

Knowledge And Attitude Regarding Adverse Drug Reaction Reporting And Associated Factors Among State Pharmacist In Northern Province, Srilanka

ML. Kaluarachchi^{1#}, S. Thuvaragan¹, PAD.Coonghe², and SN. Thihahiny³

¹ Department of Pharmacy, Faculty of Allied Health Sciences, University of Jaffna, Sri Lanka.

² Department of Community & Family Medicine, Faculty of Medicine, University of Jaffna, Sri Lanka.

³ Department of Pharmacology, Faculty of Medicine, University of Jaffna, Sri Lanka.

#medara1994@gmail.com

Abstract – Adverse drug reaction (ADR) is a significant cause of morbidity and mortality worldwide. Reporting of ADRs is considered to be an important step to achieve a safe drug use. Reporting of ADR becomes a part of professional obligation of a pharmacist, as expanding of the role towards patient care rather than the dispensing. This study was conducted to assess the knowledge, attitude regarding ADR reporting and association of socio-demographic and work-related factors among pharmacists working at Public Sector Hospitals in Northern Province, Sri Lanka. It is a descriptive cross-sectional study which was conducted among 76 pharmacists using validated self-administered questionnaire. Descriptive statistics was used to describe the data. Association of socio-demographic and work-related factors on knowledge and attitude was determined by chi-square test and fisher's extract test. Data were analyzed by using SPSS version 23. The response rate of the study was 88.2% (n=67). The mean age of participants was 35.8 ± 9.3 years and most of them were females (71.6%, n=48). Predetermined cut-off value was used as 70 % to determine the level of knowledge and attitude regarding ADR reporting with help of supervisors. Among participants, 65.2% (n=44) of participants had good knowledge about ADRs and 67.2% (n=45) had positive attitude towards ADR reporting. Extra working hours had statistically significant

influence on knowledge on ADR (p=0.048) and working experience showed significant influence on the attitude toward ADR reporting (p=0.03). This study revealed that majority of pharmacists had good level of knowledge and positive attitude towards ADR reporting.

Keywords: Adverse drug reaction (ADR), Adverse drug reaction reporting, Pharmacist

Introduction

Adverse drug reaction (ADRs) is a significant cause of morbidity and mortality worldwide. World Health Organization (WHO) has provided the definition of adverse drug reactions as “an ADR is any noxious, unintended and undesired effect of a drug, which occurs at doses used in human prophylaxis, diagnosis, or therapy”(Ahmad *et al.*, 2013). ADRs are associated with prolonged length of hospital stay, increased economic burden and increased death; many studies have reported that ADRs were responsible for large number of hospital admissions. Thus reporting of ADRs is considered to be an important step in maintaining and achieving medication safety. All sectors of the healthcare system would need to be involved in the ADR reporting process. Wherever treatments are being started, there should be an alertness to observe and report unwanted adverse events (both expected and

unexpected)(WHO, 2002). Reporting of ADR becomes a part of professional obligation of a pharmacist, as expanding of the role towards patient care rather than the dispensing of medication. These roles include reporting ADRs, improving patient health, and economic outcomes(Hepler and Strand, 1990; Manley and Carroll, 2002). Since pharmacists directly involve with patients, they are expected to play an important role in providing drug information and reporting of ADRs. Having good knowledge and positive attitude towards ADR reporting could promote spontaneous ADR reporting not only by pharmacist themselves but, also by patients through providing appropriate drug information.

