Knowledge, attitudes and practices of Adverse Drug Reaction reporting among healthcare professionals in Teaching Hospital Karapitiya

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Abstract

Objectives

The objectives of this study were to describe the knowledge, attitudes and practices of Adverse Drug Reactions (ADR) reporting among healthcare professionals in Teaching Hospital Karapitiya (THK).

Methodology

A descriptive cross-sectional study was conducted at THK. The healthcare professionals working in THK who were available during the study period were invited to the study. A self-administered pre-tested questionnaire was given to the participants. Respondents were evaluated for their knowledge, attitudes and practices related to ADR reporting. The data was analyzed using SPSS statistical software.

Results

Of the total 444 respondents, 31% were doctors and 69% were nurses. Majority of respondents, 90% (n=400) were aware about the term ADR, while 64.8% (n=288) could correctly define it. Among the respondents, 30.8% (n=137) knew about the types of ADR and only 15.5% (n= 70) were able to correctly mention a drug that is banned due to ADR. Among the respondents, only 38.7% (n=172) were aware about formal process of reporting ADR and, only 35.3% (n=157) stated that they have seen ADR reporting form. Further, only 33.7% (n=150) respondents have recognized ADR in the practice and only a small proportion 18.2% (n=81) have ever reported an ADR during their practice. Regarding attitudes of ADR reporting, overall 84.1 (n=373) had positive attitude towards ADR reporting while 13.54% (n=60) of them stayed neutral and 2.25% (n=10) had negative attitude towards ADR reporting.

Conclusions

Although the majority was aware about ADR and the importance of their reporting, the knowledge and practices regarding the spontaneous reporting of ADR is inadequate. However, most of the respondents have shown a positive attitude towards ADR reporting. Sincere and sustained efforts should be made by concerned bodies to improve the knowledge, attitudes, and practices of health care professionals.

Introduction

The national medicine regulatory structures in most countries rely on spontaneous reporting of Adverse Drug Reactions (ADR). It is a process of suspected cases of ADR are voluntarily reported and submitted by health care professionals to a national pharmacovigilance scheme. According to the definition of World Health Organization (WHO), ADR are ‘responses to a drug which are noxious and unintended, and which occur at doses normally used to treat a patient for diagnosis, prophylaxis, therapy or for the modification of a physiological function[(1)]. ADR can range from minor discomfort to fatal complication. Most of these ADRs detected around the world were serious and unusual ones which were not detected during the drug development process. ADR is classified as the sixth leading cause of mortality

worldwide[2]. A systematic literature review done by using 69 studies worldwide in 2002 evaluated the ADR rate, and it showed 5.5%- 7.7% of ADR rate around the world[3]. Hence the clinical and economic impacts of ADRs-related hospital admissions to the health care delivery system are extensive. Thus the spontaneous reporting of ADR plays an important role in order to ensure the standards of safety and efficacy of the drugs.

Uppsala Monitoring Center (UMC) is the international drug monitoring center which collaborates with World Health Organization (WHO)[4]. From the countries that had already established national structures to report ADR and who were willing to contribute their data were selected and a common reporting form was developed by UMC. It uses WHO guidelines for entering information, common terminologies, and classifications[5, 6]. Although many ADR reporting methods were introduced the main drawback is under-reporting. A systematic review done in 2006, evaluated the degree of under-reporting of ADR to the national reporting systems that included 37 studies from 12 different countries. The median under-reporting rate across these studies was 94% [7]. In 2002, Hughes et al conducted a study among 18 countries which showed that national spontaneous reporting schemes are different in many ways according to the country. The number of ADR reports received by each country fluctuates considerably from a few hundred each year in South Africa to over 20,000 in the USA [8].

