Starting a pharmacovigilance program within a teaching hospital: Challenges and experiences from Lalitpur, Nepal

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Abstract

Pharmacovigilance plays an important role in the rational use of medicines by providing information about adverse drug reactions (ADRs) in the general population. Knowledge of ADRs caused by drugs is important for effective treatment. KIST Medical College has recently joined the national pharmacovigilance program as a regional center. Clinicians, pharmacists, house officers, nurses and other staff are encouraged to report ADRs to the center. The center started functioning from mid-July 2008. The objective of this study was to report the various ADRs presented to the center in its first seven months of operation. Doctors and other health care professionals were briefed regarding the ADR reporting system. An ADR reporting form was designed and circulated to all the departments in the hospital. The reported reactions were analyzed for causality, severity and preventability using different scales. To date, thirty six ADRs have been reported. The majority of the reports (23) were from the Department of Medicine. Other departments like Pediatrics, Obstetrics-Gynecology and Radiology have also reported ADRs. As per the causality assessment, 21 (58.3%) reports were found to be “possible” and 15 (41.6%) were found to be probably associated with the named medication. With respect to severity, 17 (47.2%) reports were mild and 19 (52.7%) were moderate. As per the preventability scale, 8 (22.2%) ADRs were definitely preventable while 28 (77.7%) were not preventable. The ADRs are reported to the Uppsala Monitoring Center through Vigiflow via the Department of Drug Administration.

Keywords

Adverse drug reactions, Nepal, Pharmacovigilance, Spontaneous reporting

Introduction

Pharmacovigilance plays an important role in the rational use of medicines by providing information about adverse drug reactions (ADRs) in the general population. Deficiencies of clinical trials are that they are conducted under controlled conditions, generally enrol a selected, limited number of patients and may not include certain sections of the population. Therefore, post marketing surveillance of drugs is necessary to ensure an understanding of the safety profile in the general population. Every country needs to have its own pharmacovigilance program due to differences in disease patterns and incidence of adverse reactions. There may be differences in disease and prescribing practices and genetic composition of the population. There could also be differences in drug manufacturing processes, distribution and use. Traditional and complementary drugs may be used along with modern allopathic medicines and this may vary from country to country. Data derived from within a country has relevance for that particular population and may be helpful for regulatory decision making. The development of a better system of reporting ADRs has been
recommended as a top priority action to prevent ADRs and adverse drug events (ADEs) in hospitals 4.

**Adverse Drug Reactions (ADRs) and Pharmacovigilance**

The World Health Organization (WHO) defines an adverse drug reaction 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 modification of physiological function’ 5. Pharmacovigilance is defined by the WHO as ‘the detection, assessment, understanding and prevention of adverse effects or any drug related problems’. In earlier days, pharmacovigilance was considered as ADR monitoring or drug surveillance; but these days, its aims have been broadened to cover all kinds of drug related problems including drug interactions, drug resistance, counterfeiting, quality problems, drug abuse, poisoning and medication errors. Adverse drug reactions are the fourth to sixth largest cause of mortality in the United States of America (USA) 6. The percentage of hospital admissions due to ADRs in some countries is close to or in excess of 10% 7, 8, 9. The prevalence of ADRs in certain hospitals in the Kathmandu valley is 0.86% with 8% incidence in terms of anti-tubercular induced hepatotoxicity 2, 10, 11, 12. Services to treat ADRs impose a high financial burden on the healthcare system due to hospitalization of patients as some countries spend up to 15-20% of their hospital budget dealing with drug complications.