The thalidomide tragedy in the mid twentieth century triggered a chain of activities, which established monitoring schemes based on reporting of suspected ADRs(WHO, 2004a). Most countries developed their national pharmacovigilance system after the thalidomide disaster in 1960s(Reddy *et al.*, 2014). Most developed countries and many developing countries follow spontaneous reporting systems (SRS s) e.g. UK Yellow card scheme for reporting for suspected adverse drug reactions(Herdeiro, Figueiras and Pol, 2006). The SRS receives ADR reports from medical practitioners and other health care professionals, such as pharmacists and nurses(Hazell and Shakir, 2006). The main function of the SRS is detection of signals of new, rare or serious ADRs. ADR spontaneous reporting systems are the basic components for the comprehensive post-marketing surveillance of drug induced risks(Pal *et al.*, 2013). Recently Sri Lanka was being a full-time member of the WHO collaboration center for the ADR monitoring and reporting. Mainly, the major drawback in spontaneous voluntary system used in Sri Lanka is under reporting of suspected drug

related problems(Munasinghe, 2002). It is highly depending on attitude and knowledge regarding reporting of ADR. Therefore, the objective of this study was to assess the knowledge and attitude among pharmacist, working in Northern Province, Sri Lanka and association of socio-demographic and work-related factors.

Methodology

The study was an Institutional based descriptive cross-sectional study among the state pharmacist in Northern Province, Sri Lanka. A self-administered questionnaire was used to collect data which included four sections (A, B, C, D). A and B designed to collect the information about socio-demographic and work related factors respectively. Section C and D designed to assess knowledge and attitude regarding ADR reporting respectively. Questionnaire was designed through literature review of the published journals and WHO guideline(WHO, 2004b; Ahmad *et al.*, 2013; Khan, 2013; Suyagh, Farah and Abu Farha, 2015). Questionnaire was validated by circulating it among 3 experts such as senior pharmacist, consultant physician and pharmacologist. Data collection was done after getting the ethical clearance from Ethical Review Committee, Faculty of Medicine, University of Jaffna. Permission for data collection was obtained from Provincial/ Regional Director of Health Services, Director of hospitals and chief pharmacists accordingly. The data collection was conducted over two months. Descriptive statistics was used to describe the data. Association of socio-demographic and work-related factors on knowledge and attitude was determined by chi-square test and fisher's extract test. Data were analyzed by using SPSS version 23 (Statistical package for social sciences version 23).

Results

Socio-demographic factors of participants

Out of the 76 pharmacists, 67 of them were responded with response rate of 88.2%. In this study 71.6% of participants were female and 28.4% were male. The average age of the participants was 35.5 years. 88.1% of them were Sri Lankan Tamil.

Work-related factors of participants

In this study few of them were qualified as B. Pharm or Bsc In pharmacy (10.4%, n=7). Working experience of participants ranged from 5 months to 28 years with the average of 8.4 years. Only 17.9% (n= 12) of participants had participated service training program regarding ADR reporting and 14.9% (n= 10) of them had participated in seminars regarding ADR reporting.

Knowledge level of participants

Among the participants 35.8% (n=24) were able to correctly define the ADR while 11.9% (n=8) of them were unable to define at all. More than half of participants had good knowledge on Incidents which could be reported. However 61.2% (n=41) of participants failed to give correct answer for the location of National pharmacovigilance center. In this study all the participants had awareness of ADR reporting system in Sri Lanka and 97% of them had awareness on availability of structured form for reporting of ADRs. Almost all of participants (n=65, 97%) had good knowledge regarding the information which they need to include while reporting an ADR. Nearly two third of participants (n=44, 65.7%) were stated that the conformation of ADR with particular drug is necessary before reporting. 83.6% (n=56) participants were aware of ADR reporting system in Sri Lanka.

Attitude level of participants

More than half of participants (n=37, 55.2%) had positive attitude towards reporting ADR with their routine duties, while one third of

participant (33.3%, n=23) stated, that is time consuming and highly affects their routine duties. Majority of them were not believed that fear of legal liability (n=44, 65.6%) and lack of confidence in discussing ADR with a prescriber (n=36, 53.7%) as a reason them to discourage reporting. Only 16.4% (n=11) were stated that the, ADR reporting is neglected because pharmacists were overloaded with duties due to large number of patients at the clinics. About one tenth of participants (9%) had negative attitudes towards ADR reporting as they feel their reports would not be considered as valuable.