Studies from different countries have concluded that inadequate knowledge regarding ADR among health care professionals as well as negative attitudes are associated with a great degree of under-reporting [9–11]. When considering the South Asian context, the first systematic review and meta-analysis were carried out in India in 2016 regarding health Professionals' knowledge, attitudes and practices about pharmacovigilance. It included 28 studies and overall 55.6% of the population was not aware of the existing pharmacovigilance program in India and 28.75% of them ignored the reporting of ADR and 74.5% had never reported any ADR to pharmacovigilance centers [12]. In Sri Lanka no studies were carried out to find out the factors determining the under-reporting of ADR of healthcare professionals (HCP).

In Sri Lanka, the national pharmacovigilance center is National Medicine Regulatory Authority (NMRA) which is an independent authority governs by the Ministry of Health and Indigenous Medical services. The NMRA has introduced a national ADR reporting form together with a set of guidelines which entails all the details concerned regarding the monitoring and reporting of ADRs in Sri Lanka[13]. Further, a Google form has been introduced to report ADR which can be filled by logging in to the website of NMRA[14].

This study was aimed to describe the knowledge, attitudes, and practices of ADR reporting among HCP in Teaching Hospital Karapitiya and to suggest potential methods of improving ADR reporting.

Methodology

- Study design and setting

A descriptive cross-sectional study was conducted in Teaching Hospital Karapitiya (THK).

- Study population

All the doctors and nurses working in THK who were available during the study period and willing to participate in the study were invited to the study.

- Inclusion criteria

Doctors and nurses working in THK and who consented were enrolled to the study.

- Exclusion criteria

Those who were not consented and those were on leave during the study period were excluded from the study.

- Sample size

The sample size was calculated using the following formula given by Lwanga and Lemeshow for the single proportion of size less than 10000 [15].

$$n = \frac{z^2 p(1-p)}{d^2}$$

n = Sample size d = absolute error or precision – 0.05

z = 1.96 Valve of the standard normal distribution corresponding to a significance level of 0.05

P = Expected proportion in the study population taken as 50% (as there were no evidence of similar study in Sri Lanka and worldwide literature review shows different percentages in South Asian studies ranging from 28%-55.6%)

n = 384

Additional 10% is added for the non-responses = 39

Total sample size = 423

The minimum sample size for this phase is 423.

- Sampling technique

The total number of HCP (doctors and nurses) working in THK is found to be 2065.

Consultants – 95

Medical Officers – 520

Nurses- 1450

Assuming variations among HCP's knowledge, attitudes and practices towards ADR reporting, study subjects were recruited using stratified random sampling technique with proportional allocation. Hence 19 consultants, 106 medical officers and 297 nursing officers were recruited.

Consultants – 95/2065 *423 = 19

Medical officers – 520/2065*423 = 106

Nurses – 1450/2065 *423 = 297

- Data collection Instrument

A self-administered pre tested questionnaire (Annexure 1) was given to the participants. Various self-administered questionnaires used to determine knowledge, attitudes and practices (KAP) in similar studies which were carried out in different countries were reviewed [16–18] and a unique questionnaire was designed as multiple choice questions, and questions based upon the degree of agreement. The questionnaire was designed in English, Sinhala and Tamil languages.

Questionnaire is consisted of following domains.

- Demographic data of the participants- 7 questions
- Questions about the knowledge regarding ADR-Part A: 11 questions
- Questions related to the practice of reporting ADR-Part B: 7 questions
- Questions regarding attitudes/ reason for poor reporting of ADR -Part C: 11 questions

Knowledge and practices related questions were designed as best response questions, but more than one answer was allowed in some questions:

The validity of the questionnaire was assessed by asking panel of content experts to review the relevance of each question on a 3 point Likert scale: 1- not essential, 2- useful but not essential, 3- essential. Then the content validity ratio were calculated for each question by employing Lawshe's method[19].

$$CVR = \frac{ne - N/2}{N/2}$$

CVR is the content validity ratio where *ne* is the number of panel members indicating "essential" and N is the total number of panel members. Final value of CVR was taken from a table including the number of panel members vs. minimum CVR valve[19]. The questionnaire was modified according to the minimum CVR of each question. Questions which do not have minimum CVR were excluded from the questionnaire.

