World Journal of Pharmaceutical Sciences
ISSN (Print): 2321-3310; ISSN (Online): 2321-3086
Available online at: http://www.wjpsonline.org/
Short Communication

Pharmacovigilance: Our experience in Aden

[1]Mohammed Alshakka and [2]Wafa F.S. Badulla

[1]Section of Clinical Pharmacy, [2]Department of Analytical Chemistry, Faculty of Pharmacy, Aden University, Aden, Yemen

Received: 19-08-2018 / Revised Accepted: 24-10-2018 / Published: 26-10-2018

ABSTRACT

Pharmacovigilance (PV) is a main key for safe and suitable use of medicines. Adverse drug reactions (ADRs) considered a substantial health problem that may lead to serious sickness and in some cases to death. Reporting of ADRs is a fundamental part of the PV program for any country. Regrettably, there is notable under reporting of ADRs in developing countries in general and specially in Yemen, due to several challenges and difficulties. Adequate Knowledge of PV importance, among all healthcare professionals (HCPs) could be a foundation for rapid intervention and proper reporting system to decrease ADRs.

Keywords: Pharmacovigilance, Adverse drug reactions, healthcare professionals, Aden

Address for Correspondence: Assoc. Prof. Mohammed Alshakka, Department of Clinical Pharmacy, Faculty of Pharmacy, Aden University, Khormakser-Aden, Yemen, E-mail: alshakka400@gmail.com.

How to Cite this Article: Mohammed Alshakka and Wafa F.S. Badulla. Pharmacovigilance: our experience in Aden. World J Pharm Sci 2018; 6(11): 57-61.

INTRODUCTION

Pharmacovigilance (PV) performed a main role in the healthcare system by estimating, monitoring and detection the assurance and efficiency of medicines and other pharmaceutical products and their effects on human. The World Health Organization (WHO) defines pharmacovigilance as "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" [1]. According to WHO ADRs "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function" [2] WHO 1972].

A PV program should involve all aspects and resources that protect the community from harmful effect of pharmaceutical products in both private and public health care facilities. The PV intention is to attain this safety through decisive and appropriate recognition, gathering, and evaluation of adverse drug reaction ADRs, and evaluating the hazards and benefits to assist taking a true decision about medicines in different parts of health care system. Besides that, PV supports the safe, rational and more effective (including cost-effective) use of medicines and endorse recognition, education and clinical training in PV and its effective communication to the public.

The PV is very significant because the information obtained in the course of pre-marketing of medicines is inevitably insufficient regarding the probable adverse effects. The test carried out on animals may not reflect the human safety. Preclinical trials are limited in duration and design to selected patients with restricted number, also the situations of using may differ from those in real clinical practice. In addition, information relating to the infrequent but critical side effects, chronic toxicity, use in distinct groups (as children, the elderly or pregnant women) or drug-drug interaction is frequently unfinished or not obtainable. However, post-marketing monitoring of possible ADRs in the real clinical practice is an essential step which can only be carried out through applying PV system.

WHO began in 1968 a program for International Drug Monitoring with Uppsala Monitoring Centre (UMC) in Sweden. The requirement for monitoring ADRs has been spread worldwide, in 2002 more than 65 countries have their own PV centers. An official and authorized ADRs monitoring system was established in Yemen in 2011 by the Supreme Board of Drugs and Medical Appliances (SBDMA). However, there are no official data or reports released by the SBDMA relating to the number of ADRs being reported and how they processed it.

The idea for starting the new PV program was established by academics from the Faculty of Pharmacy at the University of Aden in corporation with the official SBDMA, to initiate the PV center of SBDMA. The aim of this center was to involve the whole country and to establish a strategy to perform the elementary stages to establish the PV program that conformed with the (UMC) guidelines. At the end of 2014, many activities were established such as; initiating the center, designing the website and formatting the reporting form, arrangement of poster and procures to initiate knowledge among the athletes, pharmacists and consumers. Yemeni magazines have published several articles relating to PV and the poster have been delivered in hospitals, recurrent visit to the hospitals, educating PV at Aden university for pharmacy undergraduate and carry out researches in the awareness of medicine. All healthcare professionals should have a role in a PV system. Pharmacists play a main role in reporting ADRs by their own or with the assistance of other HCPs in order to decrease the risks of ADRs by identifying, reporting and evaluating any suspected ADRs. They can also teach, advise and inspire physicians, nurses and other HCPs for reporting ADRs. As well as, the pharmacy program followed in faculties in Yemen, should effectively prepare pharmacists for this significant obligation. Many HCPs have no information about the existence of ADRs reporting forms and the reporting process. This could be a participating factor against under reporting by HCPs shown by previous studies in Yemen conducted by Dr. Alshakka et al in 2014 and 2016. The study indicated that costumer load in community pharmacies can be the main factor for providing less time to patients and providing all medicine-related information by HCPs [3,4]. Other study conducted to evaluate the knowledge, attitude and practice (KAP) of HCPs in Tertiary care Teaching Hospital in Aden showed the physicians and nurses had relatively good PV knowledge [5].

