Shri Gopi Chand Group of Institutions, Baghpat 250609, UP, India. Tel.: +91 9896516778
E-mail: ankurrohilla1984@rediffmail.com

Access this article online
www.japer.in

NEED OF PHARMACOVIGILANCE

It is widely accepted that clinical development of medicines is a complex process which require huge amount of time for its completion. Once a drug is marketed, it leaves the secure and protected scientific environment of clinical trials and is free for consumption by the general public. At this point, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. Hence, need of pharmacovigilance arises which include, securing the early detection of new adverse reactions or patients subgroups of exceptional sensitivity; and introducing certain measures in order to manage such risks. [11] Moreover, it is essential that new and medically still evolving treatments are monitored for their effectiveness and safety under real-life conditions after being marketed. Furthermore, more information is generally needed about use in specific population groups like children, pregnant women and the elderly, about the efficacy and safety of chronic use in combination with other drugs. [12-13] Numbers of adverse effects, drug-interactions and risk factors have been reported later in the years of drug release (Table 1).

OBJECTIVES OF PHARMACOVIGILANCE

Improvement of patient care and safety in relation to the use of medicines with medical and paramedical interventions remains to be an important parameter. The main objectives of pharmacovigilance involve exhibiting the efficacy of drugs by monitoring their adverse effect profile for many years from the lab to the pharmacy; tracking any drastic effects of drugs improving public health and safety in relation to the use of medicines; encouraging the safe, rational and cost-effective use of drugs; promoting understanding, education and clinical training in pharmacovigilance; and effective communication to the generic public. [14] In addition, providing information to consumers, practitioners and regulators on the effective use of drugs alongwith designing programs and procedures for collecting and analyzing reports from patients and clinicians conclude to the objectives of pharmacovigilance studies. [3,14]

ROLES OF PHARMACOVIGILANCE

Pharmacovigilance has been widely accepted to possess a significant role in early observation of the risk associated with the drug. All the medicines are tested on a concerned small ratio of population before it is approved for post-marketing surveillance. The pharmacovigilance has been known to possess various roles like, identification, quantification and documentation of drug-related problems; contribution towards reducing the risk of drug-related problems in healthcare systems; and enhancement of knowledge and understanding of factors and mechanisms which are responsible for drug-related injuries. [4] However, in order to fulfill various roles of pharmacovigilance, the interactions and influence of many stakeholders in society with decision-making powers has been required, which include, politicians at national, regional and local levels; healthcare administrators; drug regulatory authorities; pharmaceutical companies; healthcare professionals like physicians, dentists, pharmacists and nurses; academic institutions; media representatives; health insurance companies; lawyers; and patient group. [15]

ADHERENTS OF PHARMACOVIGILANCE

An imperative relationship has been known to exist between wide ranges of partners in drug safety monitoring process. These partners are required to anticipate, understand and respond to the continually increasing demands and expectations of the public, health administrators, policy officials, politicians and health professionals. [14] Numbers of adherents of pharmacovigilance have been widely known, which involve the quality assurance and safety centres, which are a part of the Department of Essential Drugs and Medicines Policy, within the WHO Health Technology and Pharmaceuticals cluster, the purpose of which is to improve health by closing the huge gap between the potential that essential drugs have to offer and help save lives. [16] Another important follower of pharmacovigilance is the uppsala monitoring centre, the principal function of which is to manage the international database of adverse drug reports received from national centers. [17] The national pharmacovigilance centers have been considered as another adherent of pharmacovigilance that play a significant role in increasing public awareness of drug safety. Major centers in developed countries have established active surveillance programmes using record linkage and prescription event monitoring systems to collect epidemiological information on adverse reactions to specific drugs. [18-19] A number of medical institutions have developed adverse reaction and medication error close watch systems in their clinics, wards and emergency rooms, during which various case-control studies and other pharmacoepidemiological methods have increasingly been used to estimate the harm associated with marketed medicines. [20-22] Other important followers of pharmacovigilanve are the health professionals: Originally physicians were the only professionals who observe different kinds of drug related problems by exercising the skill of differential diagnosis. [23-24] Last of all, the patients form the most important adherent of pharmacovigilance as, a patient knows the actual benefit and harm of a medicine prescribed to him. Direct patient participation in the reporting of drug related problems has increased the efficiency of the pharmacovigilance system significantly. [25]