Upon receiving the responses from experts, internal consistency reliability of the questionnaire was assessed by giving it to a sample of randomly selected doctors and nurses. Test-related reliability was verified by finding the intra-cluster correlation on the same sample after a week. After the modifications final questionnaire was employed to collect data from the major sample.

- Data collection procedure

The proposal was submitted to the Ethical Review Committee of Faculty of Medicine, University of Ruhuna and approval was obtained. The administrative approval was obtained from the THK.
• Data analysis

After collecting, data was entered in to the SPSS for analysis. Checking, clearing and coding of the data were done before starting analysis process. The attitude related questions were analyzed based upon the participant's degree of agreement using a Likert scale. The degree of agreement were changed from strongly disagree to strongly agree.
Numbers with percentages for categorical variables were used where appropriate.

Results

- Demographic characteristics

Total, 467 questionnaires were distributed among doctors and nurses in THK. Out of 467 questionnaires, 444 were duly filled giving a response rate of 95.07%. Of the total 444 respondents, 134 (31%) were doctors and 310 (69%) were nurses. Among them 358 (80.6%) HCPs were female and 86 (19.4%) were male. The mean age of all respondents was 37.6 years (± 8.3). /The majority of participants (41%) were in 25–34 age groups.

Demographic characteristics of participants who participated in this study are presented in Tables 1 and 2.

Table 1
Demographic characteristics of Healthcare professionals-Doctors

	Category	Frequency	Percentage
Age	< 25	0	0
	25–34	67	50.00
	35–44	40	29.85
	> 44	27	20.15
Gender	Female	63	47.01
	Male	71	52.99
Designation	House Officers	36	26.87
	Medical officers	70	52.24
	Consultants/SR	28	20.90
Work experience	< 5 years	43	32.09
	5-9years	41	30.60
	10–14 years	22	16.42
	15–19 years	6	4.48
	> 19 years	22	16.42

Table 2
Demographic characteristics of Healthcare professionals-Nurses

Socio-demographic characteristics	Category	Frequency	Percentage
Age	< 25	2	0.65
	25–34	119	38.39
	35–44	126	40.65
	> 44	63	20.32
Gender	Female	295	95.16
	Male	15	4.84
Work experience	< 5 years	77	24.84
	5-9years	43	13.87
	10–14 years	88	28.39
	15–19 years	35	11.29
	> 19 years	67	21.61

- Description of knowledge regarding ADR

Regarding the knowledge of ADR, as shown in Table 3, 62.8% (n = 279) participants were aware about the term pharmacovigilance while 47.3% (n = 210) could correctly define the term. Majority of respondents, 90% (n = 400) were aware about the term ADR, while 64.8% (n = 288) could correctly define it. Among the respondents, 30.8% (n = 137) knew about the types of ADR and only 15.5% (n = 70) were able to correctly mention a drug that are banned due to ADR. However 38.7% (n = 172) respondents have marked ADR reporting centers correctly. Most of the respondents 61.7% (n = 274) mentioned that they used several sources to gather ADR information, while 9% (n = 40) of them used text books and 10.3% (n = 46) of them used internet to gather ADR information.

Table 3
Healthcare professionals' knowledge regarding ADR

Questions regarding knowledge	Doctors	Nurses	All respondents
Heard about Pharmacovigilance	84(62.7%)	195(62.9%)	279(62.8%)
Correctly defined Pharmacovigilance	50(37.3%)	160(51.6%)	210(47.3%)
Heard about ADR	131(97.7%)	269(86.8%)	400(90%)
Correctly defined ADR	107(79.8%)	181(58.4%)	288(64.8%)
Knew the types of ADR	55(41%)	82(26.4%)	137(30.8%)
Named a drugs that is banned due to ADR	42(31.3%)	28(09.3%)	70(15.5%)
Marked an ADR reporting center correctly	46(34.3%)	126(40.6%)	172(38.7%)
Source of ADR knowledge			
Text books	26(19.4%)	14(4.5%)	40(9.0%)
Colleagues	3(2.2%)	9(2.9%)	12(2.7%)
Medical Representatives	1(0.7%)	5(1.65)	6(1.3%)
Seminars	4(2.9%)	20(6.4%)	24(5.4)
Internet	8(5.9%)	38(12.3%)	46(10.3%)
From few sources	89(66.4%)	185(59.7%)	274(61.7%)