Additionally, many medicines are accessible from community pharmacies without a physician 's prescription which promote self-medication and may cause irrational use of medicines, especially antibiotics. Pharmacists and others working in community pharmacies are the main participants for confirming the safe and rational use of medicines. So, there is a need to develop university curriculum for teaching the key aspects of PV for all students of medicine and health sciences faculties. This curriculum should be based on the WHO guidelines such as; International Society of Pharmacovigilance (ISoP), European programme in

Pharmacovigilance and Pharmacoepidemiology (EU2P), clinical pharmacology and therapeutics (CPT) and others [6-11]. Taking into consideration all factors relating to the health care issues in Yemen because the PV program varies from country to another [12]. Are gular PV educational program for HCPs should be carried out due to its positive influence in ADR reporting [13-17]. In addition, a good collaboration between HCPs has a positive influence on early determination of ADRs and awareness of ADR reporting [18].

There are many problems concerning medicines such as; Trafficking of medicines, Counterfeit medicines, improper strategies of medical corporation in developing countries, absence of dynamic national policy, lack of regulation, entry of medicines without scientific standard, unplanned medicine supply, incorrect drug prescription by physicians, wrong dispensing by pharmacists or sales people, inaccurate consumption, inappropriate use of medicines by patients, self-medicines, poor post-marketing quality monitoring, absence of ADRs monitoring, illegal promotion of medicines, no surveillance of medical prescriptions and medication mistakes. Therefore, it is necessary to implement strategies to ensure patients and public safety in relations to medicines use. In developing countries generally, there is limited coverage and under-reporting of ADRs. The effectiveness of PV activities in a country is directly dependent on the active participation of HCPs, patients and consumers. The more information about the collected ADRs will definitely be useful for creating a national database. Therefore, all should be briefed regarding the ADRs reporting system and encouraged to report ADRs even suspected ones.

There are numerous challenges that encountered the implementation of powerful PV activities in Yemen and developing countries such as; deficiency of knowledge and consciousness about the significance of drug safety among in charge authorities, limitation of funding to run, creation and ensure an adequate surrounding for PV center and establishing a safety culture among HCPs and the public. Other problems facing the PV program in Yemen and developing countries are that, the PV activities have not been accomplished by the pharmaceutical factories in the right way, poor regulation, lower proficiency level, low awareness and poor knowledge among HCPs and public regarding ADRs reporting and PV as it shown in some studies conducted in the developing countries [19-24] and some developed countries [25-26]. In addition, communication problems between the HCPs, managers and pharmaceutical corporations, fake drugs which is a very vital issue and underreported problem in developing countries, self-medication, conventional and herbal medications which are commonly used in developing countries without medical regulation and absence of proficiency and training programs in the developing countries all of this, makes reporting ADRs to a health professional or PV centers unattainable.

The situation becomes more complicated due to the circumstances of the war and the destruction of the building of the Supreme Medical Organization by the militias of Huthi. Although, some initiatives were established even in the absence of a permanent headquarters for the Center or budget for its operation. However, self-initiatives by the staff of the center and in cooperation with the Faculty of Pharmacy, forms of reporting were distributed in Aden hospitals. Some other initiatives which were active at January 2015such as;

1. Publication of articles on drug alertness in Yemen and its websites.
2. An article was published in the Swedish journal of the Uppsala World Center for Monitoring the Harmful Effects of Drugs on Drug Alert in Yemen.
3. Field access to hospitals and clinics with the help of two students to distribute the forms of reporting and provide them with an article that outlines the guidelines for reporting the adverse effects of drugs.
4. Publish articles and short texts on the importance of reporting in the sites of doctors and pharmacists in the social networking sites of Facebook doctors and pharmacists frequently.
5. Preparation of poster and 2 brochure and printed in appropriate quantities to disperse the importance and objectives of vigilance and create awareness of the importance of reporting to doctors and pharmacists.
6. Preparation of the draft guidelines for reporting the adverse effects of drugs in Arabic and English.
7. Conduct research on medical alertness among pharmacists of the society, doctors and nurses. Five scientific researchers were completed in English, some of which were published in international journals, and the rest in the Faculty of Pharmacy – Aden.
8. Preparation of a scientific publication issued by the Center, addressed to doctors and pharmacists in English and Arabic.
9. The number of communications received by the Center has reached today.

In order to reach to the recommended objectives of WHO for the desirable PV program the following recommendation should be followed:

1. Efforts should be made to revive the previous activities because most of them were frozen due to war.
2. Proper funding of PV activities.
3. Developing an academic PV program for all medicine and healthcare faculty's students.
4. Providing effective collaboration between all HCPs for proper reporting of ADRs.
5. Connecting the health centers in the Republic with an electronic medical record to monitor all cases ADRs.
6. The drug industries should also participate by maintaining post-marketing monitoring of ADRs.
7. PV researches should be carried out all over the republic to reflect the real situation of PV in Yemen.
8. The Ministry of Health and Population should benefit from these researches to develop a strategy to solve the problems related to PV program.
9. Adopting a new policy commensurate with the circumstances of the country.
10. Developing international collaboration, exchange program to take benefit of past experiences.