Discussion

Adverse drug reaction reporting plays a major role in pharmacovigilance process, which introduced by World Health Organization in order to assess, detect and prevent unwanted health outcomes related to drugs and other medicine related items. In the present study 38.8% of participants knew the location of National pharmacovigilance center. It was almost similar to the study done in India, in which 30% of them knew the location of pharmacovigilance center (Ahmad *et al.*, 2013). In accordance with the findings of this study all of the participants (100.0%) had awareness of ADR reporting system in Sri Lanka. In contrast, two studies conducted in Kuwait and Saudi Arabia reported very low level of awareness regarding availability of ADR reporting system, where only 7% and 10% of participants were aware of the existence of reporting system respectively (Khan, 2013; Alsaleh *et al.*, 2017). When considering all dimensions of attitude, the present study has found that 67.2% of participants had positive attitude towards ADR reporting. There 65.6% of them were disagreed to the fear of legal liability as a discouraging factor for ADR reporting. But different figures had been reported in studies from Northern China and

Jordan, 93.3% and 59.6% respectively (Su, Ji and Bs, 2010a; Suyagh, Farah and Abu Farha, 2015). Only 16.4% of participants were accepted the work load as factor which leads to consider ADR reporting negligence. This finding is higher with the study done in Saudi Arabia, in which only 6.3% of participants mentioned that they are not report ADR due to their workload (Mauhmoud, Alswaida and Alshammari, 2014). In the present study, few participants (9%) stated that pharmacist will do ADR reporting if there is a reward. Almost Similar figure had been reported in Northern china, in which only 6.9% of pharmacist were suggested fee for ADR reporting (Su, Ji and Bs, 2010b). In the present study majority of participants (89.6%) were diploma holders. In contrast, different situation exist in countries like Saudi Arabia, Norway and Jordan, where 100.0%, 65.7%, 77.9% of the participants were degree holders respectively (Granat et al., 2007; Khan, 2013; Suyagh, Farah and Abu Farha, 2015). This study shows the low involvement of training programs regarding ADR reporting (17.9%) which is lower than the value from a study from neighboring country India, in which 30% of participants were trained for ADR reporting (Ahmad *et al.*, 2013). In this study 14.9% of participants had participated in seminars/ workshops regarding ADR. It is higher than the study conduct in Jordan, in which only 8.2% had participated a workshop regarding ADR reporting (Suyagh, Farah and Abu Farha, 2015). When considering the influence of work-related factors on knowledge, working experience of the participants had not showed statistically significant association with knowledge on ADR reporting (p value= 0.095). Similar figure has been reported in an Ethiopian study (Necho Mulatu, 2014). In contrast same study found a statistically significant association between participation of training program with the knowledge on ADR reporting (p value <

0.05), whereas present study participant's knowledge was not influenced by the participation of service training program regarding ADRs (p value= 0.207). Working experience of participants was influenced on the level of attitude towards ADR reporting among participants (p value= 0.03). Younger participants who recently joined to the pharmacy profession showed a positive attitude when compare with more experienced participants. It may due to the expansion of the scope of pharmacist. Younger participants may realize their responsibility in clinical side as well as patient care. In study conducted in Northern China showed significant association between working experience with attitudes as similar to present study (Su, Ji and Bs, 2010b). However, participation of training programs was not influenced with attitude (p value= 0.162). It is not accordance with the study conducted in Northern China, it revealed a positive influence on attitude with the participation of training programs (p value= 0.03) (Su, Ji and Bs, 2010b).

Conclusion

The finding of the study revealed that, majority (65.7%) of participants had good knowledge on adverse drug reaction reporting (ADR) and 67.2% of participants had positive attitude towards the adverse drug reaction (ADR) reporting. There is correlation between attitudes towards ADR reporting with the work experience, participants who engaged recently to the profession have positive attitude than more experienced participants. Conducting in – service training programs, workshops and seminars will improve pharmacy professional's knowledge and attitude regarding ADR reporting which will subsequently improve the patient safety.

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