PHARMACOVIGILANCE PROGRAMME

The national pharmacovigilance system plays a vital role in increasing public awareness of drug safety. However, minimum requirements for a functional national pharmacovigilance system are required which include a national pharmacovigilance centre with designated staff, stable basic funding, clear mandates, well defined structures and roles and collaborating with the WHO programme for international drug monitoring; the existence of a national spontaneous reporting system with a national individual case safety report (ICSR) form; a national database or system for collating and managing adverse drug reaction reports; a national pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation; and a clear communication strategy for routine communication and crises communication. [14,26-27] However, the national pharmacovigilance system has been known to exhibit various functions which include, promoting pharmacovigilance in the country in

orderto collect and manage adverse drug reaction; reporting of medication errors and suspected substandard drugs; collaborating and harmonizing with existing adverse reaction collection activities within the country; identifying signals of medicine safety; undertaking assessment of risk and options for risk management; identifying the possible quality problems in medicines resulting in adverse reactions; supporting the identification of medicine quality issues; providing effective communication on aspects related to medicine safety; applying resulting information from pharmacovigilance for the benefit of public health programmes, individual patients and national medicines policies and treatment guidelines; developing and maintaining drug utilization information; and identifying issues associated with unregulated prescribing and dispensing of medicines. [28-30]

CONCLUSION

Pharmacovigilance play an important role in meeting the challenges offered by the increased range and potency of medicines. After the appearance of adverse effects and drug toxicities, it is essential that these are reported, analyzed and communicated to the general public having knowledge to interpret the information. Although, a significant amount of information regarding the effective use and adverse reactions has been collected, but more information is required in order to offer effective drug use in specific populations like children, pregnant women and the elderly. Moreover, providing the regulators with the necessary information to amend the recommendations on the use of the medicines; improving communication between the health professionals and the public; and educating the health professionals to understand the effectiveness and risk of medicines they prescribe, is the need of the moment.

Table 1: Common Drug Interactions

Class of Drugs	Effects
Tetracycline	Poor absorbtion of tetracyclines
Amino glycoside	Hearing problem, kidney problem
Anti diabetic	Lower blood sugar
Warfarin	Increased risk of bleeding
Phenytoin	CNS and Respiratory depression
Barbiturates	Muscle weakness,Reduced consciousness, coma
Lithium	Hypothermia
Alprazalon, Diazepam	CNS depression, sedation
Warfarin	Haemorrhage
Methotrexate	Bone marrow suppression
Benzodiazepines	Sedation and Respiratory suppression
Ethanol	Additive CNS effect, Death
Predmisone	Edema
Theophyllines	Insomnia, seizures, restlessness
Miconazole	Severe hypoglycaemia

REFERENCES

1. WHO Policy Perspectives on Medicines. Geneva: WHO; 2004. Geneva: World Health Organization. Looking at the Pharmacovigilance: ensuring the safe use of medicines.
2. Klepper MJ. The periodic safety update report as a pharmacovigilance tool. Drug Saf 2004;27:569-78.
3. Livio F, Renard D, Buclin T. Pharmacovigilance. Rev Med Suisse 2012;8:116-9
4. Pharmacovigilance. Mann RD, Andrews EB, eds. John Wiley & Sons Ltd, Chichester, 2002.
5. Harmark L, van Grootheest AC. Pharmacovigilance: Methods, recent developments and future perspectives. Eur J Clin Pharmacol 2008;64:743-52.
6. Biswas P, Biswas A. Setting standards for proactive pharmacovigilance in India: The way forward. Ind J Pharmacol 2007;39:124-8.
7. Skalli S, Soulaymani Bencheikh R. Safety monitoring of herb-drug interactions: a

component of pharmacovigilance. Drug Saf 2012;35:785-91.

