

Research Article

Knowledge and Attitudes on Adverse Drug Reaction Reporting of Selected Hospital-based Health Practitioners in Manila, Philippines

Rogie Royce Carandang*, Karen Cao, Nikki Beatrice Jose, Frances Diana Almonte, Ron Michael Tinio
College of Pharmacy, Adamson University, City of Manila, Philippines

***Corresponding author**

Rogie Royce Carandang

Email: rroycarandang@gmail.com

Abstract: Adverse drug reaction (ADR) reporting is fundamental in the science of pharmacovigilance. However, under-reporting still exists and remains a major limitation of the system. This study sought to assess the knowledge and attitudes of hospital-based health practitioners in Manila towards adverse drug reaction reporting. A convenience sampling method was used among health professionals in selected hospitals in Manila. Data was collected using self-administered questionnaires from randomly selected pharmacists (23), physicians (47) and nurses (70). Results indicated that there is under-reporting of suspected ADRs. Majority of the health professionals (77%) have adequate knowledge on the ADR reporting. However, there is a significant difference on the level of knowledge of these practitioners. Nurses have the highest proportion of respondents (86%) with adequate knowledge. In addition, a higher percentage of respondents (80%) have unfavorable attitude towards ADR reporting. But still, the respondents acknowledged that ADR reporting is a professional obligation. Only years of practice in the profession appeared to possess a significant relationship to the practitioners' knowledge. Meanwhile, only history of ADR reporting exhibited a significant influence to the attitudes of health practitioners. Those who had experienced reporting ADR are more likely to report ADRs. Knowledge and attitudes showed a strong influence in the ADR reporting of health professionals. Thus, development of education strategies which focused on recognition of ADRs as well as altering wrong beliefs and negative attitudes will hopefully develop a "reporting and learning culture" among the health professionals.

Keywords: knowledge, attitudes, adverse drug reaction, hospital, health practitioners.

INTRODUCTION

Moore once said that, "All drugs are dangerous. Some may be useful". This is the current dictum of many drug safety experts in the world [1]. Such principle has already been acknowledged by the World Health Organization (WHO) as early as 1946.

The advent of the Thalidomide scare that resulted to phocomelia among children of mothers who were exposed to Thalidomide has brought into the attention of the global health experts the value of drug safety; thus, bringing about the science of pharmacovigilance (PV) [2]. Article 21 of the WHO constitution in 1946 stipulates that there should be an adoption of regulations concerning standards with respect to the safety, purity and potency of biological and pharmaceutical products moving to international commerce by world health assembly [3]. Hence, in 1971, there was an emergence of the practice and science of PV.

In the Philippines, the science of PV has been recognized by the local health authority and Food and Drug Authority (FDA; formerly known as BFAD or Bureau of Food and Drug). In pursuant to the Republic

Act 3720, otherwise known as the "Food, Drugs and Devices, and Cosmetic Act", a Memorandum Circular no. 5 of 1994 was signed by Dr. Quintin Kintanar, the then Director of BFAD on April 24, 1994. This circular requires that all serious ADR reports shall be submitted to BFAD within two weeks after the receipt of the same. Other ADR reports shall be submitted on or before the 15th of January of each year.

On August 1994, the ADR reporting system in the Philippines was established and was recognized as a national center member of the World Health Organization International Drug Monitoring (currently known as the Uppsala Monitoring Centre) on February 1995 [4].

This memorandum circular was amended on 16 April 2010 through the FDA Circular 2010-09, and the amendment includes the change of timeline of reporting from two weeks to within 72 hours (3 working days) but no later than seven (7) working days for the serious ADR reports. Meanwhile for other ADR reports, these will be submitted every 30th of the first month of each quarter, and not annually during the 15th of January each year as previously stated in the original

memorandum [5-6]. Currently, a clearer PV administrative order is being finalized to replace the above circulars

Although there is an established national ADR reporting scheme in the country, compliance to such is still a pressing concern to local health authorities. Under-reporting of ADRs has remained widespread despite their extensive campaigns. Health professionals including physicians, nurses, and pharmacists are amongst the primary source of ADR reports as they have constant encounter with patients in their day to day practice. The knowledge and attitudes of these practitioners affect their practice of ADR reporting. As such, it is of great interest to look into the level of awareness of health practitioners working in different secondary and tertiary hospitals about the ADR reporting system in the country as well as their attitudes towards reporting.

