MEDWIN PUBLISHERS
Committed to Create Value for Researchers

Nursing & Healthcare International Journal
ISSN: 2575-9981

Pharmacovigilance and Nursing context: "Nothing less than Safety"

Singh M[1], Kumar S[2] and Pareek S[3]*

[1]Quadra Institute of Nursing, India
[2]Bhagwan Mahaveer Cancer hospital & research Centre, India
[3]Indian Railway Health Services, India

***Corresponding author:** Shatrughan Pareek, Indian Railway Health Services, Bikaner, Rajasthan, India, Email: shatrughan.pareek@gmail.com

Review Article
Volume 5 Issue 1
Received Date: January 18, 2021
Published Date: February 01, 2021
DOI: 10.23880/nhij-16000232

Abstract

Adverse drugs reactions are major public health concern in worldwide. Pharmacovigilance is a complex process of clinical and scientific discipline that ensures the safety of the medication and avoids adverse drug reactions. Poly-pharmacy, poly-physician, co-morbidities, drug administration errors, use of over the counters (OTCs) drugs, lack of awareness about medications are major cause of the reactions. India joined hand with WHO-UPPSALA in 1997 with the aim to improve the safety of drugs and health of the patients. Despite global concern regarding drug safety there is a lack of understanding and knowledge and reporting of Adversed Drug Reactions (ADRs) among health care professionals. Nurses serve as advocates for the health and safety of patients and may play a crucial role in the pharmacovigilance system & avoiding the mitigating the risks to the patient, promoting public health and determining and maintaining the safety of medicines. Nurses need appropriate knowledge and experience in the field of health care setting including early identification, management and reporting of medicine safety issues and should have a combination of pharmacovigilance training and participating in research studies.

Keywords: Pharmacovigilance; India; Adverse drug reactions; Nurses; Patients; Healthcare Professionals

Abbreviations: OTCs: Over The Counters; ADRs: Adversed Drug Reactions; AMC: ADRs Monitoring Center; IPC: Indian Pharmacopoeia Commission; NCC: National Co-ordination Center.

Introduction

Medications safety & High quality medical care is the core element of healthcare. Pharmacovigilance is a complex process of clinical and scientific discipline that ensures the safety of the medication and avoids adverse drug reactions. Adverse drugs reactions are major public health concerned in worldwide and India has 7th rank in contribution (3%) to the global safety database for year 2013 [1]. Claude Bernard was great Physiologist once said "Everything is poisonous, Nothing is poisonous" all depends on dose that we used [2]. Poison can be used as a medicine in proper dose. No drug is poisonous and No drugs is safe it means Safety and efficacy of a drug depends on the dose of drug & adverse Drugs Reactions are major cause of Morbidity and Mortality in Human beings [3]. According to DJP Barker "There are three mechanism of action of a drug The one we want, the one we don't want and the one we don't know about" [4]. The WHO promoting pharmacovigilance along with Collaborating Center for International Drug Monitoring, Uppsala with various countries of world [5]. According to WHO: Pharmacovigilance is the science and Activities relating to the Detection, Assessment, Understanding and Prevention of Adverse effects of drugs [6]. Pharmacovigilance is the science of collecting, monitoring, researching, Assessing and evaluating information from healthcare providers and patients on the adverse reaction of medications, Biological

products [7]. According to WHO: A response to a drug which is noxious and unintended and occurs at dose normally used in main for prophylaxis, diagnosis or therapy of disease or for modification of physiological function [8]. Adverse drug reactions are toxic, Noxious and unwanted side effects of a drug and ADRs are huge challenges related to drugs and biomedical products in the 21st Century in Healthcare settings and for public health. Poly-pharmacy, poly-physician, co-morbidities, Drug Administration errors, insufficient experimental Research evidence or data related to drugs and use of OTCs drugs, lack of Awareness about medications are major cause of ADRs [9]. In India, 0.7% of ADRs are the main cause of hospital admission and 3.7% of hospitalized patients experience ADRs & 1.8% of ADRs count fetal ADRs [10]. Research has shown that adverse drug reactions are the fourth to sixth leading cause of human mobility [11]. ADRs account for approximately 5-15% of all hospital admissions and an average death rate of 2.7% due to ADRs [12] and 10-20% hospitalized patients faced ADRs in the worldwide [13].