CONCLUSION

Based on the data of the previous researches about the PV, this paper summarizes the PV program situation in Yemen since time of establishing the PV center in SBDMA till the moment. Highlight the challenges to overcome and providing the future prospective for improving the PV program in respect to the Yemen situation after the war. It seems that reaching to the WHO recommendation for good PV program a distant dream, but an intensive effort must be made by academics and healthcare workers to raise awareness about PV and develop an appropriate PV system in Yemen.

REFERENCES

[1] World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. Geneva: WHO; 2002. [Cited on March 10, 2018]. Available from http://whqlibdoc.who.int/hq/2002/a75646.
[2] World Health Organization. International Drug Monitoring: The Role of National Centers (WHO Technical Report Series No. 498). Geneva: WHO;1972.
[3] Al-shakka MA et al. Safety Monitoring of Medicines: The Available Mechanism in Yemen. Research in Pharmacy and Health Sciences 2016; 2 (4): 242-145.
[4] Al-shakka MA et al. Knowledge, attitude beliefs and practices of community pharmacy dispensers in Aden, Yemen towards adverse drug reaction reporting. World Journal of Pharmaceutical Sciences 2015; 3 (10): 2111-2118.
[5] Al-shakka MA et al. Knowledge and perception towards pharmacovigilance among Healthcare professionals in Tertiary care Teaching Hospital in Aden, Yemen. J Pharm Prac Community Med. 2016; 2(1):21-8.
[6] World Health Organization. Patient Safety Curriculum guide, Multi-professional edition. 2011. [Cited on March 28,2018). Available from http://www.who.int/patientsafety/ education/mp_curriculum_guide/en/.
[7] Bate A et al. Developing a crowdsourcing approach and tool for pharmacovigilance education material delivery. Drug Saf. 2017; 40 (3):191–9.
[8] Beckmann J et al. Teaching pharmacovigilance: the WHO-ISoP core elements of a comprehensive modular curriculum. Drug Saf. 2014; 37: 743–59.
[9] The first European training programme in pharmacovigilance and pharmacoepidemiology. Eu2P [Cited on March 28, 2018] Available from https://www.eu2p.org/about-eu2p/ education-programme.
[10] Brinkman DJ et al. Pharmacology and Therapeutics Education in the European Union Needs Harmonization and Modernization: A Cross- sectional Survey Among 185 Medical Schools in 27 Countries. Clin Pharmacol Ther. 2017; 102(5): 815–822.
[11] Meyboom R et al. Teaching pharmacovigilance. In: Mann RD, Andrews EB, eds. Pharmacovigilance. Chichester: John Wiley and Sons; 2002: p. 506-8.
[12] Al-Mashraqi AM. Yemen Pharmaceutical Country Profile; Published by the Ministry of Public Health and the Population of the Republic of Yemen, in collaboration with the WHO 2011.
[13] Pagotto C et al. Impact of educational interventions on adverse drug events reporting. Int J Technol Assess Health Care. 2013;29(4):410–7.
[14] Gerritsen R et al. Effectiveness of pharmacovigilance training of general practitioners: a retrospective cohort study in the Netherlands comparing two methods. Drug Saf. 2011;34(9):755–62.
[15] Jha N et al. Effect of an educational intervention on knowledge and attitude regarding pharmacovigilance and consumer pharmacovigilance among community pharmacists in Lalitpur district, Nepal. BMC Res Notes. 2017;10(1):4.
[16] Yu YM, Lee E. Enhanced knowledge of spontaneous reporting with structured educational programs in Korean community pharmacists: a cross-sectional study. BMC Med Educ. 2017;17(1):95.

[17] Sarayani A et al. A 3-armed randomized controlled trial of nurses' continuing education meetings on adverse drug reactions. J Contin Educ Health Prof. 2015;35(2):123–30.
[18] Achike FI et al. Advancing safe drug use through interprofessional training (IPL): a pilot study. J Clin Pharmacol. 2014;54(7):832–9.
[19] Sanvidhan G Suke et al, Role of Pharmacovigilance in India: An overview. Online Journal of Public Health Informatics 2015;7(2): 1-34.
[20] Elshafie S et al. Pharmacovigilance in developing countries (part I): importance and challenges. Int J Clin Pharm. 2018;40(4):758-763.
[21] Pirmohamed M et al. Pharmacovigilance in developing countries. BMJ 2007; 335:462
[22] Kabore L et al. Pharmacovigilance Systems in Developing Countries: An Evaluative Case Study in Burkina Faso. Drug Saf. 2013; 36(5): 1-13.
[23] Ahmed AM et al. The Importance of the Consumer Pharmacovigilance System in Developing Countries: A Case of Malaysia. Journal of Clinical and Diagnostic Research. 2010 ;(4): 2929-2935.
[24] Olsson S et al. Pharmacovigilance in resource-limited countries. Expert Rev. Clin. Pharmacol.2015; 8(4): 449-460.
[25] Green CF et al. Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. Br J Clin Pharmacol 2001; 51(1):81-86.
[26] Grootheest AC van et al. Attitudes of community pharmacists in the Netherlands towards adverse drug reaction reporting. Int J Pharm Pract. 2002; 10:267-72.