The overall goal of this study was to evaluate the culture of ADR reporting among selected hospital-based health practitioners. The respondents' knowledge and attitudes towards ADR reporting and its relationship to their profession will be determined. This study also considered every aspect of the respondents' personal and professional information such as age, gender, years of practice, work environment and history of ADR reporting that has an impact on their performance in ADR reporting.

METHOD

Research Design

A qualitative cross-sectional study design was used for the study on knowledge and attitudes of hospital-based health practitioners on adverse drug reaction reporting because determination of variables will be done at one point in time.

Research Setting

The study was carried out in the City of Manila, which is the capital of the Philippines. It consists of 14 municipalities and 6 congressional districts. It is the second most populated city in the National Capital Region (region with the largest distribution of health practitioners in the Philippines) next to Quezon City and it is one of the most densely populated cities in the world [7]. As of December 31, 2014, there are 28 hospitals in Manila, 17 are private and 11 are government-owned [8].

Sampling Design and Sample Size

The sample size was computed based on a study on "Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal" by Palaian, S., Ibrahim, M.I., and Mishra, P. using open epi software version 2. The total sample size was divided among pharmacists, physicians and nurses in a ratio of 1:2:3 to mimic the actual distribution of health practitioners in the Philippines.

The sampling frames used are 140 randomly selected health practitioners (23 pharmacists, 47 physicians, and 70 nurses) who are working hospital-based from all the secondary and tertiary level hospitals in Manila that gave their approval for the conduct of the study.

Research Instrument

A questionnaire was used to gather information from the concerned health practitioners. The questionnaire was adapted from two previous studies that assessed knowledge and attitudes of different medical professionals to ADR reporting in Nigeria [9-10]. These questionnaires were used instead of constructing our own to ensure reliability of the questionnaire and to allow comparison of results with previous studies. Some modifications however were done to narrow down the investigation to just two categories for both knowledge and attitude assessment. The procedures and purposes of the ADR reporting system in the Philippines was used to determine knowledge while attitudinal queries was limited to the motivations to reporting ADRs and to factors that may discourage them from reporting.

The resulting questionnaire was divided into 4 sections. Corresponding sections was used to obtain the demographics of the health practitioners to get information about their knowledge of ADR reporting, to identify their attitudes to reporting and to know their experience with ADR reporting. Demographic characteristics included in the study are age, gender, years of practice, type of practice, and work environment. Ten questions on knowledge were assessed by 2 options (yes/no). Health practitioners who correctly answer 8-10 were classified as having adequate knowledge and those getting scores below 8 was classified as having inadequate knowledge. Health practitioners' attitudes toward ADR reporting were gauged on a 5-point Likert scale, ranging from 'strongly agree' to 'strongly disagree'. Their responses was summated and health practitioners who get a score of 40 - 50 will be considered to have favorable attitude towards ADR reporting whereas those scoring 10 - 39 were classified as having unfavorable attitude. The final section inquired about the health practitioners' identification and actual reporting of an ADR, which will be answered by a yes/no.

Validity and Reliability

Content validity of the questionnaire was ensured by obtaining comments and suggestions from qualified health professionals (pharmacist, physician, and nurse) knowledgeable on ADR reporting who are working hospital-based. Further modifications were made in accordance with the suggestions.

In order to assure the reliability of the questionnaire, it was subjected through pilot study by 30 selected health practitioners in one hospital in Manila. After the collection of data, the questionnaire

underwent Cronbach’s alpha to measure internal consistency. It yielded 0.737 reliability value.