Pharmacovigilance in India

The National Pharmacovigilance Program was established in India in Jan.2005 with the primary objective of promoting safe drug use in healthcare setting and setting up more reporting centers for ADRs in India [9]. It has two zone centers, one is the South-West zone centre, and the North-East Zone Center. Both zones collect all ADR information and report it to the Gajiabhad (U.P.) Indian Pharmacopeia Commission [11]. This improves the safety of patients and provides a vital knowledge database for Indian regulators. India joined forces with WHO-UPSALLA in 1997 with the aim of improving the safety of drugs and health of patients in India [12].

Adverse Drug Reactions Reporting Process in India

ADRs monitoring center (AMC): ADR reporting rooms are set up in each Medical College, Private Hospital and District Hospital under India's National Pharmacovigilance Program. In the adverse drug reactions reporting room, any suspected ADRs must be reported and all suspected ADR information is recorded in the AMC through Vigiflow software.

National co-ordination center (NCC): Indian Pharmacopoeia Commission (IPC) acts as an NCC. All ADRs Monitoring Centers report their Information to NCC.

WHO-upsalla monitoring center (Sweden): It is the World Pharmacovigilance Coordination Center for all countries. NCCs report or share all ADR-related data to UPSALLA from all countries. It conducted research & analysis the data of drug-specific and adverse drug effects such as severity of ADRs, common side effects, lethal life threading side effects, new side effects and issue new information to FDA about drug on modifications, warning, black box warning and drug withdrawal from the market [9].

Role of Nursing Professionals in Pharmacovigalance

Recent studies have shown that ADRs are poorly documented especially in developing countries by health care providers and is despite global concern regarding drug safety there is a lack of understanding and knowledge and reporting of ADRs among health care professionals. Singh J, et al. conducted a cross-sectional questionnaire-based study among young health care professionals in North India. The responses were collected from doctors and nursing professionals. The study revealed that only 26.1% nurses were oriented of ADR reporting system in India, while 61% nurses reported an ADR. The main discouraging factor in ADR reporting was time constraint while lack of knowledge was also highlighted by the HCPs. The researchers emphasized on the urgent need of awareness program regarding pharmacovigilance and its practices [13]. Additionally, a descriptive study was conducted by Wadivkar PP, et al. to assess the knowledge towards pharmacovigilance among the nurses. Out of 100 nurses, only 63% subjects were familiar about the term pharmacovigilance while 41% of these could correctly define it. Furthermore, knowledge regarding ADR was limited (39%) among the nurses. Majority of the subjects (76%) were not aware of any National Programme of Pharmacovigilance. The study focused on the major drawbacks in efficient ADR reporting system and adequate training [14]. Bigi C, et al. conducted a study to assess the reporting of ADRs by community nurses. ADR reports by the nurses in few nations are evaluated in terms of quality & numbers. Data on ADRs reporting by community nurses are recently limited. However, various studies emphasized the challenges faced by the nurses in reporting the reactions. The investigators highlighted that nurses should play central roles in pharmacovigilance activities, mainly in identifying ADRs [15]. Nurses serve as advocates for the health and safety of patients and may play a vital role in the pharmacovigilance system, as nurses are frontline health care provider who spend much of their time with patients can play a crucial role in avoiding, mitigating the risks to the patient, promoting public health and determining and maintaining the safety of medicines. In order to ensure patient and medication safety, nurses needed appropriate knowledge and experience in the field of health care environment including early identification, management and reporting of medicine safety issues and should have a combination of pharmacovigilance training and research study.

Discussion

Establishment of national pharmacovigilance systems for the reporting of adverse events are important for patient's safety which ensures safe clinical practice of drugs and provides the guarantee of drug safety through regulatory agencies [16]. It play crucial role in safety related to clinical trials, pre marketing, post marketing surveillance, help in Monitoring & early detection of post marketing adverse drug reactions which required improve patients care, safety in clinical setting and Public Health care setting through identification and reporting of new ADRs & conducts researches, understand mechanism of actions of ADRs & keep up to date information about adverse drug reactions to the health personnel and public [17]. It is also a vital tool for generating more awareness in public about benefits and risks associated with use of drugs. It helps in identification of early adverse drug reactions and encourages spontaneous reporting of ADRs to patient's safety reporting system & developed nationwide center to promote patients safety reporting system and improve communications system with National and International agencies working in pharmacovigilance [18]. Nurses are the key stakeholders in health-care settings so, it is their orientation and knowledge towards pharmacovigilance is vital for the community.