8. Arnott J, Hesselgreaves H, Nunn AJ, Peak M, Pirmohamed M, Smyth RL, et al. What can we learn from parents about enhancing participation in pharmacovigilance?. Br J Clin Pharmacol 2012; in press.
9. Gerritsen R, Faddegon H, Dijkers F, van Grootheest K, van Puijenbroek E. Effectiveness of pharmacovigilance training of general practitioners: a retrospective cohort study in the Netherlands comparing two methods. Drug Saf 2011;34:755-62.
10. Kshirsagar N, Ferner R, Figueroa BA, Ghalib H, Lazdin J. Pharmacovigilance methods in public health programmes: the example of miltefosine and visceral leishmaniasis. Trans R Soc Trop Med Hyg 2011;105:61-7.
11. The importance of pharmacovigilance. Geneva: World Health Organization; 2002.
12. Joshi SR, Sapatnekar SM. Pharmacovigilance in India: how safe are the new drugs? How sure are we?. J Assoc Physicians Ind 2008;56:933-4.
13. Olsson S. Pharmacovigilance training with focus on India. Ind J Pharmacol 2008;40: S28-S30.
14. WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
15. The Importance of Pharmacovigilance, WHO 2002.
16. WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003.
17. Olsson S. The role of the WHO Programme for International Drug Monitoring in coordinating worldwide drug safety efforts. Drug Saf 1998;19:1-10.
18. Coulter DM. The New Zealand intensive medicines monitoring programme in proactive safety surveillance. Pharmacoepidemiol Drug Saf 2000;9:273-80.
19. Mackay FJ. Post-marketing studies: The work of the drug safety research unit. Drug Saf 1998;19:343-53.
20. Folb PI, ten Ham M. Drug monitoring in developing countries: A drug regulator's perspective. Drug Inf J 1995;29:303-5.
21. Talbot JC, Nilsson BS. Pharmacovigilance in the pharmaceutical industry. Br J Clin Pharmacol 1998;45:427-31.
22. Moore N. The role of the clinical pharmacologist in the management of ADRs. Drug Saf 2001;24:1-7.
23. Hall M, McCormack P, Arthurs N, Feely J. The spontaneous reporting of ADRs by nurses. Br J Clin Pharmacol 1995;40:173-5.
24. Hornbuckle K, Wu HH, Fung MC. Evaluation of spontaneous adverse event reports by primary reporter: A 15-year review (1983 to 1997) Drug Inf J 1999;33:1117-24.
25. Jeetu G, Anusha G. Pharmacovigilance: a worldwide master key for drug safety monitoring. J Young Pharm 2010;2:315-20.
26. WHO. Safety monitoring of medicines. Guidelines for setting up and running a pharmacovigilance centre. Geneva, World Health Organization, 2000.
27. Department of CDSCO, Ministry of health & family welfare, Government of India: Protocol for national pharmacovigilance programme, November 2004.
28. WHO. The World Health Organization Collaborating Centre for International Drug Monitoring [web site]. The World Health Organization Collaborating Centre for International Drug Monitoring, Uppsala.
29. Biswas P. Pharmacovigilance: Safety matters. Ind J Phamacol 2008;40:1-2.
30. Dikshit RK. Challenges in pharmacovigilance. Ind J Pharmacol 2010;42:333.

Ankur Rohilla, Nishant Singh, Vipin Kumar, Mohit Kumar Sharma, Amarjeet Dahiya, Ashok Kushnoor; Pharmacovigilance: Needs and Objectives, J. Adv. Pharm. Edu. & Res. 2012: 4: 201-205

Source of Support: Nil, **Conflict of Interest:** Nil