Data Collection

For ethical clearance, a letter of request was forwarded to the medical director/ administrator of the hospital to seek permission for the conduct of the survey. Only those who approved the conduct of the study in their institution were included in the study. Informed consent was also sought from the health practitioners.

The health practitioners who received the questionnaires were given a time frame of one week to completely fill out the required information. Health practitioners who answered all questions were included in the study. Those who failed to answer even one item on the questionnaire were excluded from the respondents.

Data Analysis

Analysis of the responses to the questionnaire was carried out using the Statistical Package for the Social Sciences (SPSS for MS Windows version 16). Cross-tabulation of variables was examined using the chi-square test distribution accepting $P < 0.05$ as significant. This encompassed analyses on the level of knowledge and attitude on ADR reporting of registered physicians, nurses and pharmacists. Meanwhile, Pearson chi-square was used to relate demographics and history of ADR reporting with their knowledge and attitudes.

RESULTS AND DISCUSSION

A total of 140 respondents completed and returned the questionnaire within the stipulated time frame giving a response rate of 100%. From the 140 respondents, 23 (16%) were Pharmacists, 47 (34%) were Physicians, and 70 (50%) were Nurses.

History of ADR reporting

Table-1 shows the history of ADR reporting of the respondents. It is interesting to note that while over 29% and 53% of the respondents have encountered a potential ADR within the last 6 months and for their entire duration or practice, only 14% and 32% respectively have actually reported a potential ADR. This only shows that there is under-reporting of ADRs among health practitioners in Manila. Indeed, despite the fact that there is an established national ADR reporting scheme in the country, compliance to such has remained elusive.

Among the health practitioners, physicians are more likely to encounter potential ADRs in the last six months (38%) and for the entire duration of practice (64%). This can be attributed to their frequent interaction with patients during rounds and consultations. Nurses, however, are least likely to encounter potential ADRs (21% and 47% respectively) despite them being in the ward most of the times to monitor the patients’ condition. Perhaps, this is due to their lack of sufficient background on what constitutes an ADR. They could have already observed an ADR without them recognizing that it is actually an ADR. A study conducted in Northern Nigeria among health professionals identified lack of knowledge of what constituted ADRs as contributing to their non-reporting of ADRs [11].

Although, pharmacists have low encounter with potential ADRs, they are more likely to report potential ADRs in the last six months (26%) and for the entire duration of practice (35%). This can be attributed to the strong emphasis of the importance of pharmacovigilance in their undergraduate curriculum.

Table-1: History of ADR reporting of respondents

Scenario	Yes		No	
	n	%	n	%
Encountered a potential ADR within the last 6 months	40	29	100	71
Reported a potential ADR within the last 6 months	20	14	120	86
Encountered a potential ADR for the entire duration of practice	74	53	66	47
Reported a potential ADR for the entire duration of practice	45	32	95	68

Knowledge on ADR Reporting

Under-reporting can be affected by various factors. One of which is knowledge. Table-2 shows the

knowledge of pharmacists, physicians and nurses on ADR reporting.

Table-2: Knowledge of respondents on ADR reporting

Health Practitioner	Knowledge				Total	χ^2	Sig
	Adequate		Inadequate				
	n	%	n	%			
Pharmacists	14	61	9	39	23	41.257	0.000*
Physicians	34	72	13	28	47		
Nurses	60	86	10	14	70		
Total	108	77	32	23	140	Significant	

* P value is significant i.e. < 0.05

In general, the respondents have a high level of knowledge on ADR reporting, 77% have adequate knowledge and only 23% have an inadequate knowledge. There is a significant difference in the knowledge among hospital-based physicians, pharmacists and nurses. Nurses (86%) have the most knowledgeable respondents followed by physicians (72%). Pharmacists (61%), on the other hand, have the least adequate knowledge.

The low level of knowledge among pharmacists may be attributed to their lack of exposure in the clinical practice thus being less familiar with the ADR reporting process. A study among pharmacists reported that the major deterrent to reporting is the time available in clinical practice [12]. Nurses, on the other hand, being always in the ward monitoring patients' condition, are more predisposed to ADR reporting thus having a high level of knowledge regarding its process.