An attempt was made to find out the overall knowledge regarding ADR and reporting procedures. One mark was given for each expected answer and if multiple answers are present marks were allocated accordingly. The median score was 4 (IQR: 5 – 3) and the maximum marks they obtained was 7 out of 9. Further, the study revealed health professionals with relatively better knowledge towards ADR are more likely to identify ADR compared with those with insufficient knowledge (0.01 level :2-tailed). (Table 4)

Table 4
Healthcare professionals' overall knowledge regarding ADR

Marks scored for the Knowledge questions	Frequency	Percentage
0	25	5.6
1	36	8.1
2	63	14.2
3	76	17.1
4	96	21.6
5	112	25.2
6	32	7.2
7	4	0.9
Total	444	100.0

Table 5
Relationship between Healthcare professionals' overall knowledge and recognition of ADR

Correlations			
		Recognizing ADR	Knowledge
Recognizing ADR	Pearson Correlation	1	.159**
	Sig. (2-tailed)		.001
	N	444	444
Knowledge	Pearson Correlation	.159**	1
	Sig. (2-tailed)	.001	
	N	444	444
**Correlation is significant at the 0.01 level (2-tailed).			

• Description of practices regarding ADR

Among the respondents, only 38.7% (n = 172) were aware about formal process of reporting ADR and, only 35.3% (n = 157) stated that they have seen ADR reporting form. Further, only 33.7% (n = 150) respondents have recognized ADR in the practice and only a small proportion 18.2% (n = 81) have ever reported an ADR during their practice. Majority of respondents 94.4% (n = 420) stated that they have not received a training on ADR reporting. However, most of them 96.6% (n = 429) were willing to receive a proper training on ADR reporting.

Table 6
Healthcare professionals' practices regarding ADR reporting

Questions regarding practice	Doctors	Nurses	All respondents
Aware about formal process of reporting ADR	58(43.3%)	114(36.7)	172(38.7%)
Seen an ADR reporting Form	58(43.3%)	99(31.9%)	157(35.3%)
Who recognized ADR in the practice	42(31.3%)	108(34.8%)	150(33.7%)
Ever reported an ADR	23(17.1%)	58(18.7%)	81(18.2%)
Not participated to a training on ADR reporting	128(95.5%)	292(94.2%)	420(94.6%)
Willing to receive proper training for ADR reporting	127(94.8%)	302(97.4%)	429(96.6%)

- Description of attitudes regarding ADR

There were 8 questions regarding attitude of HCP with regards to ADR reporting. Responses were analyzed based upon the participant's degree of agreement using a Likert scale.

Table 7
Healthcare professionals' attitudes regarding ADR

Respondents' attitude towards ADR reporting	Strongly agreed	Agreed	Neutral	Disagreed	Strongly disagreed
No time to fill an ADR reporting forms	14(3.1%)	50(11.2%)	64(14.4%)	224(50.4%)	92(20.7%)
No time to actively look for an ADR	12(2.7%)	50(11.3%)	64(14.4%)	224(50.5%)	9(21.2%)4
No idea about available places of ADR forms	39(8.8%)	165(37.2%)	93(20.9%)	105(23.6%)	42(9.5%)
Filling an ADR is an extra work	6(1.4%)	33(7.4%)	54(12.2%)	254(57.2%)	97(21.8%)
Unnecessary to report already known ADR	13(2.9%)	35(7.9%)	74(16.7%)	194(43.7%)	128(28.8%)
Not necessary to report minor ADR	10(2.3%)	73(16.4%)	92(20.7%)	183(41.2%)	86(19.4%)
Worrying about legal problems of ADR	15(3.4%)	75(16.9%)	95(21.4%)	190(41.25)	69(15.5%)
Thinking that ADR has no outcome	8(1.8%)	30(6.8%)	31(7.0%)	194(43.7%)	181(40.8%)