Conclusion

Adverse drugs reactions are a major public health concern worldwide and India has 7th rank in contribution (3%) to the global safety database for 2013. WHO promotes pharmacovigilance along with Collaborating Center for International Drug Monitoring, Uppsala? Adverse drug reactions are toxic, Noxious and unwanted side effects of a drug and ADRs are huge challenges related to drugs and biomedical products in the 21st Century in Healthcare settings and for public health. ADRs account for approximately 5-15% of all hospital admissions and an average death rate of 2.7% due to ADRs. Establishment of national pharmacovigilance systems for the reporting of adverse events is important for patient's safety. It ensures safe clinical practice of drugs and provides the guarantee of drug safety through regulatory agencies. It is also a vital tool for generating more awareness in public about benefits and risks associated with use of drugs. It helps in identification of early adverse drug reaction and encourages spontaneous reporting of ADRs. It also helps in Monitoring & early detection of post marketing adverse drug reactions. To enhance the ADR reporting among nursing professionals, it is suggested that planned, education and training programmes should be there at different levels for nurses on pharmacovigilance and ADR reporting. Moreover, the continuous availability of ADR reporting forms in the hospital settings will increase ADR reporting.

Funding: Self-funded

Acknowledgement: Nil

Conflict of Interest: Nil

Competing Interest: None

Contributor's Statement

Mr. Shatrughan Pareek would act as the overall guarantor and the corresponding author of the manuscript.

References

1. Ahmed B, Nanji K, Mujeeb R, Patel MJ (2014) Effects of Polypharmacy on Adverse Drug Reactions among Geriatric Outpatients at a Tertiary Care Hospital in Karachi: A Prospective Cohort Study. PLoS ONE 9(11): e112133.

2. Bhalla N, Duggan C, Dhillon S (2003) The incidence and nature of drug-related admissions to hospital. Pharmaceutical Journal.

3. McKenney JM, Harrison WL (1976) Drug-related hospital admissions. Am J Hosp Pharm 33(8): 792-795.

4. WHO (2002) The importance of pharmacovigilance. World Health Organization, UK.

5. Thind M, Kowey PR (2020) The Role of the Food and Drug Administration in Drug Development: On the Subject of Proarrhythmia Risk. J Innov Card Rhythm Manag 11(1): 3958-3967.

6. James H. Kim, Anthony R. Scialli (2011) Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease. Toxicological Sci 122(1): 1-6.

7. Goldman DA (2001) Thalidomide use: past history and current implications for practice. Oncol Nurs Forum 28(3): 471-477.

8. Sturm JM, Temprano J (2014) A survey of physician practice and knowledge of drug allergy at a university medical centre. J Allergy Clin Immunol Pract 2(4): 461-464.

9. Adithan C (2005) National Pharmacovigilance programme. Indian J Pharm 37(6).

10. WHO (2020) The Importance of Pharmacovigilance, World Health Organisation, Geneva, pp: 48.

11. Atul Kumar (2017) Pharmacovigilance: Importance, concepts, and processes. Am J Health-Sys Pharm 74(8):

606-612.

12. Pipasha B, Biswas AK (2007) Setting standards for proactive pharmacovigilance in India: The way forward. Indian J Pharmacol 39(3): 124-128.

13. Singh J, Singh H, Rohilla R, Kumar R, Gautam CS (2018) Lack of awareness of pharmacovigillance among young health-care professionals in India: An issue requiring urgent intervention. Int J App Basic Med Res 8(3): 158-163.

14. Wadivkar PP, Zad VR, Vakharia MP, Shah KU (2015) Assessment of knowledge of pharmacovigilance among the nurses of tertiary care hospital. Int J Basic Clin Pharmacol 4(6): 1194-1197.

15. Bigi C, Bocci G (2017) The key role of clinical and community health nurses in pharmacovigilance. Eur J Clin Pharmacol 73(11): 1379-1387.

16. Dangoumau J, Evreux JC, Jouglard J (1978) Mehtod for determination of undesirable effects of drugs. Therapies 33(3): 373-381.

17. Hutchinson TA, Dawid AP, Spiegelhalter DJ, Cowell RG, Roden S et al. (1991) Computerized aids for probabilistic assessment of drug safety: I. A spreadsheet program. Drug Inf J 25(1): 29-39.

18. Hutchinson TA, Dawid AP, Spiegelhalter DJ, Cowell RG, Roden S (1991) Computerized aids for probabilistic assessment of drug safety: I. A spreadsheet program. Drug Inf J 25(1): 29-39.