Despite their relatively adequate knowledge on the process of ADR reporting, the turnout of ADR reports from the healthcare practitioners is still low. In this study, knowledge displayed a weak influence on the reporting of ADRs. However, a study on doctors shows that clear information on how and what should be reported is essential in improving ADR reporting rates [13]. Moreover, on a study among pharmacists by Irujo et al., stated that knowledge is an important factor in ADR reporting and that its development can reduce under-reporting [14].

Attitudes on ADR Reporting

Attitude is among the factors which show a strong association with the reporting probability. Based on the responses from attitudinal statements, majority (88%) of the respondents agreed that reporting is a professional obligation. However, they would be more inclined to report if the reaction is certainly an ADR. Perhaps this is because of the assumption that only ADR forms with causal relationship are acceptable. This belief can be also associated to the fear of appearing ridiculous for reporting merely suspected ADRs (diffidence). Similarly, majority of the health practitioners surveyed in a study in Southwest Ethiopia

complained that there should be a need to be sure that ADR is related to the drug before reporting [15].

Moreover, 58% of the respondents said that reporting an ADR is difficult when ADR forms are not easily available. Although ADR forms can be downloaded from the FDA website and can be acquired from the PV unit of their respective institutions, absence of readily available forms has still remained a barrier. This factor can also be associated to procrastination, lack of interest or time to find a report card (lethargy). A similar study by Desai, et al. cited that the major reason of prescribers for not reporting ADRs one of which is the lack of easy access to ADR reporting forms [16]. In addition to, non-availability of ADR forms was also found to be one of the main reasons for not reporting ADRs in another study among doctors in India [17].

Just a little over half of the respondents disagreed and strongly disagreed to the statements that only reactions that are serious should be reported (ignorance) and only reactions new to a product should be reported. From this it can be derived that still a considerable number of the respondents are not sure of the type of reactions to be reported.

Inman has proposed eight reasons that affect ADR reporting. These are ignorance, diffidence, lethargy, indifference, ambition, complacency, guilt, and fear [18]. In this study, only diffidence, lethargy, and ignorance appeared to be the factors dissuading practitioners from reporting.

Meanwhile, table-3 presents the differences in the attitudes of the three health practitioner towards ADR reporting. It can be seen that their attitude differs significantly. Physicians (89%) have the most unfavorable attitude towards ADR reporting, followed by pharmacists (83%) and nurses (73%). Given that the respondents have adequate knowledge on ADR reporting process, it can then be conceived that under-reporting of ADRs by health practitioners in Manila can be attributed to their unfavorable attitude towards ADR reporting.

Table-3: Differences in attitudes of respondents regarding ADR reporting

Health Practitioner	Attitude				Total	χ^2	Sig
	Favorable		Unfavorable				
	n	%	n	%			
Pharmacists	4	17	19	83	23	50.400	0.000*
Physicians	5	11	42	89	47		
Nurses	19	27	51	73	70		
Total	28	20	112	80	140	Significant	

* P value is significant i.e. < 0.05

Relationship of respondents' demographics with their Knowledge and Attitudes on ADR reporting Age and Gender

Both age and gender do not have an influence on the knowledge and attitudes of health practitioners towards ADR reporting. This only shows that the age of the health practitioners, whether they are young, middle-aged or senior does not have a strong influence. Gender, regardless male or female, does not have significant effect with knowledge and attitudes on ADR reporting. Similarly, a study by Herdiero *et al.* showed that age and sex failed to have an effect on adverse drug reaction reporting [19]. A study, however, by Irujo *et al.* showed that age of a community pharmacist have an influence

on ADR reporting as the probability of reporting increases with increasing seniority [14].

Years of practice in hospital and profession

The length of practice of health practitioners in a certain hospital does not influence their knowledge and attitudes on ADR reporting. However, their years of practice in their profession showed a significant relationship on the knowledge but not on the attitudes (Table-4). This shows that as the length of experience increases, the knowledge of practitioners also increases. This finding was further supported by the study of Irujo *et al.*, which says that the probability of reporting also increases with length of work experience [14].