The degree of agreement were changed from strongly disagree to strongly agree. As the questions were negatively worded strongly disagreed and disagreed responses were considered as positive attitude, strongly agreed and agreed responses were taken as poor attitude while the respondents who stayed

neutral were considered as neutral attitude. The answer of strongly disagreed was assigned with the score of 5, disagreed with 4, agreed with 2 and strongly agreed with 1 mark.

As shown in Table 7, majority of them disagreed and strongly disagreed with the statement that there is no adequate time to fill an ADR form. This means 71.7% of respondents (n = 316) have adequate time to complete an ADR report. Further, they have adequate time to actively look for an ADR during the practice. Of the total, 46% (n = 204) have no idea about the available places of ADR forms. Among the respondents, 78.6% (n = 349) of them do not consider filling an ADR form as an additional work. Further, 74.7% (n = 332) HCP stated it is necessary to report already known ADR and 60.6% (n = 269) knew the importance of reporting minor ADR. Regarding the legal aspect of the ADR reporting, 58.3% (n = 259) of HCP were not worrying about the legal aspect of ADR reporting whereas majority of them 84.3% (n = 374) accepted ADR has an outcome.

In general, the respondents had good attitudes towards ADR reporting. Overall 84.1 (n = 373) had positive attitude towards ADR reporting while 13.54% (n = 60) of them stayed neutral and 2.25% (n = 10) had negative attitude towards ADR reporting.

Table 8
Type of attitudes of healthcare professionals' towards ADR reporting ADR

Respondents' attitude towards ADR reporting	Positive attitude	Neutral attitude	Negative attitude
No time to fill an ADR reporting forms	316(71.2%)	64(14.4%)	64(14.4%)
No time to actively look for an ADR	316(71.2%)	73(16.4%)	55(12.4%)
No idea about available places of ADR forms	146(32.8%)	93(20.9%)	204(46%)
Filling an ADR is an extra work	349(78.6%)	54(12.2%)	41(9.2%)
Unnecessary to report already known ADR	332(74.7%)	64(14.4%)	48(10.8%)
Not necessary to report minor ADR	269(60.6%)	92(20.7%)	83(18.7%)
Worrying about legal problems of ADR	259(58.3%)	95(21.4%)	90(20.3%)
Thinking that ADR reporting has no outcome	374(84.3%)	31(7.0%)	38(8.6%)

There were two more questions regarding factors contributing ADR reporting. Among the respondents 61% (n = 271) were mentioned that they had no idea about ADR reporting procedure while 39% (n = 173) mentioned that unavailability of the ADR reporting forms is the reason for under reporting.

Discussion

This is the first study in Sri Lanka which was conducted to find out the knowledge, attitudes and practices of ADR reporting among healthcare professionals. Although most respondents could select the correct definitions of ADR and pharmacovigilance, majority of HCP did not aware about the types of ADR, Banned drugs due to ADR and ADR reporting centers. Further, this study showed that HCP with relatively better knowledge towards ADR are more likely to identify ADR compared with those with insufficient knowledge. These findings are in line with similar study, a systematic review carried out in India[12]. Another systemic review carried out in Europe which included 17 different publications showed healthcare professionals' low knowledge about the pharmacovigilance activities and drug safety is directly co-relate with ADR under-reporting [20]. This implied the importance of healthcare professionals' knowledge to improve the ADR reporting. Worldwide various interventions were introduced to improve ADR reporting while educational interventions were the commonest among them. A cluster randomized controlled trial carried out in Portugal in 2007, showed that the ADR reporting rate among physicians had been increased by 10-fold (95% CI, 3.8 to7.5) in the year following an hour long educational intervention[21]. As majority of respondents of the current study (97%) were willing to receive a proper training regarding ADR reporting, there is a potential to promote ADR reporting in healthcare professionals in Sri Lanka by educational interventions.