**The need for a pharmacovigilance program in Nepal**

In Nepal, there is no law making it mandatory for drug manufacturers to submit safety data from the Nepalese population prior to approval of the medicines. Hence, it is very much necessary to monitor the side effects of the medicines that are available in the market as the information collected during the pre-marketing phase is inevitably incomplete with regard to possible ADRs 2, 13. Nepal is a developing country and has several medicine use problems including the use of alternative medicines which may interact with allopathic medicines and predispose the individual to ADRs. The majority of drugs used in Nepal are manufactured in foreign countries and the safety profile of the excipients used is unknown in the Nepalese population. The genetic makeup of Nepalese population is varied and different; there are different races and ethnic groups which might be a predisposing factor for ADRs 9, 14. Moreover, there are no mandatory requirements for clinical trial data to be submitted to the drug regulatory authority prior to drug registration in Nepal. Recently, the Human Immunodeficiency Virus (HIV) infection has become widespread in Nepal and these patients are receiving newer medicines. There is very little safety data on these drugs in the Nepalese population. A pharmacovigilance program can identify the safety of drugs used in public health programs such as vaccines, anti-tubercular medicines and antimalarials. Thus, it is important to monitor the safety of these medicines in Nepal 14. Moreover, the number of drug preparations available in Nepal is also increasing 15. The hilly terrain, poor socio-economic status, high cost of modern medicines coupled with self-medication are some of the other reasons to establish a pharmacovigilance centre in a teaching hospital in Nepal 15.

**Pharmacovigilance in Nepal**

In Nepal, hospitals report various ADRs to the regional pharmacovigilance centers and from there reports are sent to the national pharmacovigilance center at Department of Drug Administration (DDA), Ministry of Health. From here reports are sent to the Uppsala Monitoring Center (UMC), Sweden. At present, there are four regional pharmacovigilance centers in Nepal located in teaching hospitals 16. These regional centers report ADRs to the national center via a web based system called ‘Vigiflow’.

**Medicine and Therapeutics Committee (MTC) and pharmacovigilance**

Medicine and Therapeutics committees are a key recommendation for promoting the rational use of medicines 17. MTCs can carry out both educational and managerial interventions to improve medicine use. In our institution, the hospital pharmacy runs under the guidance of the MTC. KIST Medical College (KISTMC) has been recognized as a regional pharmacovigilance center since mid-July, 2008. The pharmacovigilance activity is a commitment of MTC.
towards the safer use of medicines for patients in Nepal.

Establishing a pharmacovigilance center at KIST Medical College

The concept of ADR monitoring and pharmacovigilance is new to Nepal. DDA has however, taken steps to establish an ADR monitoring program. In the year 2006, Nepal was granted full member status by the Uppsala Monitoring Centre\(^1\), the WHO collaborating center for ADR monitoring. DDA has established regional centers that report ADRs. The pharmacovigilance officer of KISTMC liaised with the DDA for establishing the regional center at KISTMC.

Several meetings were arranged with the clinicians and other related health care professionals regarding pharmacovigilance activities. Meetings were arranged formally and informally with all the concerned personnel periodically. A training programme regarding the process of spontaneous reporting of observed ADRs was conducted. The ADR reporting forms were designed and placed in all the wards and outpatient departments. If requested, information on the management of the ADR is provided. All reports received by the center were analyzed for severity, causality and preventability and reported to the UMC via the DDA. Since mid-July 2008, the pharmacovigilance center has received a total of thirty-six reports. Majority of the reports were from medicine department while some were from the departments of pediatrics, gynecology and radiology. On carrying out the causality assessment, 21 (58.3%) reports were found to be “possible” and 15 (41.6%) were found to be probably related to the drug concerned. Similarly, for severity 17 (47.2%) reports were mild and 19 (52.7%) were moderate. As per the preventability scale, 8 (22.2%) ADRs were definitely preventable while 28 (77.7%) were not preventable.

The management of KISTMC is supportive of the program. There are many obstacles however. The hospital is new and the number of patients is relatively less. The orientation program, which is a continuous process, is repeated within short intervals for new staff including faculty, clinicians, nurses, pharmacists and other healthcare professionals. Continuous follow up and reminders about the service could be a method to get more ADRs. ADRs may also be obtained from other private clinics and hospitals in Lalitpur as there is no other pharmacovigilance center in the district.

Concluding Remarks

The effectiveness of national pharmacovigilance activities in Nepal is directly dependent on the active participation of health professionals. More information about ADRs will definitely be helpful for creating a national database. Efforts are underway to encourage clinicians, nurses and other allied health care workers to report all ADRs even suspected ones, with the aim of improving medicine use.

References