Table-4: Relationship of respondents' years of practice in profession to their knowledge and attitudes towards ADR reporting

		Years of Practice in Profession			Pearson χ^2	Sig
		<10	10-20	>20		
Knowledge	Adequate	79 (56%)	22 (16%)	7 (5%)	6.290	0.043*
	Inadequate	16 (11%)	13 (9%)	3 (2%)		
Attitude	Favorable	21 (15%)	6 (4%)	1(1%)	1.067	0.587
	Unfavorable	74 (53%)	29 (21%)	9 (6%)		

* P value is significant i.e. < 0.05

Work environment

There is no significant relationship between the health practitioners' work environment with their knowledge and attitudes on ADR reporting. Regardless of which department in the hospital they are working in, this does not show an influence to the knowledge and attitude of health practitioners.

Encounter and Reporting of potential ADR

Table-5 shows that the history of ADR reporting for the entire duration of practice of practitioners showed a significant relationship to the attitudes on reporting. This only shows that health practitioners who have experienced ADR reporting are more inclined to report again. Moreover, those with unfavorable attitude are more likely not to report potential ADR.

Table-5: Relationship of respondents' history of ADR reporting for the entire duration of practice to their knowledge and attitudes

		History of ADR reporting for the entire duration of practice		Pearson χ^2	Sig
		Yes	No		
Knowledge	Adequate	32 (23%)	76 (54%)	1.368	0.242
	Inadequate	13 (9%)	19 (14%)		
Attitude	Favorable	14 (10%)	14 (10%)	5.117	0.024*
	Unfavorable	31 (22%)	81(58%)		

* P value is significant i.e. < 0.05

CONCLUSIONS

Results of the study shows that under-reporting of adverse drug reactions are indeed present among health practitioners. This is evident in the low percentage of respondents who encounter or recognize potential ADRs and the even lower percentage of respondents who report observed potential ADRs. Under-reporting of ADRs can be attributed to the practitioners' knowledge and attitudes towards ADR reporting as well as personal and professional factors.

Majority of the respondents have adequate knowledge on ADR reporting. However, the knowledge

of pharmacists, physicians, and nurses on ADR reporting varies significantly. Nurses have the highest percentage of respondents who have adequate knowledge in ADR reporting. Contrary to that, pharmacists have the lowest percentage of respondents who have adequate knowledge on ADR reporting. This might be because of the low exposure of the pharmacists to the clinical practice thus being less familiar with knowledge of the ADR reporting process. Nurses, on the other hand, being always in the ward monitoring patients' condition, are more predisposed to ADR reporting thus having a high level of knowledge regarding its process.

Although, health professionals have relatively adequate knowledge on the process of ADR reporting, still the number of ADRs reported remains low.

Meanwhile, health practitioners in Manila have unfavorable attitude towards ADR reporting. Despite of this, majority of the health professionals still acknowledge that reporting ADRs is a professional obligation. The attitudes of the three practitioners differ significantly.

Healthcare professionals would be more inclined to report if the reaction is certainly an ADR. This might be because they assume that only ADRs with causal relationship should be reported. This can also be attributed to one of Inman's proposed reason, diffidence. The health practitioners may tend to report ADRs if it is certainly an ADR because they fear of appearing ridiculous for reporting a merely suspected one. Respondents also said that reporting an ADR is difficult when ADR forms are not easily available. Practitioners may tend to procrastinate from reporting an ADR since forms are not readily available. There can also be lack of interest or time of the practitioner to find an ADR report form (lethargy). From the responses on the attitudinal section, it can be derived that still a considerable number of the respondents are not sure of the type of reactions to be reported.

Among the demographic variables observed, only the years of practice in the profession showed a significant relationship to the knowledge of respondents. This means that as the length of experience increases, knowledge is also improved. Moreover, results also indicate that health practitioners who had an experience to report an ADR for the entire duration of their practice are more inclined to report ADRs.

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