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Original Article:

Effectiveness of an intervention to improve pharmacovigilance among selected government hospitals in a district of Sri Lanka

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Keywords:
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Abstract

Introduction: Issues related to doctors' pharmacovigilance exist due to their lack of knowledge and the challenges of a rapidly changing society. In addition, issues exist with the subject's existing systems. Proper intervention with a comprehensive system of pharmacovigilance can resolve these problems.

Objective: This research is intended to assess the knowledge, perception, and practices of pharmacovigilance among medical officers in a district of Sri Lanka with surveillance systems through interventions.

Methodology: A pre-and post-intervention design research study was conducted among 237 doctors in the curative sector in the Hambanthota district. All the doctors in these hospitals were considered the study population, and no sampling method was employed. A self-administered questionnaire was used to collect the data using active and passive surveillance data systems and workshops.

Results: The results indicated that most of the doctors were from the 31-40 age category (55.3%), females (53.59%), preliminary and grade 2 medical officers (67.1%, 37.6%) who are working in the base hospitals (64.1%) of the area with a basic medical degree (90.8%). A large proportion of them (67.5%) had training in this area as undergraduates (25%). The overall knowledge of pharmacovigilance was poor (69.7%). The overall perception was positive (53.2%). Overall, practices were poor. Knowledge and perception have improved with the intervention.

Conclusion and recommendations: This research revealed poor general knowledge, practices, and a positive perception regarding pharmacovigilance, which improved through an intervention. Substantial consideration should be paid to including those topics in undergraduate and postgraduate curricula. Continuous

professional development and in-service training programmes should be arranged for doctors with a comprehensive system of surveillance.

Keywords: Pharmacovigilance, Knowledge, Perception, Practice

Introduction

Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse drug reaction to medicine. The ultimate goal of this activity is to improve the safe and rational use of medicines. Adverse drug reaction is a response to a medicine used in humans or medicines which is noxious and unintended, including lack of efficacy and which occurs at any dosage and can also result from overdoses, misuse or abuse of drugs.[1]

According to the studies conducted in developed countries, about 5% of patients admitted to hospitals due to adverse drug reactions [ADR] and 6-10% of in-patients experienced a serious ADR during hospitalization. However, literature is scarce on comprehensive assessments of the burden of ADR in global healthcare. The healthcare cost of managing ADR is considerable for most of the countries. All healthcare professionals are requested to report all suspected ADRs. For this purpose, doctors, dentists, pharmacists and nurses have a pivotal role. There should be a comprehensive awareness and established surveillance system for it to work. Uniform management protocols, guidelines, facilities, and expertise should be readily available in every hospital [1].

Uppsala Monitoring Centre is the international database for adverse drug reaction reports received from national centres. National systems in the UK and New Zealand show that the cost of maintaining a pharmacovigilance system is very small compared with the national expenditure on medicines and the cost of managing adverse drug reactions. Pharmacoeconomic studies on the costs of adverse drug reaction shows that governments pay a considerable amount of money from health budgets for covering costs associated with them [2]

The Yellow Card scheme was introduced in 1964 to help the government monitor the safety of medicines and all medical devices in the UK. It allows health professionals, patients and carers to report side effects to medicines also known as adverse drug reactions. Yellow card system has captured extremely important data in a systematic way, which has been used to inform the development of medicines, the reaction to any serious incidents and the future direction of pharmacovigilance on an international scale. Patients and carers could help to reduce the current gap in reporting.

Patients not only provide a different perspective, but also report different drug reaction types compared with health professionals and are more likely to report the symptoms and impact of an adverse drug reaction. [3, 4]

Objective

The objective of this study was to improve pharmacovigilance among medical officers of the selected government hospitals in the Hambanthota district of Sri Lanka.

Methodology

This study employed a pre -post-intervention design with a single group in selected government hospitals in Hambanthota district. The study population

consisted of all medical officers who are working in selected government hospitals in Hambanthota district. The research was conducted in BH- Thissamaharamaya, BH Wallasmulla, BH Tangalle, and DGH-Hambanthota. After getting permission from the relevant institutions, the study was conducted among the grade medical officers who have given consent and fulfilled the inclusion and exclusion criteria by applying the self-administered questionnaire. The questionnaire consisted of Socio-demographic data, knowledge, perception and practices regarding the pharmacovigilance according to the guidelines, circulars, policies and standard operating procedures. Educational interventions were conducted by relevant academic experts with workshops and surveillance data systems.

Scores were given for poor, fair, and good categories according to correct-1, incorrect-0, and don't know as 0. Most of the questions were close-ended, and a few were open-ended. The questionnaire was prepared in English. A pre-test was done among the medical officers with the same characteristics, socio-cultural environment, and categorizations in an adjacent district located in the western province.

The respondents were informed of the general purpose of the study and assured of confidentiality of information. This was done to ensure completeness of the filled questionnaires and truthful expression of information. Informed written consent was obtained from the respondents before administering the questionnaire. Ethics approval for the study was obtained from Ethics Review Committee, Faculty of Medicine, and University of Colombo.

Results

The total study population was 320. According to the inclusion and exclusion criteria, the number of eligible study participants was 270. Self-administered questionnaires were handed over to the eligible participants to complete and return. Out of them, 237 responded, and 33 did not return the questionnaire. The non-respondents rate was 13 %. The total number of subjects included in the analysis was 237. According to table 1, 127 of the participants (53.59%) were females, and 110 (46.41%) were males. The highest proportion (55.3%) of the participants, numbering 131, were in the 31-40-year age category. The lowest percentage, 7.6%, belonged to the 41-50 age category.