The ADR reporting practices among doctors and nurses were far below than expectation. Among the respondents only smaller proportions have seen an ADR reporting form and have recognized ADR during their clinical practice. Further the healthcare professionals who have ever reported ADR were very low (18.2%). Respondents have stated that unaware about the reporting procedure and the unavailability of the ADR reporting forms are the major contributory factors for poor ADR reporting. Hence, raising awareness among the healthcare professionals and convincing the magnitude of the drug safety problems would be good options to improve ADR reporting which have not been addressed so far in Sri Lanka.

The attitudes of HCP towards ADR reporting are interesting. This study disclosed that majority of HCP believed that they have adequate time to fill an ADR reporting and filling an ADR reporting form is not considered as extra work. Those findings can be considered as positive impression which helpful to improve future ADR reporting. The study findings are compatible with many studies conducted regarding the topic which showed the positive attitude strongly related with the ADR reporting [22–24].

Strengths And Limitations

- Strengths of the study

The data collection instrument was newly developed and validated according to the expert opinion and pre tested in similar setting. The data collection was carried out by the principle investigator.

Both quantitative data and qualitative data were used to explore the results and yield to potential solutions.

- Limitation of the study

As data were collected based on self-reported information, the possibility of reporting errors and recall biases could not be ruled out.

Conclusions

The collective results of this study disclosed that the healthcare professionals' knowledge and practices regarding ADR reporting procedures are not satisfying. However they have positive attitudes towards ADR reporting which is a favorable fact to improve ADR reporting. It is essential to have a system with easily access and efficient for health care professionals to report ADR. Considerable attention should be paid for executing a national program in order to develop the concept and practice of pharmacovigilance in the country. Following recommendations can be suggested based on the current study results.

- Raise awareness of the magnitude of the drug safety problems by conducting workshops
- Convince the health professionals that reporting ADRs is their professional obligation
- Make ADR reports freely available in the hospitals including Emergency treatment centers and out patients departments
- Each hospital should have an ADR data base which will be monitored by national pharmacovigilance center
- Establishment of further regional centers to coordinate ADR reporting and pharmacovigilance activities
- Introduce more user-friendly ADR reporting methods to report ADR

Finally we recommended further studies at national level to implement policies to increase ADR reporting in Sri Lanka.

Declarations

- Ethical Approval

Ethical Clearance was obtained from the Ethical Review Committee, Faculty of Medicine, University of Ruhuna. The administrative approval will be obtained from the THK.

- Consent to participate and publish

All the participants who enrolled to this study were given an information sheet (Annexure 2) before getting consent and informed written consents (Annexure3) were taken prior to the study. They were allowed to withdraw from the study at any point without stating reason for withdrawal. Consents were taken to participate for the study and publication of the study results.

- Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

- Authors' contributions

M.T. Madhushika conceived the idea. P.L.G.C Liyanage and S.S. Jayasinghe helped to develop the proposal and questionnaire. M.T. Madhushika and WAD Malinda conducted the study. M.T. Madhushika wrote the first and subsequent drafts. P.L.G.C Liyanage, S.S. Jayasinghe and P Abeykoon developed the ideas. All authors read and approved the final article.

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- Availability of data and materials

Personal identification data was not collected. The privacy and confidentiality were maintained and data was used for scientific publications only. Gathered data were kept confidential with the principal investigator without disclosing to any third party and all data will be destroyed five years after the final analysis has been completed. Soft copies of the data are kept with a pass word protected whereas hard copies are kept in locked cabinet.

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Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- QuestionnierAnnexure1.pdf