Table 01: Distribution of the study participants by sex, age religion, ethnicity, duration of service and grade (N=237)

Variable	Pretest Number (Percentage)	Posttest Number (Percentage)
Sex		
Male	110 (46.41%)	110 (46.41%)
Female	127 (53.59%)	127 (53.59%)
Age category		
20-30	88 (37.1%)	88 (37.1%)
31-40	131 (55.3%)	131 (55.3%)
41-50	18 (7.6%)	18 (7.6%)
Level of education		
Graduate	216 (90.8%)	216 (90.8%)
Postgraduate	21 (9.2%)	21 (9.2%)
Service duration		
0-5	172 (72.6%)	172 (72.6%)
6-10	47 (19.8%)	47 (19.8%)
11-20	18 (7.6%)	18 (7.6%)

Grade		
preliminary	159 (67.1%)	159 (67.1%)
Grade2	75 (31.6%)	75 (31.6%)
Grade1	3 (1.3%)	3 (1.3%)

Table 02: Distribution of the study participants according to the total level of knowledge scores (n=237)

Level of knowledge	**Pretest Number (Percentage)**	**Posttest Number (Percentage)**
Poor	166 (69.7%)	83 (35%)
Fair	72 (30.3%)	152 (64%)
Good	-	2 (1%)

As shown in table 2, most of the participants, 166 (69.7%), have had a poor level of knowledge regarding pharmacovigilance, and 72 of them (30.3%) have had a fair level of knowledge in the pre-intervention. There were no participants with a good level of knowledge. Most of the participants, 152 (64%), have had a fair level of knowledge regarding pharmacovigilance in post intervention than the pre-intervention.

Table 03: Distribution of the study participants according to the total level of perception scores(n=237)

Level of perception	**Pretest Number (Percentage)**	**Posttest Number (Percentage)**
Positive	126 (46.8%)	145 (61.2%)
Negative	111 (53.2%)	92 (38.8%)

According to the total perception scores shown in Table 3, 126 (46.8%) of the study participants had a positive perception and 111 (53.2%) had a negative perception of pharmacovigilance during the pre-intervention. Out of the total, 145(61.2%) of the participants have had a positive perception, and 92 (38.8%) have had a negative perception of pharmacovigilance after the intervention. According to perception, majority of them have responded as having positive perception for pharmacovigilance.

According to the practices of Pharmacovigilance (Table 4), although they know their hospital system of ADR reporting and monitoring system, the majority of them have not reported an ADR in the last year (71. 8%). Most of them think that there is a need to report an ADR (81.1%). According to the practices majority of them have responded as having good practices for the given scenarios of pharmacovigilance and the practices have changed towards establishing a good culture of reporting and prevention of ADR, after the intervention.

Discussion

This research project was conducted to explore the knowledge, perception, and practices regarding pharmacovigilance among a doctor population in a district in the curative sector in Sri Lanka.

Table 4: Distribution of the pre-and post-intervention responses given for practices of pharmacovigilance. (n=237)

Practices	**Yes**		**No**		**Don't Know**	
Number (Percentage)	**Pretest**	**Posttest**	**Pretest**	**Posttest**	**Pretest**	**Posttest**
1. Do you know of the ADR reporting and monitoring system in your hospital?	142 (59.7%)	187 (78.9%)	65 (27.3%)	35 (14.8%)	30 (13.0%)	15 (6.3%)
2. Do you take measures to prevent ADR during your practice?	186 (78.5%)	193 (81.1%)	28 (11.8%)	33 (13.9%)	16 (6.7%)	18 (7.6%)
3. Do you only report severe or life-threatening ADR?	52 (21.8%)	26 (11%)	167 (70.2%)	189 (78.7%)	18 (8.0%)	22 (9.3%)
4. Do you mention ADR on patients' reports/ diagnostic cards?	194 (81.5%)	198 (83.5%)	35 (14.7%)	23 (9.7%)	8 (3.4%)	16 (6.8%)
5. Do you think that there is no need to report an ADR?	34 (14.3%)	54 (22.6%)	193 (81.1%)	182 (68.1%)	10 (4.6%)	21 (8.9%)

Many participants had poor overall knowledge of pharmacovigilance, 166 (83%). Their overall perception of selected scenarios and situations given in the study was negative, 126 (53.2%). This is comparable with a study done in Saudi Arabia [5, 6]. Both knowledge and perception improved with the intervention. This is also comparable to a study done in India [7]. Overall, practices were not good. This is also comparable to a study done in Nigeria [8].

A large proportion of them are trained 160 (67.5%) but only at undergraduate level. 146(91.25%). Most of them have not experienced ADR personally as well and most of them are not reporting ADR as general practitioners, 198 (83.54%) and 174(73.4%), respectively. When considering the surveillance data, there is

an underreporting of ADR, and the quality of data is affected by timeliness and accuracy. This is comparable with a study done in Pakistan [9]. These findings are comparable with a study done in the same type of setting in Sri Lanka [10].

Conclusion and recommendations

This study revealed poor general knowledge, practices, and a positive perception regarding pharmacovigilance, which improved through an intervention. Substantial consideration should be paid to including those topics in undergraduate and postgraduate curricula. Continuous professional development and in-service training programmes should be arranged for doctors with a comprehensive system of surveillance.

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